USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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JUN 2 8 2016

Dr. Loïc Evain
Chief Veterinary Officer
Direction Générale de l'Alimentation / Ministère de l'Agriculture
251 Rue de Vaugirard
75735 Paris Cedex 15
France

Dear Dr. Evain,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of France's Meat inspection system from August 31 to September 18, 2015. Enclosed is a copy of the Final Audit Report. The comments and corrective actions received from the Government of France are included as an attachment to the report.

Regarding the determination whether France is eligible to resume beef and veal exports to the United States, FSIS has been working with your technical experts relative to France's sampling and testing programs for *Escherichia coli* O157:H7 and non-O157 shiga toxin-producing *Escherichia coli* (STEC). FSIS will summarize the outcome of the equivalence review of France's documented inspection program for beef (veal) trim and other intact beef (veal) intended for non-intact use, such as ground beef (veal), in a separate letter.

For all additional questions, please contact Mary H. Stanley in the Office of International Coordination at mary.stanley@fsis.usda.gov.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

FRANCE

August 31 – September 18, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING PORK MEAT PRODUCTS AND BEEF PRODUCTS INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

June 14, 2016
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from August 31 - September 18, 2015, to verify that France's food safety system governing the production of pork continues to be equivalent and to determine whether France is eligible to resume beef exports, in the form of veal, to the United States. The FSIS auditor identified several findings that will require a response from the Central Competent Authority (CCA) - the *Direction Gènèrale de l'Alimentation, General Directorate for Food* (DGAL).

The audit focused on six components: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP), (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

The previous FSIS audit of France's meat inspection system occurred from June 17 - June 27, 2013. The FSIS auditor verified that the previous audit findings were corrected. The current FSIS audit identified issues related to the Statutory Authority and Food-Safety Regulations, Sanitation, and HACCP components indicating inadequacies in the CCA's oversight at the United States-certified establishments including the beef (veal) establishment. The individual observations are described in their relevant component.

In addition to these observations, the audit identified the following findings that raise questions about the CCA's ability to maintain equivalence:

- Documentation was not available from either the CCA or the establishments to support how the pork processing establishments attain a non-detectable performance standard for *Salmonella* in ready-to-eat (RTE) (shelf stable, not heat treated (dried cured ham)) products to ensure safety.
- Memorandum DGAL/SDSSA/2015-647 specifies the detection limit for *Listeria monocytogenes* as "not present in a 25 g sample;" however, the Alert Management Guide document stated that the tolerance of *Listeria monocytogenes* in the product is 100 cfu/g before a recall is issued. Thus, these guidelines contradict each other, and clarification is necessary as to whether the 100 cfu/gram allowance is intended for products destined for the United States.

In response to the audit findings, the CCA proffered corrective actions which were evaluated and determined to be acceptable by FSIS. It is noted that France stated, in a comment to the Final Draft Audit Report, that the technical instructions for exports to the United States are currently being amended to include the shiga toxin-producing *Escherichia coli* (STEC) analyses to be performed and will be provided to the FSIS for evaluation. In the light of above, FSIS is not able to determine the reinstatement for beef equivalence at this time. Comments and corrective actions received from Government of France are included as an attachment to the report.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) conducted an on-site equivalence verification audit in conjunction with a beef reinstatement equivalence audit of France's meat inspection system from August 31 - September 18, 2015. The audit began with an entrance meeting held on August 31, 2015, in Paris, France, with the participation of representatives from the Central Competent Authority (CCA) - *Direction Générale de l'Alimentation, General Directorate for Food* (DGAL) and FSIS.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine audit to verify the ongoing equivalence of France's meat inspection system for pork products, as well as to determine whether to reinstate the equivalence of that country's inspection system for beef products. The audit objective was to ensure that France's meat inspection system continues to be equivalent to that of the United States, with the capacity to produce products that are safe, unadulterated, and properly labeled. In addition, the FSIS auditor verified implementation of corrective actions by the DGAL in response to the previous FSIS audit in 2013.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process also included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through the foreign inspection system's Self-Reporting Tool (SRT).

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA, including members from the departmental[1] or local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP), (5) Government Chemical Residues Testing Programs, and (6) Government Microbiological Testing Programs.

FSIS reviewed administrative functions at DGAL headquarters, two departmental offices, and five local inspection offices in order to evaluate the implementation of the management control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

[1]Metropolitan France is divided into 96 administrative divisions called Départments**.** For the purpose of the organizational structure of France's Meat Inspection System, the Department is the lowest one of the three levels among the national and 18 administrative regions. In addition to 96 departments in metropolitan France, there are 5 overseas departments, which also are classified as regions.

During visits to two pork slaughter and processing establishments, two pork processing establishments, and one beef (veal) slaughter and processing establishment, the FSIS auditor closely examined the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in an equivalent manner as provided in 9 Code of Federal Regulations (CFR) 327.2, the FSIS regulations addressing equivalency determinations for foreign country inspection systems.

Additionally, FSIS audited two laboratories to verify their ability to provide adequate technical support to the inspection system.

Central Competent Authority Visits		**#**	**Locations**
Central Competent Authority	Central	1	DGAL – Paris
	Departmental Offices	2	Direction Départementale des Services Vétérinaires (DDSV) • DDSV - Pau Cedex • DDSV - Périgueux Cedex
Laboratories		2	• One government microbiology laboratory located in Périgueux Cedex • One government residue laboratory located in Pau Cedex
Establishments		5	• Two pork slaughter and processing establishments located one in Quimper and one in Pau Cedex • Two pork processing establishments located in Pau Cedex • One beef (veal) slaughter and processing establishment located in Périgueux Cedex

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

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of France's meat inspection system included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

France has equivalence determinations in place for the following:

- Private laboratories analyze samples for *Salmonella,*
- Establishment employees collect the samples for *Salmonella,* and
- FSIS has determined the use of *Enterobacteriaceae* and Total Viable Count in lieu of generic *E. coli* is acceptable for all European Union (EU) exporting countries.

A detailed analysis of the CCA's continued ability to meet the original commitments related to these equivalence determinations is provided under the Government Microbiological Testing Programs component.

III. BACKGROUND

Currently, France is eligible to export only pork products to the United States. From October 1, 2012, to July 27, 2015, a total of 167,784 pounds of pork products were imported to the United States from France, of which a total of 79,112 pounds were re-inspected at the Point-of-Entry (POE). None of the imported products were rejected. Ninety-seven percent of imports received included thermally-processed commercially-sterile product, with the remaining 3 percent in the shelf-stable, not heat-treated category (cured ham products).

France requested that FSIS reinstate its eligibility to export beef to the United States following the March 2014 USDA-Animal and Plant Health Inspection Service (APHIS) regulation that lifted restrictions on the importation of beef from countries classified as "controlled risk" for Bovine Spongiform Encephalopathy (BSE) by the World Organization of Animal Health (OIE). In response, FSIS requested France to update its SRT to provide information on its beef inspection program. France provided information pertaining to the beef inspection system including France's microbiological testing program related to the implementation of *Escherichia coli O157:H7* and other Shiga toxin-producing *E. coli* (STEC).

