



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Handwritten notes: "1/11/04", "1/11/04", "8/4/04"

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

AUG 2 2004

Dear Dr. Chmitelin:

The Food Safety and Inspection Service has completed an enforcement audit of France's meat and poultry inspection system. The audit was conducted from January 14 through February 12, 2004. Comments from France have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have questions regarding the audit, please contact me at 202.720.3781. My fax number is 202.690.4040 and my email address is [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

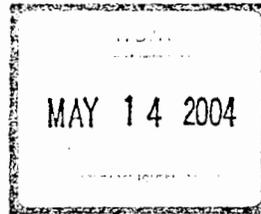
Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

- Besa Kotati, Agricultural Counselor, US Embassy, Paris
- Christian Berger, Counselor for Agriculture, Embassy of France, Washington, DC
- Tony van der Haegen, EU Mission to the US, Washington, DC
- Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
- Linda Swacina, Deputy Administrator, FSIS
- Karen Stuck, Assistant Administrator, OIA
- William James, Deputy Asst. Administrator, OIA
- Scott Bleggi, FAS Area Officer
- Robert Macke, ITP, FAS
- Donald Smart, Director, Review Staff, OPEER
- Sally White, Director, IES, OIA
- Clark Danford, Director, IEPS, OIA
- Mary Stanley, Director, IID, OIA
- Amy Winton, State Department
- Nancy Goodwin, IES, OIA
- Todd Furey, IES, OIA
- Country File-France—final—Jan04

**FINAL**



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

JANUARY 14 THROUGH FEBRUARY 12, 2004

Food Safety and Inspection Service  
United States Department of Agriculture

## TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
  - 6.1 Legislation
  - 6.2 Government Oversight
  - 6.3 Headquarters and Department Audits
7. ESTABLISHMENT AUDITS
8. SANITATION CONTROLS
  - 8.1 SSOP
  - 8.2 EC Directive 64/433
  - 8.3 Other Sanitation Deficiencies
9. ANIMAL DISEASE CONTROLS
10. SLAUGHTER/PROCESSING CONTROLS
  - 10.1 Humane Handling and Slaughter
  - 10.2 HACCP Implementation
  - 10.3 Testing for Generic *Escherichia coli*
  - 10.4 Testing for *Listeria monocytogenes*
  - 10.5 EC Directive 64/433
11. RESIDUE CONTROLS
  - 11.1 FSIS Requirements
12. ENFORCEMENT CONTROLS
  - 12.1 Daily Inspection
  - 12.2 Testing for *Salmonella*
  - 12.3 Species Verification
  - 12.4 Monthly Reviews
  - 12.5 Inspection System Controls
13. CLOSING MEETING
14. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority—General Food Directorate
DGAL	General Food Directorate
DDSV	Veterinary Services
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

## 1. INTRODUCTION

The enforcement audit took place in France from January 14 through February 12, 2004.

An opening meeting was held on January 14, 2004 in Paris, France, with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of France's meat and poultry inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA and/or representatives from the Department inspection offices.

## 2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit. The objective was to determine if France could continue to export meat and poultry products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, nine Department offices (DDSV), three slaughter establishments, and eight processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	0	Not applicable
	Department	9	
Laboratories		0	
Slaughter Establishments		3	
Processing Establishments		8	

## 3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or Department offices. The third part involved on-site visits to 11 establishments: three slaughter establishments and eight processing establishments.

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

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors also assessed how inspection services are carried out by France and determined if establishment and inspection system controls were in place to ensure the production of meat and poultry products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditors explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Third, the auditors would audit against the corrective action plan submitted by France to address the audit deficiencies from FSIS' April/May 2003 audit of France's meat and poultry inspection system.

Lastly, the auditors would audit against any equivalence determinations that have been made by FSIS for France under provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures.

- France suspends an establishment's eligibility to export the first time it fails to meet a *Salmonella* performance standard.
- France uses ISO 6579:2002 to analyze for *Salmonella*.

#### 4. LEGAL BASIS FOR THE AUDIT

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

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

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

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

## 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:  
[www.fsis.usda.gov/OPPDE/FAR/index.htm](http://www.fsis.usda.gov/OPPDE/FAR/index.htm)

The following concerns arose as a result of the FSIS audit of France's meat and poultry inspection system conducted in April/May 2003:

### Government Oversight

- Inadequate documentation by inspection personnel of establishment compliance or lack of compliance with U.S. inspection requirements in seven of ten establishments.
- At the local levels, some inspectors and establishment personnel still had not had adequate HACCP training: in three of the establishments audited, the Inspectors/Veterinarians-In-Charge had had no HACCP training courses in more than six years.

### SSOP

- In one establishment, there was practically no documentation of daily operational sanitation activities, findings, corrective actions, or preventive measures. This was a repeat finding in this establishment from the October 2002 audit.
- In one establishment, condensation was obvious, heavy, dripping, and out of control in the main bacon cooler, directly above exposed product. No corrective actions were taken either by establishment or inspection personnel.
- In one establishment, the documentation of the recording of water temperatures in sanitizers on the slaughter floor during operations was audited. During the period between January 1 and March 31, 2003, *all* of the recorded temperatures, without exception, were well below the required 180°F (82°C). The temperatures recorded ranged down to 125°F (52°C). There was no documentation of any corrective actions taken, and apparently no corrective actions were taken. Slaughter operations were allowed to continue with non-compliant sterilizers.

- In three establishments, there was daily documentation of both pre-operational and operational activities, but more detail was needed in the written descriptions of corrective actions and/or preventive measures.
- In one establishment, there was evidence of rodents inside the establishment.
- In one establishment, there was inadequate pre-operational cleaning of equipment.
- In one establishment, there was inadequate sanitizing of slaughter equipment.
- In one establishment, there were inadequate hand-washing facilities.
- In one establishment, there was insanitary storage of clean equipment.

#### Other Sanitation Deficiencies

- In four establishments, corrective actions in response to serious condensation problems were either lacking, inadequate, or ineffective. In one other establishment, condensation was out of control.
- In three establishments, maintenance and cleaning of over-product equipment had been neglected. This was a repeat finding from the October 2002 audit.
- In three establishments, pest control was inadequate: in one of these, rodent droppings were found, and in the other two, cobwebs were found in dry-storage areas.
- In two establishments, hand-washing facilities were inadequate to prevent contamination of product if employees' hands were contaminated in the course of their operations. This was a repeat finding from the October 2002 audit.
- In two of the five slaughter establishments, cross-contamination of carcasses with equipment (splitting saw housings) was observed on slaughter floors.
- In two establishments, product was stored under insanitary conditions.
- In two establishments, cleaned product-contact equipment was stored under insanitary conditions.
- In three establishments, pre-operational cleaning of some product-contact equipment was inadequate.
- In two establishments, slaughter equipment was not adequately sanitized before each use.
- In two establishments, waste container lids in production areas were hand-operated.

- In one establishment, the controls to document, correct, and prevent visible fecal contamination were inadequate. The zero-tolerance policy was not being adequately enforced as fecal contamination was observed on carcasses that had passed both establishment and inspection controls, and corrective actions taken as a result were not adequate.
- In one establishment, the facilities for sanitizing slaughter equipment were inadequate.
- In one establishment, water under high pressure was being used on equipment and on the floor near exposed product, and was being directed toward that exposed product.
- In one establishment, deteriorated equipment in need of repair or replacement was being used for exposed product.
- In one establishment, there was inadequate segregation of containers used for edible product and inedible materials.
- In one establishment, packaged product was being packed into dirty containers for shipping.

#### HACCP

- In four establishments, HACCP verification procedures were inadequate.
- In two establishments, HACCP critical control points and/or critical limits were not adequately described.
- In two establishments, monitoring procedures for critical limits procedures were inadequate.
- In two establishments, some HACCP verification activities were described and performed, but more detail on these activities was needed.
- In one establishment, HACCP documentation in general was inadequate.
- In one establishment, a pre-shipment document review form had not been developed, although critical limits and corrective actions were documented.
- In one establishment, rework product was not included in the flow chart and had not been considered in the hazard analysis.
- In one establishment, there were illegible corrections in the log for monitoring CCPs.
- In one establishment, the HACCP plan had not been re-evaluated annually as required.

### Testing for Generic *E. coli*

- In two establishments, statistical process control methods had not been developed to evaluate the results of testing for generic *E. coli*.
- In one establishment, the carcass selection for testing for generic *E. coli* was not random.

### EC Directive 64/433

- In one establishment, some carcasses were not being inspected, backs of carcasses were not observed, inspectors did not require viscera to be presented with all carcasses, plucks and viscera in un-split carcasses were not being inspected, and viscera presented on the line were not adequately observed.
- In another establishment, lymph nodes, plucks, and viscera were not being inspected adequately.

## 6. MAIN FINDINGS

### 6.1 Legislation

The auditors were informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into France's legislation.

### 6.2 Government Oversight

#### 6.2.1 CCA Control Systems

The food safety system in France is based on collaboration between three independent ministries: the Ministry of Agriculture, Food, Fishery and Rural Affairs; the Ministry of Trade and Commerce; and the Ministry of Public Health. The Ministry of Agriculture, Food, Fishery and Rural Affairs serves as the lead agency regarding food safety. Further, DGAL, under the Ministry of Agriculture, Food, Fishery and Rural Affairs, is the lead agency for the development and implementation of food safety policy.

The DGAL is based upon a single chain of command. All direction to each of the individual departments is given from the Headquarters in Paris. Recently, the DGAL created a new position, a National Technical Expert. The role of this individual is to oversee all establishments that are eligible to export product to the U.S. The National Technical Expert provides technical support to the inspectors, supervisors and coordinators. However, the National Technical Expert is merely an advisory position with no direct supervisory authority.

At the local level, France is divided into 96 departments (there are 4 overseas departments.) Each has a Director of Veterinary Services (DDSV). Each of these Directors is a veterinarian, employed by the government, and is a sworn-in officer. 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 their Department regarding all the certified meat and poultry slaughter and processing establishments. According to the volume of activity within the department, the deputy has other colleagues who work with him/her and report to him/her; these make up the Food Safety Service within the department. These are either veterinary officers or technical assistants with specific public health training. Larger departments are divided into districts, each of which is under the supervision of a Veterinary Officer.

Many of the deficiencies identified by the FSIS auditor were documented by the French inspection personnel in written and electronic reports distributed throughout the organizational structure. However, the findings were not acted upon in a manner that would ensure enforcement of the requisite laws and regulations in all establishments. The CCA did not ensure that U.S. requirements were being met by the establishments.

### 6.2.2 Ultimate Control and Supervision

DGAL headquarters in Paris has the ultimate control and supervision of France's meat and poultry inspection system. Although France's inspection system is centralized, there appears to be little to no communication between Department offices and the certified establishments regarding FSIS inspection requirements and little to no follow-up activities by the inspection service to ensure that the requirements are effectively implemented.

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

### 6.2.3 Assignment of Competent, Qualified Inspectors

At all levels, adequate training of inspection personnel in HACCP still has not been completed. Similar findings in many of the establishments indicate that the national training program was insufficient.

The national training program, referred to in France's April 2003 corrective action plan, was a brief, two-day overview of CODEX HACCP principles. It did not include specific information on how to implement FSIS' HACCP requirements. A sufficient understanding of FSIS' HACCP requirements was not observed during this audit.

In addition, inspection personnel have not been adequately trained in SSOP and sanitation principles. The April 2003 corrective action plan referred to training in SSOP and sanitation principles. Inspection personnel referred to the national training programs that took place in November and December 2003 as the source of their training. This training did not include SSOP or sanitation principles training. The sanitation

deficiencies found during this audit demonstrate that there is little or no understanding of FSIS' SSOP and sanitation requirements.

