



United States Department of Agriculture

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JUN 04 2014

Dear Dr. Angot,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of France's Meat inspection system from June 15 through June 28, 2013. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-0676, or electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov)

Sincerely,

A handwritten signature in blue ink, appearing to read "Shaukat H. Syed".

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit

Enclosure

**FRANCE**  
**FINAL AUDIT REPORT**

March 14, 2014  
Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) on June 17 - 27, 2013, to determine whether France's food safety system governing the production of meat and poultry remains equivalent to that of the United States with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. France currently exports only pork products to the United States, although they are also eligible to export poultry. Since May 2010, France has chosen not to export poultry to the United States. Therefore, FSIS audited the French food safety system for meat products and the only establishment certified to export pork products to United States.

The audit focused on six main system components: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs. In addition, the auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the September 2009 audit findings were being implemented. In 2009, the deficiencies noted involved inadequate HACCP documentation including the flowcharts, the HACCP plan, and monitoring and verification records.

None of the 2009 audit deficiencies were noted during the 2013 audit. An examination of FSIS Point-of-Entry (POE) findings since June 2012 showed no product refused entry.

In FY 2013, the FSIS auditor observed an ill-fitting door leading from the warehouse area to outdoors that would not prevent the entrance of pests. Also, the area for receiving packaged raw materials was open to the outdoors, thus allowing for the entrance of pests or other sources of contamination potentially resulting in unsanitary conditions and/or adulterated product. The CCA identified and documented these issues in inspection system reports approximately six months before the FSIS audit, but it had done nothing to verify that the corrective actions were completed. Consequently, the CCA's oversight of these corrective actions was a source of concern for the FSIS auditor. After the 2013 audit, however, FSIS's concerns were allayed when it received evidence that the establishment had installed a new door for the warehouse and completely enclosed the receiving dock area.

The audit results indicate that France's food safety inspection system continues to maintain equivalence with the United States system and is operating at an "adequate" level of performance. The CCA meets the core criteria for all six equivalence components and has had no POE refusals for more than one year. During the exit meeting, the CCA noted that it verify the corrective actions to address the above audit findings.

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## **I. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of France's meat inspection system on June 17 - 27, 2013. France is eligible to export raw and processed pork and poultry products to the United States.

Between June 1, 2012 and October 31, 2013, France exported approximately 103,978 pounds of thermally-processed, commercially sterile pork products to the United States of which 55,109 pounds were re-inspected at a United States Point-of-Entry (POE). None of the product was refused entry. One establishment is certified and exports only pork products.

This audit was conducted pursuant to the specific provisions of the United States laws (United States Code, U.S.C.) and regulations (Code of Federal Regulations, CFR), in particular:

- Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906), and
- Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations

The audit standards applied during this audit included all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process, and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

## **II. AUDIT GOAL AND OBJECTIVES**

FSIS' overall goal for the audit was to verify that France's food safety inspection system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled. To achieve this goal, the audit focused on six equivalence components to determine whether each component continues to be equivalent to that of the United States: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

The FSIS auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the September 2009 FSIS audit had been implemented. All 2009 audit deficiencies were corrected.

In FY2013, the certified establishment that was audited conducted pork slaughter, cutting, and thermal processing.

## **III. AUDIT METHODOLOGY**

FSIS utilized its established four-phase process to conduct this equivalence verification audit - plan, execution (onsite), evaluation, and feedback. Each phase is described below.

The first phase is document and data review and analysis of previous audit findings and other available information. Therefore, prior to conducting the June 2013 onsite audit, FSIS examined the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and other data collected since the last FSIS audit in 2009. The findings from the previous audit were primarily from an establishment that is no longer certified. The 2009 findings at the currently certified establishment concerned HACCP recordkeeping. These are detailed in the HACCP Component section of this report. The 2013 audit confirmed that the corrective actions are in place and effective. The other previous finding was the failure to feed animals that had been held for more than 12 hours; this was a finding from an FSIS audit against EU regulations. During the 2013 audit, FSIS confirmed that the establishment has a program to feed animals kept more than 12 hours. In addition, the FSIS auditor reviewed information obtained directly from the CCA, through the Self-Reporting Tool (SRT), outlining the structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for planning the onsite audit itinerary.