For the verification of its beef inspection program, the DGAL presented one veal slaughter establishment, which slaughters cattle less than 30 months of age limiting FSIS' verification activities to only Specified Risk Material (SRM). Given the limited scope of FSIS verification, FSIS could not verify the CCA's controls of SRM, their handling and disposition, and microbiological testing including verification activities for STECs in raw beef products. While the auditor was able to verify the CCA and establishment's controls that ensures the removal and disposition of tonsillar tissues and distal ileum, the auditor was unable to verify SRM specific to cattle of all ages which includes tissues from brain, skull, eyes, trigeminal ganglia, spinal cord, portion of vertebral column, and dorsal root ganglia. For similar reasons, the auditor was unable to verify establishment and government controls related to the mitigation of shiga-toxin producing *Escherichia coli* (STEC) as a food safety hazard likely to occur in the beef (veal) slaughter process.

Prior FSIS final audit reports for France's meat inspection system are available on the FSIS website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)

The first of the six equivalence components that the auditor reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all

official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

In France, the inspection system overseeing food safety is collaboratively distributed among directorates from three ministries. FSIS recognizes the DGAL as a CCA which is part of the Ministry of Food, Agriculture and Fisheries (MFAF). The DGAL bears oversight responsibility for the production of food of animal origin, animal welfare, and slaughterhouses. The DGAL collaborates with the Directorate General for Competition, Consumer Affairs, and Fraud Representation (DGCCRF) of the Ministry of Trade and Commerce and the Directorate General for Health (DGS) of the Ministry of Public Health. While the DGCCRF has the sole responsibility for processed food of non-animal origin and non-food products, the three directorates share the responsibilities of inspection related tasks in the sectors of processing, restaurants, direct sales, by-products, animal feed, and transport and storage.

The delivery of France's inspection system is organized on three levels. The first level includes DGAL headquarters in Paris, which has the ultimate control and supervision of France's meat inspection system. At the second level, regional offices serve as conduits between headquarters and the local level. France is divided into 18 administrative regions, 13 of which are in Metropolitan France and five of which are overseas regions. Each region has its own directorate known as *Direction règionale de l'alimentation, de l'agriculture et de la forêt* (DRAAF) which is responsible for food, agriculture, and forestry in their respective regions. All establishments certified for export to the United States are located in the Aquitaine and Brittany regions.

At the third level or local level, France is divided into 96 departments (there are also five additional overseas departments). Based on the organization of the administrative services, a department can be identified as a Departmental Directorate for the Protection of Population (DDPP) or a Departmental Directorate for Social Cohesion and Protection of the Population (DDCSPP). These departments are also identified by a two-digit number. This audit covered DDPP-29, DDPP-64, and one DDCSPP-24. Each type of Departmental Directorate has a Veterinary Services Directorate responsible for enforcement, control and surveillance of animal health and food laws, including United States import requirements. Each Director of Veterinary Services is supported by at least two Chiefs of Service, one of which is assigned to the Service of Animal Health and Welfare and the other to the Service of Food Safety.

The scope of the current audit included the review of the administrative functions at the Directorate of Local Veterinary Services (DDSV) in two departmental directorates identified as DDPP-64 and DDCSPP-24. These local veterinary service directorates provide the oversight to three of the four United States-certified establishments eligible to export pork meat products to the United States and are responsible for ensuring that all FSIS requirements are met at these facilities. The auditor verified that the Directorate of Local Veterinary Services provides periodic supervisory reviews at the United States-certified establishment. The auditor examined examples of reviews to determine whether these reviews are conducted to ensure that requirements referred to in relevant subsections of 9 CFR 327.2 are met. Except as noted below, no concerns were identified during the audit of Local Veterinary Service Directorate at either DDPP-64 or DDCSPP-24.

- The auditor's review of periodic supervisory reports noted that they did not capture the concerns identified during the audit of ready-to-eat (RTE) establishments and the veal slaughter establishment located in departmental directorates DDPP-64 and DDCSPP-24 respectively.

The hiring of inspectors assigned to all establishments follows the recruitment process stipulated in Law No. 2007-148 of 2 February 2007. Applicants wishing to enter into the civil service need to meet the general and job specific requirements outlined in this legislation.

In order to verify the CCA's and the Departmental Directorates' ability to recruit qualified official veterinarians (OVs) and official auxiliaries (OAs) to be assigned to the United Sates-certified establishments, the FSIS auditor reviewed examples of hiring procedures and determined whether the recruitment adheres to the requirements of the law. The auditor further reviewed samples of inspector performance records and determined that annual performance reviews were conducted by the supervisors in accordance with the departmental standards. The auditor confirmed that inspectors assigned to the United States-certified establishments are direct hires of the government either on a permanent or on a contractual basis. The duration of the contract is not to exceed more than 2 years, and the contract can be renewed following this period.

The FSIS auditor verified that the DGAL, in collaboration with Departmental Directorates, provides an ongoing training program to ensure that inspection officials are aware of specific inspection requirements pertaining to meat exports to the United States. The FSIS auditor reviewed the inspection personnel's training records at DDSV and local inspection offices. This review indicated that in-plant inspection personnel assigned to the United States-certified establishments have completed classroom training similar to what FSIS inspectors receive on the subject of animal and public health diseases. The auditor determined that the supervisory chain of command of the DDSVs has a mechanism that assesses the inspector's training needs and provides recommendations to the DDSV as appropriate. There is a consistently maintained intranet training portal at the central level that offers a series of courses on a wide range of topics including food safety and animal health. Employees can access the site voluntarily to improve their skills for career advancement or to fulfill requirements to complete specific courses mandated by the DGAL. Additionally, United States- based consulting groups delivered training during calendar years 2011, 2013, 2014, and 2015 on a wide variety of food safety subjects, with special emphasis on HACCP, Sanitation Standard Operating Procedures (SSOP), and FSIS requirements.

The DGAL continues to administer the country's meat inspection system.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide for humane

handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

In order to determine the DGAL's legal authority to enforce the appropriate laws and FSIS requirements, the auditor reviewed the information provided in the SRT by the CCA. As a part of the pre-audit analysis of the DGAL's controls pertaining to this equivalence component, the auditor reviewed selected sections of the following documents:

EU Regulations:

- Regulation No. 852/2004,
- Regulation No. 853/2004,
- Regulation No. 854/2004,
- Regulation No. 1099/2009,
- Regulation No. 2073/2005,
- Council Directive 96/22/EC,
- Council Directive 96/23/EC, and
- Council Directive 98/179 EC.

French Laws and Regulations:

- French Rural Code (authority of official controls over regulated food operating business),
- The Order 4 of June 8, 2006 (laws concerning approval of establishments for marketing products derived from animal for human food),
- French regulation of May 4, 2010 (laws pertaining to withdrawal time of veterinary drugs in animal for human food), and
- The Order of July 29, 2013 (laws on definition of first and second category health hazards for animal species).

The CCA has developed procedures and issued numerous documents to enforce EU regulations and FSIS requirements. Each of these documents is referred to as a "Memorandum" and will be referenced as appropriate in this report.

