

United States Department of Agriculture

Food Safety and Inspection Service

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

Dear Dr. Soubeyran,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service conducted a hybrid verification audit of France's meat inspection system June 5 - 21, 2023. Enclosed in a copy of the final audit report. The comments received from the Government of France are included as an attachment to the report.

Sincerely,

Michelle Catlin, PhD International Coordination Executive Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF FRANCE JUNE 5–21, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING RAW AND PROCESSED MEAT PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

November 8, 2023

Food Safety and Inspection Service U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of France conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) June 5 – 21, 2023. The purpose of the audit was to verify whether France's food safety inspection system governing raw and processed meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. France currently exports Raw-Intact and Raw-Non Intact veal products; and Raw-Intact, Raw-Non Intact, Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Fully Cooked-Not Shelf Stable pork products to the United States.

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 Points (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 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

Government inspection personnel did not verify that HACCP plans complied with the
Directorate General for Food (DGAL), the Central Competent Authority's requirements
for HACCP plan content. Ongoing verification activities (e.g., calibration of the process
monitoring instrument, direct observation of monitoring activities, and review of records)
or their frequencies were not listed on the HACCP plans at multiple audited
establishments.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

• DGAL did not ensure that livestock animals (veal and swine) whose meat is destined for export to the United States were included in DGAL's official government chemical residue sampling program.

During the audit exit meeting, DGAL officials committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of DGAL'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 U.S. Department of Agriculture (USDA) conducted an onsite audit of France's food safety inspection system June 5–21, 2023. The audit began with an entrance meeting held June 5, 2023, in Paris, France, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)—La Direction Générale de l'Alimentation—The Directorate General for Food (DGAL). Representatives from DGAL accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference June 21, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products ¹
Raw - Non Intact	Raw Ground, Comminuted,	Veal - All Products Eligible
	or Otherwise Non-intact Beef	except Advanced Meat
		Recovery Product (AMR);
		Finely Textured Beef (FTB);
		Partially Defatted Chopped
		Beef (PDCB); Partially
		Defatted Beef Fatty Tissue
		(PDBFT); and Low
		Temperature Rendered
		Product
Raw - Non Intact	Raw Ground, Comminuted,	Pork - All Products Eligible
	or Otherwise Non-intact Pork	except Mechanically
		Separated and Advanced
		Meat Recovery Product
		(AMR)
Raw - Intact	Raw Intact Beef	Veal - All Products Eligible
		except Cheek Meat, Head
		Meat, Heart Meat, and
		Weasand Meat.
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed -	Thermally Processed,	Pork - All Products Eligible
Commercially Sterile (TPCS)	Commercially Sterile	

-

¹ All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products ¹
Not Heat Treated - Shelf	Ready-to-Eat (RTE)	Pork - All Products Eligible
Stable	Acidified-Fermented Meat	
	(without cooking)	
Not Heat Treated - Shelf	Ready-to Eat (RTE) Dried	Pork - All Products Eligible
Stable	Meat	
Fully Cooked - Not Shelf	RTE Fully Cooked Meat	Pork - All Products Eligible
Stable		
Fully Cooked - Not Shelf	RTE Meat Fully Cooked	Pork - All Products Eligible
Stable	Without Subsequent	
	Exposure to the Environment	

The USDA's Animal and Plant Health Inspection Service (APHIS) has the following restrictions regarding meat products imported from France:

- Veal imported from France is subject to foot-and-mouth disease requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.11, and the bovine spongiform encephalopathy requirements specified in 9 CFR 91.18 or 9 CFR 94.20.
- Pork imported from France is subject to African swine fever requirements specified in 9 CFR 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed France's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether France's food safety inspection system governing raw and processed meat products is being implemented as documented in the country's SRT responses and supporting documentation.

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 3-year period, in addition to information obtained directly from DGAL through the SRT.

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 administrative functions at DGAL headquarters, two regional offices, and eight local inspection offices within the 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 documented in the country's SRT responses and supporting documentation.

