USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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AUG 14 2019

Dr. Loïc Evain
Chief Veterinary Officer
Direction Générale de l'Alimentation / Ministère de l'Agriculture
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France

Dear Dr. Evain,

The United States Department of Agriculture, Food Safety and Inspection Service (FSIS) conducted an on-site equivalence verification audit from March 4 through March 15, 2019. Enclosed is a copy of the final audit report. The comments received from the Government of France are included as an attachment to the report.

If you have any questions, please contact the Office of International Coordination by email at internationalcoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

FRANCE

MARCH 4 THROUGH 15, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

May 22, 2019

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 March 4 through 15, 2019. The purpose of the audit was to determine whether France's food safety inspection system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. France currently exports the following categories of meat products: raw intact, raw non-intact, thermally processed - commercially sterile, and not heat treated-shelf stable veal and pork products.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

Government Oversight (e.g., Organization and Administration)

- The Central Competent Authority (CCA) does not include provisions to prohibit inspection officials from signing export certificates for product destined for the United States until all inspection laboratory verification sample test results for chemical residue are received and found acceptable.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)

- At all audited slaughter establishments, documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by government inspection personnel.

Government Microbiological Testing Programs

- The laboratory does not routinely use a positive control in conjunction with its screening method (GENE-UP®). FSIS considers the use of a positive control necessary for ensuring the validity of each analysis.
- The laboratory could not demonstrate (e.g., by written procedure) that the entire N-60 sample would be tested in the event that the sample submission is greater than the size of the test portion prescribed by the screening method (375 g).

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of France's food safety inspection system from March 4 through 15, 2019. The audit began with an entrance meeting held on March 4, 2019 in Paris, France, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – *Direction Générale de l'Alimentation – Directorate General for Food* (DGAL).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. France is currently eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products
Raw Product – Non-Intact	Raw ground, comminuted, or otherwise non-intact beef	Veal - All Products Eligible except Advanced Meat Recovery Product; Finely Textured Beef; Partially Defatted Chopped Beef; Partially Defatted Beef Fatty Tissue; and Low Temperature Rendered Product
Raw Product – Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product
Raw Product – Intact	Raw intact beef	Veal - All Products Eligible except Cheek Meat, Head Meat, Heart Meat, and Weasand Meat.
Raw Product – Intact	Raw intact pork	Pork- All Products Eligible
Thermally Processed - Commercially Sterile	Thermally processed, commercially sterile	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	NRTE otherwise processed meat	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	RTE acidified/fermented meat (without cooking)	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	RTE dried meat	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	RTE salt-cured meat	Meat - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes France as free of foot-and-mouth disease (9 CFR §94.11), free of swine vesicular disease (9 CFR §94.13), free or low risk of classical swine fever, as part of APHIS-defined European CSF region (9 CFR

§94.31), controlled risk of bovine spongiform encephalopathy (9 CFR §92.5), and subject to European Union (EU) designation of African swine fever (ASF) restricted zone in the EU, established by the EU because of detection of ASF in domestic or feral swine (9 CFR §94.8).

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) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed France's SRT responses and supporting documentation. During the on-site audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether France's food safety inspection system governing meat products is being implemented as documented in the country's SRT responses and supporting documentation.

Representatives from DGAL accompanied the FSIS auditors throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed the administrative functions at CCA headquarters, two regional offices, and local inspection offices in each of the seven establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended. The FSIS auditors visited a sample of seven establishments from ten eligible establishments certified to export meat to the United States. Three of the ten eligible establishments are cold storage facilities. The audit included three swine slaughter and processing establishments, two swine processing only establishments, one veal slaughter and processing establishment, and one cold storage facility.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, two government microbiology and chemical residue testing laboratories were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• DGAL, Paris
	Regional Offices	2	• Departmental Directorate for Protection of Populations (DDPP-29), Quimper • Departmental Directorate for Social Cohesion and Protection of Populations (DDCSPP-24), Périgueux
Laboratories		2	• Laboratoire départemental d'analyse et de recherché de Dordogne (LDAR24) – government microbiological and chemical residue laboratory, Périgueux • Laboratoire Public Conseil, Expertise et Analyse en Bretagne (LABOCEA) -government microbiological and chemical residue laboratory, Quimper
Swine slaughter and processing establishments		3	• Establishment FR 29.225.001 CE, Jean Henaff Production, Pouldreuzic • Establishment FR 64.305.002 CE, Fipso Industrie, Lahontan • Establishment FR 79.246.002 CE, Cooper Arc Atlantique, Sainte-Eanne
Veal slaughter and processing establishments		1	• Establishment FR 24.053.001 CE, Sobeval, Boulazac Isle Manoire
Swine processing establishments		2	• Establishment FR 64.010.003 CE, Aicirits, Camou-Suhast • Establishment FR 64.063.004 CE, Pyragena, Arzacq-Arraziguet
Cold storage facilities		1	• Establishment FR 79.246.003 CE, Sofrimaix, Sainte-Eanne

FSIS performed the audit to verify that France's food safety inspection system met requirements equivalent to those 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. 1901, *et seq.*); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of France's inspection system for meat products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*; and includes the following:

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;

- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

From September 1, 2015 to August 31, 2018, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 464,090 pounds of pork and 166,908 pounds of veal products exported by France to the United States. FSIS also performed re-inspection on 127,650 pounds of pork and 48,157 pounds of veal at point-of entry (POE) for additional types of inspection, testing for chemical residues and microbiological pathogens (e.g., *E. coli* O157:H7 and non-O157 Shiga Toxin-producing *E. coli* (STEC)) of which a total of 1,372 pounds of raw intact veal cuts were rejected for testing positive for non-O157 STEC (O103). The current audit included the sole veal slaughter establishment certified to export veal to the United States, to assess controls for *E. coli* O157 *and* non-O157 STEC in raw veal.

The previous FSIS audit in 2017 identified the following findings.

Government HACCP System

- The DGAL did not provide adequate guidelines to their inspection personnel on how to evaluate the establishment's HACCP system, as evidenced by a veal establishment that was unable to provide support for decisions made about their hazard analysis in adequately addressing *Escherichia coli (E. coli)* O157:H7 and non-O157:H7 STEC.
- The DGAL did not provide adequate instructions to inspection personnel on how to evaluate the supporting documentation required to support decisions made in the hazard analysis, as evidenced by the veal establishment using an antimicrobial intervention for which it was unable to demonstrate the effectiveness of the intervention on reducing or eliminating *E. coli* O157:H7 and non-O157:H7 STEC.