Within France, as required by Article 7 of EU Regulation No. 1099/2009 on animal welfare, all slaughter establishments must develop procedures to ensure that "slaughtering and related operations are carried out by persons with the appropriate level of competence to do so without causing the animals any avoidable pain, distress or suffering." The FSIS auditor verified that at the beef (veal) slaughter and two pork slaughter establishments, livestock presented for slaughter are handled humanely and are in compliance with the EU regulation. FSIS previously determined that these EU regulations are equivalent to comparable FSIS regulatory requirements. The following facility deficiency was observed:

- In one swine as well as the veal slaughter establishment audited, the auditor observed some steel brackets with sharp pointed edges in the receiving pens and at the unloading docks. These protrusions posed a potential for injury to the pigs or calves being presented for slaughter at these facilities. Therefore, the requirement of articles 1.3 and 2.5 of Annex II of

EU Regulation No. 1099/2009 was not met at these facilities. The CCA immediately notified establishment management, and the deficiencies were corrected by management at both slaughter establishments while the audit was in progress. Although the deficiencies were corrected, neither the government inspectors nor supervisory reviews identified the problems and the need to correct them before the audit.

The requirements for establishment construction and facilities and equipment are drawn from EU Regulation No. 852/2004 Annex II, and 853/2004 Annex III. Annex 2 of the French Order 4 of June 8, 2006, lists the documents that an establishment seeking approval for the intra-community trade needs to submit prior to approval. In order for an establishment to be eligible to export to the United States, it needs to satisfy the facility provisions specified in the above referenced EU regulations. One of the functions of the Department Directorates is to provide recommendations to the DGAL regarding new establishments seeking certification for United States export. The recommendations to the DGAL are based on the outcome of the site visit to the establishment to determine whether the applicant establishment is in full compliance with the national standards. The FSIS auditor reviewed an example of the establishment approval and recommendation documents for the last establishment that received certification for United States export. The auditor determined that approval of the establishment followed the procedures described above.

The DGAL outlined procedures in Memorandum DGAL/*Sous direction de la sécurité sanitaire des aliments*/sub directorate for food safety (SDSSA)/N2010-8171 to facilitate the implementation of relevant overarching EU regulations pertaining to ante-mortem. The memorandum also provides details regarding facility requirements that an establishment must meet in order for ante-mortem inspection to be compliant with EU regulations. The DGAL has issued instructions in a document titled "Ante and Post-mortem Inspection of Hogs" for the inspectors assigned to the United States-certified establishments. This guidance document is used by inspection personnel assigned to the United States-certified establishments to conduct ante-mortem inspections on United States destined exports. Per Memorandum 2015-647 "Terms for certification for places of business exporting meat and meat products to the USA," the slaughter of non-ambulatory cattle is prohibited for United States export.

The FSIS auditor verified that in-plant inspection personnel assigned to the two swine and the beef (veal) slaughter establishments audited conduct ante-mortem inspection on the day of slaughter by reviewing the receiving logs and the pen cards of these establishments. The inspection personnel determined whether animals are fit for slaughter for human purposes by observing all the animals at rest and in motion in the designated holding pens. Sick or suspect animals are maintained in designated holding pens for further examination as needed. The FSIS auditor observed and verified that all animals have access to water in all pens, and provisions for access to feed are made for the animals that are held for more than 12 hours. The auditor verified that all the United States-certified establishments slaughtering livestock met FSIS requirements to conduct ante-mortem examinations.

Regarding procedures for conducting post-mortem inspection, FSIS assessed requirements through on-site record reviews, interviews, and observations of inspection activities in all audited slaughter establishments. The CCA provided instructional guidance (Memorandum_NS2013-8180_List A and_ List B) containing a comprehensive list of lesions and pathological conditions

and corresponding dispositions of product to both the Official Veterinarians (OVs) and Official Auxiliaries (OAs). The FSIS auditor observed and verified that proper presentation, examination, and disposition of carcasses and parts are implemented. Both OVs and OAs are adequately trained in performing their on-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 FSIS' criteria for post-mortem examination.

The CCA presented one beef (veal) slaughter and processing establishment for FSIS verification of controls to ensure the product is free from SRM. The auditor verified that the trained OVs and OAs utilize their knowledge and skills to identify tonsils and distal ileum the known SRM associated with cattle of less than 30 months of age in the product and ensure any beef products they inspect and pass are free of these SRM. The auditor further verified that OAs working under the supervision of the OV retain carcasses and parts thereof that are pathologically suspect for veterinary disposition.

On February 26, 2015, the CCA issued a Technical Instruction, "DGAL/*Sous direction du pilotage des resources et des actions transversales*/sub directorate", for the management of resources and transversal actions (SDPRAT)/2015-182 to the field staff for uniform application of inspection procedures for compliance verification at the regulated establishments. There is a portion of the document on procedures for ensuring follow-up on noncompliance issues until they are completely resolved.

Through a records review at the local inspection offices as well as interviews conducted with the representatives of the CCA, the FSIS auditor verified that the requirements for continuous (daily) inspection at all the slaughter/processing and processing establishments audited are being met. The FSIS auditor also observed the functions of the off-line inspector who conducts daily verification activities. These daily verification activities include direct observation and review of establishment records, including HACCP, SSOP, Sanitation Performance Standards (SPS), *Enterobacteriaceae*, and Total Viable Count (TVC) sampling techniques and conducting *Salmonella* sampling and testing for the Pathogen Reduction Program. All stages of production destined for United States export are separated by time or space from any domestic production or production intended for another export market.

The objective and scope of the DGAL's "The National Quality Procedure" document is to outline the procedures to be carried out by the supervisory staff involved in the inspection activities of DGAL in order to ensure that skills are maintained and that practices are standardized. This guidance document establishes the frequencies of various types of supervisory activities based on risk evaluation.

There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by the DGAL. In conclusion, France's meat inspection system has legal authority and a regulatory framework to implement requirements necessary to ensure food safety and public health.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the DGAL must provide general requirements for sanitation, sanitary handling of products, and SSOP.

Pertaining to sanitation controls, France has adopted EU Regulation No. 852/2004 on the hygiene of foodstuffs, EU Regulation No. 853/2004 dealing with specific hygiene rules for the food of animal origin, EU Regulation No. 854/2004 describing-specific rules for the organization of official controls on products of animal origin intended for human consumption, and EU Regulation No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health, and animal welfare rules.

In addition to complying with EU hygiene legislation for requiring food operating businesses to maintain sanitary operating conditions and prevent product contamination, France requires all United States-certified establishments to meet FSIS requirements for sanitation consistent with provisions specified in 9 CFR Part 416. To facilitate the implementation, the DGAL issued Memorandum 2015-647 and Appendix 2 of technical instructions DGAL/*Sous direction des affaires sanitaires européennes et internationales*/sub directorate for international and European sanitary affairs (SDASEI)/2014-393 dated May 20 2014, which delineates the procedures into SSOP and SPS. The technical instruction documents cited above further obligate the food operating businesses eligible to export to the United States to:

- Train staff responsible for sanitation in SSOP,
- Have an SSOP plan that delineates procedures for pre-operational and operational sanitation, and
- Update these procedures following any changes in the working areas, equipment, or staff.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at all audited establishments. In the beef (veal) slaughter and processing establishment audited, the FSIS auditor verified the actual pre-operational inspection by shadowing the in-plant inspector conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures begin after establishment personnel conduct their pre-operational sanitation procedures and determine that the facility is ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspection personnel conduct this activity in accordance with the DGAL's established procedures in the technical instructional documents referenced above.