A sample of eight establishments was selected from a total of ten establishments certified to export to the United States. This included three swine slaughter and processing establishments, three swine processing-only establishments, one bovine (veal) slaughter and processing establishment, and one cold-storage facility (swine). The products these establishments produce and export to the United States include Raw-Intact, Thermally Processed-Commercially Sterile, Not Heat Treated - Shelf Stable pork, and Fully Cooked - Not Shelf Stable pork; and Raw-Intact veal.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditors assessed DGAL's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also visited an official chemical residue testing laboratory and an official microbiological testing laboratory to verify that these laboratories provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority Central		1	DGAL headquarters, Paris.
Regional Offices		2	 Departmental Directorate for Protection of Population (DDPP29), Quimper. Departmental Directorate for Protection of Population (DDPP24), Périgueux.
Laboratories		2	 Laboratoire des Pyrénées et des Landes, a government microbiological laboratory, Lagor. Laboratoire des Pyrénées et des Landes, a government chemical residue laboratory, Mont-de- Marsan.
Swine slaughter and processing establishments		3	 Establishment No. FR 29.225.001 CE, Jean Henaff SAS, Pouldreuzic. Establishment No. FR 64.305.002 CE, Fipso Industrie, Lahontan. Establishment No. FR 79.246.002 CE, Cooperlarc Atlantique, Sainte-Eanne.
Bovine (veal) slaughter and processing establishment		1	Establishment No. FR 24.053.001 CE, Sobeval, Boulazac Isle Manoire
Swine processing establishments		3	 Establishment No. FR 14.752.020 CE, Broceliande-Alh, Villers-Bocage. Establishment No. FR 64.063.004 CE, Pyragéna, Arzacq-Arraziguet.

		•	Establishment No. FR 65.284.001 CE, SA Salaisons de l'Adour, Louey.
Cold storage facility	1	•	Establishment No. FR 79.246.003 CE, Sofrimaix, Sainte-Eanne.

FSIS performed the audit to verify that France's food safety inspection system meets 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.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

The audit standards applied during the review of France's inspection system for raw and processed 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.

III. BACKGROUND

From February 1, 2020, to January 31, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 959,454 pounds of meat from France. This included 233,882 pounds of TPCS pork; 127,057 pounds of RTE dried pork; 52,930 pounds of raw intact pork; and 545,585 pounds of raw intact veal exported by France to the United States. Of these amounts, additional types of inspection were performed on 97,342 pounds of meat, including physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*L. monocytogenes*]) and *Salmonella* in RTE products) and Shiga toxin producing *Escherichia coli* (STEC) serogroups O157, O26, O103, O111, O121, and O145 in raw veal. As a result of this additional testing, no meat product was rejected for issues related to public health. An additional 129 pounds of pork products and 6 pounds of veal products were refused entry for non-food safety reasons such as shipping damage, labeling, or other miscellaneous issues.

FSIS conducted the previous audit of France remotely April 12–May 12, 2021, and did not identify any systemic findings representing an immediate threat to public health.

The most recent final audit reports for France's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

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

France's national government organizes and manages the meat inspection system. DGAL is the CCA for France and is part of the Ministry of Agriculture and Food Sovereignty (MAFS). The organizational structure and management approach of DGAL are described in Technical Instruction DGAL/SDPRAT/2016-941, the National Quality of the DGAL Organization Manual.

The FSIS auditors confirmed that, since the previous FSIS audit in 2021, the organizational structure of DGAL was consolidated from three to two major services: (1) the Health Actions Service (HAS), and (2) the Performance and International Management Service (PIMS). Each service has three sub-directorates under its jurisdiction. The Sub-directorate for Health and Plant Protection; the Sub-directorate for Food Safety; and the Sub-directorate for Animal Health and Welfare are under HAS while the Sub-directorate for Europe, International, and Integrated Risk Management; the Sub-directorate for Resources and Services Management; and the Sub-directorate for Support for Food and Agro-ecological Transition are under the purview of PIMS. Each sub-directorate has offices under its jurisdiction.