#### 6.2.4 Authority and Responsibility to Enforce the Laws

DGAL has the authority and the responsibility to enforce all U.S. requirements. However, our auditors found that U.S. inspection requirements were not being enforced.

#### 6.2.5 Adequate Administrative and Technical Support

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

### 6.3 Audit of Headquarters and Department Offices

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

- Internal review reports,
- Supervisory visits to establishments that were certified to export to the U.S.,
- Training records for inspectors,
- New laws and implementation documents such as regulations, notices, directives and guidelines,
- Sanitation, slaughter and processing inspection procedures and standards, and
- Export product inspection and control including export certificates.

The following concerns arose as a result the examination of these documents.

- Training of inspection personnel in SSOP, sanitation principles, and FSIS' HACCP requirements is inadequate. The similar findings in many of the establishments indicate that the national training program was insufficient.

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 11 establishments: three slaughter establishments and eight processing establishments. (One of 12 originally certified establishments was delisted by France days before the auditor was due to arrive.) During the audit, three establishments were delisted for failure to meet U.S. requirements. In addition, France issued two other establishments a Notice of Intent to Delist because of inadequate implementation of SSOP and HACCP in these establishments.

Specific deficiencies are noted on the attached individual establishment reports.

## 8. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat and poultry inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

### 8.1 SSOP

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

- In nine establishments, the SSOP was not effectively implemented.
  - Pre-operational sanitary conditions were inadequate. For example:
    - Fat particles from the previous day's production were identified on a plastic interlock conveyor in the grinding/blending room. The conveyor was ready for use for the day's production of food products.
    - Plastic tubs used to transport finished product were not cleaned and sanitized daily to remove product residue from the previous day's production.
    - In the ready-to-eat slicing room, grey watery material was identified on the product contact surface of a slicing machine belt; 25 to 30 black unidentified particles were identified on the product contact surface of a product table; product residue from the previous day's production was identified on cooling racks; the cooling oven and scale supports which were in contact with the surface of a product table; and all equipment was presented for use for the day's production of food products.
    - Black unidentified material was identified in a yellow product tub previously cleaned and ready for use for the day's production of food products.
- In one establishment, the SSOP did not describe all of the procedures used to monitor the daily operational sanitation activities.
  - The SSOP did not describe a procedure for the reconditioning of product dropped onto the floor.
  - The SSOP did not describe a procedure for monitoring the temperature of 82° centigrade water equipment sanitizers.
  - Operational sanitary conditions were inadequate. For example:
    - Condensation was dripping onto defeathered and partially de-paraffined ducks between the cold paraffin tank and the paraffin removal cabinet in the defeathering room.
    - Copious amounts of condensation were dripping onto employees and their work stations in the evisceration room.
    - Duck meat that had been dropped onto the floor was accumulated in bulk and shipped to a further processing establishment without reconditioning. This was an ongoing process described in the

SSOP, and the procedure had been approved by the applicable Department office. The auditor was informed that product accumulated in bulk and shipped to a further processing establishment without reconditioning was acceptable because the floor was clean and the product was cooked.

- Sausage hangers and the container which held the sausage hangers were contaminated with multiple fat scraps. This was observed while operations were being conducted in the sausage stuffing room. The sausage hangers were round hollow tubes and were not sealed at each end.
- In one establishment, corrective actions were insufficient to restore sanitary conditions and did not ensure proper disposition of contaminated product.
  - In reference to the sausage hangers, hangers contaminated with fat particles from the previous day's production, were placed onto the sausage hanging table, contaminating the surface of the table where sausage products were produced and therefore contaminating the sausage product. The establishment did not take immediate corrective actions to restore sanitary conditions and did not ensure proper disposition of contaminated product.
- In nine establishments, preventive measures for corrective actions were not included in the daily records for sanitation noncompliances.

## 8.2 EC Directive 64/433

In nine of 11 establishments, the provisions of EC Directive 64/433 were not effectively implemented. Specific deficiencies are noted in the attached individual establishment reports.

## 8.3 Other Sanitation Deficiencies

- In five establishments, equipment and utensils used for processing or otherwise handling edible product or ingredients were not adequate to maintain sanitary conditions. For example:
  - Identity of grey, yellow and red plastic tubs used for edible product was not maintained. The tubs were used for edible, inedible and non-product storage purposes. This posed a substantial potential for inedible product to be used for edible purposes.
  - A company employee contaminated the top of a product transportation cart with the sole of their boot and then placed an edible product tub onto the same cart. The cart would normally be placed on a product table, therefore causing contamination of the product table with residue from the sole of the boot.
  - Cones from the whole bird cutup line were coming into contact with product that had piled up on the floor at the end of the line. This posed a potential for contamination of edible product from the product accumulated on the floor.

- The dropped meat reconditioning station was not identified or equipped to maintain sanitary conditions. This posed a substantial risk for the station to be used for purposes other than dropped product and reconditioned product to be recontaminated from a surface that was not cleaned and sanitized properly between each use.
- In five establishments, equipment and utensils were not maintained in sanitary condition so as not to adulterate product. For example:
  - A partially covered gondola of spices was stored under an unprotected wooden pallet in the spice room. This posed a substantial risk for contamination of the gondola and spices with particles and wood splinters from the pallet.
  - Product tubs located close to the floor were cross contaminated with tops of employees' boots. This posed a substantial risk for contamination of edible product contained in the tubs by residue from the boots.
  - After cleaning, product carts were stacked with the wheels in contact with the top surface of the cart below. The wheels were constructed of materials that could not be cleaned and sanitized adequately. Plastic product tubs used for edible product were stacked on the top surface of the carts and then placed on edible product tables.
- In five establishments, product was not protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments. For example:
  - An overhead door for unloading trucks remained open providing direct access to exposed raw product.
  - Packaging material and box flats were stored against the walls of the storage room.
  - Black unidentified material was identified on the ceiling around the refrigerator unit in the red offal cooler.
  - Cartons of raw meat products were covered with ice and frost.
- In five establishments, ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions was not provided. For example:
  - Excessive amount of frost was identified on the ceiling and walls of the liver and scallion storage freezer.
  - Condensation was identified over product in the carcass cooler and the red offal cooler, and over workers and personnel traffic areas in some of the processing rooms, shipping dock and carcass load out.
  - Condensation was observed on pipes next to the flaking machine in the raw product processing room.
- In three establishments, the establishments were not maintained to prevent conditions that could lead to insanitary conditions or adulteration of product. For example:
  - The filled can storage room was not cleaned at a frequency sufficient to prevent insanitary conditions.

- A rodent dropping was found on two separate pallets in the filled can storage room.
- Dust, cobwebs and damp floors were identified in the annex used to store finished products.
- In two establishments, establishment buildings were not kept in good repair. For example:
  - The overhead of the white offal room was rusty and equipment was maintained in poor condition.
  - Miscellaneous debris was identified behind the storage racks along the floor-wall junction.

## 9. ANIMAL DISEASE CONTROLS

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

No deficiencies were noted.

## 10. SLAUGHTER/PROCESSING CONTROLS

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

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

### 10.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

### 10.2 HACCP Implementation

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

The HACCP programs were reviewed during the on-site audits of the 11 establishments. None of the 11 establishments had fully and adequately implemented FSIS' HACCP requirements. The following deficiencies were noted.

- In six establishments, the hazard analysis and HACCP plan was insufficient. For example:
  - Rework and returned product were not included in the flow chart or considered in the hazard analysis.
  - Two different products from different processes were controlled by one CCP in the HACCP plan. There were two separate and distinct critical limits for the one CCP.
  - Biological, chemical and physical hazards were not considered for each processing step in the hazard analysis.
  - The intended use, special labeling instructions and ingredients were not included in the HACCP plan.
  
- In eight establishments, ongoing verification activities were not adequately described in the HACCP plan.
- In four establishments, monitoring activities were not adequately described in the HACCP plan.
- In one establishment, monitoring activities were performed for zero-tolerance, but the written procedure in the HACCP plan described two levels of monitoring.
- In five establishments, the written HACCP plan did not include measures to prevent recurrence after a corrective action was implemented.
- In five establishments, the establishment did not maintain all of the required records documenting their HACCP plan. For example:
  - Records were maintained that documented food safety hazards that were reasonably likely to occur, but biological, chemical and physical hazards were not considered in the hazard analysis for all processing steps described in the flow chart.
  - Calibration of equipment was performed, but the establishment did not maintain a written procedure for the calibration of equipment used to measure critical limits.
  - Preventive measures for a deviation from a critical limit were not described in the records documenting corrective actions for the deviation.
- In one establishment, the establishment did not reassess the adequacy of the HACCP plan annually.

### 10.3 Testing for Generic *E. coli*

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

Three of the 11 establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiencies were noted.

#### 10.4 Testing for *Listeria monocytogenes*

Three of the 11 establishments audited were producing ready-to-eat products for export to the U.S. In accordance with FSIS requirements, the HACCP plans must be reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to exist. The following deficiency was noted.

- In two establishments, the reassessment of the HACCP plan did not adequately address the presence of *Listeria monocytogenes*.

#### 10.5 EC Directive 64/433

In nine establishments, the provisions of EC Directive 64/433 were not effectively implemented. Specific deficiencies are noted in the attached individual establishment reports.

### 11. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls.

No deficiencies were noted.

### 12. ENFORCEMENT CONTROLS

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

#### 12.1 Daily Inspection in Establishments

Inspection was not being conducted daily in one establishment.

- In one establishment, daily inspection was not provided for the maturation process of fermented dry pork sausage.

#### 12.2 Testing for *Salmonella*

France has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures.

- Analytical Methods—France uses ISO 6579:2002 to analyze samples for *Salmonella*, and
- Enforcement Strategy—France suspends an establishment from export the first time it fails to meet a *Salmonella* performance standard.

No deficiencies were noted.

### 12.3 Species Verification

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

### 12.4 Monthly Reviews

During this audit, it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required. However, in some establishments, the reviews did not accurately reflect establishment conditions and/or where deficiencies were noted, effective corrective actions were not taken by the inspection service.

### 12.5 Inspection System Controls

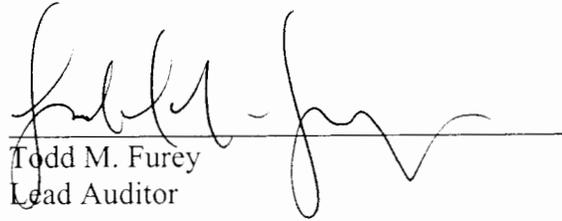
These controls include ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

The following deficiencies were noted.

- In two establishments, pre-operational sanitation was not performed in an adequate manner. For example:
  - The sausage hang area containing sausage trees, sausage hangers, and containers which held the sausage hangers has never been scheduled for pre-operational sanitation inspection. The establishment has been in operation for three years.
  - Pre-operational sanitation verification was performed five times in the last 12 months. Many pre-operational sanitation noncompliances were identified during this audit, therefore the frequency was not adequate to verify the effectiveness of the establishment's pre-operational sanitation program.
- A careful post-mortem examination and inspection was not made of the parts of all livestock slaughtered at one establishment. For example:
  - In one establishment, viscera dropped from carcasses into the bleeding trough did not receive post-mortem inspection. All viscera were not inspected to determine the wholesomeness of each carcass.

### 13. CLOSING MEETING

A closing meeting was held on February 12, 2004, in Paris, France, with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.