Although the audit analysis did not identify any issues with the general requirements of sanitation in the United States-certified establishments, lack of effective enforcement measures exerted by inspectors resulted in SSOP and SPS related deficiencies being observed by the auditor in two of the five establishments audited:

- During preoperational sanitation verification in the beef (veal) slaughter and processing establishment, the auditor observed that the split saw platform and the split saw did not receive cleaning and sanitation after their use on the previous day.

- In one pork establishment and in the veal slaughter establishment, condensation was observed on the overhead units and on carcass rails in the cooler. Although no direct product contamination was observed, the specific locations of the condensation evidenced a problem that was ongoing and recurring in nature, i.e., insufficient ventilation in this area.
- In the pork establishment referred above, the auditor observed that the overhead rail at the entrance to the cooler was covered with black powdery material. Some of this extraneous material was also observed to have fallen on the floor. Edible product in a steel bin was stored nearby.

The FSIS auditor determined that the DGAL's inspection system continues to maintain sanitation requirements. In-plant veterinary officials and departmental supervisors demonstrated an overall ability to verify maintenance of sanitary conditions. The auditor found concerns, however, about the implementation of sanitation performance standards in pork slaughter and processing establishments and SSOP in the beef (veal) slaughter establishment.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTTROL POINTS (HACCP)

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement, and maintain a HACCP plan and verify the effectiveness of processes and process controls.

The DGAL has adopted the EU Regulations to ensure safety of food at all stages of production, processing, distribution, and marketing of food intended for human consumption. One feature of the hygiene legislation, as it commonly known, is the requirement that member states of the EU need to comply with the importing country's requirements. This requirement obligates France to meet any third country import requirements, including United States import criteria that are not satisfied within the hygiene legislation or other EU directives. The DGAL developed procedures and issued official memoranda to implement EU regulatory requirements. Similarly, without prejudice to EU requirements, France provided official instructions to the United States certified establishments and the inspectors assigned to those establishments to meet all criteria for HACCP or Sanitation that are not covered in the hygiene legislation discussed above.

The evaluation of this component included a review of the information provided by the DGAL in the SRT which includes:

- Service Memo DGAL/SDSSA/N2006-8138 issued on June 7, 2006,
- Memorandum-NS2012-8156_Inspection_HACCP-Official Control Plan, and
- Part A of Technical Instructions DGAL/SDSSA/2015-647 (special requirements of health authorities in third countries).

One feature of the Service Memo cited above is that, in addition to daily inspection activities, pursuant to Article 10, paragraph 2d of EU Regulation No. 882-2004, the OV is required to conduct periodic audits of good hygiene practices and the HACCP system. These audits are comprehensive and are conducted in order to determine the adequacy and maintenance of the establishment's overall food safety program.

Part A of the Technical Instruction of DGAL/SDSSA/2015-647 follows FSIS's HACCP regulatory requirements prescribed in 9 CFR Part 417 which addresses the evaluation of written HACCP programs, monitoring, verification, corrective actions, record keeping, and hands-on verification inspection.

The DGAL requires and routinely verifies that establishments certified for export to the United States employ control measures to prevent adulteration of RTE products by *Listeria monocytogenes* and *Salmonella*. The FSIS auditor confirmed that the DGAL requires two pork processing establishments intending to export RTE post-lethality exposed products to the United States to control *Listeria* by adopting measures consistent with one of the three alternatives[2] provided in 9 CFR 430.2. The establishments audited adopted alternative 2b to control *Listeria* in their shelf stable not heated (dry cured ham) product and met the criteria for alternative 2b except that:

- At the deboning step, the hazard of "re-contamination" of RTE post-lethality exposed product was not taken into consideration in the establishment's hazard analysis plan. This finding also applies to all subsequent steps in the processes after the deboning step.
- Known pathogens *Listeria monocytogenes* and *Salmonella* were not being considered as hazards in the production of shelf stable not heat treated (dry cured ham) products at some processing steps.
- Documentation supporting that the pork processing establishments attain at least a 5 Log_{10} reduction of *Salmonella* in shelf stable not heat treated (dried cured ham) products to ensure safety and the absence of *Salmonella* was not presented for the auditor's review.

The audit verification activities also evaluated the HACCP system of the beef (veal) slaughter establishment. The FSIS auditor verified through interviews conducted at the DGAL's headquarters, departmental directorate of DDCSPP-24, and inspection officials assigned to the slaughter establishment that the requirements of HACCP and verification were being met.

Furthermore, through a records review and observation, the FSIS auditor verified that the in-plant inspection personnel at the beef (veal) slaughter establishment conducted daily verification of HACCP plans in accordance with the methodology described in the above cited instructional documents. The official verification activities included the evaluation of written HACCP programs, monitoring, corrective actions, recordkeeping, and hands-on verification inspection. The in-plant daily inspection verification included Critical Control Points (CCP) verification with results entered in the in-plant inspection personnel records. The review of Hazard Analysis (HA) reveals that the establishments identified all known hazards associated with slaughter of cattle younger than 30 months of age. All identified hazards in HA were addressed either with

[2] 9 CFR part 430 (The *Listeria* Rule) lays out three alternative approaches establishments can take to control *Listeria* in their environment. These include:
Alternative 1: use of a post-lethality treatment and an antimicrobial agent.
Alternative 2a: use of a post-lethality treatment.
Alternative 2b: use of an antimicrobial agent.
Alternative 3: use of sanitation alone.

control points or with CCPs as appropriate and were supported with sound decisions. The review of the establishment's corrective actions indicated that HACCP related deviations are addressed in accordance with requirements stipulated in Memorandum 2015-647.

FSIS has major concerns in regard to the adequacy of the DGAL's inspection verification procedures in two RTE establishments producing post-lethality exposed product. Failing to identify the hazard of "re-contamination" of RTE post-lethality exposed product as well as the hazards of *Listeria monocytogenes* and *Salmonella* in the not heat treated - shelf stable products casts doubt on the continued ability of France's inspection system to ensure the safety of these products. The DGAL must provide supporting documentation concerning corrective action to address audit findings within 60 calendar days.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAMS

The fifth of the six equivalence components the FSIS auditor reviewed was Government Chemical Residue Control Programs. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' residue control program, the CCA's program needs to include random sampling of internal organs, fat, and muscle from carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA needs to identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; to provide a description of its residue sampling and testing plan and the process used to design the plan; to describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and to provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

The National Residue Program (NRP) in France follows the provisions in the EU Directives 96/22 and 96/23. The requirement of Article 5 of the Directive 96/23 mandates that the country update the national residue control plan for the following year based on the results of the previous year in order to consider changes in chemical group and detection measures. The DGAL develops the NRP plans to control chemical residues in food of animal origin. The NRP plan for 2015, which is contained in the document "Technical Instruction DGAL/SDSPA/2014-1026," was issued on November 12, 2014, and was disseminated to the regional DRAAFs and to local veterinary services of DDPP and DDCSPP for implementation. The DRAAFs, in coordination with their respective departments, are responsible for sample distribution among regions and departments. The DGAL uses the information system *The Système d'Information Général de l'Alimentation* (SIGAL) for the management of residue control plans including the distribution and monitoring of chemical residues. National reference laboratories and other public laboratories conducting analyses on samples for chemical residues upload the results directly to SIGAL, so that the results are available to the DGAL, DRAFF, and departments for review and immediate enforcement action, if needed.