DGAL's oversight of the meat inspection system is based on a continuous chain of command comprising three levels: national, regional, and local. At the national level, DGAL is the only body responsible for designing policies for primary production of meat products and meat byproducts, animal welfare, and slaughterhouses. DGAL has the legal authority and responsibility to develop and oversee the implementation of inspection procedures in accordance with international standards, European Union (EU) regulations, and national regulations. These laws and regulations are applicable to all certified establishments that export meat products to the United States. Furthermore, the laws and regulations also provide DGAL with the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection maintained in the United States. This includes the legal and regulatory authority to suspend operations and to remove the eligibility of establishments to export to the United States. DGAL is led by a Director General for Food, assisted by a Deputy Director General, and is headquartered in Paris.

The Regional Directorate for Food, Agriculture, and Forest (DRAAF) links the national level to the local level by coordinating and managing the interactions between the national and local levels. DRAAF assigns the chemical residue sampling to the Departmental Directorates for Protection of Population (DDPP). There are currently 13 regions.

At the local level, public veterinary offices (PVO) are responsible for the implementation and enforcement of food safety policies. Additionally, the FSIS auditors confirmed that Decree No. 2020-1545 created new departmental units known as the Departmental Directorates for Employment, Labor, and Solidarity (DDETS) and the Departmental Directorates for Employment, Labor, Solidarity, and Protection of Population (DEETS-PP). The DDETS and DEETS-PP replaced the Departmental Directorates of Social Cohesion (DDCS) and the Departmental Directorates of Social Cohesion and Protection of Populations (DDCS-PP). PVOs are either located at the DDPP or at the DDETS and DEETS-PP. There are 96 departments in

metropolitan France and 5 overseas departments. Each type of Departmental Directorate includes a Veterinary Services Directorate (VSD) responsible for the enforcement, control, and surveillance of animal health and food laws, including FSIS import requirements. Each VSD is led by two Chiefs of Service, one being assigned to the Service of Animal Health and Welfare and the other to the Service of Food Safety.

DGAL is the only body vested with the legal authority to certify and decertify establishments that export meat products to the United States. DGAL is responsible for conducting audits to determine initial and annual approval of official establishments, including those eligible for export to the United States, as required by Regulation (European Commission (EC)) No. 853/2004. Technical Instruction DGAL/SDSSA/2022-349 requires that before the grant of approval, official services review and evaluate the required Sanitary Control Plan (SCP) submitted by establishments applying for eligibility to export meat products to the United States. Establishments are certified as eligible for export by the head of the department, and the certification specifies the category of products and the nature of activity for which it is granted.

Article L. 231-1-1 of the Rural and Maritime Fisheries Code (hereinafter referred to as the Rural Code) provides DGAL agents with the authority to access official premises of establishments that export products to the United States; conduct official controls including during the loading or unloading of live animals, products of animal origin, foodstuffs containing products of animal origin, animal feed and/or animal by-products; gather any information or justification required for those controls either onsite or by request; collect samples; and require corrective actions.

As an EU member, France has adopted Regulation (EC) No. 178/2002 regarding the definition of adulterated and misbranded products. Regulation (EC) No. 178/2002 establishes overarching guiding principles and legitimate objectives for food law to ensure a high level of health protection and the effective functioning of the internal market. The regulation includes requirements related to (a) the responsibilities of establishments (Article 17); (b) product traceability (Article 18); (c) the withdrawal, recall, and notification for food and feed (Articles 19 and 20) in relation to food and feed safety (Articles 14 and 15); and (d) imports and exports (Articles 11 and 12). Establishments bear the legal responsibility to market safe and unadulterated products only and must recall any adulterated product that has entered commerce.

Detailed traceability and recall or withdrawal procedures must be included in the SCP before an establishment is approved for export to the United States. Should an establishment fail to meet the recall requirements specified in both the European legislation (Regulation EC No. 178/2002) and the Rural Code (Article L.232-1), then DGAL uses the information obtained from traceability procedures (that the establishment is required to make available), to destroy, recall, or detain any adulterated product.