The second phase is the onsite audit or execution phase. FSIS conducted this onsite audit to verify the CCA's oversight activities as they relate to each equivalence component. The auditor gathered data on all six components through document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the audit by representatives from the CCA, Director Generale de l'Alimentation (DGAL), General Directorate for Food, including members from the departmental or local inspection offices.

Management, supervision, and administrative functions were reviewed at the CCA headquarters, Finistère Departmental Office and at one pork slaughter/cutting/thermal processing establishment to verify that the national system of inspection, verification, and enforcement was being implemented as required to maintain equivalence. Two regulations were primarily used to determine this equivalence. The first was French Directive DGAL/SDSSA/SDAEI/N2012-8274 (DGAL 2012-8274) of 26 December 2012, which contains the regulatory requirements for establishments exporting meat and meat products to the United States. The second was French Directive NS DGAL/SDSSA/SDASEI/N2011-8254 (DGAL 2011-8254) of 30 November 2011, which is a summary of the approval requirements for establishments exporting fresh meat, meat and poultry products, dairy products, and fishery product to specific third countries and provisions for compiling the list of approved establishments for exports to these third countries. During the establishment visit, the auditor paid particular attention to the extent to which the government and industry interact to control hazards and prevent program deficiencies that may threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9, Code of Federal Regulations (CFR), parts 327.2 and 381.196.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories, including a review of the CCA's laboratory audit reports and laboratory-related data compiled for a 9-month period preceding the 2013 audit, and through onsite interviews with inspection personnel. In addition, FSIS examined the IDHESA laboratory, a public laboratory located in Quimper, Finistère, which was conducting analytical testing as part of France's national residue program as well as microbiological testing of official samples.

The third phase is an evaluation of all data collected onsite to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. An extensive analysis of all data was used to make the equivalence decision.

The final phase is a feedback phase that begins with providing the CCA a draft audit report with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. The Agency also developed an action plan to address any issues raised by the audit.

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT**

The first of the six equivalence components reviewed was Government Oversight. The FSIS import eligibility requirements state that an equivalent foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States meat inspection system. The evaluation of this component included a review of documentation submitted by the CCA as support for the responses and corrective actions, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices and in the audited establishment.

France's administration of food safety is divided between national and departmental levels. France is a part of the EU and governed by the European Commission (EC). The national government oversees the 26 regions, 22 of which are located in France itself. At the national level, the Direction Générale de l'Alimentation (DGAL), General Directorate for Food, is France's CCA. The DGAL has one central office and 100 departmental offices. Food safety is addressed jointly by three Ministries. The General Directorate for Food (DGAL) has the responsibility for primary production (animal and plant), animal welfare, and slaughterhouses. The Directorate General for Competition, Consumer Affairs, and Fraud Representation (DGCCRF) and the Directorate General for Health (DGS) have joint responsibility for food-of-animal-origin processing, restaurants, direct sale, by-products, animal feed, and transport and storage. The DGCCRF has sole responsibility for processing food of non-animal origin and non-food products.

The DGAL's authority to enforce inspection laws comes from EC Regulation No. 178/2002 of the European Parliament and of the Council of 28 January 2002 defining the general principles and requirements of food law, establishing the European Food Safety Authority and defining procedures in matters of food safety. This authority is further supported by Directive DGAL 2012-8274 and Directive DGAL 2011-8254 as mentioned above.

The CCA has the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. All meat exported to the United States in the sole eligible establishment is segregated from domestic production by physical barriers that was verified by the FSIS auditor.

The departmental level consists of 100 offices across the country. Currently, only one of these offices has authority over the establishment that is certified to export pork to the United States. This office is responsible for conducting periodic reviews of the United States-eligible establishment and recommending the approval and withdrawal of establishments. The inspection personnel in the

establishment are assigned by the departmental office with direct jurisdiction over them. The Official Veterinarian assigned to the establishment has direct supervisory control over the veterinary public health inspection personnel.