In conjunction with the NRP, the DGAL issued a memorandum titled "Technical Instruction DGAL/SDPRAT/2014-898 17/11/2014." The objective of this technical guidance document is

to provide the field staff with the procedures that they are to follow in implementing the sampling program. The other highlights of the instructions include:

- Sample allocation among DDPPs and DDCSPPs,
- Sample selection, storage, and transportation methodology,
- Testing schedule, and
- Testing results, noncompliant results, and enforcement management.

The DGAL has legal authority to take enforcement action when a test detects samples that exceed maximum residue levels. Upon completion, the plan is evaluated for its success in achieving the objectives and targets.

For analysis of samples collected under the NRP, the DGAL uses a system of laboratories that include public laboratories located in France. Many of these laboratories are designated as reference laboratories for specific residue areas. The FSIS auditor reviewed the *"Laboratories des Pyrenees et des Landes (LPL)"* laboratory for its chemical residue testing program. This laboratory is accredited by the *Le Comitè français d'accrèditation* (COFRAC) for International Organization for Standardization (ISO) 17025 in the specific areas of testing for anabolics, steroids, heavy metals, and residues from veterinary medications. The COFRAC audited the laboratory in 2015 for certification of ISO 17025 standards. The auditor confirmed that the LPL addressed all the recommendations made to the laboratory during the accreditation audit of the facility by COFRAC. The certification issued to LPL is valid from August 8, 2015 - March 31, 2019.

The document reviews establish that analysts had successfully completed intra-laboratory and inter-laboratory evaluations administered by the supervisor and possessed the competencies necessary to conduct the analyses assigned to them. Additionally, sample handling and frequencies, timely analyses, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control are performed in accordance with the laboratory's quality management program. The auditor observed the laboratory personnel at the sample receipt area check sample integrity and security, assign the identification, and store the samples in accordance with the laboratory's standard operating procedure.

Based on the evaluation of information contained in the SRT and pre-audit analysis of supporting documents in conjunction with the information gathered during the on-site audit, FSIS determined that the Government Chemical Residue Control Programs component includes a national program that is managed and implemented by the DGAL as intended.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Government 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 and wholesome and meet all equivalence criteria.

France developed procedures to implement the requirements of EU Regulation No. 2073/2005 on Microbiological Criteria for Foodstuffs. The DGAL issued Memorandum 2015-647 to facilitate the correct implementation of Microbiological Criteria on meat products destined for the United States export. This memorandum outlines the microbial testing requirements derived from the aforementioned EU regulation for process control verification; pathogen reduction standards; RTE-Post Lethality Exposed products; and *Escherichia coli* O157:H7 and other STECs for establishments slaughtering cattle. The DGAL provides a guidance document titled "Sample Management" concerning the maintenance of sample integrity during sample collection and dispatch.

France requires all slaughter establishments to develop and implement a sampling and testing program for the detection of indicators of fecal contamination in order to assess the effectiveness of process controls during the production of raw meat derived from pork or beef. For official verification of the establishment's testing programs and evaluation of the results, inspectors refer to Appendices 2-6 of Memorandum 2015-647 for guidance. The auditor verified that the two pork slaughter and the beef (veal) slaughter establishments audited were testing for *Enterobacteriaceae* and Total Viable Count (TVC) in accordance with Memorandum 2015-647 based on the provisions in EU Regulation No. 2073/2005. Testing for *Enterobacteriaceae* in lieu of *E. coli* testing is recognized as equivalent by FSIS. The auditor verified *Enterobacteriaceae* and TVC test results at two pork slaughter and the beef (veal) slaughter establishment, for which no concerns were identified. The method to detect *Enterobacteriaceae* is BIO 12/21-12/06 and total viable count utilized the BIO 12/35-05/13 method.

The DGAL has a *Salmonella* testing program for chilled livestock (cattle and swine) carcass sampling that is consistent with the provisions of Annex I, chapter 2 of EU Regulation No. 2073/2005. Appendix 3 of Memorandum 2015-647, titled "Reduction of pathogens-*Salmonella*," establishes performance standards for all slaughter species. The attachment provides details on the acceptable limit, method of analysis, and action to be taken when samples test positive for the presence of *Salmonella*. The guidance on the *Salmonella* performance standard is consistent with the provisions of Annex I, chapter 2 of EU Regulation No. 2073/2005 regarding the *Salmonella* testing program for chilled livestock (cattle and swine) carcass sampling. The auditor determined that the *Salmonella* testing program instituted by the DGAL meets FSIS' criteria for microbiological testing for this pathogen.

Through interviews with the government officials at headquarters and his review of the official records maintained at two pork and one beef (veal) slaughter local inspection offices, the FSIS auditor verified that the microbiological testing program for *Salmonella* was implemented as intended.

FSIS has made the following equivalence determinations for France regarding official testing for *Salmonella* in raw product:

- Use of ISO 6579:2002 to analyze for *Salmonella.*

The method used by official laboratories to detect the absence or presence of *Salmonella* is BKR 23/04-12/07 Sm (*Salmonella mobiles*), which is a validated method for ISO 6579:2002 to

analyze *Salmonella Spp.* The auditor verified *Salmonella* testing results for the latest set of tests conducted at all three slaughter establishments audited, and determined the establishments to be in compliance with EU Regulation No. 2073/2005 standards.

Pertaining to France's sampling and testing program for *Escherichia coli* O157:H7 and other STECs in raw beef products, the CCA submitted the following documents with its beef SRT for FSIS' equivalence determination review:

- EU Regulation No. 2003/99: surveillance system of zoonotic agents, including STEC,
- Memorandum 2015-647 "Terms for certification for places of business exporting meat and meat products to the USA",
- Memorandum DGAL/SDSSA/N2013-8043 Annex 15 issued on February 19, 2013 "Amendment to memorandum DGAL/SDSSA/2012-8279 on the monitoring plan for shiga toxin-producing Escherichia coli (STEC) contamination in manufacturing beef and beef patties during the production stage-2013",
- Memorandum DGAL/SDSSA/N2013-9912, "Conditions for the Approval of Facilities Exporting Meat and Meat Products to the USA, issued on December 23, 2013",
- Memorandum DGAL/SDSSA/N2012-8181 issued on August 13, 2012 "Production of minced meats and meat preparations in approved facilities or facilities subject to approval",
- Order of March 17, 1992 on the conditions to be met by slaughterhouses of red meat animals for the production and marketing of fresh meat and determining the requirements for the health inspections of these establishments, and
- Française De Sècuritè Sanitaire Des Aliments (AFSSA)'s Opinion of July 15, 2008 - ANSES No. 2010-SA-0031 "Opinion of the French Food Safety Agency on the advisability of revising the definition of pathogenic STEC."