Todd M. Furey  
Lead Auditor

14. ATTACHMENTS TO THE AUDIT REPORT

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

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Madrange Feytiat, France	2. AUDIT DATE 01/28/2004	3. ESTABLISHMENT NO. 87-065-01	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<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.	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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<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	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Aromont Montcornet, France	2. AUDIT DATE 02/04/2004	3. ESTABLISHMENT NO. 02-502-01	4. NAME OF COUNTRY France
	5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<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	
<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	X
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	
<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.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. Notice Of Intent to Delist.	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Rougie Bizac Sarlat, France	2. AUDIT DATE 01/23/2004	3. ESTABLISHMENT NO. 24-520-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		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.		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.			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	X
24. Labeling - Net Weights			52. Humane Handling	O
25. General Labeling			53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>			55. Post Mortem Inspection	O
27. Written Procedures		O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		O	56. European Community Directives	
29. Records		O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>			58.	
30. Corrective Actions		O	59.	
31. Reassessment		O		
32. Written Assurance		O		

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Castaing Saint Sever, France	2. AUDIT DATE 01/26/2004	3. ESTABLISHMENT NO. 40-282-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<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.		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	
<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	X
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	X
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.	X	<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	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59. Delistment	X
31. Reassessment	O		
32. Written Assurance	O		

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Société Nouvelle Lamaudie Figeac, France	2. AUDIT DATE 01/21/2004	3. ESTABLISHMENT NO. 46-102-04	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Capel la Quercynoise Gramat, France	2. AUDIT DATE 01/22/2004	3. ESTABLISHMENT NO. 46-128-02	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<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	X
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	
<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.		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	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<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	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Olympig Josselin, France	2. AUDIT DATE 02/02/2004	3. ESTABLISHMENT NO. 56-091-01	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
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
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	X	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Notice Of Intent to Delist	X
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 Salaison Polette Teilheide, France	2. AUDIT DATE 01/19/2004	3. ESTABLISHMENT NO. 63-427-01	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<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.		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	
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/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.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	X	<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	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59. Delistment	X
31. Reassessment	O		
32. Written Assurance	O		

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Feyel Artzner Schiltigheim, France	2. AUDIT DATE 01/16/04	3. ESTABLISHMENT NO. 67-447-05	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ets Georges Bruck Strasbourg, France	2. AUDIT DATE 01/15/2004	3. ESTABLISHMENT NO. 67-482-21	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<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.	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.		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	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Rougié Bizac International Les Herbiers, France	2. AUDIT DATE 01/30/2004	3. ESTABLISHMENT NO. 85-109-01	4. NAME OF COUNTRY France
5. NAME OF AUDITOR(S) Dr. Don Carlson		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<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.		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	X
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	
<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	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<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	O	59. Delistment	X
31. Reassessment	O		
32. Written Assurance	O		



Old  
4/30/04

EMBASSY OF FRANCE IN THE UNITED STATES  
ECONOMIC DEPARTMENT  
THE MINISTER COUNSELOR

Washington, April 22 2004

**Subject:** comments on the USDA / FSIS draft report

**Contact:** Carol Buy  
**Tel.:** (202) 944 6000  
**Fax:** (202) 944 6336  
**Email:** carol.buy@dree.org

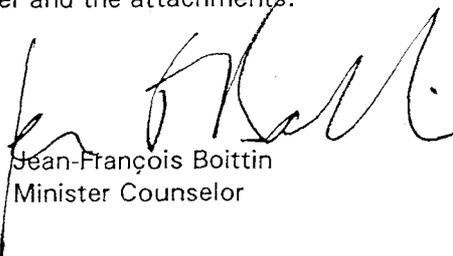
Ms Sally Stratmoen  
Director  
International Equivalence Staff  
Office of International Affairs  
Food Safety and Inspection Service  
US Department of Agriculture  
Room 2143 - S  
1400 Independence Avenue, SW  
Washington DC 20250

Dear Ms Stratmoen,

Please find enclosed a letter from Dr Isabelle Chmitelin, Chief Veterinary Officer and Deputy General Director for the French General Directorate for Food, Ministry of Agriculture, Food, Fisheries and Rural Affairs, together with three attachments, in reply to your letter of February 24, and to the draft report on a visit to USDA-certified French establishments and to 9 Departmental Veterinary Services (DDSV).

I have also attached an unofficial translation of the letter and the attachments.

Sincerely,



Jean-François Boittin  
Minister Counselor

Copy : M. Gérard Depayre  
(Delegation of the European Commission)

OIES/308  
BW 4/23/04

Dear Ms Stratmoen,

In accordance with the provisions of the Veterinary Agreement of March 1998 between the United States of America and the European Community, I have the honor to reply to your letter of February 24, and to the draft report on a visit to USDA-certified French establishments and to nine Departmental Veterinary Services (DDSV). This was the sixth inspection audit of French establishments since 2000 under article 9, paragraph 2 of the Agreement mentioned above. I also learned of the memorandum you sent to the European Commission (DG Sanco) the same day.

In this memorandum, I would like to present the overall view of the French authorities. It is accompanied by three attachments: The first is a general comment on the draft inspection audit report; the second contains specific comments on each of the establishments visited; and the third details additional measures undertaken since the conclusion of the American mission. All of this is of course with a view to the rapid and broad resumption of meat-product exports to the United States.

1.-The immediate suspension of French exports in the form of a safeguard clause, presented as an urgent measure to protect the health of American consumers, seems disproportionate and consequently unjustified. Indeed, it indiscriminately affects all the certified enterprises, even though some were considered by your services as having globally satisfied the American rules. Furthermore, no facts have been presented characterizing the real or potential risk to consumers, whether they be American or European. I would also note that the inspectors did not find any fault with our service's inspections for animal diseases (including zoonoses) and chemical or bacterial contaminants (salmonella, E. coli). Finally, I would underscore that in every case, the chemical and microbiological performance objectives met the U.S. requirements.

2.-Since 1999, our services have made a special effort to satisfy American demands (between 1999 and 2004, ten memoranda were written to clarify American regulations to the DDSV). Following each inspection, the experts' report was transmitted to the concerned DDSV office, accompanied by the appropriate recommendations. Since May 2003, the DDSV has had a significant consultation and control mechanism (see my letter of May 6, 2003). Between June 2003 and January 2004, 82 inspections were carried out at 12 certified establishments, in addition to the regular and oversight visits provided for by American regulations. Interregional technical officers (8 nationwide) have taken part in oversight visits. A national technical officer (referent) responsible for providing inspectors with specific training about USDA health requirements also took part in these visits.

Furthermore, our services had to adjust to the changing assessment made on a case-by-case basis by the inspector appointed by your services during each inspection mission, on the mode of operation of certain establishments. Moreover, without making any changes, facilities considered satisfactory in structure and mode of operation (particularly with regard to the implementation of the HACCP) by the inspector in spring 2003 no longer were less than a year later (see for example, the selection of measures for the management of products that had fallen on the ground/illustrations in attachment 2). These developments in themselves constitute uncertainty factors that make it difficult to comply with American demands.

IES/308  
BW 4/23/04

3.-With respect to the observations made in the French establishments that were visited, attachment 2 details the corrective measures that were immediately put in place wherever warranted.

4-You presented this enforcement mission as an audit of the system designed to evaluate the ability of inspection services to monitor the certified enterprises' respect of USDA requirements. The general suspension decision therefore could be motivated only by an observation of the French system's overall failure. Yet I see nothing of this in the provisional report, as the specific audit of French veterinary services by the lead inspector noted only that the DDSV training program was insufficient.

You will understand that I cannot, in these circumstances, share your conclusion.

5.-The French authorities strive to guarantee a level of excellence in the areas of both the HACCP and the SSOP. We expend considerable effort to do so, as indicated in attachment 3 to this memorandum. The new measures that have been implemented revolve primarily around second-level technical assessment, for which responsibility has been entrusted to Dr. Bernard Vanhoye, Chief inspector of veterinary public health, under the direct authority of the Director General, Food General Directorate (DGAL); technical support to USDA-certified plants assigned to our national technical officer (Dr. Maryse Flamme); an upcoming European-American seminar in Ireland on HACCP systems and standard sanitary operating procedures (SSOP); and improving inspector training in these two areas. I hope that this training might be enhanced by the presence of an experienced FSIS inspector, who could share his experience. If you agree, I will take the liberty of requesting that when the time comes.

6.-I hope that the different elements presented herein as well as the measures taken in recent weeks by France and the European Union will result in the rapid and broad resumption of French meat-product exports to the United States of America. In the immediate term, the French authorities ask you to kindly resume without delay and without further formalities the imports of the 6 enterprises that did not elicit any negative decisions by the inspector upon the conclusion of his visit.

Sincerely,

Cc: Mr. Lambert, Ms. Rossat Mignod (office of the minister)  
Mr. Checchi-Lang, Mr. Scannell (DG Sanco)

**APPENDIX 1 – GENERAL COMMENTS ON THE PROVISIONAL DRAFT REPORT.**

**3. PROTOCOL**

*During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health.*

Comment: Both in the provisional report and in the course of the closing meeting of February 12 2004, the auditors gave no information on the nature, the extent and degree to which non-compliance findings impacted on food safety and public health. The expressions « causing contamination », « substantial risk » ... which appear in the provisional report are not appropriate wording in this context.

Many examples illustrating this lack of detail and precision are listed in appendix 2.

Let us take as an example establishment RBI 24-520-02, where employees use an overhead walkway to walk over the deveined livers' conveyor belt. A sheet of plexiglass covers the entire part of the conveyor belt situated under the walkway in order to protect products. The auditor asked for two holes (about 1 cm in diameter) in the plexiglass to be filled because he considered there was the possibility that an employee walking across the walkway might cause elements to fall which then, by falling through one of these holes, might likely end up on the liver conveyor belt... The corrective measure was immediately implemented.

**6.2.2 Ultimate Control and Supervision**

*DGAL headquarters in Paris has the ultimate control and supervision of France's meat and poultry inspection system. Although France's inspection system is centralized, there appears to be little to no communication between Department offices and the certified establishments regarding FSIS inspection requirements and little to no follow-up activities by the inspection service to ensure that the requirements are effectively implemented.*

Comment: The chart showing the number of « visits » carried out per establishment qualifies the statement made by the auditor according to which there are little follow-up activities by the inspection service to ensure American requirements are implemented.

The chart hereunder indicates the number of inspections of visits carried out between the previous audit (April-May 2003) and the audit of January-February 2004.

	Inspection USA Production Days	Inspection pre- operational	Supervision	Support export coordinator	Support National technical expert	Other support DDSV, director BMP, CS SSA
87 Madrangé	85	3	9	3	3	
56 Olympig	12	3	7	4	2	2
40 Castaing	18	3	7	3	1	6
40 Labeyrie	27	1	12	1	1	1
2 Aromont	51	2	12	5	3	
67 Feyel	7	1	4	2	1	

Artzner						
67 Brück	2	0	3	1	1	
24 RBI	28	4	9	4	3	11
63 Polette	17	2	7	2	2	
85 RBI	Every day between May and January	4	14	4	2	4
46 Larnaudie	5	4	4	2	1	
46 La Quercynoise	76	4	9	2	1	

### 6.2.3 Assignment of Competent, Qualified Inspectors

*At all levels, adequate training of inspection personnel in HACCP still has not been completed. Similar findings in many of the establishments indicate that the national training program was insufficient.*

Comment: The provisional report does not take into account the training program set up between the previous audit (April – May 2003) and the January – February 2004 audit.

### 6.3 Audit of Headquarters and Department Offices

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

- Internal review reports,*
- Supervisory visits to establishments that were certified to export to the U.S.,*
- Training records for inspectors,*
- New laws and implementation documents such as regulations, notices, directives and guidelines,*
- Sanitation, slaughter and processing inspection procedures and standards, and*
- Export product inspection and control including export certificates.*

*The following concerns arose as a result the examination of these documents.*

- *Training of inspection personnel in SSOP, sanitation principles, and FSIS' HACCP requirements is inadequate. The similar findings in many of the establishments indicate that the national training program was insufficient.*

Comment: The mission of the « lead » inspector at the DGAL and in the 9 Department Veterinary Services (DDSV) was not reported whether it is in general or specific terms. No mention is made in the provisional report of any findings on the 6 points mentioned above in relation to the individual Department Services.