The FSIS auditor identified an issue in 2013 related to oversight at the Departmental and in-plant level of France's inspection system pertaining to the Sanitation equivalence component. This finding will be further detailed in that section of this report. The FSIS auditor noted a concern regarding the CCA's ability to exercise effective oversight over the construction and maintenance of establishments eligible to export to the United States. This deficiency results from a documented in-plant inspection system reports by the CCA, but without appropriate follow-up and verification that corrective actions were completed. The corrective actions were not completed until February 2014.

Since the last FSIS audit in 2009, the CCA has provided inspection personnel limited ongoing training about the United States requirements. The official personnel assigned to the one certified establishment have been present since the last audit. The FSIS auditor interviewed inspection personnel and reviewed their training records. Training records showed some training with an emphasis on requirements to export to the United States. New changes in the FSIS regulations are transmitted electronically from the headquarters to the departmental office and then to the in-plant inspection personnel. The inspection system must first comply with the EU regulations, most of which have been deemed equivalent to the applicable United States food safety regulations. There are only a few additional requirements, such as daily inspection and HACCP recordkeeping documentation, that must be followed to maintain an equivalent verification inspection system. These requirements must be codified into the exporting countries' inspection documents. These additional requirements were known to the in-plant inspection personnel and were verified by the FSIS auditor during the onsite review. Findings during the previous audit were pertained to HACCP documentation; the FSIS auditor verified that these had been corrected and the present records follow all regulatory requirements.

The departmental office has the responsibility to conduct periodic supervisory reviews of the certified establishment. There are several persons at the departmental level who share this responsibility. The responsibility of oversight of the chemical residue and microbiological laboratories is assigned to a third-party national system because all laboratories do not conduct all analyses. The reports of these laboratory reviews are shared at the central and departmental levels. Both the central and departmental levels have the authority to conduct additional reviews of laboratories if needed. The FSIS auditor reviewed both supervisory and laboratory reviews generated for the previous year at the departmental level and at the audited laboratory.

During the onsite visit to the Finistère departmental office and the one certified establishment, the FSIS auditor reviewed inspector-generated records and interviewed in-plant inspection personnel as well as departmental personnel who conduct supervisory reviews. The FSIS auditor reviewed the last year of periodic supervisory reviews (the CCA conducts these on a quarterly basis) and interviewed the departmental personnel who conduct these reviews. These reviews were complete and well-documented including follow-up to previous findings. The only findings that the supervisory reviews had not noted were the open receiving area and poorly-fitting door.

The FSIS auditor also reviewed in-plant official documentation of daily tasks and interviewed those in-plant personnel responsible for their accomplishment. These tasks were appropriate to the processes within the establishment and were well-documented.

The FSIS auditor verified the payment of inspection personnel by a government agency at both the CCA and Finistère departmental offices by viewing payroll records. In-plant personnel are employees of the departmental office.

The FSIS' onsite audit, including observations, document reviews, and interviews, in combination with the FSIS' review of the SRT and document analysis of the CCA's control measures, establishes that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS's requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to the establishments certified eligible to export to the United States. The evaluation of this component included an analysis of information provided by the CCA, the SRT, interviews, and observations during the onsite portion of the audit. The FSIS auditor verified that official inspection and verification activities were conducted in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified the regulatory authority maintained by the CCA as outlined in official legislation, regulations, and other instructions issued in accordance with the EC Regulations 178/2002 (as above); 852/2004 on the hygiene of foodstuffs; 853/2004 describing specific hygiene rules for the food of animal origin; 854/2004 describing-specific rules for the organization of official controls on products of animal origin intended for human consumption; 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; Decision 98/258/EC on the conclusion of the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products; and Ministerial Decree of 8 June 2006, in its amended version, on approval of establishments marketing products of animal origin or foodstuffs containing products of animal origin; and DGAL 2011-8254 and 2012-8274 (as above).