As part of audit verification for beef equivalence reinstatement, the auditor evaluated the information in the SRT and supporting documents pertaining to France's beef inspection program, in particular, testing for *Escherichia coli* O157:H7 and STECs.

The DGAL presented only a single beef (veal) slaughter establishment that slaughters cattle less than 30 months of age for audit. As such, the auditor was not able to verify all aspects of France's beef inspection system, including the implementation of the CCA's official testing program for *Escherichia coli* O157:H7 and other shiga toxin-producing *Escherichia coli* in raw beef product. Since France does not seek to export veal trim, ground veal, and other intact veal intended for grinding, the DGAL did not provide the testing methods or analytical results for these products.

In order to verify France's *Listeria* control program for RTE products that are exposed to the production environment after receiving lethality treatment, the auditor reviewed the information provided in the SRT. As part of the pre-audit review, the following CCA- issued instructional documents were evaluated:

- Alert Management Guide "Guidance for the management of food borne alerts between food-chain operators and the administration when a product or a batch of products is identified as contaminated", and

- Technical Instructions DGAL/SDSSA/2015-647 "Terms for certification for places of business exporting meat and meat products to the USA".

The document titled "Alert Management Guide" discusses procedures the DGAL employs in order to recall product in the event the product tests positive for known pathogens of human health concern in food products of animal origin.

According to the Alert Management Guide document, the tolerance of *Listeria monocytogenes* in the product which results in the recall of the product, according to the French system, is 100 cfu/gram.

- Memorandum DGAL/SDSSA/2015-647 specifies the detection limit for *Listeria monocytogenes* as "not present in a 25 g sample;" however, the Alert Management Guide document stated that the tolerance of *Listeria monocytogenes* in the product is 100 cfu/g before a recall is issued. These guidelines contradict each other, and further clarification is necessary as to whether the 100 cfu/gram allowance is intended for products destined for the United States.

The second document identified above, provides details on the controls and testing programs required to be implemented by the establishments producing RTE-Post Lethality Exposed products. This document outlines the official verification testing program with frequencies for each testing regimen. Additionally, the document refers to FSIS' *Listeria* compliance guidelines and FSIS Directive 5100.1 Rev. 3 to provide further guidance to inspection personnel and to the industry.

The technical instruction DGAL/SDSSA/2015-647 specifically requires RTE establishments to consider the hazard of *Listeria monocytogenes* contamination of RTE products and control the pathogen either through their HACCP plans, SSOP, or other prerequisite programs. Appendix 2 of the instruction contains requirements for microbiological testing that establishments producing RTE-Post Lethality Exposed product are to implement to verify the efficacy of their *Listeria* control program. The regimen for the testing program includes product testing, testing of food contact surfaces (FCS), and testing of the production environment with frequencies similar to those utilized domestically in the United States.

Through interviews with government officials and review of official records maintained at the local inspection office, the auditor verified that the DGAL routinely conducts official sampling of RTE- Post Lethality Exposed products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective.

Regarding analytical testing methods to test RTE product, FCS, and the production environment, the DGAL approved "BRD 07/04-09/98," which is an official method that is used to detect the presence of *Listeria monocytogenes* or *Listeria Spp*. The "BRD 07/04-09/98" is an alternative method to the NF EN ISO 11290-1 method and is certified and validated in accordance with the ISO 16140 standard for the detection of *Listeria monocytogenes* and other *Listeria* species.

For *Salmonella* testing on the RTE product, the DGAL uses AES 10/04-05/04 as an alternative method to ISO 6579 for the detection of *Salmonella spp.* The alternative proprietary methods applicable when testing foodstuffs against the food safety criteria are specified in Annex 1, chapter 1 of EU Regulation No. 2073/2005.

To determine the efficacy of the microbiological testing program implemented at the two establishments producing post-lethality-exposed product, the auditor reviewed certificates of analyses of the establishment's testing and official CCA testing. The review did not identify any concerns.

In order to determine whether the CCA has adequate administrative and technical support to operate the inspection system, among other verification activities, the auditor also included a review of a microbiological laboratory in the scope of the current audit. The French document "Order of December 19, 2007" establishes the general conditions for approval of analytical laboratories according to standards specified in EN ISO/IEC 17025. The *"Laboratoire départemental d'analyse et de recherchè"* is a government laboratory located in DDCSPP- 24 that conducts official microbiological testing on raw pork and beef products for *Salmonella* performance standards for the establishments in DDCSPP- 24. The selected laboratory has jurisdiction for official testing over the one United States-certified establishment seeking to export raw intact beef (veal) products to the United States.

During the entrance meeting with the laboratory officials, the auditor learned that the laboratory held the accreditations for the analytical methods for *E. coli O157:H7* and Non-O157 STECs. Since France is currently not exporting beef products that require testing for *E. coli O157:H7* and non-O157 STECs, the laboratory did not receive requests for any testing for these pathogens in the last two years. Because of this inactivity, the laboratory has lost the accreditation for the analytical methods for the aforementioned pathogens. The officials who were interviewed affirmed that the laboratory, if needed, will proceed with validation procedures for analytical methods for *E. coli O157:H7* and non-O157 STECs.

Concerning the oversight of the laboratory, the CCA requires that any laboratory conducting official testing must be accredited by COFRAC for ISO 17025 standards and must maintain accreditation standards at all times. As part of the document review, the auditor reviewed the last ISO accreditation audit report for the audit conducted by COFRAC of this laboratory. The FSIS auditor reviewed the training materials, records, and the results of laboratory proficiency testing. The review of the documents was correlated with the interviews of the analysts to assess their competency, skill, and knowledge of FSIS requirements pertaining to analytical methods used on samples. No concerns arose as a result of the laboratory audit.

Based on the document analysis and on-site audit verification including observations, document reviews, and interviews conducted with the officials from DGAL and microbiological laboratory, FSIS determined Government Microbiological Testing Programs are being managed and implemented by the DGAL as intended.

X. CONCLUSION AND NEXT STEPS

An exit meeting was held on September 18, 2015, at the DGAL headquarters in Paris, France. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor. The audit identified concerns related to the Statutory Authority and Food-Safety Regulations, Sanitation, and HACCP components indicating inadequate CCA oversight at the United States-certified establishments. The individual observations are described in their relevant component.

In addition to these observations, the audit identified the following findings that raise questions about the CCA's ability to maintain equivalence:

- Documentation was not available from either the CCA or the establishments to support how the pork processing establishments attain a non-detectable performance standard for *Salmonella* in ready-to-eat (RTE) (shelf stable, not heat treated (dried cured ham)) products to ensure safety.
- Memorandum DGAL/SDSSA/2015-647 specifies the detection limit for *Listeria monocytogenes* as "not present in a 25 g sample;" however, the Alert Management Guide document stated that the tolerance of *Listeria monocytogenes* in the product is 100 cfu/g before a recall is issued. Thus, these guidelines contradict each other, and clarification is necessary as to whether the 100 cfu/gram allowance is intended for products destined for the United States.