The FSIS auditor determined that the CCA's corrective actions in response to the prior findings were implemented and effective. The FSIS 2017 final audit report for France's food safety inspection system is 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 (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety 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; to ensure the uniform enforcement of requisite laws; to provide sufficient administrative technical support; and to assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

FSIS auditors verified that the national government of France organizes and administers the meat inspection system as mandated by French statutes. The CCA for France is the Direction Générale de l'Alimentation – Directorate General for Food (DGAL). DGAL's authority to enforce inspection laws stems from Regulation (EC) No. 178/2002 of the European Parliament. The EC regulations are the primary overarching laws for regulating meat inspection. France's agricultural and sanitary matters are shared between the EU and member States, as France is a member of the EU. France is responsible for ensuring that adulterated or misbranded products are not exported to the United States through enforcement of its national legislation and implementing regulations.

The National Quality of the DGAL Organization Manual (DGAL/SDPRAT/2016-941) provides instructions detailing the organizational structure and management approach of DGAL. There have been no major changes in DGAL's organizational structure since the last FSIS audit in 2017. At the national level, DGAL is within the Ministry for Agriculture, Agrifood, and Forestry (MAAF) and is responsible for designing policies for primary production, animal welfare, and slaughterhouses.

DGAL has the legal authority and responsibility to develop and oversee the implementation of inspection procedures in accordance with national standards, in addition to those standards imposed by importing countries. These laws and regulations are applicable to all establishments certified to export to the United States. The laws and regulations provide DGAL with the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States including suspension of operations and removing the eligibility of establishments to export to the United States.

At the local level, veterinary service offices are located in either large departments called the Departmental Directorate for Protection of Populations (DDPP) or smaller departments called the Departmental Directorate for Social Cohesion and Protection of Populations (DDCSPP) and are responsible for implementation and enforcement of policies. There are 96 departments in France. 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. 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, support each Director of Veterinary Services.

The Regional Directorate for Food, Agriculture, and Forest links the national level to the local level and is responsible for coordination and management between the national and local levels. There are 13 regions in France.

The FSIS audit of DGAL headquarters included an examination of its oversight activities, with verification of audits that represents periodic supervisory reviews of establishments certified to export to the United States. DGAL is responsible for conducting audits to determine initial and annual approval of official establishments, including those eligible to export to the United States.

The DGAL has an approval process in place for the certification of establishments and is the only body with authority to certify and decertify establishments as eligible to export to the United States. Once the DGAL verifies, through document review and an on-site audit, that an establishment has fulfilled all official requirements in EC regulations and the United States equivalence criteria, the DGAL approves and adds it to the list of eligible establishments certified by France to export meat to the United States.

The FSIS auditors reviewed documents specifically associated for the approval process of three establishments that were newly certified to export to the United States in the latter part of 2017 (Establishments 79246002, 79246003, and 65284001). This review indicated that the above referenced approval process was implemented as intended at these facilities. The current FSIS audit also included on-site visits to two of these establishments.

Memorandum DGAL/SDSSA/2016-355 states that inspection of the food safety management plan by government services is mandatory before the grant of approval, and during scheduled inspections of approved establishments. The Rural and Maritime Fisheries Code empowers DGAL to conduct controls, enter premises, obtain information, collect samples and require corrective actions. *Memorandum DGAL/SDASEI/2018-635* provides the specific requirements for the export of meat and meat products to the United States. The Memorandum includes requirements for corrective actions consistent with 9 CFR §416 and §417. DGAL issued a Technical Instruction to the field staff for uniform application of inspection procedures for compliance verification at the regulated establishments.

FSIS auditors verified implementation of the certification review process, including audit reports of the establishments, sanitation requirements, facility maintenance, sanitation standard operating procedures (sanitation SOPs), HACCP programs, and microbial testing. The audit reports demonstrated that DGAL evaluated the written food safety programs, audited the facilities, and evaluated their compliance with the FSIS requirements before granting certification of eligibility to export meat to the United States.

The FSIS auditors reviewed the administrative functions in two departmental offices. These departmental offices provide oversight and are responsible for ensuring that all the FSIS requirements are met at establishments within their respective regions certified to export to the United States. The FSIS auditors verified that the departmental offices provide periodic supervisory reviews at the establishments certified to export to the United States.

The FSIS auditors examined a sample of documented reviews to determine whether these reviews were conducted to ensure that requirements referred to in relevant subsections of 9 CFR §327.2 were met. The results of the documentation review are detailed under component 2, Government Statutory Authority and Food Safety and Other Consumer Protection Regulations.

FSIS auditors verified that DGAL ensures that source materials used in processing operations, originate only from establishments certified to export to the United States in eligible countries in accordance with *Memorandum DGAL/SDASEI/2018-635.* This memorandum describes the process by which meat and meat products can be exported to the United States. The official veterinarian (OV) inspects these procedures before approval is granted to the establishment and continues to be evaluated during routine inspections of the facility.

France has adopted the definition of adulterated and misbranded product exactly as written in the Regulation (EC) No. 178/2002. The *Alert Management Guide* provides additional guidance regarding the requirements of this regulation. The CCA would use the Alert Management Guide – Notification through the Rapid Alert System for Food and Feed (RASFF) to notify FSIS that adulterated product has been shipped. FSIS auditors verified that DGAL has a mechanism to notify FSIS that adulterated product has been shipped to the United States and requires establishments certified to export to the United States to maintain a recall plan. FSIS auditors verified written recall plan documents at each audited establishment.

FSIS auditors verified that inspection personnel perform all aspects of verification activity before issuing and signing export health certificates per *Memorandum DGAL/SDASEI/2018-635.* The OV signs the export certificates, which are recorded in the server register with each number being unique. There is an embossed stamp affixed on the last page of the health certificate. The government seal and security accountability logs are kept in a secured and locked environment. A tracking system is in place at DGAL headquarters and at the establishment level by OVs.

FSIS auditors verified that all inspection personnel conducting government verification activities, including ante-mortem and post-mortem inspection are government-paid employees, maintaining competent and qualified personnel to ensure the production of safe, wholesome, and accurately labeled product in establishments certified to export to the United States. FSIS auditors verified that all DGAL personnel are employees of the government of France and subject to administrative policies that apply to all government officials. An annual allocation of financial resources to pay the government inspection personnel is determined at the central level and distributed to the regions.