In addition, the length of the visits of the 9 Department Veterinary Services Directorates (DDSV) which lasted between ½ hour and 3 hours, most of the time only 2 hours, without any preset guidelines, did not allow for a systematic review of all the points mentioned in paragraph 6.3 above. It is therefore difficult for the French authorities to agree with the unfavorable general conclusion drawn by the American authorities at the end of the mission.

**APPENDIX 2 - COMMENTS ON THE ESTABLISHMENT AUDIT REPORTS AND CORRECTIVE ACTIONS IMPLEMENTED**

**France. Est. 02-502-01: Ets Aromont, Montcornet, February 4, 2004.**

**13/51)**

***Preventive measures for corrective actions were not included in the daily records documenting pre-operational and operational sanitation noncompliances.***

Comment: This is a requirement, which is specific to American regulations. In practice, deficiencies are reported on a daily basis and the establishment quality assurance team during meetings, which are held at regular intervals, examines appropriate preventive measures.

**15/51)**

***1. the establishment did not considered biological, chemical and physical hazards for all processing steps.***

Comment: The hazard analysis, in spite of a lot of work already been done, was admittedly not exhaustive. This deficiency has been corrected since the audit.

***2. Rework product was not included in the flow chart and was not considered in the hazard analysis.***

Comment: In practice, instructions are given for rework products. An instruction originating from the establishment's quality assurance department gives, in general terms, the possible destinations of a technically non-compliant product. In addition, since these products are to be reworked, they are considered as non compliances and, for this very reason, can no longer be included in the production flow chart. The flow chart is to include only products, which are edible.

***3. One CCP for temperature controlled cooling processes in multiple cooling rooms.***

Comment: The HACCP plan has actually redefined the critical points for the temperature in each cooling room individually. The cooling rooms (about 10) are now numbered and their individual number appears on the temperature-recording document.

***4. Identification of the cause of a deviation and preventive measures for a deviation from a critical limit were not described in the HACCP plan.***

Comment: Even though they did exist, the measures were not formalized in the HACCP plan.

**22/51)**

***Identification of the cause of a deviation and preventive measures for a deviation from a critical limit were not described the records documenting corrective actions for the deviation.***

Comment: The comment made for 15/51) 4 apply here as well.

**41/56)**

***Condensation was observed on pipes next to the flaking machine in the raw product processing room, and under refrigeration units in several product storage areas.***

Comment: There was condensation, but non protected products are never placed under the areas concerned and the SSOP plan includes monitoring and regular wiping of the areas of condensation. In the areas where condensation is likely to appear, the products themselves are protected directly (conditioning, plastic film...) or indirectly (removable awning placed above containers during emptying activities).

46/56/51)

**1. Unidentified black particles were observed on packages of ingredients stored in the ingredient storage room.**

Comment: Ingredients are always at least conditioned and even sometimes wrapped. As a consequence, risk of product contamination is negligible.

**Ingredients were unprotected and stored under wooden pallets.**

Comment: some sort of conditioning process always protects Ingredients. Most of the pallets used were made of plastic. The ingredients mentioned were in fact bags of sugar wrapped in Kraft paper.

**2. Cartons of raw meat products stored in temporary storage trailers were covered with ice and frost.**

Comment: One must take into account the fact that the establishment had talked in detail, as of the end of 2003, of its intention to extend its cooling capacity to replace the temporary outside storage trailers.

46/56/ 38/51)

**1. Dust and cobwebs were identified on the second level of the annex used for dry storage. 38/51)**

Comment: The auditor did in fact find a few cobwebs, but all products, which are shelf-stable, are conditioned in air-tight buckets and the buckets are placed under plastic covers. It should be noted that in the past months, the establishment has made considerable efforts to improve the storage conditions of these products.

**2. Dust, cobwebs and damp floors were identified in the annex used to store finished products.**

Comment: Same as above.

**3. One end of the annex use for the storage of finished product was used to store unused equipment. The area was very congested and equipment was not stored in a manner that facilitated adequate cleaning.**

Comment: This non-compliance has been noted, see corrective action described hereunder.

General comment: During the debriefing session, the auditor acknowledged the excellent level of reactivity on the part of the establishment (operators and management) and did not add anything to the comments made by the supervisor.

Actions implemented in response to the non-compliances mentioned in the provisional report.

*Excessive condensation:*

Reinforcement of existing measures.

Drafting of a specific instruction which gives special heed to the risk of employee cross-contamination.  
Plan to install an air extractor in the raw product atelier ("concentré protéines solubles" (CPS)) in April 2004.

*Storage coolers:*

Plan to extend capacity – construction work to be completed by June 2004.

*Outside storage areas:*

Improvement of control of sanitary conditions in these areas, especially by ensuring correct closing of access points and cleaning and tidying up in packaging storage area.

Pest control is now outsourced to a service provider.  
A storage platform is presently under construction.  
A procedure to ensure upkeep of outside structures is under study.

*Wooden pallets:*

Ingredients are no longer stored on wooden pallets.  
Plastic pallets have replaced the remaining wooden pallets.

*HACCP Plan:*

A complete review of the HACCP plan is being completed.

**France. Est. 24-520-02 : Ets Rougie Bizac, Sarlat, January 23, 2004.**

*Extract from the provisional report.*

***In three establishments, the establishments were not maintained to prevent conditions that could lead to insanitary conditions or adulteration of product. For example:...Dust, cobwebs and damp floors were identified in the annex used to store finished products.***

Comment: The auditor observed the presence of dust and one cobweb in the annex used to store sterilized finished products which were conditioned in metal cans and packaged (in cartons). He insisted that the frequency of cleaning and disinfecting of this area should be reviewed. It is difficult to understand how the observations made in this area could possibly lead to insanitary conditions or adulteration of the products.

The observation made by the auditor was taken into account by the establishment and cleaning and disinfecting of the area were performed. The areas used to store finished products were cleaned in order to eliminate the dust. The cleaning frequency of the areas used to store finished products and of the areas used to store raw goods was reviewed: instead of cleaning the areas once a year, cleaning will be done on demand, which means as soon as there is evidence of dust.

***13/51)***

***Preventive measures for corrective actions were not included in the daily records documenting pre-operational and operational sanitation non-compliances. This was a repeat finding identified during the previous audit of April/May 2003.***

Comment: This remark was made following the review of records dating back to 2003 because since the beginning of 2004, an additional item appears on the recording form for pre-operational and operational monitoring in order to note down preventive measures. This means that the corrective action has already been implemented.

***15/51)***

***1. Critical limits were measured, but were not described in the HACCP plan and were not definitive or appropriate.***

Comment: The establishment has committed to reducing the number of critical limits per CCP. As an example, for the « seaming » CCP which was observed during the audit, the establishment will only take into account one critical limit (measure of the overlap zone between the body hook and bottom hook must be larger than 1 mm)

***2. Ongoing verification procedures were performed, but were not described in the HACCP plan.***

Comment: The establishment has committed to having the monitoring procedures carried out by the monitor noted down in writing.

22/51)

**1. Records documenting the monitoring of CCPs were not signed or initialed by the monitor.**

Comment: Initials of the person responsible for monitoring the CCPs will, from now on, appear on the records. The corrective action is implemented.

**2. Preventive measures for a deviation from a critical limit were not described in the records documenting corrective actions for the deviation.**

Comment: The establishment has undertaken to formalize this point.

**France. Est. 40-282-02: Ets Castaing, Saint Sever, January 26, 2004.**

Preliminary comment: The atmosphere was particularly tense during the documentary audit.

7/51)

**The SSOP did not describe all procedures used to monitor the daily operational sanitation activities.**

**1. The SSOP did not describe a procedure for the reconditioning of product dropped onto the floor.**

Comment: It is said that the SSOP does not describe a procedure for products dropped onto the floor. Nevertheless, the establishment does have a procedure describing how such incidents should be managed.

**2. The SSOP did not describe a procedure for monitoring the temperature of 82°C water equipment sanitizers.**

Comment: The auditor noted that there was no written procedure concerning the recording of the temperature of the knife sanitizers. It is true that the procedure is not written down, but the establishment carries out extremely detailed recordings, regularly updated, at all production stages. In fact, the knife sanitizers' temperatures are recorded each day by a person in charge and the person in charge of quality assurance, who was being interviewed, was able to produce in a very short time frame, all the records to show them to the auditor. These records are easy to check and particularly well organized.

10)

**The following product contact equipment was identified as requiring additional cleaning and sanitizing during pre-operational sanitation verification by French Veterinary Services:**

**1. In the not ready-to-eat areas, product residue from the previous day's production was identified on product slicing parts, tumbling machine, vegetable cooker, fat cookers, hand operated knives, and the inside of can filling pipes. Rust was identified on the blade of a ban saw.**

Comment: In the areas for hot and cold food processing, it is indicated that product residue from the previous day's production was identified on small pieces of equipment, as well as on certain machines. Obviously this refers to product residue on the cookers. It is true that on the day of the audit, there was a cooker with fat, but fat is necessary for the cooking of the confits. In addition, the small pieces of equipment mentioned were immediately cleaned.

**2. In the ready-to-eat slicing room, grey watery material was identified on the product contact surface of a slicing machine belt, 25 to 30 black unidentified particles were identified on the surface of a product table, product residue from the previous day's**

*production was identified on cooling racks, the cooling oven and scale supports which were in contact with the surface of a product table.*

*All equipment was presented for use for the day's production of food products.*

Comment: In the magret (duck breast) slicing room, it is also mentioned that there is product residue from the previous day. Here again, certain pieces of equipment had to be cleaned again, but this did not prove necessary for the whole room. In addition, there were much less than « 25 to 30 black unidentified particles on the surface of a product table » (most probably, they were just a few particles projected by the refrigerating unit). The establishment reacted quickly and appropriately to correct the situation.

The remarks in points 1 and 2 above are critical of the general conditions of the establishment's facilities at the time of the pre-operational audit. In fact, the establishment was on the whole maintained quite adequately (small pieces of equipment, the different areas).

**13/51)**

***1. Preventive measures for corrective actions were not included in the daily records documenting operational sanitation non-compliances.***

Comment: However, the establishment has made it a point to write down all the necessary observations on the SSOP documents and has paid specific attention to the application of the relevant corrective and preventive measures.

***2. Non compliances were not adequately described in the daily pre-operational sanitation records.***

Comment: It is true that certain non-compliances were reported succinctly in some of the reports. Nevertheless, these reports date back to the beginning of 2003. After reviewing the issue, the establishment had set up a system whereby description of non-compliances was much more detailed. The auditor was shown the reports of the end of 2003 and beginning of 2004 where non-compliances were adequately described.

***3. Records documenting operational and pre-operational sanitation reflected repeat deficiencies and repetitive preventive measures for pre-operational sanitation non-compliances that were not effective.***

Comment: A certain number of repeat non-compliances associated with identical corrective or preventive measures were observed. The repetitive character of the preventive measures is a necessary feature of the approach, which is to raise awareness among the staff as to sanitation issues. In addition, as mentioned under 2), the establishment did re-examine the issue of the records as well as the implementation of concrete measures. In addition, this point contradicts point n° 1 where the auditor notes that he did not see any written description of preventive measures.

**15/51)**

Preliminary comment: Concerning the HACCP plan in general, the person responsible for quality control was not given the possibility to explain clearly and calmly the structure and rationale of the establishment's HACCP plan. (See preliminary remark on the rather tense atmosphere during the audit).