In response to the audit findings, the CCA proffered corrective actions which were evaluated and determined to be acceptable by FSIS. It is noted that France stated, in a comment to the Final Draft Audit Report, that the technical instructions for exports to the United States are currently being amended to include the shiga toxin-producing *Escherichia coli* (STEC) analyses to be performed and will be provided to the FSIS for evaluation. In the light of above, FSIS is not able to determine the reinstatement for beef equivalence at this time. Comments and corrective actions received from Government of France are included as an attachment to the report.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

Appendix B: Foreign Country Response to the Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Jean Henaff Production Ker Hastell 29710 POULDREUZIC Quimper	09/02/2015	FR 29.225.001	France
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Date: 09/02/2015 Est. #: FR 29.225.001 (Jean Henaff Production, Quimper [P/CS]) (Sarlat, France)

41/51/56 Beaded condensation on the overhead railing in a chiller was observed which was immediately brought into control by the establishment. No product was affected.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	Alam Khan DVM 09/02/2015

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fipso Industrie RTE De Bellocq 64270 Lahontan Pau	09/07/2015	FR 64.305.002	France
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Date: 09/07/2015 Est. #: FR 64.305.002 Fipso Industries Slaughter/processing (Pau, France)

46/51/56 Overhead rails at the entrance to the cooler was covered with black powdery material some of which was has fallen on the floor. The edible product in a steel bin was stored nearby. The official veterinarian retained the product for the evaluation of possible contamination of the product.

52/51/56 The auditor observed some steel brackets with sharp pointed edges in the receiving pens and at the unloading docks. These protrusions posed a potential for injury to swine being presented for slaughter. The CCA immediately notified facility management and deficiencies were corrected by the establishment's management while the audit was in progress.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM 09/07/2015

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Haraguy-Jambon De Bayonne Rte De Sauveterre 64120 Aicirits Camou Suhast	09/08/2015	FR 64.010.003	France
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
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Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Date: 09/08/2015 Est. #: FR 64.010.003 (Haraguy-Jambon De Bayonne,[RTE]) (Pau, France)

15/51/56 Known pathogens Listeria monocytogenes and Salmonella were not being considered as hazards in the production of shelf stable not heat treated (dry cured ham) products at some processing steps.

At the deboning step, the hazard of "re-contamination" of RTE post-lethality exposed product was not taken into consideration in the establishment's hazard analysis plan. This finding also applies to all subsequent steps in the processes after the deboning step.

22/51/56 Documentation supporting that the pork processing establishments attain at least a 5 Log_{10} reduction of *Salmonella* in shelf stable not heat treated (dried cured ham) products to ensure safety and the absence of *Salmonella* was not presented for the auditor's review.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	09/08/2015

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pyragena Abiopole Rte De Samadet 64410 Arzacq Arraziguet, Pau	09/09/2015	FR 64.063.004	France
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Date: 09/09/2015 Est. #: FR 64.063.004 (Pyragena [RTE]) (Pau, France)

15/51/56 Known pathogens Listeria monocytogenes and Salmonella were not being considered as hazards in the production of shelf stable not heat treated (dry cured ham) products at some processing steps.

At the deboning step, the hazard of "re-contamination" of RTE post-lethality exposed product was not taken into consideration in the establishment's hazard analysis plan. This finding also applies to all subsequent steps in the processes after the deboning step.

22/51/56 Documentation supporting that the pork processing establishments attain at least a 5 Log_{10} reduction of *Salmonella* in shelf stable not heat treated (dried cured ham) products to ensure safety and the absence of *Salmonella* was not presented for the auditor's review.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	Alam Khan DVM 09/09/2015

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sobeval Zone Industielle Av Louis Lescure Boulazac, 24750 Perigueux	09/14/2015	FR 24.053.001	France
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Date: 09/14/2015 Est. #: FR 24.051.001 (Sobe-val [veal-slaughter]) (Perigueux, France)

10/51/56 During the pre-operational sanitation verification the auditor noted that one split saw had meat and fat residues from the previous day use. The inspector incharge rejected the equipment and issued a non-compliance record to the establishment.

41/51/56 Beaded condensation was observed in one of the carcass cooler. The establishment took immediate corrective action.

52/51/56 The auditor observed some steel brackets with sharp pointed edges in the receiving pens and at the unloading docks. These protrusions posed a potential for injury to calves being presented for slaughter. The CCA immediately notified facility management and deficiencies were corrected by the establishment's management while the audit was in progress.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM 09/14/2015

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FRENCH REPUBLIC

MINISTRY OF AGRICULTURE, AGRIFOOD, AND FORESTRY

Directorate General of Food Supply

Department for Governance and International Affairs in Health and Food Supply
Directorate for European and International Health
Non-member Export Office

Mrs. Jane Doherty
[TN: Stamp in English]
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue
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Paris, 1 JUNE 2016

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Ref.: SDASEI EXP 373/16

Re: Response to FSIS draft audit report on the porcine and bovine sectors
Encl.: 6

Dear Madam Director,

I am pleased to send you, attached herewith, the comments from the General Directorate of Food Supply relating to the FSIS draft audit report, pursuant to the mission that was conducted in France from August 31 to September 18, 2015.

You will find:

- the corrective actions for the findings stated for each business;

- a bibliographic study done by the Bayonne Ham Consortium based on studies performed on Parma ham, which justifies the similarity of the manufacturing processes of these two types of ham and thereby proving that the process in place in the facilities enables 5-log sanitizing [reduction] of *Listeria monocytogenes* and *Salmonella spp*.

Additionally, the actions to be taken in case of a positive result for *Salmonella spp*. and *Listeria monocytogenes* have been specified in the amended technical instructions for exports from France to the United States of America.

Therein it is now clearly stated that:

> "If the presence of *Listeria monocytogenes* / 25g or *Salmonella spp*. / 325g is detected on the finished products, the batch of affected products is declared non-compliant with regard to the microbiological criteria defined by the FSIS: this batch must not be exported to the USA. What happens with this batch is defined according to the provisions of the Hygiene Package and in particular according to (EC) regulation no. 178/2002 and (EC) regulation no. 2073/2005."

Lastly, with regard to the export of veal meat, I hereby inform you that the technical instructions for exports from France to the United States of America is currently being amended to include the STEC analyses to be performed on the carcasses.

This note will be sent to your department in the near future for your opinion, then validated and published for immediate effect.

Very sincerely yours,

[Initials]
[Stamp: Deputy General Director of Food Supply
Department Manager for Governance and International Affairs
CVO
Loïc EVAIN]

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RÉPUBLIQUE FRANÇAISE

MINISTERE DE L'AGRICULTURE, DE L'AGRO-ALIMENTAIRE ET DE LA FORET

Direction Générale de l'Alimentation

Service de la gouvernance et de l'international dans les domaines sanitaire et alimentaire
Sous-direction des affaires sanitaires européennes et internationales
Bureau de l'exportation pays tiers

251 rue de Vaugirard
75732 Paris cedex 15
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Référence : SDASEI EXP 373/16

Madame Jane Doherty
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue
SW Washington, D.C. 20250-3700

Paris, - 1 JUIN 2016

Objet : Réponse au rapport d'audit provisoire du FSIS concernant les filières porcine et bovine
PJ : 6

Madame la Directrice,

J'ai l'honneur de vous adresser en annexe les commentaires de la Direction générale de l'alimentation relatives au rapport d'audit provisoire du FSIS, faisant suite à la mission qui s'est déroulée en France du 31 août au 18 septembre 2015.