The auditor confirmed that the CCA provided the departmental offices and establishment offices with the appropriate regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to establishments certified eligible to export to the United States.

The mandatory implementation of HACCP in the EU is slightly different from that of FSIS. However, Directive DGAL 2012-8274 addresses how HACCP is to be developed, implemented, and maintained for any French establishment to be eligible for export to the United States.

The FSIS auditor verified that the CCA exercises its legal authority to require these certified establishments to develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination and the creation of insanitary conditions. This authority is in accordance with DGAL 2012-8274 for the regulatory requirements for establishments exporting meat and meat products to the United States. In this Directive, “meat” refers to products of animal origin and includes poultry.

During the onsite visit to the Finistère departmental office, which oversees the one eligible establishment, the FSIS auditor conducted an examination of the departmental offices’s oversight activities, including periodic supervisory reviews, laboratory reviews (as furnished by the third party), inspection enforcement activities, and training records for official personnel by interviewing the departmental personnel and reviewing documentation.

Periodic supervisory reviews are conducted quarterly by the departmental personnel. These supervisory reviews are conducted using a standard format called the Local Inspection Grid. Each supervisory review emphasizes certain sections of that grid, such as pre-operational sanitation inspection, operational sanitation inspection, HACCP, and USDA requirements. Each section has its own checklist and comment areas. There are also checklists for each area or process occurring within the establishment, such as slaughter, cutting, cooking, and thermal processing. This review report is distributed to the establishment management, the in-plant inspection personnel, the departmental office, and the CCA headquarters. The in-plant personnel are responsible for the verification of corrective actions resulting from the review, and their results are recorded in the subsequent review. If the corrective actions either do not occur or are not effective, they may request assistance from the departmental office.

The overall condition of the audited establishment is the same as documented in the supervisory periodic review reports except in the situations of the open receiving area and poorly-fitting doors, which had not been recorded in supervisory reviews.

The FSIS auditor accompanied and observed one of the departmental personnel responsible for conducting the periodic supervisory reviews. During the review, the personnel verified requirements for ante-mortem examination, humane handling and slaughter, post-mortem examination, *Salmonella* and generic *Escherichia coli* (*E. coli*) sample collection, verification of pre-operational and operational sanitation verification procedures, and HACCP verification activities, including the zero tolerance CCP verification. Verification activities also included the live animal pens, all areas of slaughter and cutting, storage of products, and further processing including thermal processing.

Products destined for the United States were not being produced on the day of the audit; however, slaughter and cutting areas were active, and thermally processed products were being produced according to equivalent policy. All products currently produced for the United States are thermally-processed, commercially-sterile (TPCS), and packaged in either cans or glass jars. The review included the CCA’s and establishment’s written programs for the production of TPCS within this establishment with emphasis on adequate thermal processing to include how and what critical limits were specified to ensure that all products are rendered free of microorganisms capable of growth at non-refrigerated temperatures.

The FSIS auditor verified that in-plant inspection personnel conduct ante-mortem inspection on the day of slaughter by reviewing the receiving logs and the pen cards. The inspection personnel observed all animals at rest and in motion in designated holding pens prior to slaughter in order to determine whether they are fit for slaughter and for human food purposes. The designated holding pens for sick or suspect animals were maintained for further examination of these animals as needed. The FSIS auditor observed and verified that all animals have access to water in all pens, and that provisions are made for animals that are held for more than 12 hours to have access to feed (EU requirement is 12 hours, whereas the FSIS requirement is 24 hours). The extension of feed for the additional 12 hours was a corrective action in response to a 2009 FSIS audit finding. The FSIS auditor concluded that the implementation of the ante-mortem inspection complies with EU regulations deemed equivalent by FSIS.

The FSIS auditor also assessed post-mortem inspection examinations through onsite record reviews, interviews, and observations of in-plant inspection personnel performing post-mortem examinations. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented and concluded that in-plant inspection personnel are adequately trained in performing their in-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with EU regulations that have been deemed equivalent by FSIS. The design of the post-mortem inspection stations, including proper lighting, meets equivalent requirements.