***2. The establishment did not consider biological, chemical and physical hazards for all processing steps.***

Comment: it cannot be said that the establishment does not take into account biological, chemical and physical risks for all production steps. This observation arose after a misunderstanding between the auditor and the person in charge of quality assurance. In fact, it is obvious that the establishment takes all three types of hazards into consideration, but chemical and physical hazards have been grouped together whereas biological hazards are examined for all production steps for each product. As with the SSOP, even if certain procedures were not adequately described in the HACCP plan, the

establishment was nevertheless able to provide all the information regarding production and was able to answer all the questions asked.

**4. The frequency for measuring critical limits was not stated in the HACCP plan.**

Comment: All the control points required by the auditor were effectively taken into account. The deficiency he observed was a lack of formal written description of the procedures. For instance, evidence was given to show that the temperature of the sanitizers was monitored daily, even though there was no specific written procedure.

**21/51)**

**The establishment did not include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or of an indicator organism, is maintained as required by 9CFR 430 alternative III.**

Comment: The establishment does ensure effective control of *Listeria monocytogenes*, and, to that end, has implemented a protocol recommended by the USDA. The only item missing was scientific justification for the testing frequency. This observation is proof that the establishment is strongly committed to integrating in the production processes all the aspects included in the American requirements. One documentary item was missing in the procedure, but from a practical standpoint, it has no impact on the validity of the procedure itself, because this item is not directly involved in the actual testing procedure.

**38/51/56)**

**1. Many cobwebs were observed under pallets and between pallets in the filled can storage room and the packaging storage room. This was a repeat finding identified during the previous audit of April/May 2003.**

Comment: The above observation actually refers to the presence of a few cobwebs and two mouse droppings in the filled can storage area and the packaging storage room. The auditor was particularly meticulous during the visual check of these areas (he practically checked each pallet in the storage area individually). As a result, he had a biased impression of the storage management system of the establishment. In fact, the establishment has made significant efforts for the overall maintenance of its storage areas. On the day of the visit, as on any production day, these areas were clean, and there was no problem to access each of the storage areas. The two cobwebs were found in the packaging storage room, on a pallet holding packaging material wrapped in plastic, and the person in charge of quality assurance immediately removed them. And in any case, there was nothing, which could have had an impact on the safety of the products made by this establishment.

**2. Evidence of rodents inside this establishment was observed. A rodent dropping was identified on two separate pallets in the filled can storage room.**

Comment: The two mouse droppings were found on pallets used to store mushroom (boletus) cans coming from another establishment. It should be mentioned that this area is the storage area for finished canned goods, and there is no risk of product contamination. Despite his thorough inspection, the auditor found no other evidence of rodent activity in the establishment.

**3. The rodent control program did not include inside traps, bait stations or a written corrective action procedure for rodent infestation. The rodent control program was not effective.**

Comment: The establishment did have a rodent control program, but it is true that the focus was on controlling the areas surrounding the facilities.

**41/56)**

**Condensation was identified on refrigeration lines in the canning room, fat cooler and the slicing room.**

Comment: The observation regarding condensation on several of the refrigeration units in the establishment seems excessive. It is true that there was one drop of condensation stuck to the refrigeration line in the slicing room, but it was frozen, and the pipe was not located in a production area and therefore had no possible effect on product safety. The auditor insisted heavily on this issue throughout the visit, and went so far as to wait for a drop to fall.

**43/56)**

***The hot water supply to the sink located at the entrance to the ready-to-eat slicing room was too hot for proper hand washing procedures.***

Comment: The non-manual operated hand washing sinks installed throughout the establishment were all in working order, clean and in good condition on the day of the visit. However, these sinks are not programmed to supply water at a stable temperature for a long period of time. On the day of the audit, the people participating in the visit (10) washed their hands, one after the other, and this explains why the last ones in line had water that was too hot (the establishment does need to correct this situation).

**46/51/56)**

***1. An overhead door for unloading trucks remained open providing direct access to exposed raw product stored in the receiving cooler.***

Comment: The auditor mentions that during the visit, a sliding door which opens onto the outside on the raw goods reception dock was left open. In reality, when the first visitors arrived in this area, a truck was parked alongside the dock and was unloading merchandise. During the time which elapsed between the first and the last auditor walking into this area, the door between the dock and the receiving cooler had obviously to remain open. The arrival of a large group of people created a « panic situation » which would not have occurred in the normal course of activities, with the truck departing before the door was closed.

***2. Packaging material and box flats were stored against the walls of the storage room.***

***3. General house keeping of the part of the dry storage room used for storage of archived records and the filled can storage room was poor.***

***4. Product equipment, storage shelves and packaging material used on a daily basis, was stored in the packaging storage room.***

Comment on points 2, 3 and 4: The auditor made observations on the general housekeeping of the storage areas. Even if it is true that along a distance of a few feet, packaging material was stored against the walls, it was nevertheless always possible to visualize all of the material stored. There was available access to all areas and all areas could be checked. Observation n° 4 about the storage of production equipment used on a daily basis in the storage areas needs to be put into context. It is true that, due to the fact that this was a slow period of activity, the establishment had stored production equipment in a large passage way next to the washing area (but not, as was reported, in the storage areas). Finally, the observation on the poor housekeeping of the room used for archives is also somewhat surprising because this area, which is isolated from the other storage areas, was tidy and well kept.

**51)**

***Pre-operational sanitation verification was performed by French Veterinary Services five times in the last 12 months. Many pre-operational sanitation non-compliances were identified during this audit; therefore the frequency was not adequate to verify the effectiveness of the establishment's pre-operational sanitation program.***

Comment: The minimum frequency recommended in the Megareg for pre-operational visits is one visit per quarter. In this establishment, the inspector made 5 pre-operational visits during the year 2003 (3 of these visits having taken place between the two last audits, see chart in appendix 2).

59)

*French Veterinary Services voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective as of the start of operations on the day of this audit. The FSIS auditor was in agreement with this decision.*

Comment: It should however be recognized that, throughout the 13 hour-long audit, the person in charge of quality assurance and team were very reactive to the observations made by the auditors.

Actions implemented as a result of the non-compliances mentioned in the provisional report

*1 – Measures taken at the documentary level:*

SSOP: The establishment will improve its method of drafting in-house documents, and will take into account the observations made regarding the inadequacy of written procedures. In particular, a written procedure for the recording of the temperature of the knife sanitizers has already been drafted. And, preventive measures will, from now on, be written down during production.

HACCP: During 2004, the establishment will completely review and update its HACCP plan. The HACCP plan will be certified by a private certifying agency.

*2 – Measures implemented at the establishment level:*

The establishment has just invested in a hot water regulation system for the non-manually operated hand washing sinks. This system will ensure that water is kept at a stable temperature throughout the entire supply network, thanks to a buffer system.

The establishment is currently examining a possible fumigation system, which would eliminate cobwebs in the storage areas.

The rodent control program will shortly be adapted with the installation of bait stations inside the storage areas.

**France. Est. 46-102-04: Société Nouvelle Larnaudie, Figeac, January 21, 2004.**

15/51)

**1. Calibration of equipment was performed, but ongoing verification for calibration of equipment was not described in the HACCP plan.**

Comment: Verification is performed but not formally described.

**2. Calibration of equipment was performed, but the establishment did not maintain a written procedure for the calibration of equipment used to measure critical limits.**

Comment: Same comment as under 1) above.

38/39/51/56)

**Cleaning of auxiliary areas was performed, but clean frequencies were not stated in the SSOP. The filled can storage 56/51) room was not cleaned at a frequency sufficient to prevent insanitary conditions. Conditions identified:**

**1. Dust was identified on the top of all boxed and canned product.**

**2. Miscellaneous debris was identified behind the storage racks along the floor-wall junction.**

**3. Cobwebs were identified between the wooden parts of storage pallets and between the pallets and walls.**

Comments on point 1, 2 and 3: No impact on safety of packaged products.

General comment: it should be noted that the previous auditor never made any observation on this establishment. In the debriefing meeting, he mentioned some issues needing improvement, as confirmed by a representative of the DGAI who accompanied the mission. Nevertheless, from his analysis of the situation, he saw that the establishment was quick to react and considering the low impact of the existing deficiencies, he concluded that these did not entail a product safety risk.

Actions implemented as a result of the non-compliances mentioned in the provisional report.

*13/51) Preventive measures for corrective actions were not included in the daily records documenting pre-operational and operational sanitation noncompliances.*

A procedure has been set up under the control of the new person in charge of production and it has been formalized since the beginning of April 2004.

*15/51)*

*1. Calibration of equipment was performed, but ongoing verification for calibration of equipment was not described in the HACCP plan.*

*2. Calibration of equipment was performed, but the establishment did not maintain a written procedure for the calibration of equipment used to measure critical limits.*

1. and 2. : The in-house procedure for the monitoring and recording of the calibration of equipment used to measure critical limits of CCPs is described (gauge rod / micrometer, ELAB/ retort). The recording documents are in the process of being formalized.

*3. Preventive measures for a deviation from a critical limit were not described in the HACCP plan.*

Preventive measures in the event of a deviation from a critical limit are described.

For the seaming: resetting followed by monitoring and then decision on destination of products is taken.

For the retort: presently, theoretical schedule is applied. A new procedure to predict deviations is under study.

*22/51) Preventive measures for a deviation from a critical limit were not described in the records documenting the corrective actions for the deviation.*

Recording of preventive measures for a deviation from a critical limit: preventive measures are implemented, but not yet formally described; this point is currently being formalized.

*38/39/56/51) Cleaning of auxiliary areas was performed, but clean frequencies were not stated in the SSOP. The filled can storage room was not cleaned at a frequency sufficient to prevent insanitary conditions. Conditions identified:*

*1. Dust was identified on the top of all boxed and canned product.*

*2. Miscellaneous debris was identified behind the storage racks along the floor-wall junction.*

*3. Cobwebs were identified between the wooden parts of storage pallets and between the pallets and walls.*

The filled can storage room has been cleaned. The cleaning – disinfecting schedule and monitoring of its effectiveness are being reviewed. The cartons and boxes are clean. The floor-wall junction has been cleaned.

The pallets are satisfactory. There are no more cobwebs.

15/51)

**1. Monitoring activities were performed for zero-tolerance, but the procedure written in the HACCP plan described two levels of monitoring.**

Comment: In the HACCP plan, it is stipulated that critical points are to be monitored only at one level. The fact of having two levels of monitoring, which does happen sometimes, ensures a higher degree of safety but does not strictly comply with the HACCP principles.

41/56)

**Condensation was dripping from the vents of a refrigeration unit in the liver packaging room. The condensation was dripping over an employee walkway and an area where product was transported.**

Comment: The auditor observed condensation and droplets (only a few) under a refrigeration unit located in the liver packaging room. The way the establishment deals with this kind of problem is to avoid placing goods underneath the unit and also by cleaning and disinfecting the vents every day. Tests have been done and the results show lack of contamination. The issue had been raised by the previous auditor who had admitted that daily cleaning and disinfecting was effective together with bacteriological control tests. In the course of his mission, the auditor also seemed to agree with this procedure.

45/56

**2. Cones from the whole bird cutup line were coming into contact with product that had piled up on the floor at the end of the line. This posed a potential for contamination of edible product from the product accumulated on the floor.**

Comment: This observation did not appear in the report of the 2003 audit.

Actions implemented as a result of the non-compliances mentioned in the provisional report.

15/51)

**1. Monitoring activities were performed for zero-tolerance, but the procedure written in the HACCP plan described two levels of monitoring.**

The monitoring of the fecal contamination CCP will be redefined and modified by the end of April 2004 in the slaughterhouse HACCP plan. In the meantime, there are still two levels of monitoring.