The DGAL is an agency funded by the national government and does not receive any other funding. Fees assessed to meat establishments go to the general budget of the state and not directly to DGAL, nor to the Ministry of Agriculture. All sanitary inspectors and veterinarians, whether they are permanent or temporary hire, are government employees. They are directly paid by the government, hired and fired by the government through DGAL. They have the same obligations regarding training, independence, confidentiality, impartiality, and integrity, and have the authorization to take control on behalf of the government. The DGAL has ultimate control and supervision over the activities of all inspectors.

FSIS auditors verified that each certified establishment has adequate qualified government inspectors to provide inspection coverage continuously (on the line) during slaughter operations, and at least once per production shift during processing operations when producing meat products for export to the United States, including during planned or unplanned government inspector absences. FSIS auditors verified the implementation of DGAL *Memorandum DGAL/SDASEI/2018-635*, which requires prior consultation between the establishments and the inspection services of manufacturing schedules for meat products exported to the United States. These schedules are planned in advance and recorded before the slaughter and processing of meat products intended for export to the United States.

FSIS auditors verified the training records of government inspection personnel, in addition to observing their performance while conducting inspection activities, concluding they have sufficient training to perform their inspection activities. The FSIS auditors verified that the DGAL has implemented and conducted ongoing training programs intended to ensure that government inspection personnel are aware of specific food safety and inspection requirements that pertain to France's meat export to the United States. There is a well-maintained training on an intranet 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.

FSIS auditors verified that the DGAL provides government inspectors with technical support to ensure that official tasks of control are performed according to Regulation (EC) No. 854/2004. DGAL maintains administrative and technical support to operate its laboratory system. The DGAL ensures that the laboratories possess the personnel, facilities, equipment, and methods necessary to fulfill their mission. Each laboratory is accredited in accordance with *International Organization for Standardization/International Electrotechnical Commission* (ISO/IEC) 17025, *General requirements for the competence of testing and calibration laboratories*, standard by the French Accreditation Committee- the *Comité français d'accréditation* (COFRAC). COFRAC conducts periodic reviews of the activities of the laboratories that the DGAL oversees. The laboratories are also subject to inter-laboratory proficiency testing. The DGAL has the authority to suspend any laboratory at any time.

The FSIS auditors verified that government inspection personnel carry out the sampling for official testing programs. The FSIS auditors reviewed records, at the regional veterinary offices and establishments certified to export to the United States, showing the results of official government chemical residue and microbiological sampling and testing programs.

The FSIS audit included on-site visits to the *Laboratoire départemental d'analyse et de recherché* (LDAR24), a government microbiological laboratory located in Périgueux, conducting microbiological testing of samples for establishments certified to export to the United States and the *Laboratoire Public Conseil, Expertise et Analyse en Bretagne* (LABOCEA), a government residue and microbiological laboratory located in Quimper, conducting analytical testing as part of France's national residue program, as well as microbiological testing of official samples.

A significant section of the government microbiological laboratory in Périgueux, LDAR-24, caught fire on December 2018, which resulted in the suspension of its COFRAC accreditation. However, the laboratory continues to operate under its quality manual and procedures developed in association with the initial ISO 17025 accreditation process. DGAL authorized the relocation of laboratory equipment and staff to a dedicated building at the University of Périgueux until the final reconstruction of the burned laboratory is concluded in early 2021. At that temporary location, the laboratory officials recalibrated all equipment and validated its procedures. All reagents and media are ordered from approved commercial suppliers. Review of the laboratory records indicated that all government samples collected in accordance with the national sampling plan had been tested as planned, with reasonable turnaround times. The DGAL provided FSIS auditors with written notification, dated January 09, 2019, from the Ministry of Agriculture and Food authorizing the laboratory to operate officially on a temporary basis.

The FSIS auditors verified that the DGAL maintains oversight of its residue laboratories, through the COFRAC annual audit of the residue laboratory quality system in accordance with the ISO/IEC 17025 standard. Testing of certain residues is compulsory by EU regulations while others are determined by risk analysis. The *Agence National de Sécurité sanitaire de l'alimentation, de l'environnement et du travail*, is responsible for risk evaluations. In accordance with EU regulations, EC Directive No. 96/23, France develops and implements a national residue program each year. This program is furnished to FSIS annually with the previous year's results. France, as a member of the EU, has residue plans that are acceptable by EU standards and therefore equivalent to FSIS criteria.

The FSIS auditors observed a demonstration by laboratory personnel on sample receipt and handling, including checking sample integrity and security, registration of the sample per the laboratory quality assurance system, assigning the identification and storage of samples in accordance with the laboratory's standard operating procedure. FSIS auditors verified that the laboratory performs analysis of samples in a timely manner. The program did not reference the holding of carcasses or parts when samples are taken for routine chemical analysis. The FSIS auditors identified the following finding:

- The CCA does not include provisions to prohibit inspection officials from signing export certificates for product destined for the United States until all inspection laboratory verification sample test results for chemical residue are received and found acceptable.

FSIS auditors observed official veterinarians reviewing documentation about on-farm treatment and withdrawal periods for animals brought to slaughter. DGAL requires that carcasses of suspect animals to be retained at slaughter facilitates pending receipt of acceptable test results. However, DGAL does not require retention of carcasses for routine residue sampling.

FSIS determined that France's government organizes and administers the country's food safety inspection system and that DGAL government inspection personnel enforce laws and regulations governing production and export of raw and processed meat at establishments certified to export to the United States. DGAL is committed to provide FSIS with corrective action plans, which FSIS will verify once the corrective actions are implemented.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

The evaluation of this component included a review and analysis of the information provided by The DGAL in the updated SRT, direct observations, on-site records review, and interviews during the on-site audit. The FSIS auditors verified that DGAL maintains regulatory authority as outlined in official legislation, regulations, decrees, policies, and guidelines. The DGAL ensures that only meat products originating from establishments certified to export to the United States, and currently not restricted by the USDA's Animal and Plant Health Inspection Service, are designated for export to the United States.

FSIS auditors reviewed the slaughter practices at each of the four audited slaughter establishments and determined that inspection personnel verify that humane handling and slaughter of livestock is conducted in accordance with Regulation (EC) No. 854/2004, Regulation (EC) No.1099/2009, and *Memorandum SDASEI/2018-635*. FSIS auditors confirmed that the inspection personnel verify that operators comply with humane handling and slaughter requirements. This includes daily observations of loss of consciousness and accompanying indicative signs of adequate stunning before swine or calves are shackled and bled. FSIS auditors observed and verified that all animals have access to water in all holding areas, and that establishments have procedures to provide feed if animals are held for more than 24 hours.