The FSIS auditor also observed the functions of the off-line inspector (the Official Veterinarian in this establishment) who conducts daily inspection verification activities. These daily verification activities include direct observation and review of establishment records of HACCP, Sanitation Standard Operating Procedures (SSOP), and Sanitation Performance Standards (SPS) activities, generic *E. coli* sampling techniques, and *Salmonella* sampling and testing for the Pathogen Reduction Program. The off-line inspector/Official Veterinarian also oversees the submission of samples to the laboratory for *Listeria monocytogenes (Lm)* and *Salmonella* for the thermally processed products, as well as the sampling of other processes and products not eligible for export to the United States. All stages of production with an eventual United States destination are separated by time or space from any domestic production or production for another export market.

France's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the FSIS system of meat inspection in the United States. The analysis and onsite verification activities indicate that the CCA continues to maintain equivalence and is operating at an "average" level of performance for this component.

## **VI. COMPONENT THREE: SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. An equivalent inspection system must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the onsite portion of the audit, the auditor reviewed documentation provided by the CCA concerning sanitation including EU regulations and DGAL Directives 2011-8254 and 2012-8274. These documents provide instructions to the official inspection personnel to conduct a daily rigorous assessment of inspection activities during routine verification of sanitation issues. There are no fundamental differences between the United States and EU sanitary risk control systems. The

FSIS auditor verified that the in-plant personnel conduct verification of sanitary conditions in accordance with the above requirements.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at the audited establishment. The FSIS auditor verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification inspection. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification activities. The in-plant inspection personnel conducted this activity in accordance with the established equivalent procedures.

The FSIS auditor followed the departmental auditor and observed in-plant inspection verification of operational sanitation procedures. These verification activities included direct observation of operations and review of the establishment's associated records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection verification records. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishment maintained sanitation records sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date.

The FSIS auditor reported a finding concerning the CCA's ability to exercise official controls over the construction and maintenance of establishments eligible to export to the United States. This was based on the observation of the following deficiencies:

- The door leading from the warehouse area to the outside did not fit well and would not prevent the possible entrance of pests into the area.
- The area for receipt of packaged raw materials had a ceiling and three walls, but had an opening to the outside on the fourth side allowing for the possible entrance of pests or other contamination of the product.

These deficiencies had been documented in in-plant inspection system reports by the CCA, but no short-term corrective actions had been taken. There are plans to install a new door and close off the receiving dock area. A new door for the warehouse area has now been ordered as well as a project begun to close in the receiving area.

The FSIS auditor did not note any direct evidence of pest activity or product contamination related to these findings. The FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOP. In-plant veterinary officials and departmental supervisors enforce the regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions. The enforcement by the CCA of the corrective actions to the deficiencies above is being addressed. Therefore, the audit findings support that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

## **VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or similar type of preventive control plan to maintain equivalence. France's meat inspection system follows the EU requirements (especially EC Reg. 852/2004) for HACCP for all exporting establishments along with adding the specific requirements for HACCP that must be followed to maintain an equivalent system with that of the United States meat inspection system. These requirements are primarily in the areas of recordkeeping and preventive measures. These requirements are specified in DGAL Directive 2012-8274, which contains the regulatory requirements for establishments exporting meat and meat products to the United States. By these regulations, DGAL imposes regulatory requirements for the development, implementation, and maintenance of HACCP programs on the establishments certified eligible to export to the United States. The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the onsite audit. The FSIS auditor verified through record review and observation that the in-plant inspection personnel at the certified establishment conducted daily verification of HACCP plans in accordance with the methodology described in the above regulations and Directive, which included the evaluation of written HACCP programs, monitoring, verification, corrective actions, recordkeeping, and hands-on verification inspection. The in-plant daily inspection verification included Critical Control Points (CCP) verification with results entered in in-plant inspection records.