41/56)

**Condensation was dripping from the vents of a refrigeration unit in the liver packaging room. The condensation was dripping over an employee walkway and an area where product was transported.**

The condensation dripping from the vents of the refrigeration unit in the liver packaging room is already included in the cleaning and disinfecting plan, (daily cleaning as well as disinfecting, regular bacteriological surveillance). As of the end of May, in-house tests will be added to the disinfecting control schedule (surface area testing with sponging).

45/56)

**1. Identity of grey plastic tubs used for edible product in the cutting room was not maintained. The tubs were used for edible and inedible product storage purposes. This posed a substantial risk for inedible product to be used for edible purposes.**

The establishment is in the process of implementing a system to identify the different tubs used in the cutting area according to the intended use of the products. By the end of April 2004, the establishment will purchase tubs to store edible products, which have gone through thermal treatment, and the HACCP plan will be modified once these new tubs are in service.

2. Cones from the whole bird cutup line were coming into contact with product that had piled up on the floor at the end of the line. This posed a potential for contamination of edible product from the product accumulated on the floor.

Since March 15, 2004, the carcass kick-off machine at the end of the cone cutting line has been modified. Stainless steel sheets have been installed on the edge of carcass kick-off machine. All carcasses are ejected and systematically collected on the disposal conveyor belt.

**France. Est. 56-091-01: Olympig, Josselin, February 2, 2004.**

**15/51)**

**1. The intended use, special labeling instructions and packing materials were not included in the HACCP plan.**

Comment: This observation has been taken into account, see paragraph below for actions implemented.

**2. Monitoring procedures were performed, but were not described in the HACCP plan. This is a repeat finding identified during the previous audit of April/May 2003.**

Comment: As indicated in the corrective measures, the HACCP plan is currently being reviewed.

**3. Ongoing verification procedures were performed, but were not described in the HACCP plan. This was a repeat finding from the previous audit conducted in April/May of 2003.**

Comment: Same as previous observation.

**4. The HACCP plan did not address all four parts of corrective action.**

Comment: Wrong. The HACCP plan settles preventive and corrective actions.

**21/51)**

**The establishment did not reassess the adequacy of the HACCP plan annually.**

Comment: The HACCP is reassessed annually. However, the date on which it was reassessed is not mentioned on the documents.

**39/45/51/56)**

**The overhead of the white offal room was rusty and equipment was maintained in poor condition.**

Comment: The overhead of the white offal room was effectively rusty. But it did not create a product safety risk.

**41/56)**

**Condensation was identified over product in the carcass cooler and the red offal cooler, and workers and personnel traffic areas in the Dutch cutting room, GMS room, shipping dock and carcass load out. This was a repeat finding identified during the previous audit of April/May 2003.**

Comment: The only place where there was over-product condensation was in the refrigerated storage of carcasses and in the red offal cooler. In all cases, corrective measures have been taken by the establishment in order to solve the problem and to prevent further contamination of products and personnel.

**46/56/51)**

***Black unidentified material was identified on the ceiling around the refrigeration unit in the red offal cooler.***

Comment: It was dust.

**47/56)**

***An establishment employee failed to wash his hands between handling each carcass retained for veterinary disposition.***

Comment: The auditor was told that the employee had to wash his hands every time he handled a carcass that was obviously contaminated, for instance by fecal material. A corrective measure was nevertheless implemented as indicated below.

**47/51/56)**

***A Veterinary Services inspector at the viscera inspection station failed to wash his hands after palpating contaminated viscera and prior to palpating the next set of viscera.***

Comment: This is a basic mistake, and it was easily corrected.

**55/51)**

***Viscera dropped from carcasses into a bleeding trough did not receive postmortem inspection from French Veterinary Services. All viscera were not inspected to determine the wholesomeness of each carcass.***

Comment: All the viscera dropped on the floor are withdrawn from human consumption. The viscera of carcasses, which might be withdrawn from human consumption, are inspected and declared unfit for human consumption.

A corrective measure was nevertheless implemented as indicated below.

**58)**

***The French Veterinary Services auditor who was leading the audit concluded on going HACCP and SSOP requirements and repeat deficiencies warranted the issuance of a Notice of Intent to Delist if corrective actions were not in place within 30 days of this audit. The FSIS auditor conducting the audit of this establishment was in agreement with this decision.***

Comment: If we agree with most of the remarks, we have focused on the point that the main problems met during the two last audits, condensation and grease, had been solved or reduced to a great extent. We note that the notice of intent to delist was a proposal from the auditor, taking into account the history of the establishment, which had been delisted in 2000.

Actions implemented as a result of the non-compliances mentioned in the provisional report.

The condensation in the red offal cooler is now under control.

Sanitary measures to be adopted by the operator in charge of moving the carcasses to the observation station. Raising awareness of the operator so that he follows the procedure put in place (washing and disinfecting of hands after handling heavily contaminated carcasses) and disinfecting of hands with a disinfectant towelette between each retained carcass which shows no evidence of contamination on the areas touched by the operator.

At the inspection station positioned along the line, any suspect carcass and corresponding viscera are identified with the same number. Red and white offal, once they have been identified, are taken off the hook and put into yellow tubs which are then taken along with the carcass to the observation station to undergo thorough inspection by the veterinary inspector. This procedure has been adopted as a temporary arrangement until the line is modified so as to allow for automatic conveying of offal and carcass.

The cleaning and disinfecting schedule for the red offal quick chilling cooler has been updated.

The whole structure (casings area) has been cleaned and the establishment plans to invest in the renovation of this area by the end of June 2004.

The HACCP plan is being reviewed so as to include the definition of the product as well as its intended use.

The Veterinary Services were able to witness within the 30 days, which followed the visit of the auditor, that the establishment had implemented corrective measures.

**France. Est. 63-427-01: Salaison Polette, Teilheide, January 19, 2004**

**10)**

***Pre-operational sanitation: Fat particles from the previous day's production were identified on a plastic interlock conveyor in the grinding/blending room. The conveyor was ready for use for the day's production of food products. French Veterinary Services was requested to re-inspect the conveyor three times prior to the release of the conveyor. This was a repeat finding from the previous audit conducted in April/May of 2003.***

Comment: The three fat particles were so discolored due to repeated use of detergents and disinfectants on the sausage meat conveyor belts that they were highly unlikely to entail a risk for the safety of the production. The conveyor belt is also made of a US licensed material, validated by the USDA, which is particularly resistant to deterioration (scrubbing, water jet and chemical products).

**10/51)**

***1. Plastic tubs used to transport finished product were not cleaned and sanitized daily to remove product residue from the previous day's production.***

Comment: Careful, the non compliance observed relates to the cleaning frequency of the tubs which is considered to be inadequate and not to their state of cleanliness. It only concerns the tubs intended for finished products and they are cleaned every week.

***2. Sausage hangers and the container, which held the sausage hangers, were contaminated with multiple fat scraps from the previous day's production. This was observed while operations were being conducted in the sausage stuffing room. The sausage hangers were round hollow tubes and were not sealed at each end.***

Comment: There were a few discolored fat scraps on some of the hangers used for hanging the sausages. The tubes are indeed hollow and galvanized. But the sausages are not in direct contact with these materials. Nevertheless, cleaning and disinfecting of the frames and tubes are included and done within the general cleaning and disinfecting program for all the equipment.

**12/51)**

***1. Sausage hangers contaminated with fat particles from the previous day's production, were placed onto the sausage hanging table, contaminating the surface of the table where sausage products were produced and therefore contaminating the sausage product. The establishment did not take immediate corrective actions to restore sanitary conditions and did not ensure proper disposition of contaminated product.***

Comment: The establishment immediately set up a corrective measure to cover all the hangers: thorough cleaning and disinfecting. However, there were no immediate corrective measures concerning the sausages already produced hanging on the frames (11 meters / 36 feet high). The establishment did suggest doing thorough in-house checks of the batches of sausages involved before shipment. In its risk analysis, the establishment did not take into account this "secondary"

contamination of the skin of the sausages. This explains why there was no written procedure regarding this non compliance, especially since the auditor had not mentioned this non compliance during his visit in spring 2003.

***2. The reconditioning procedure for sausage dropped onto the floor did not include provisions to restore sanitary condition of the sausage and did not ensure proper disposition of the sausage. Procedure for sausage dropped onto the floor: "Dry brush the sausage and powder with talcum powder".***

Comment: The auditor considers the « dropped sausage » procedure inadequate. According to this procedure, the sausages are brushed off and powdered with talcum powder. During the 2003 visit, the procedure was not considered to be a non-compliance.

***13/51)***

***Preventive measures for corrective actions were not included in the daily records for most pre-operational and operational sanitation noncompliances. This was a repeat finding from the previous audit conducted in April/May of 2003.***

Comment: Some preventive measures were described several times in the same manner with identical wording (for instance, « training of personnel »). The measures that match this description have been modified so as to avoid their reiterative character and they have also been formalized in more detail.

***21/51)***

***The establishment was testing for Listeria Monocytogenes in raw product, finished dry sausage product, product contact surfaces and non-product contact surfaces. The establishment did not meet the following requirements as required in 9CFR 430 alternative III.***

Comment: In-house testing is done on finished products and surfaces; it is true that the protocol and procedures for the testing are not formally described. Nevertheless, testing for Listeria has been done ever since the establishment was certified in 2000. Aging studies are also being done. These documents were shown during the visit. It should be mentioned that this Listeria protocol has only very recently been included in the American requirements (October 2003).

***1. The establishment did not have sanitation measures incorporated in its HACCP plan, Sanitation SOP, or other prerequisite program.***

Comment: It is true that the «Listeria » risk had not until now been taken into consideration in the HACCP plan.

***2. The establishment did not identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of food contact surfaces for L. monocytogenes, or an indicator organism, is maintained.***

Comment: The absence of Listeria monocytogenes on contact surfaces has always been demonstrated (results are available).

***1. The establishment did not state the frequency with which the testing will be done.***

Comment: The number of in-house tests on products as well as on surfaces is definitely described by the establishment.

***2. The establishment did not include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes, or of an indicator organism, is maintained.***

Comment: The in-house testing states very clearly the absence of Listeria monocytogenes .

45/56

**3. Product carts were stacked with the wheels in contact with the top surface. Plastic product tubs used for edible product were stacked on the top surface and then were nested inside edible product tubs and were used for the transport of finished dry sausage.**

Comment: This non compliance relates to the presence of carts with wheels stacked one on top of each other and intended to hold the tubs. The auditor noted that there was a possibility of minor cross contamination between the top surface having been in contact with the wheels and the plastic tubs. The previous auditor's report had not mentioned this type of non-compliance, even though this storing system was already in place at the time.

51)

**French Veterinary Services did not schedule the sausage hang area containing sausage trees, sausage hangers and containers which held the sausage hangers for pre-operational sanitation. French Veterinary Services have never scheduled this area for pre-operational sanitation. The establishment has been in operation for three years.**

Comment: This is the first time this observation is being made because no requirement regarding this issue had been mentioned in 2003.

50/51)

**Daily inspection was not provided for the maturation process of fermented dry pork sausage.**

Comment: We don't agree. Inspections of the establishment are done on a regular basis and are carried out according to the following schedule: on each day of U.S.A. production, the morning before production, once a week during the maturation and drying processes, which means during a period of 45 days, as well as each time products are exported to the U.S.A.

Actions implemented as a result of the non-compliances mentioned in the provisional report.

*SSOP:* the following items are taken into account in the plan:

- The monitoring of the implementation of the cleaning and cleanliness of the tubs holding the hanger tubes, the tubes themselves and the frames in the pre-operational phase.
- The drafting of preventive and corrective measures.