The DGAL personnel document the results of ante-mortem inspection and numbers of livestock presented for slaughter. Each audited establishment maintained a designated holding pen for further examination of sick or suspect animals. The OV examines any suspect livestock identified with conditions that may preclude slaughter and documents the results on a form designated for ante-mortem inspection. Additionally, the OV documents livestock condemned on either ante-mortem or post-mortem inspection on a condemnation form and all products are rendered unsuitable for human food. The implementation of ante-mortem inspection complies with United States requirements for ante-mortem inspection of livestock. However, FSIS auditors identified an isolated finding pertaining to sorting of calves during ante-mortem inspection which is noted in the corresponding establishment checklist attached to this report (Appendix A).

FSIS auditors verified that government inspection personnel who are physically present in the facility during every stage of slaughter conduct post-mortem inspection. Post-mortem inspection is conducted for every animal slaughtered, whether for domestic use or export to another

country. The requirements for conducting post-mortem inspection are described in legislation and are documented procedures of DGAL, *Memorandum DGAL/SDASEI/2018-635*.

FSIS auditors verified on-line post-mortem inspection of each and every swine and veal carcass, head, and viscera during and after slaughter through on-site record reviews, interviews, and observations of inspectors conducting post-mortem inspection. This includes post-mortem inspection activities performed by the on-line government inspection personnel to ensure that each and every swine and veal carcass, head, and viscera are free of visible fecal material, milk, and ingesta during all slaughter operations. Government inspection personnel are trained in performing post-mortem inspection activities.

FSIS auditors verified that the proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. Disposition of suspect animals during ante-mortem and post-mortem inspection and verification of acceptability of the final product are the responsibility of the OV, who prepares daily post-mortem disposition reports to document his/her official control actions. The government inspection personnel verification procedures and instructions are documented in *Memorandum DGAL/SDASEI/2018-635*. This document also details specific instructions for verification of United States requirements.

FSIS auditors verified that product eligible for export to the United States is separated from domestic products. Government inspection personnel verify that establishments certified to export to the United States comply with the requirement for separation of product destined for the United States and appropriately documented results. FSIS auditors verified use of product codes with designated codes to export to the United States and confirmed segregation of final boxed product.

FSIS auditors verified that government inspection occurs at least once per shift during the processing of meat products and observed off-line OVs conducting daily inspection and verification activities in all audited establishments. The OVs are permanently located in all meat slaughter and/ or processing establishments and are responsible for the supervision of inspection personnel assigned to those establishments. The inspection system provides for continuous (daily) inspection of preparation of meat products and oversight by government supervision.

The OV's verification activities include direct observation and record review procedures related to sanitation SOPs, HACCP, residue sampling, *Salmonella* species (spp.), *Enterobacteriaceae*, and N60 sampling techniques. DGAL has developed specific risk-based verification frequencies and each establishment OV is responsible for drafting official monitoring plans based on those frequencies, which include yearly and weekly schedules. The OV ensures that government inspection personnel perform verification procedures at the frequency identified in the monitoring plan with results documented electronically.

The FSIS auditors verified the controls to ensure the veal product is free from specified risk materials (SRMs) at the veal slaughter and processing establishment. The FSIS auditors verified that the government inspection personnel identify tonsils and distal ileum associated with cattle less than 30 months of age and ensure that any veal products they inspect, and pass are free of these SRMs.

The FSIS auditors reviewed and verified at DGAL headquarters and the audited establishments the documentation of conducted supervisory reviews of establishments certified to export to the United States. The reviews consisted of the evaluation of the adequacy of establishments' food safety systems and delivery of inspection and verification services. Supervisory reviews are conducted using a standard form that consists of a checklist. This form is used for evaluating the adequacy of the establishments' food safety systems, including items related to inspection verification of Sanitation Performance Standard (SPS) elements, sanitation SOPs, HACCP, and microbiological control for generic *E.coli, Enterobacteriaceae*, and *Salmonella*. Additionally, the form includes questions for evaluating the knowledge, skills, and abilities of government inspection personnel to conduct assigned responsibilities at establishments certified to export to the United States.

The periodic supervisory review reports are distributed to the audited establishment's management and the related departmental office. The OV is responsible for the verification of corrective actions resulting from the review. The supervisory reviews evaluate the adequacy of the establishments' food safety systems and the capability of government inspection personnel of conducting inspection activities at establishments certified to export to the United States. FSIS auditors did not identify any negative trends based on the supervisory review records and inspection related verification activity records reviewed. However, the DGAL's supervisory review verification activity elements did not consider assessment of ante-mortem and post-mortem inspection performance. The FSIS auditors identified the following finding:

- At all audited slaughter establishments, documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by government inspection personnel.

FSIS auditors observed the government inspection personnel are adequately performing ante-mortem and post mortem inspection procedures which comply with United States requirements for inspection of livestock.

FSIS auditors determined that DGAL has legal authority to establish regulatory controls over certified meat establishments that export products to the United States. However, the supervisory review grid for performance assessment was missing ante-mortem and post-mortem elements. DGAL committed to provide FSIS with corrective action plans, which FSIS will verify once the corrective actions are implemented.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the DGAL requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions. The evaluation of this component included a review and analysis of the information provided by the DGAL in the updated SRT, direct observations, on-site records review, and interviews during the on-site audit.

FSIS auditors verified that the meat inspection system of France requires all establishments certified to export to the United States develop, implement, and maintain sanitation programs, including sanitation SOPs, to prevent the creation of insanitary conditions and direct product contamination. Government inspection personnel assess the risks posed by conditions that could cause direct product contamination, and when a noncompliance is identified, they require the establishment to implement adequate corrective actions.

The DGAL requires all establishments certified to export to the United States to meet the FSIS requirements for sanitation consistent with provisions specified in 9 CFR §416. The DGAL issued *Memorandum DGAL/SDASEI/2018-635* delineating the procedures into sanitation SOPs and SPS. The DGAL conducts verification of sanitary conditions in accordance with the aforementioned documents, including the evaluation of written sanitation programs, verification of both preoperational and operational sanitation implementation and monitoring of sanitation procedures, including hands-on verification inspection, and records review. FSIS auditors verified that the DGAL enforces these requirements at establishments certified to export to the United States. The government inspection personnel conduct verification of sanitation SOPs requirements whenever product destined for export to the United States is produced.