The programs for the monitoring and testing of seals for both cans and bottles were reviewed as well as records supporting the successful implementation of these programs to ensure that the containers are hermetically sealed (airtight) and protect the product from the entry of microorganisms during and after processing. Other programs for the handling and preparation of these containers as well as the handling and preparation of the food products were also reviewed. The in-plant inspection personnel had written requirements and verification procedures to address operations, equipment, and procedures for heat processing systems, processing deviations, finished product inspection (i.e., incubation, container condition), and the training of thermal processing operators and closure technicians. Records created by the in-plant inspection personnel and supporting the above programs and requirements were reviewed. No concerns were identified as a result of these reviews.

In the 2009 FSIS audit, the following findings were reported under HACCP documentation in this establishment:

- The establishment monitoring records for CCP 9B (retort) did not include the dates of monitoring activities.
- The establishment monitoring records for CCP 9B did not include the initials of the responsible employee making the entries.
- The establishment monitoring records for CCP 1 (zero tolerance for fecal and ingesta) did not include the quantifiable values, the times, or the initials of the responsible establishment employee making the entries.

FSIS was assured by the inspection officials and establishment management that all deficiencies found in that audit would be corrected immediately. In the current audit, the FSIS auditor reviewed the establishment HACCP records and verified that the corrective actions taken following the 2009 FSIS audit had been successfully implemented and maintained. No HACCP recordkeeping deficiencies were identified. The FSIS auditor also reviewed in-plant inspection personnel records and supervisory reviews for any findings for HACCP recordkeeping; there were no reports of deficiencies in this area.

No non-compliance trends were detected as a result of the document reviews. The FSIS auditor verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities.

The FSIS auditor verified that the certified establishment had developed, implemented, and maintained an equivalent HACCP system in accordance with the above regulations and Directive. There were no HACCP deviations identified. In-plant inspection personnel and departmental supervisors monitor, verify, and enforce the implementation of the HACCP regulatory requirements in the audited establishment. The analysis and onsite audit verification indicate that the CCA's meat inspection system continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

## **VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM**

The FSIS auditor reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that conducts effective regulatory activities to prevent chemical residue contamination of food products. To be equivalent, the program needs to include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue plan and the process used to design the plan; a description of the actions taken to address unsafe residue as they occur; and oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

France, in accordance with EU regulations, EC Directive 96/23, develops, and implements a national residue program each year. Program documentation is furnished to FSIS annually with the previous year's results. France, as a member of the EU, has residue plans that are acceptable by EU standards and therefore equivalent to the FSIS criteria. France has had no residue violation in the past 3 years based on review of the FSIS' POE records.

The FSIS auditor reviewed the IDHESA laboratory located in Quimper, Bretagne, which conducts some of the residue analysis of government samples from the one establishment certified to export to the United States. Other samples go to other government and public laboratories as no one laboratory conducts analyses for all residues. The DGAL uses a system of laboratories that includes public laboratories located in France and other laboratories located throughout the EU. Many of these laboratories are designated as reference laboratories for specific residue areas. This laboratory is accredited by the EU and the French accreditation body for ISO 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary

medications. The FSIS auditor reviewed the accreditation and third-party review and audit documents and had no concerns from this review. Proficiency testing is proceeding as designed and all results reviewed were acceptable.

The FSIS auditor found no concerns with the CCA's chemical residue control program. The analysis and onsite audit verification indicated that the CCA's meat inspection system continues to maintain equivalence and is operating at an "average" level of performance for the residue control programs component.

## **IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS**

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The evaluation of this component included a review and analysis of EU Regulation 2073/2005 on Microbiological Criteria for Foodstuffs and DGAL Directive 2012-8274 which contains the regulatory requirements for establishments exporting meat and meat products to the United States.

France has a self-testing microbiological testing program for *Enterobacteriaceae* that has required implementation by all slaughter establishments to show process control. The establishments that are certified eligible for export to the United States have the option to conduct generic *E. coli* testing instead. The one certified establishment has been conducting generic *E. coli* testing but is considering changing to *Enterobacteriaceae* as it must already conduct this testing for other exports. *Enterobacteriaceae* testing has been accepted as equivalent to generic *E. coli* by the FSIS. The auditor reviewed the establishment's in-plant program and records and had no concerns as a result of this review.