The 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. DGAL's Mission of Health Emergencies uses the Rapid Alert System for Food and Feed to notify FSIS that adulterated products have been shipped to the United States through the Economic Service of the French Embassy in Washington, D.C.

The FSIS auditors confirmed that government inspection personnel are to ensure that products eligible for export to the United States are not commingled with domestic or other products that are not eligible, as required by Section II.G.2 of Technical Instruction DGAL/SDASEI/2021-253. Additionally, in accordance with Technical Instruction DGAL/SDASEI/2021-253, the FSIS auditors confirmed that government inspection personnel ensure that source materials used in processing operations originate only from French establishments certified as eligible to export to the United States.

Technical Instruction DGAL/SDASEI/2021-253 describes the standards for the approval of establishments that intend to export meat and meat products to the United States. These standards are consistent with FSIS requirements in 9 CFR parts 416 and 417. DGAL, through the local PVOs, ensures that the same laws, regulations, and policies are applied consistently to all establishments certified to export meat products to the United States. Technical instruction DGAL/SDASEI/2021-253 requires that only establishments certified by DGAL can export meat or meat products to the United States.

An establishment that wishes to export meat products to the United States submits a request for approval in Expadon 2, an automated database for information management regarding export regulations. Expadon 2 allows PVOs to see in real time the sanitary and phytosanitary status of animals and animal products, as well as plant condition and export requirements of products to foreign countries. A technical file is assigned to the application, which is then forwarded to the head of the local DDPP. The request for approval must include both a summary of and an all-inclusive SCP that describes all the procedures implemented by the slaughter establishment and/or processing establishments to ensure hygienic practices, food safety, and compliance with FSIS import requirements. Furthermore, the SCP must also include detailed procedures regarding traceability, withdrawal, and recall. The Veterinary Officers (VO) review these procedures before approval is granted to the establishment and continues to evaluate the procedures during routine inspections of the facility.

When those prerequisite conditions are met, the establishment is then placed on a pre-listing status. Afterwards, as per Technical Instruction DGAL/SDASEI/2014-393, an official of the local DDPP conducts a site visit to ensure that the establishment meets FSIS import requirements. Once the DDPP official confirms that all FSIS import requirements are met, the establishment is added to the list of approved establishments that is then updated and forwarded to FSIS by DGAL. In addition, Technical Instruction DGAL/SDSSA/2019-38 states that inspection of the SCP by government services is mandatory before the grant of approval and during scheduled inspections of approved establishments. The FSIS auditors confirmed that DGAL implements a hold and test protocol, requiring that results for all microbiological pathogens (e.g., *Salmonella*, *L. monocytogenes*, and STEC) in product that is presented for export to the United States be found compliant prior to signing the export certificate.

The FSIS auditors verified that DGAL monitors the FSIS website for any update and/or change in the FSIS meat import requirements and receives updated news from the Agricultural Counselor (an employee of the Ministry of Agriculture), who is stationed at the Economic Service of the French Embassy in Washington, D.C. In the event of a change or update in FSIS import requirements, the Agricultural Counselor communicates news of the change to DGAL

officials in Paris who, in turn, relays it to the local DDPPs via regular mail and e-mail. The FSIS auditors confirmed that government inspection personnel stationed at the eight audited establishments maintain up-to-date knowledge of FSIS import requirements.

The FSIS auditors verified that all government inspection personnel assigned to certified establishments to perform ante-mortem and post-mortem inspections, certify exports, collect official samples, and conduct sanitation and HACCP verification activities are employees of and paid by the French national government. At some slaughterhouses, private veterinarians also conduct post-mortem inspection. Private veterinarians have a contractual agreement with DGAL and are directly supervised by VOs who are public civil servants. Government inspection personnel are subjected to administrative policies that apply to all civil servants.