FSIS auditors evaluated the adequacy of pre-operational sanitation by observing government inspection personnel conducting pre-operational verification of the establishment's sanitation program at one of the audited establishments. The government inspection personnel conducted this activity in accordance with the established procedures, including a pre-operational record review of the establishment monitoring results and an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity). FSIS auditors verified the DGAL's ability to identify insanitary conditions and exercise appropriate regulatory control to ensure sanitary conditions and operations.

FSIS auditors observed the government inspection personnel's verification of requirements for sanitation in all seven audited establishments, comparing the overall sanitary conditions of all audited establishments to the government inspection verification documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records at all establishments.

The FSIS auditors examined the government inspection personnel's documentation of noncompliance reports and supervisory reviews of establishments. The government inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination. The FSIS auditors noted that the inspection and establishment records were reflective of the actual sanitary conditions of the establishment.

In addition to the basic requirements outlined above, the DGAL has developed specific requirements for sanitation in establishments producing ready-to-eat (RTE) product in *Memorandum DGAL/SDASEI/2018-635*. Establishments are required to verify sanitation by testing food contact surfaces for *Listeria monocytogenes (Lm)* or indicator organisms and develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, sanitation SOPs, or other prerequisite program.

The FSIS auditors evaluated government inspection personnel verification of sanitary dressing procedures in slaughter establishments. Government inspection personnel routinely verify establishment sanitary dressing and perform daily verification on at least ten swine or veal carcasses for zero tolerance for fecal material, ingesta, and milk.

FSIS auditors observed the government off-line inspection verification activity to check the absence of contamination by visual inspection is performed according to predefined procedures on randomly selected carcasses. The number of carcasses selected for visual inspection of internal and external surfaces depends on the number of animals slaughtered. The sampling location is commonly after the post-mortem inspection station and before cooling.

At each audited slaughter establishment, the FSIS auditors observed the sanitary dressing processes to verify implementation of practices that maximize the prevention of contamination during dressing procedures and viscera removal. The FSIS auditors also observed government inspection personnel conducting verification of monitoring of the critical control point (CCP) for zero tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results.

Overall, the DGAL requirements and verification procedures were sufficient to ensure that each slaughter establishment adheres to sanitary dressing principles. The FSIS auditors did not observe any systemic sanitary dressing concerns.

In three of the seven audited establishments, FSIS auditors identified isolated sanitation findings that are noted in their respective individual establishment checklist provided in Appendix A of this report. FSIS auditors concluded that the DGAL's meat inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

France's meat inspection system follows EU requirements for establishments certified to export to the United States, Regulation (EC) Nos. 854/2004 and 852/2004, in which HACCP regulatory requirements are prescribed and found equivalent to 9 CFR §417. Instructions for further implementing HACCP regulatory requirements in establishments certified to export to the United States are documented in *Memorandum DGAL/SDASEI/2018-635*.

The FSIS auditors conducted an on-site review of each audited establishment's HACCP system, including hazard analysis, HACCP plans, and CCP monitoring records. The FSIS auditors reviewed zero-tolerance CCP records for feces, ingesta, and milk at four slaughter establishments and verified the physical CCP locations by observing inspection personnel conducting hands-on verification activities in accordance with Annex IV of *Memorandum DGAL/SDASEI/2018-635*.

At the two establishments producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. The FSIS auditors noted that the establishments producing dry-cured pork products maintained validated HACCP programs to support a 5-log reduction for *Salmonella* in these products. Furthermore, it was determined that these establishments maintained the required sampling and testing programs for *Lm* and *Salmonella* for finished products and *Lm* for food-contact surfaces (FCS) and environmental surfaces.

The FSIS auditors verified that the establishment certified to export veal to the United States had addressed contamination of carcasses with STEC (O157:H7, O26, O45, O103, O111, O121, and O145) within the context of its HACCP systems in accordance with section "F - Specific Requirements *E. coli* STEC" of *Memorandum DGAL/SDASEI/2018-635*. This included the use of a validated lactic acid spray, as well as additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. An isolated finding related to the government's documentation of their verification activities for these controls (i.e., carcass spray and carcass chilling) is noted on the establishment checklist in Appendix A.

The FSIS auditors' analysis and on-site verification activities indicate that DGAL requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category. FSIS determined that the HACCP program as described is consistent with criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. Prior to the on-site visit, FSIS' residue experts thoroughly reviewed France's 2019 *National Residue Control Plan* (NRCP) submission, associated methods of analysis, and additional SRT responses outlining the structure of France's chemical residue testing program.

In accordance with EC Directive No. 96/23, DGAL develops and implements a national residue program each year. As a member of the EU, France has residue plans that are acceptable by EU standards and therefore equivalent to the FSIS criteria. DGAL uses a system of laboratories that includes public laboratories located in France and other laboratories located throughout the EU. Many of these laboratories are designated as reference laboratories for specific residue areas. DGAL maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The requirement of Article 5 of the EC Directive No. 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 annual monitoring plan takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. The plan specifies the analytes to be detected, the method of analysis to be used, the matrix to be collected, the tolerance, and the total number of samples to be collected. On-farm controls of veterinary pharmacies, along with controls carried out in slaughterhouses, ante-mortem, and post-mortem inspections, and chemical residue control plans, ensure that all requirements regarding veterinary drugs and their extra-label use are met.

Within Section IV of its *DGAL/SDSPA/2019-39*, DGAL provides specific procedures for addressing violative test results. This includes specific instructions for reporting of results, product sequestration, on-farm investigation, and follow-up sampling. DGAL utilizes RASFF that informs another country of residues exceeding established tolerances in the event that such product is shipped. While on-site, the FSIS auditors reviewed documents associated with a 2018 violative result for flunixin (a nonsteroidal anti-inflammatory drug) in a bovine originating from within the department where the establishment certified for the export of veal to the United States is located. The FSIS auditors were able to conclude that the procedures outlined in the technical instruction where followed as intended through the reporting, investigation, and follow-up phases, and that ultimately, no adulterated product was exported to the United States.

The FSIS auditors' review of the government sampling records for the four audited slaughter establishments indicated that the 2019 sampling program was being adhered to as scheduled. Monitoring residue samples are collected by government personnel and are shipped under inspection seal. Samples are shipped to the laboratory in accordance with protocols outlined in *DGAL/SDSPA/2019-39*, and typically involves direct pick-up by a courier dispatched from the receiving laboratory.