For official testing for *Salmonella* in raw product, France has a special program designed specifically for those establishments certified for export to the United States. France maintains a zero tolerance for *Salmonella* in raw meat products. The FSIS auditor reviewed this program, the implementation of the program within the certified establishment by the in-plant personnel, and the results and records resulting from the program. This verification review raised no concerns. This establishment has not had a positive *Salmonella* result in the last three years, and so no actions pertaining to the *Salmonella* program have been taken. France suspends the shipments to the United States on the first *Salmonella* positive result as stated in their *Salmonella* Performance Standards Program.

The FSIS auditor reviewed the ISO accreditation of IDHESA for microbiological testing from the EU and the French accreditation body. This accreditation contains all microbiological analyses necessary to support the one certified establishment.

France has microbiological testing programs for *Salmonella* in Ready-to-Eat (RTE) products, and for *Listeria monocytogenes (Lm)* in RTE products, product-contact surfaces, and non-product-contact surfaces (environmental). The FSIS auditor verified that the system has implemented certain sampling and testing programs to ensure that pork products intended for export to the United States are safe and

wholesome and the equivalence criteria have been met. The FSIS auditor reviewed the accreditation and third-party review and audit documents and had no concerns from this review. Proficiency testing is proceeding as designed and all results reviewed were acceptable.

There is a regulatory definition for RTE products in the EU Regulation 2073/2005 that requires countries to fulfill the microbiological requirements of importing countries. Therefore, the definition of in 9 CFR 430.1 also applies to establishments certified for export to the United States. According to EU Regulation No 2073/2005, there is a zero tolerance for *Lm* in RTE foods intended for infants and RTE foods for special medical purposes, as well as for RTE foods able to support the growth of *Lm* before the food has left the control of the establishment that has produced it. For other RTE foods, there is a limit of 100 cfu/g of *Lm* during their shelf-life. This last requirement is superseded by the requirement to meet the importing countries requirements. Therefore, there is zero-tolerance for *Lm* in products exported to the United States.

The methods of analyses are ISO 6579 for *Salmonella* (both raw and RTE) and ISO 11290-1 for *Lm*, both methods have been found to be equivalent by FSIS. In-plant inspection personnel and departmental supervisors are required to verify test results of official testing and establishment self-check testing and to institute enforcement actions if necessary.

According to EU Regulation 852/2004, all establishments producing products for human consumption must implement and maintain a permanent procedure based on HACCP principles. Specific rules for testing and minimum sampling are written in EU Regulation 2073/2005.

The FSIS auditor reviewed training materials and records and the results of proficiency testing. No concerns were noted for the Microbiological Testing Programs Component. Therefore, the CCA continues to maintain equivalence and is operating at an "average" level of performance for this component.

## **X. CONCLUSIONS AND NEXT STEPS**

The audit determined that France's inspection system continues to maintain equivalence and is operating at an "adequate" level of performance. The inspection program met the established criteria for all six equivalence components. However, the finding related to sanitation indicates a need for DGAL to improve its oversight of the construction and maintenance of establishments eligible to export to the United States. It needs to ensure that establishments respond to deficiencies in a timely fashion. The auditor discussed this finding with the CCA at the exit meeting on June 27, 2013, in Paris. The CCA understood and accepted the nature of the finding. At this time, DGAL also indicated that it has already begun working with the establishment to address the construction-related deficiencies, with resolution of the project to be documented during a subsequent supervisory visit.