All of these monitoring activities will be validated by the person responsible for production and by the person in charge of quality control.

*Pre-operational monitoring of the conveyor belts:* Despite the high quality of the belts, the establishment has asked the company Intralox to install a helicoid-shaped brush especially designed for brushing the conveyor belt on its way back. This brush should be able to pull off the particles stuck on the hinges of the conveyor belts. In addition, the establishment has increased the visual inspection of the conveyor belts before using them.

*Management of the tubs:* The identification of each tub is done by a color code and is applied throughout the establishment. There is a written procedure describing this measure.

*Sanitization of knives:* A procedure to monitor the temperature and working order of the thermostat is described in the operational and pre-operational measures.

*Controlling the risk related to the presence of Listeria monocytogenes. :* An instruction has been issued, with the following details:

1. the surface for sponging, the compulsory sampling areas: conveyor belts, grinders, blenders, sausage filling machines, evaporators;

2. the frequency of the weekly sampling (but the day for taking samples changes from one week to the next);
3. corrective measures concerning finished products in the event of a positive result (positive results for raw goods or for contact surfaces).

These results will be processed by an independent laboratory (agreement to be signed shortly). There will be a quarterly report and summary of the results. It should be mentioned that for the time being, the person in charge of quality prepares a weekly report of the results of all the in-house tests. Corrective measures (monitoring of product) and preventive measure (modification of cleaning program and reinforced monitoring) are in place.

*Sausages dropped on the floor and other alterations of the product:* The instruction has been modified. Finished or semi-finished products dropped onto the floor are from now on destroyed and sent to the rendering plant.

*Carts with wheels:* A specific location has been chosen to store carts waiting to be used in order to avoid the risk of cross contamination. The weekly cleaning – disinfection of these carts is being done since the beginning of February.

*Each time a non-compliance is observed, ensuing corrective and preventive measures implemented are described in detail in a record.*

**France. Est. 67-447-05 : Ets Feyel-Artzner, Schiltigheim, January 16, 2004.**

**15/51)**

**1. Rework and returned product were not included in the flow chart or considered in the hazard analysis.**

Comment: The quantity of rework or returned products is tiny. These products are only used in the production of sterilized foods such as pâtés. They are not used for making foies gras or smoked foods.

**2. Ongoing verification of the monitoring activities was performed, but the procedures were not adequately described in the HACCP plan.**

Comment: Most of the data relating to these activities is reported on the recording form (critical limits, frequency).

**45/56**

**1. Identity of grey, yellow and red plastic tubs used for edible product was not maintained. The tubs were used for edible, inedible and non-product storage purposes. This posed a substantial potential for inedible product to be used for edible purposes.**

Comment: On the one hand, non-edible goods can be traced thanks to an identification system, which is independent from the color of the tub. On the other hand, all the tubs, after use, undergo extremely thorough cleaning and sanitizing.

**2. A company employee contaminated the top of a product transportation cart with the sole of their boot and then placed an edible product tub onto the same cart. The tub would normally be placed on a product table, therefore causing contamination of the product table with residue from the sole of the boot.**

Comment: This was a handling mistake and it was immediately corrected.

**3. After cleaning, product carts were stacked with the wheels in contact with the top surface. The wheels were constructed of materials that could not be cleaned and sanitized**

***adequately. Plastic product tubs used for edible product were stacked on the top surface and then placed on edible product tables.***

Comment: The carts undergo the same cleaning and disinfecting process as the tubs. Surface testing is done as part of the monitoring of the cleanliness of the wheels after cleaning and disinfecting.

***4. Identity of product carts was not maintained. The carts were used in edible, inedible and storage rooms and then returned to a central area to be cleaned. This posed a substantial risk for product to become contaminated from the use of inedible carts for edible product tubs***

Comment: The carts are cleaned and disinfected in the same way as the tubs and this means at least once a day, which considerably reduces the eventual risk of contamination, by a cart, between food and the outside of a spice bag, for instance.

Actions implemented as a result of non-compliances mentioned in the provisional report.

*Rework and returned product were not included in the flow chart or considered in the hazard analysis.*

This issue is currently being examined by the establishment and will be seriously taken into consideration in the HACCP plan.

*Ongoing verification of the monitoring activities was performed, but the procedures were not adequately described in the HACCP plan.*

Verification of the monitoring activities has been formalized and included in the HACCP file.

*Identity of grey, yellow and red plastic tubs used for edible product was not maintained. The tubs were used for edible, inedible and non-product storage purposes. This posed a substantial potential for inedible product to be used for edible purposes.*

The establishment has acquired different color tubs. As a result, the grey tubs will be reserved for exposed goods (livers, etc.). The red tubs will essentially be used for conditioned products. The establishment has raised awareness among the personnel so that they use the tubs according to color and intended use.

*A company employee contaminated the top of a product transportation cart with the sole of their boot and then placed an edible product tub onto the same cart. The tub would normally be placed on a product table, therefore causing contamination of the product table with residue from the sole of the boot.*

The employees concerned have been given instructions so that this deficiency does not reoccur. The cleaning of shoes and rooms has been included in the cleaning-disinfecting plan and will be carefully monitored.

*After cleaning, product carts were stacked with the wheels in contact with the top surface. The wheels were constructed of materials that could not be cleaned and sanitized adequately. Plastic product tubs used for edible product were stacked on the top surface and then placed on edible product tables.*

In order to avoid possible contamination of tubs by the pre-stacked carts, in the very near future the new procedure will be to put empty tubs of a specific color on the carts before putting the grey product tubs. This will prevent all direct contact between the grey tubs and the carts.

*Identity of product carts was not maintained. The carts were used in edible, inedible and storage rooms and then returned to a central area to be cleaned. This posed a substantial risk for product to become contaminated from the use of inedible carts for edible product tubs.*

The new procedure described above will also avoid this risk.

15/51)

**1. Records were maintained that documented food safety hazards that were reasonably likely to occur, but biological, chemical and physical hazards were not considered in the hazard analysis for all processing steps described in the flow chart.**

Comment: This observation is of procedural nature. Hazards are examined very closely, which means that they are taken into consideration within the context of the risk analysis. However, each individual hazard has not been systematically written out in the HACCP plan.

**2. Monitoring activities were performed, but the frequency for monitoring was not stated in the thermally processed Foie Gras HACCP plan.**

Comment: The sterilization parameters are recorded automatically on a graphic chart. Even though the frequency of monitoring is not stated, the sterilization process is monitored visually several times. At the end of the sterilization process, the results of the curve obtained with the thermal printer are systematically compared with the requirements set by the CTSCCV (technical center of cured meat, cold cuts and canned meat) (schedules, critical limits). In addition, all the equipment used to take measures is calibrated once a year.

**3. Records documenting the regulatory requirements for corrective actions for a deviation from a critical limit were maintained, but the HACCP plan did not include preventive measures**

Comment: Critical limits relate to seaming and sterilization (time, temperature). The seaming and sterilization processes intrinsically include preventive measures. The calibration of thermometers and the monitoring of temperatures during sterilization, for instance, are in themselves preventive measures, making it possible to reach critical limits. This means that measures are indeed included. However, they do not appear under the heading of preventive measures but under monitoring procedures. So, this observation has more to do with form than content and it has no consequence on product safety.

**4. On going verification activities were performed, but the procedure was not adequately described in the HACCP plan.**

Comment: Once again, this observation relates to a formality, since the auditor admits that the monitoring activities are effective.

Actions implemented as a result of non-compliances mentioned in the provisional report.

13/51)

*Preventive measures for corrective actions were not included in the daily records for some pre-operational and operational sanitation non-compliances.*

Comment: the establishment is currently examining this point.

15/51)

**1. Records were maintained that documented food safety hazards that were reasonably likely to occur, but biological, chemical and physical hazards were not considered in the hazard analysis for all processing steps described in the flow chart.**

Comment: The establishment is currently consolidating the risk analysis for each production process step and for each type of hazard.

*2. Monitoring activities were performed, but the frequency for monitoring was not stated in the thermally processed Foie Gras HACCP plan.*

Comment: This issue has been resolved.

*3. Records documenting the regulatory requirements for corrective actions for a deviation from a critical limit were maintained, but the HACCP plan did not include preventive measures.*

Comment: the establishment is currently examining this point.

*4. On going verification activities were performed, but the procedure was not adequately described in the HACCP plan.*

Comment: The ongoing verification procedure has been reviewed.

**France. Est. 85-109-01, Rougié Bizac International, Les Herbiers, January 30, 2004.**

**10)**

***The following findings were identified during pre-operational sanitation inspection:***

***1. Black residue was identified on product kickoffs in the bulk conditioning room.***

Comment: A corrective measure was immediately put in place.

***2. Black watery unidentified material and black smears were observed on liver transport belts in the liver preparation room.***

Comment: A corrective measure was immediately put in place. Restarting the belts made it possible to check the effectiveness of the measure.

***3. Black unidentified material was identified in a yellow product tub located in the central equipment cleaning room. The tub was previously cleaned and ready for use for the day's production of food products***

Comment: This concerns only one tub, which was immediately put aside to be washed. Corrective action was immediately implemented.

**10/51)**

***1. Condensation was dripping onto defeathered and partially de-feathered ducks between the cold paraffin tank and the paraffin removal cabinet in the defeathering room.***

Comment: The condensation is not above the products and is therefore unlikely to have an impact on product safety. The auditor heavily insisted on this point throughout his visit (which lasted 15 hours) (waiting for drops to fall, looking for drops that might be dispersed by the air flow coming from the refrigeration units, potential cross contamination by the frocks of employees walking under the areas of condensation).

***2. Copious amounts of condensation were identified dripping onto employees and their work stations in the evisceration room. Corrective action was not taken by French Veterinary Services or the establishment. This finding was previously identified during pre-operational sanitation inspection. This was a repeat finding from the previous audit conducted in April/May of 2003.***

Comment: The report does not mention the immediate corrective actions implemented by the establishment: evacuation of all the equipment located under the area of condensation, tangibly forbidding access to this area, change of clothes for all employees.

**3. Condensation was identified dripping from a refrigeration unit into product tubs located in the liver processing room. This was a repeat finding from the previous audit conducted in April/May of 2003.**

Comment: This observation is reported as a repeat finding when in fact it had never been mentioned by the previous auditor. An immediate corrective measure was implemented: the tubs concerned were sent to be washed.

**4. Duck meat that had been dropped onto the floor in the cutting room, was accumulated in bulk and shipped to a further processing establishment without reconditioning. This was an ongoing process described in the SSOP. Local Veterinary Services and the Department of Veterinary Services were aware of and approved this procedure. The auditor was informed that product accumulated in bulk and shipped to a further processing establishment without reconditioning was acceptable because the floor was clean and the product was cooked.**

Comment: It is true that non compliant products, including dropped meat are recycled, after visual check, and they are shipped to another facility of the RBI group to be cooked. But, this recycling option had been accepted by the previous auditor in April 2003 as long as there was a procedure set up for carcasses and cut products. From now on, this would constitute non-compliance. The procedure concerned is the following (summary of a document issued by the establishment):

*Packaged products:*

Room	Products on floor	Measures
Conditioning room, picking, shipping, product stocks	Vacuum sealed products	Isolation in specific cartons. Checking the integrity of the products : > if satisfactory, moves on into the circuit. > If product is no longer vacuum-sealed and there is no external contact, the products are reconditioned and sent back into the circuit. > If products are no longer vacuum-sealed and are exposed, they are sent into the category of non-compliant exposed products.

*Exposed products:*

Room	Products dropped on floor	Measures
Evisceration room	Duck	Hanging on special hanger with red label. Cutting at end of day of non-compliant products to be cooked in another company of the RBI group with identification of batch by indication of day of slaughter.
	Hot liver	Put into specific tubs. Destruction.