During review of ante-mortem inspection procedures at these establishments, the FSIS auditors observed that an official veterinarian verifies that all lots of animals are accompanied by documentation that discloses their age and origin ("passport"); veterinary examination and treatment history ("food chain"); and a declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. The FSIS auditors verified that DGAL has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet the FSIS criteria. DGAL requires carcasses to be retained for sampling of suspect animals at slaughter facilities; however, as indicated under component one of this report, it does not require retention of carcasses for routine residue sampling.

The FSIS auditors performed an on-site audit of the LABOCEA, a public residue laboratory in Quimper, which serves as an official laboratory conducting analyses of government samples for the presence of chemical residues in meat products. This laboratory is accredited by the EU and COFRAC for ISO/IEC 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The document reviews establish that analysts had successfully completed intra- 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 FSIS auditors verified receipt of samples in LABOCEA. At sample receipt, the laboratory verifies the seal is intact and matches the number on the laboratory submission form. The laboratory verifies and documents the temperature of the sample and, once verification confirms sample integrity, the laboratory assigns a unique laboratory sample number. LABOCEA rejects the sample if requirements are not met or sample integrity is not maintained. The laboratory sample number alone accompanies the sample through the analytical process to eliminate any potential bias. The FSIS auditors 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.

There have not been any POE violations related to this component since the last FSIS audit. The on-site audit activities indicate that DGAL continues to maintain the legal authority to regulate, plan, and execute activities of the food safety inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in meat products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat prepared for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis of Regulation (EC) No. 2073/2005, on Microbiological Criteria for Foodstuffs, which contains the regulatory requirements for establishments exporting meat and meat products to the United States. DGAL has further issued *Memorandum DGAL/SDASEI/2018-635* to facilitate the correct implementation of Microbiological Criteria on meat products destined for export to the United States. This memorandum outlines the microbial testing requirements derived from the aforementioned EC regulation for process control verification; pathogen reduction standards; RTE post-lethality exposed product; and *E. coli* O157:H7 and non-O157:H7 STEC for establishments slaughtering cattle.

Sample collection is performed by government employees and shipped under government seal on the day of sampling, typically through direct pick-up by a courier dispatched from the receiving laboratory. DGAL implements a hold and test protocol, requiring that results for all microbiological pathogens (i.e., *Salmonella*, *Lm*, and STEC) in product that is presented for export to the United States be found compliant prior to the export health certificate being approved.

The DGAL requires all slaughter establishments to implement a microbiological control testing program for *Enterobacteriaceae* to verify process control, in accordance with Regulation (EC) No. 2073/2005. *Enterobacteriaceae* testing has been accepted as equivalent to generic *E. coli* by FSIS. The FSIS audit included direct observation, record review, and interviews of government inspection personnel and private microbiological laboratory personnel to verify microbial process control. The FSIS auditors reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any identified loss of process control.

The DGAL has a *Salmonella* spp. sampling and testing program in raw product consistent with FSIS *Salmonella* Performance Standards. This *Salmonella* testing program for chilled livestock (cattle and swine) carcass sampling is consistent with the provisions of Regulation (EC) No. 2073/2005. Annex III of *Memorandum DGAL/SDASEI/2018-635*, entitled "Reduction of pathogens: *Salmonella*", establishes performance standards for all slaughter species. The document provides details on the acceptable limit, method of analysis, and action to be taken when samples test positive for the presence of *Salmonella*. All samples are sent to an approved microbiology laboratory for analysis for presence of *Salmonella* spp, and government inspection personnel analyze results to determine the effectiveness of each establishment's *Salmonella* control program. The FSIS auditors reviewed the carcass testing results for the last year at four slaughter establishments, noting that the *Salmonella* performance standards were met at each location. The auditors also observed government employees collecting *Salmonella* samples, for which no concerns were identified.

The DGAL has microbiological testing programs for *Salmonella* in RTE products and *Lm* in RTE products, product-contact surfaces, and non-product-contact surfaces (environmental sampling). These inspections are implemented in establishments certified to export RTE meat-based products to the United States. The technical instruction *Memorandum DGAL/SDASEI/2018-635* requires that RTE establishments consider the hazard of *Lm* contamination of RTE products and control the pathogen through their HACCP plans, sanitation SOP, or other prerequisite programs. To verify the efficacy of their *Lm* control program, establishments use Annex II of *Memorandum DGAL/SDASEI/2018-635* which contains the requirements for microbiological testing for RTE post-lethality exposed product. The regimen for the testing program includes product testing, testing of FCS, and testing of the production environment with frequencies similar to those utilized domestically in the United States.

The government inspection personnel perform systematic random sampling and testing of RTE products, with the exception of commercially sterile products. The product samples are collected to be tested for *Salmonella* spp. and *Lm* at a frequency which is based on risk. Product testing is performed in conjunction with a sampling program specifically designed for detecting *Lm* on FCS. Through interviews with government inspection personnel and review of official records maintained at the local inspection office, the FSIS auditors verified that DGAL routinely conducts official sampling of RTE post-lethality exposed product and product contact surfaces at a frequency that ensures that the establishments' control measures are effective.

The DGAL requires that establishments handling raw beef or veal intended for export to the United States are to address the risk of *E. coli* STEC (O157:H7 and six non-O157 sero-groups: O26, O45, O103, O111, O121 and O145). To control this hazard, the establishment may include measures from the SPS, sanitation SOP or HACCP plan. DGAL provides instructions for establishment sample collection; including the types of samples collected, the sampling method and frequency of sampling. In addition, the DGAL, provides instructions for official government sample collection, covering the types of samples collected, and the frequency of sampling for STEC analysis.

The on-site audit of the veal establishment indicated that the requirements of its *Memorandum DGAL/SDASEI/2018-635* were implemented as intended. While on-site, FSIS auditors noted that both establishment and government sampling comprised in collecting 60 uniform pieces (i.e., N60 sampling) from an individual day's production of primal and sub-primal cuts. The FSIS auditors reviewed documentation demonstrating that each lot of product exported to the United States was subject to establishment testing, with government verification testing occurring at a minimum of once per year.

In August of 2018, FSIS identified 1,372 pounds of raw veal that tested positive for non-O157 STEC (O103) at POE. While on-site, the FSIS auditors reviewed the documented verification activities taken by DGAL in response to this STEC-positive result, for which no additional concerns were identified. This included: a) ensuring that no additional product from the same lot had been exported to the United States; b) issuing a noncompliance report to the establishment, requiring the establishment to identify the cause of the positive test result and institute any corrective actions, as appropriate; c) increasing government verification testing for STEC to the next two lots of products; d) increasing government verification of operational sanitation, with specific emphasis on sanitary dressing procedures. Furthermore, the FSIS auditors noted that there were no additional STEC-positive results since the August 2018 occurrence, in conjunction with either government or establishment testing.