## **APPENDICES**

**APPENDIX A: Individual Foreign Establishment Audit Checklist**

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Jean Hénaff S.A.S. Ker Hastell 29710 Pouldreuzic France	2. AUDIT DATE 6/20-21/2013	3. ESTABLISHMENT NO. 29225001	4. NAME OF COUNTRY FRANCE
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

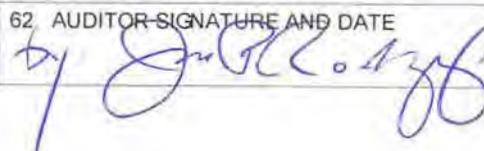
Date: 06/20-21/2013 Est. # 29225001 (Jean Hénaff S.A.S. [S/P]) Pouldreuzic, France

39/56 The doors leading from the warehouse area to the outside did not fit well and would not prevent the possible entrance of pests into the area. The area for receipt of raw materials had a ceiling and three walls but was completely open to the outside on the fourth side allowing for the possible entrance of pests or other contamination of the product. These findings were documented in inspection system reports, but there were no short-term corrective actions taken, just a future plan to install new doors and close in the receiving dock area. The new doors for the warehouse area were ordered between the first and second days of the audit. 9 CFR 416.2(b)(3), EU Directive 882/2004 (have to get the rest of that reference later)

61. NAME OF AUDITOR

for Rori K. Aaron, DVM

62. AUDITOR SIGNATURE AND DATE

by  Rori K. Aaron 6/20-21/2013

**APPENDIX B: Foreign Country Response to Draft Final Audit Report (when available)**



MINISTÈRE DE L'AGRICULTURE, DE L'AGROALIMENTAIRE ET DE LA FORÊT

Direction générale de l'alimentation  
Service de l'alimentation  
Sous-direction de la sécurité sanitaire des aliments  
Bureau des établissements de transformation  
et de distribution

Adresse : 251, rue de Vaugirard  
75 732 PARIS CEDEX 15

Dossier suivi par : Sébastien REMY  
Tél. : 01 49 55 46 90 - Fax : 01 49 55 56 80  
Réf. interne : **0150**

**Dr Shaukat H. Syed**  
International Audit Staff  
Office of Investigation, Enforcement and Audit  
USDA / FSIS  
1400 Independence Avenue, SW  
Washington, DC 20250

ETATS-UNIS

Paris, le **2 - JUIN 2014**

Objet : Commentaires de la France sur le projet de rapport final d'audit du FSIS de la mission du 17 au 28 juin 2013

Monsieur le Directeur et cher collègue,

Je vous remercie d'avoir bien voulu me transmettre, par courrier daté du 7 avril 2014, le projet de rapport final concernant la mission d'audit conduite en France par le FSIS du 17 au 28 juin 2013.

Je suis heureux de lire que notre système d'inspection continue à rester équivalent à celui des États-Unis avec la capacité de produire des produits sûrs, sains, et correctement étiquetés.

Nous n'avons pas de commentaires particuliers sur ce rapport. Cependant, je tiens à souligner que nous prêtons la plus grande attention à la maintenance des établissements autorisés à exporter aux États-Unis. Nous serons particulièrement vigilants à ce que les mesures correctives soient conduites dans le délai imparti.

Je vous prie d'agréer, Monsieur le Directeur et cher collègue, en l'assurance de ma considération distinguée.

Le Directeur Général de l'alimentation  
Chef du Service de la Coordination  
des Actions Sanitaires - C. V. O.

**Jean-Luc ARSOT**

Informal translation

Dr. Shaukat H Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit  
Food Safety and Inspection Service  
1400 Independence Avenue, SW.  
Washington, D.C.  
20250

Dear Dr. Syed,

I thank you sincerely for mailing a copy of the final draft audit report - dated April 7<sup>th</sup> 2014 - of the on-site audit conducted in France by the FSIS from June 17<sup>th</sup> to the 28<sup>th</sup>, 2013.

I am thrilled to learn that our inspection system continues to remain equivalent to that of the United States in its capacity to produce safe, healthy and correctly labeled products.

We do not have any particular comments regarding this report. I would, however, like to emphasize that we give our highest level of attention to the maintenance of the establishments authorized to export to the United States. We will take special care to ensure that the corrective measures be implemented expeditiously.

Please be assured, Dr. Syed, of my highest regards.

Jean-Luc ANGOT  
Chief Veterinary Officer  
Ministry of Agriculture/DGAL