Vous trouverez ainsi :

- les actions correctives aux constats formulés pour chaque entreprise ;
- une étude bibliographique réalisée par le Consortium du Jambon de Bayonne s'appuyant sur des études réalisées sur le jambon de Parme, justifiant la similitude des procédés de fabrication de ces deux types de jambon et prouvant ainsi que le process en place dans les établissements permet un assainissant de 5 log en *Listeria monocytogenes* et *Salmonella spp*.

Par ailleurs, les suites à donner en cas de résultat positif vis-à-vis de *Salmonella spp.* et *Listeria monocytogenes* ont été précisées dans l'instruction technique pour les exportations depuis la France vers les Etats-Unis d'Amérique modifiée.

Il y est désormais clairement indiqué :

> "En cas de détection de la présence de *Listeria monocytogenes* / 25g ou *Salmonella spp.* / 325g sur les produits finis, le lot de produits concernés est déclaré non conforme au regard des critères microbiologiques définis par le FSIS: ce lot ne doit pas être exporté à destination des USA. Le devenir de ce lot est défini dans le respect des dispositions du Paquet Hygiène et notamment des règlements (CE) n°178/2002 et (CE) n°2073/2005."

Enfin, s'agissant de l'exportation de viande de veau, je vous informe que l'instruction technique pour les exportations depuis la France vers les Etats-Unis d'Amérique est en cours de modification pour inclure les analyses STEC à réaliser sur les carcasses.

Cette note sera prochainement soumise à vos services pour avis, puis validée et publiée pour application immédiate.

Je vous prie d'agréer, Madame la Directrice, l'expression de mes salutations distinguées.

Le directeur général adjoint de l'alim.
Chef du service de la gouvernan
et de l'international
CVO
Loïc EVAIN

Response to the FSIS audit report – Audit carried out from August 31st to September 18th

	Jean Henaff Ker Hastell, 29710 POULDREUZIC (Approval n° FR 29.225.001)
Observation n° 41/51/56	Firstly, the establishment put a stainless steel protection on the beam in order to canalize beaded condensation and prevent carcass contamination. In January 2016, another decision was taken: to place a resin to make sure that the beam is waterproof. During an inspection carried out on 15 March 2016, those implementations and the absence of condensation were reported (see pictures in Annex 1).
	FIPSO Industrie, route de Bellocq 64270 LAHONTAN (Approval n° FR 64.305.002)
Observation n° 46/51/56	The surplus of mechanical lubricant was cleaned up from the overhead rail, as well as the remaining stains on the floor. The rail cleaning schedule has been improved for the area to be more frequently disinfected. This non-compliance was corrected rapidly and subjected to follow-up by the inspection veterinary services, in particular during the inspection carried out on 18 September 2015. The recurrence of this anomaly was not reported (see Annex 2).
Observation n° 52/51/56	A more appropriate lock system, preventing the animals from being injured, has been implemented. This non-compliance was corrected rapidly and subjected to follow-up by the inspection veterinary services, in particular during the inspection carried out on 18 September 2015. The recurrence of this anomaly was not reported (see Annex 2).
	HARAGUY route de Sauveterre 64120 AICIRITS CAMOU SUHAST (Approval n° FR 64.010.003)
Observation n° 15/51/56	The HARAGUY establishment has modified its hazards analysis (see Annex 3). The establishment applies specific measures in order to monitor the risk of re-contamination via *Salmonella spp.* and *Listeria monocytogenes*, in particular when boning dry cured ham and at further steps of the process. The establishment implemented: adapted cleaning and disinfection procedures; a specific surface analysis program (before and during production) defining the frequency of these analyses, the areas and sites to be sampled; analysis plans for hams as finished products, etc. These measures have been in force since the establishment was approved to export to the USA.
Observation n° 22/51/56	The *Consortium du jambon de Bayonne* (Bayonne ham consortium), in charge of managing the "*jambon de Bayonne*" PGI (Protected Geographical Indication), has carried out a bibliographical study showing that the Bayonne ham production process enables sanitizing products regarding *Salmonella spp.* and *Listeria monocytogenes* hazards. This study relies on: • a comparison of production processes between the Bayonne and Parme hams showing that raw materials used in both processes are similar, as well as the production stages and the physical and chemical characteristics of the finished product; • the results of the microbiological challenge tests carried out in 2009 by Barbuti *et al.* on Parme ham: the fresh hams were artificially contaminated with *Salmonella spp.* and *Listeria monocytogenes* up to 10^6 microorganisms/g. These challenge tests, carried out for process validation, revealed that after a 3-month process, a 5 log reduction was reported in both microorganisms. This study is available in Annex 4. Please note that the HARAGUY establishment has a self-checking plan at its disposal, regarding product loss of weight and AW measuring of finished products.

PYRAGENA Abiopole route de Samadet 64410 ARZACQ ARRAZIGUET (Approval n° FR 64.063.004)	
Observation n° 15/51/56	The PYRAGENA establishment has modified its hazard analysis (see Annex 5). Specific measures are implemented in order to control the risk of recontamination via *Salmonella spp.* and *Listeria monocytogenes,* in particular during the boning of dry cured ham and at further stages of the process. The establishment implemented: adapted cleaning and disinfection procedures; specific surface analysis program (before and during production) defining the frequency of these analyses, the areas and sites to be sampled; analysis plans for hams as finished products; and corrective action plans in case of unsatisfactory results. These measures have been in force since the establishment was approved to export to the USA.
Observation n° 22/51/56	The *Consortium du jambon de Bayonne* (Bayonne ham consortium), in charge of managing the "*jambon de Bayonne*" PGI (Protected Geographical Indication), has carried out a bibliographical study showing that the Bayonne ham production process enables sanitizing products regarding *Salmonella spp.* and *Listeria monocytogenes* hazards. This study relies on: • a comparison of production processes between the Bayonne and Parme hams showing that raw materials used in both processes are similar, as well as the production stages and the physical and chemical characteristics of the finished product; • the results of the microbiological challenge tests carried out in 2009 by Barbuti *et al.* on Parme ham: the fresh hams were artificially contaminated with *Salmonella spp.* and *Listeria monocytogenes* up to 10^6 microorganisms/g. These challenge tests, carried out for process validation, revealed that after a 3-month process, a 5 log reduction was reported in both microorganisms. This study is available in Annex 4. Please note that the PYRAGENA establishment has a self-checking plan at its disposal, regarding product loss of weight and AW measuring of finished products.
SOBEVAL ZI avenue Louis Lescure BOULAZAC (Approval n° FR 24.053.001)	
Observation n° 10/51/56	After the split saw was rejected during the pre-operational sanitation verification, it was immediately brought back into compliance after having been cleaned and disinfected anew for the activity to begin. Since then, particular attention has been paid to this equipment: the concerned staff has been trained and the cleaning and disinfection schedule has been reviewed. No further non-compliance was reported during the following pre-operational sanitation verifications.
Observation n° 41/51/56	Since construction works were finished and airflow modified, managing condensation has been better controlled.
Observation n° 52/51/56	Construction works have been finished since the audit: sharp pointed edges shall not be a potential for injury to animals anymore.