The FSIS auditors performed an on-site audit of the LDAR, a government microbiological laboratory. LDAR conducts official microbiological testing on raw pork and beef products for *Salmonella* performance standards; and on beef products that require testing for *E. coli* O157:H7 and non-O157 STEC. The FSIS auditors reviewed the training materials, records, and the results of laboratory proficiency testing. The FSIS auditors observed and verified sample receipt and handling by LDAR. The FSIS auditors verified that LDAR performs a timely analysis of samples, that they report the results to the CCA in a timely manner, apply DGAL-approved analytical methodologies, and have quality assurance programs. However, the following deficiencies were identified related to the laboratory's implementation of its STEC screening method.

- The laboratory does not routinely use a positive control in conjunction with its screening method (GENE-UP®). FSIS considers the use of a positive control necessary for ensuring the validity of each analysis.
- The laboratory could not demonstrate (e.g., by written procedure) that the entire N-60 sample would be tested in the event that the sample submission is greater than the size of the test portion prescribed by the screening method (375 g).

FSIS considers it important that the entire 60 slices of the collected sample be tested, rather than a set 375 g test portion, in order to provide sufficient statistical confidence of the sample. Otherwise, the equivalent level of assurance that a lot is non-detectable for adulterant STEC cannot be supported. Domestically, if the 60 pieces weigh more than 375 g, the FSIS laboratory creates a second sub-sample to accommodate the remaining portion. If either portion is confirmed positive for one or more adulterant STEC, FSIS will consider the product represented by both portions of the sample to be adulterated. These FSIS procedures ensure that all 60 pieces of the N60 sample will be analyzed. For example, if the 60 pieces that weigh 500 g, the FSIS laboratory would create two samples of 325 g and 175 g each. In this event, the enrichment media added to the smaller 175 g test portion would be adjusted accordingly to maintain the same sample to media ratio.

The FSIS auditors examined one establishment producing Thermally Processed-Commercially Sterile (TPCS) products. Within France, establishments producing TPCS product are required to address the hazards using HACCP principles according to Regulation (EC) No. 852/2004, Article 5. Annex II, Chapter XI, of this regulation lays down specific requirements for food in hermetically sealed containers, by stating that the heat treatment process used to process an unprocessed product or to process further a processed product is: (a) to raise every part of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process.

Further instructions for establishments producing TPCS products is provided in *Memorandum DGAL/SDSSA/2015-364*, which includes specific requirements for thermal processes, commercial stability tests, and good hygiene practices. The sterilization value (F_o) set by the establishment must meet the requirements in Regulation (EC) No. 852/2004, which clarifies that the heat treatment used should meet the requirements of an internationally recognized standard. *Memorandum DGAL/SDSSA/2015-364* specifies a minimum sterilizing value of F_o = 3, which corresponds to a 10^{12} reduction in the number of *Clostridium botulinum* spores.

Specific on-site verification activities conducted by the FSIS auditors included the review of process schedules for products exported to the United States; procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; incubation records; retort heat-distribution tests; and procedures to ensure proper closure of containers, including training of closure technicians. The FSIS auditors noted that process schedules were developed in conjunction with the "Centre Technique de la Conservation des Produits Agricoles", an industrial organization recognized by DGAL as a center of reference for the development of thermal processes. Furthermore, the FSIS auditors noted that sterilization values afforded by these processes were typically around F_o = 10, i.e., more than three times the minimum value expressed above (F_o = 3).

FSIS auditors found that France's meat inspection system has a microbiological testing program organized and administered by the national government, and that DGAL has implemented the necessary sampling and testing programs to verify the effectiveness of its system. While France's program includes microbiological sampling requirements that are equivalent to United

States standards, the auditors identified deficiencies related to the official laboratory's STEC testing method that could potentially impact the accuracy of results.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 15, 2019, in Paris, France, with DGAL. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

Government Oversight (e.g., Organization and Administration)

- The Central Competent Authority (CCA) does not include provisions to prohibit inspection officials from signing export certificates for product destined for the United States until all inspection laboratory verification sample test results for chemical residue are received and found acceptable.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)

- At all audited slaughter establishments, documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by government inspection personnel.

Government Microbiological Testing Programs

- The laboratory does not routinely use a positive control in conjunction with its screening method (GENE-UP®). FSIS considers the use of a positive control necessary for ensuring the validity of each analysis.
- The laboratory could not demonstrate (e.g., by written procedure) that the entire N-60 sample would be tested in the event that the sample submission is greater than the size of the test portion prescribed by the screening method (375 g).

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

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 INDUSTRIELLE AV LOUIS LESCURE 24750 BOULAZAC ISLE MANOIRE	03/11/2019	FR 24.053.001 CE	France
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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.	
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	X
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	
53. Animal Identification	
54. Ante Mortem Inspection	X
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	X
58.	
59.	

60. Observation of the Establishment

- 10/51: During pre-operational sanitation at the veal slaughter establishment the following deficiencies were identified: A floor mat was placed inside a stainless-steel chilling tub designated for edible veal heads; most of meat cutting boards are considerably roughened by chipping plastic, cracks, or crevices in the cutting room.

- 22/51: Government inspection personnel did not keep records of their verification activity pertaining to CCP2 (carcass spray) and CCP3 (carcass temperature).

- 41/51: At the carcass retention station, beaded condensation all around the overhead cooling unit indicating insufficient ventilation.

- 46/51: In the hide removal area, rust and algae buildup was present on the overhead rails; no direct product contamination was observed.

- 54/51: The establishment's written program for sorting livestock to be presented for antemortem inspection did not specifically indicate that non-ambulatory disabled calves (or those undergoing emergency slaughter) would be precluded from export to the United States. This is inconsistent with the requirements outlined in Section B1.1. ("*Physical Inspection and Documentation*") of DGAL's "*Conditions for approval of establishments exporting meat and meat products to the United States of America*" (EB / SDASEI / 2018-635), which states *"US regulations exclude slaughtering non-ambulatory cattle, including those with limb fractures or tendon or ligament severed. The emergency slaughtered animals therefore may not be intended for export to the United States."* However, the FSIS auditors' review of antemortem records maintained by DGAL inspection staff indicated that no non-ambulatory disabled calves were passed for slaughter (for human consumption) since this establishment was approved for export to the United States in December 2017. Therefore the nonconformity constitutes a design, rather than an implementation error, as the DGAL inspection staff was able to demonstrate that the requirements outlined in Section B1.1 were effectively met on a routine basis.