Liver room	Hot liver	Put into specific tubs. Destruction.
	Frozen livers	Put into specific tubs. Destruction.

Cutting room	Duck on floor	Hanging on special hanger with red label. Cutting. Non compliant product for cooking in other company of RBI group.
--------------	---------------	---

Cutting and conditioning room	Magret, leg	Put into specific tubs. Destruction.
-------------------------------	-------------	---

In summary, the products dropped onto the floor are either destroyed, or they go through a cooking process.

The cooking of these products intended for canning is only done in establishment RBI 19-031-02 located in Brives which is not certified for export to the United States.

Whatever the situation may be, the procedure dealing with the management of dropped products therefore excludes the American market.

**13/51).**

***Preventive measures for corrective actions were not included in the daily records documenting pre-operational and operational sanitation noncompliances. This was a repeat finding from the previous audit conducted in April/May of 2003***

Comment: Preventive measures are described on a specific deficiency form, when the deficiency is serious and repetitive. Daily activities relating to pre-operational and operational sanitation are documented, but details concerning deficiencies, corrective and preventive actions may be missing. Nevertheless, the quality department insists upon the fact that after each deficiency, preventive measures are included in the plan. We feel that major efforts have been made to adequately document deficiencies and corrective measures.

**15/51)**

***1. Biological, chemical and physical hazards were not considered for each processing step in the hazard analysis.***

Comment: it remains to be decided whether one needs to describe these hazards in detail, even if they have nothing to do with the process. It should be mentioned that the same procedure is applied in the other establishments of the group, like RBI SARLAT, and no observation has ever been made.

***3. The frequency for ongoing verification of records for zero tolerance was not stated in the HACCP plan.***

Comment: The auditor commented on the fact that the physical location for doing the monitoring was missing and not on the issue of frequency (because the frequency does exist).

**41/56)**

***1. Condensation was identified on the ceiling of the access corridor***

Comment: The corrective action (wiping) was immediately implemented.

***2. Condensation was identified over the entrance of cold liver storage cooler number 5.***

Comment: it was a small drop of condensation on an evacuation pipe for the water coming from the defrosting. It should be noted that the surface directly under this condensation cannot be used for storing products. In addition, there was no possible direct contamination of the livers as they go through this area because all the livers are protected by an upper protective layer. The corrective action involved wiping the pipe concerned.

***3. Excessive amount of frost was identified on the ceiling and walls of the liver and scallion storage freezer.***

Comment: Defrosting was done.

**46/56)**

***Product tubs located close to the floor were cross contaminated with tops of employee's boots. This posed a substantial risk for contamination of edible product contained in the tubs by residue from the boots.***

Comment: Immediate corrective action was to raise the tubs and eliminate the tubs concerned.

59)

*The auditor recommended removal of this establishment from the list of establishments certified as eligible to export to the United States, effective as of the start of operations on the day of this audit.*

Comment: The auditor said he agreed with the analysis of the Department Directorate of Veterinary Services, which was "good reactivity of the establishment, very significant improvement in the equipment and general sanitation, the establishment and the inspection service have invested a lot of effort". Nevertheless, he recommended delistment, did not agree to change his position and declared that he was under the obligation to transmit his recommendation to the central authority. The French Authorities do not understand this proposal for delistment and they do not agree with it.

Actions implemented as a result of the non-compliances mentioned in the provisional report.

*Measures taken as a result of non compliances relating to daily operations:* For points 10, 10/51-4, 41/56-3, 46/56, corrective measures were immediately implemented, and they will, from now on, be applied as an ongoing procedure throughout the establishment.

*Measures taken to respond to documentary non-compliances:* Points 13/51, 15/51. Documents were reviewed to take into account the American requirements.

*Measures taken as regards structural non compliances: condensation:* Points 10/51-1-2-3, 41/56-1-2: besides immediate measures to mark off the areas of condensation and prevent small drops from falling on products or staff, complete renovation of the establishment has just started and the work should take one year.

**France. Est. 87-065-01 : Ets Madrange, Feytiat, January 28, 2004**

**13/51)**

**1. Preventive measures for corrective actions were not included in the daily records documenting pre-operational and operational sanitation noncompliances.**

Comment: At the end of each week, the deficiencies described are mentioned at the meeting attended by the quality assurance team of Madrange and the company responsible for the cleaning, and when necessary, non-compliance forms are filled out. These forms entail a modification of the cleaning program, which corresponds to preventive measures. Since the American audit, these measures are described in detail.

**2. Sanitation noncompliances were not adequately described in the pre-operational and operational sanitation records.**

Comment: The non-compliances observed during these monitoring activities are briefly noted down. The words "conveyor belt dirty" for instance should be replaced by "presence of a piece of fat of such and such a size ..." as requested. Following the visit of the auditor, there has been improvement in the recording of monitoring activities. The time of the monitoring activity (requested by the auditor), the nature of the deficiency and the preventive measures are described in more detail.

**15/51)**

**1. Monitoring activities were performed, but were not completely described in the HACCP plan.**

Comment: The description of the precise location where CCPs are monitored was criticized. On the HACCP documents, the room where each CCP is monitored is mentioned. For example, "by-products" room, "unwrapping" room and "wrapping of cut products" room for the « metal detection » CCP. The

auditor did not consider this description to be adequate. It is nevertheless difficult to be more precise, because it seems logical to monitor the CCP either on the by-products processing line or on the cut products packaging line.

***2. All four parts of corrective action for a deviation from a critical limit were not described in the HACCP plan.***

Comment: Only the «conditioning in bags under modified environment» CCP was criticized. The frequency of monitoring was correctly described but what was missing was the number of bags monitored on each monitoring activity. This will be detailed in the HACCP documents.

***45/56)***

***The dropped meat reconditioning station was not identified or equipped to maintain sanitary conditions. This posed a substantial risk for the station to be used for purposes other than dropped product and reconditioned product to become recontaminated from a surface that was not cleaned and sanitized properly between each use.***

Comment: The tables where the very small quantity of dropped meat is trimmed are in perfect condition. They are made of PEHD (high density polyethylene). They are easy to wash and disinfect and there is water available nearby. What additional equipment can one request? A new procedure will be presented by the establishment in June 2004.

Actions implemented as a result of non-compliances mentioned in the provisional report.

Conveyor belt for the reception of hams. The level of wear and tear of the belts is checked and the preventive maintenance program provides for a change of the belts.

An internal note is drafted to ensure control of condensation on walls and ceilings in the raw and cooked rooms.

The cleaning program has been modified due to the presence of dust on the floor of the fresh product storage area. The storage areas are cleaned every week according to a rotation system of the areas which have been cleared. These operations are recorded.

The nature of the deficiency as well as the date of the monitoring activity are included in the records of pre-operational and operational monitoring activities.

Dropped meat procedure. Identification of the following points:

- Mention how often brine is changed.
- Monitoring the effectiveness (evidence of disinfectant effect of treatment) where, when, how, who.
- Procedure for cleaning the work table.

## **APPENDIX 3 –ACTION PLAN.**

### **I/ Action undertaken with respect to businesses.**

#### ***1/ Corrective measures put in place by the establishment.***

Cf. appendix 2.

#### ***2/ Technical support for establishments.***

The mission of the national technical expert (Dr. Maryse Flamme), who has occupied the post since May 6, 2003, though connected to the Direction Générale de l'Alimentation (Direction Générale de l'Alimentation = General Food Directorate for France = DGAI), has been focused on technical support for establishments with USDA approval. Relations with the DDSV will henceforth be handled within the framework of a national mission for Level Two technical evaluation (cf point II. 3 hereafter).

Maryse Flamme's scope of knowledge of American rules and regulations permits her to assist establishments in adopting them and putting them into practice correctly.

### **II/ Action undertaken by the competent Authorities.**

#### ***1/ Enhancing the training of veterinary health inspectors in American requirements.***

##### *a) Participation of a veterinary officer in internal FSIS seminars:*

The Project Chief, a French Veterinary Officer in charge of Level Two technical evaluation (see mission description below) should attend an internal training seminar for FSIS inspectors scheduled for September 2004.

##### *b) Continuing specific training sessions:*

As stated in the report dated May 6, 2003 to the Director of the Food Safety and Inspection Service, the minimum frequency of these training sessions is once per year at present.

These training sessions will obviously be continued in the area of controlling sanitary risks (general hygiene, standardized sanitation procedures (SSOP), and principles (HACCP)).

They are open to regional export coordinators, Resaq correspondents (Network of Quality Assurance Experts), inspectors in charge of establishments with export approval for the US and the supervisors in their *départements* (regional jurisdictions).

In particular, established training programs in HACCP implementation will be enhanced in both theoretical and practical aspects (including formalizing the plans and analysis of their pertinence and efficiency.)

These training seminars would greatly benefit from the participation of an experienced FSIS inspector who would share his experience with his French colleagues.

#### ***2/ Level One Monitoring***

Establishment inspections will continue to be carried out according to American terms as indicated to veterinary services in document DGAI/ SDSSA/ N°2003 n° 8139 of August 6, 2003 entitled: *Eléments d'actualisation des conditions d'agrément des établissements élaborant des produits carnés destinés à l'exportation vers les USA* (Updates of the conditions for approval of establishments producing meat-based products for export to the US).

This document indicated that the inspector in charge of the establishment must make a visit each day that production for the US takes place in order to insure that the raw materials processed come from establishments with USDA approval at the time these materials are being processed, that the working conditions meet American standards and, especially, that SSOP controls before returning to work are properly carried out and that any non-conformities observed are corrected. The inspector must also make visits before work resumes in order to measure the pertinence of SSOP controls which must be carried out systematically by professionals before the beginning of operations.

### ***3/ Establishment of a nationwide Level Two technical evaluation mission***

A nationwide mission has been created in charge of Level Two technical evaluation of establishments at central and field services levels of the DGAL. Dr. Bernard Vanhoye, was named Project Head. He is Chief Inspector of Veterinary Health and has recognized experience in inspection, having held ranking positions in field services of the DGAL. He reports directly to the DGAL Director on his evaluation missions.

From a practical point of view, he will carry out field audits and send reports to the DGAL Director which will include recommendations. He will prepare synthesis notes by theme, sector or area of activities covered related to levels of conformity observed in the execution of orders with respect to set objectives.

He will intervene nationwide in all technical areas dealing with trade or export of living animals or products of animal origin.

For the moment, the Project Head will work on the elaboration of a Level Two evaluation technique in the area of exports, particularly to the United States. The goal is to ensure that the Director of the DGAL is aware of the actual degree of application of orders given to the DDSV for the implementation of national, EU or country specific regulations and, where necessary, that appropriate corrective measures are taken to obtain better execution of these orders.

#### *Relations with existing entities.*

The report sent to the FSIS on May 6, 2003 stated that in each region or inter-region a veterinary official was designated as export coordinator by the DGAL. This official provides technical support to the DDSV, who is responsible for the sanitary inspection of establishments certified for export.

The operations of the regional export coordinators have proven their efficiency. Their prerogatives have been maintained, particularly as concerns monitoring audits of establishments approved for export to the US.

Information on American requirements and their application will be provided to regional export coordinators and Resaq correspondents by B. Vanhoye.

### **III/ A shared EU/US initiative**

An EU/US seminar on the systems of control for sanitary food safety, especially HACCP and normative sanitary operating procedures (SSOP) is to be organized by the European Commission next fall in Ireland.

This seminar should make it possible to identify points of agreement and divergence in the European and American approaches to their conceptions of sanitary control plans in agri-food businesses and monitoring of the application of these plans by competent authorities. This should help the convergence of the two points of view and, if possible, lead to a common set of references.