- 57/51: DGAL's periodic supervisory review program ("RESYTAL Grid") set forth to meet the FSIS requirements outlined in 9 CFR 327.2 ((a)(2)(iv)(B) does not include an assessment of antemortem and postmortem procedures conducted by inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/11/2019

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 Pouldreuzic	03/05/2019	29.225.001 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Periodic Supervisory Reviews	X
58.	
59.	

60. Observation of the Establishment

- 46/51/56: A clogged floor drain in the carcass de-hairing area resulted in the pooling of blood and water and the creation of insanitary conditions for employees transiting this zone. The blockage resulted from a build-up of fat, hair, and other debris which was not removed at sufficient frequency to permit drainage of blood and water from this area.

- 46/51/56: Beaded condensation was observed above the doorway where swine carcasses were entering the blast chiller. No direct product contamination was observed.

- 57/51: Documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by official inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/05/2019

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
COOPERL ARC ATLANTIQUE ZI DE VERDEIL 79800 SAINTE-EANNE	03/07/2019	79.246.002 CE	France
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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.	
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.	X
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Periodic Supervisory Reviews	X
58.	
59.	

60. Observation of the Establishment

- 10/51: At the sticking table, operator does not consistently sterilize the sticking knife between stunned carcasses.
- 10/51: At viscera inspection station; the intestine of multiple carcasses were spreading from one tray to the next, creating insanitary dressing procedure.
- 19/51: During routine verification of zero tolerance (zt) CCP, the government inspection personnel were only checking the internal portion of carcasses. The back side of carcasses was neither included in their routine check, nor was there a mirror to view the back side.
- 46/51/56: At carcass cooler, rusty pipes and rail-dust were observed above stored carcasses. No direct product contamination was observed.
- 57/51: Documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by official inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/07/2019

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	03/12/2019	64.305.002 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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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.	
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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.	
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23. Labeling - Product Standards	
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25. General Labeling	
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27. Written Procedures	
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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	
57. Periodic Supervisory Reviews	X
58.	
59.	

60. Observation of the Establishment

- 57/51: DGAL's periodic supervisory review program ("RESYTAL Grid") set forth to meet the FSIS requirements outlined in 9 CFR 327.2 ((a)(2)(iv)(B) does not include an assessment of antemortem and postmortem procedures conducted by inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/12/2019

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	03/13/2019	64.010.003 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
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19. Verification and validation of HACCP plan.	
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21. Reassessed adequacy of the HACCP plan.	
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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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/13/2019

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	03/12/2019	64.063.004 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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.	
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19. Verification and validation of HACCP plan.	
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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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/12/2019

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
SOFRIMAIX ZONE INDUSTRIELLE DE VERDEIL 79800 SAINTE-EANNE	03/07/2019	79.246.003 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
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)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
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	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/07/2019

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

Page	Extract from report	France's comments
3	Laboratoire départemental d'analyse et de recherché	Laboratoire départemental d'analyse et de recherche de Dordogne (LDAR24)
3	Jean Hénaff Production, Quimper	The establishment is located in Pouldreuzic.
3	Haraguy – Jambon de Bayonne, Camou-Suhast	The establishment is located in Aïcirits-Camou-Suhast.
7	Memorandum DGAL/SDASEI/2018-635- ~~verification~~	
7	There is an embossed stamp on ~~each~~ page	The embossed stamp is affixed on the last page of the health certificate in the dedicated area
8	Laboratoire départemental d'analyse et de recherché	Laboratoire départemental d'analyse et de recherche de Dordogne (LDAR24)
9	The CCA does not include provisions to prohibit inspection officials from signing export certificates for product destined for the US until all inspection laboratory verification sample test results for chemical residue are received and found acceptable.	Memorandum DGAL/SDASEI/2018-635 is being modified as follows: in the event a carcass to be exported to the USA is randomly selected and sampled as part of the national residue control plan, this carcass must be hold until the analytical result is obtained. The sampled carcass must under no circumstances be released until the (favorable) analytical result is obtained. Meat products issued from other carcasses of the batch produced under USDA conditions can be marketed.
11	The requirements for conducting post-mortem inspection are described in legislation and are documented procedures of DGAL, Memorandum DGALL/SDASEI/2018-635.	Memorandum DGAL/SDASEI/2018-635 specifies the inspection conditions for production for the US market.
11	The government inspection personnel verification procedures and instructions are documented in Memorandum DGAL/SDASEI/2018-635.	Not only. Inspection procedures are described in a general Vademecum (complementary). Memorandum DGAL/SDASEI/2018-635 specifies the inspection conditions for production for the US market.
12	At all audited slaughter establishments, documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by government inspection personnel.	Memorandum DGAL/SDASEI/2018-635 is being modified as follows: Slaughterhouse official inspection personnel must also be evaluated during supervisory inspections to identify deviations from US inspection requirements (see III.B.). A model evaluation grid is proposed in appendix.
13	The government inspection personnel conduct verification of SOPs requirements daily.	The government inspection personnel conduct verification of SSOP requirements every time an USDA-production is performed.

14	Instructions for further implementing HACCP regulatory requirements in establishments certified to export to the US are documented in Memo DGAL/SDASI/2018-635	Memorandum DGAL/SDASEI/2014-393 gives additional information on the conditions for the approval of export establishments.
19	The laboratory does not routinely use a positive control in conjunction with its screening method (GENE-UP®).	The LDA24 now uses a systematic positive control, in addition to the negative control and the amplification control.
19	The laboratory could not demonstrate (e.g., by written procedure) that the entire N-60 sample would be tested in the event that the sample submission is greater than the size of the test portion prescribed by the screening method (375 g).	The LDA24 procedure is modified by integrating a weighing of the pool upon receipt, a first weighing of about 300 grams, a cutting of the remaining samples in the bag to add the remaining 75 grams, ensuring that part or all of each of the samples constitute the final pool of 375 grams.
20	The FSIS auditors noted that process schedules were developed in conjunction with the CTCPA, an industrial organization recognized DGAL as a center of reference of thermal processes.	The CTCPA is declared public utility (articles L521.1 to L521-13 of *Code de la Recherche*)