When a DDPP has a vacant VO position, the chief of the inspection service makes a request to DGAL to fill the position. After that, DGAL posts an announcement with the job description in the Official Journal. One of the requirements is to have earned a doctorate in veterinary medicine. Higher technicians (HTs) and government inspectors (GIs) are the other employees who are officially stationed at certified establishments that export meat products to the United States. Once hired, all VOs, HTs and GIs have the same obligations regarding training, independence, confidentiality, impartiality, conflict of interest, and integrity, and have the authority to take regulatory control action on behalf of the government. DGAL has ultimate control and supervision over the activities of government inspection personnel. The FSIS auditors reviewed a sample contract between DGAL and a veterinarian, as well as the professional card issued by DGAL to one of the technicians stationed at one of the certified establishments, and confirmed that they are hired by the national government of France.

The FSIS auditors confirmed that one VO and an appropriate number of HTs and GIs are stationed at every slaughterhouse and ensure that government inspection of every livestock carcass, head, and viscera occurs. The FSIS auditors verified the implementation of DGAL Technical Instruction DGAL/SDASEI/2018-635, which requires prior consultation between the establishments and the inspection services on manufacturing schedules. These schedules are established in advance and recorded before the slaughter and processing of meat products intended for export to the United States. The FSIS auditors confirmed that government inspection personnel are assigned to slaughter establishments during all slaughter operations and conduct inspection activities at the processing-only establishments at least once per shift.

The FSIS auditors verified that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to perform their assigned inspection duties. In accordance with the Training of Meat Inspectors in France, only veterinary services are responsible for the food safety inspection of food products of all animal origin, including meat products. PVOs operate under the authority of the MAFS. Three categories of government inspection personnel perform meat inspection: (1) Vos, whose function is to provide scientific and technical expertise, communication, and management; (2) HTs, who assist the Vos during ante-mortem and post-mortem inspections; and (3) Gis, who provide continuous inspection at slaughterhouses. The FSIS auditors reviewed training records and confirmed that government inspection personnel received training on HACCP, sanitation standard operating procedures (Sanitation SOPs), animal welfare, ante-mortem and post-mortem inspections, thermal

processing provided by the National School of Veterinary Services, and/or in association with the National Training Institute for the MAFS. HTs must have earned a high school diploma, take a 1-year training course on food safety, and shadow a senior employee for one year. Government inspection personnel stationed at certified establishments receive their induction training from FranceAgriMer (an organization under the MAFS that supports the meat industry on export issues), and newly hired employees shadow their senior counterparts to familiarize themselves with the FSIS import requirements.

France has three types of laboratories: (1) the European and National Reference Laboratories, (2) the routine laboratories, and (3) the approved laboratories. In accordance with Article 94 of Regulation (EU) 2017/625, European reference laboratories (EURL) contribute to the improvement and harmonization of methods of analysis, test, or diagnosis to be used by official laboratories, including the analytical, testing, and diagnostic data generated by the official laboratories. The main functions of the EURLs are to provide (a) support to the National Reference Laboratories (NRL) including the organization of inter-laboratory comparative testing or proficiency tests, and (b) scientific and technical assistance to the EC.

According to Articles 2-5 of the Rural Code, the NRLs responsibilities are to perform confirmatory analysis, develop and validate methods, conduct inter-laboratory comparative testing or proficiency testing, coordinate the activities of the approved laboratories, and control reagents. The duties of the routine laboratories (which include approved third-party (private) laboratories) are to perform official tests, take part in any technical assessment process requested by DGAL, and communicate their annual business reports to DGAL, if requested. DGAL has a contractual agreement with third-party (private) laboratories that perform official tests if public laboratories do not have the capacity to perform those tests. The agreement describes the specifications and services that third-party (private) laboratories must meet to analyze official government samples for DGAL.

Article R202-10 of the Rural Code mandates that approved laboratories have the required staff, facilities, equipment, and means to perform their missions; provide guarantees of confidentiality, impartiality, and independence with regard to any individual or corporation working in the production, import, or marketing of products or goods related to their specific field of analysis; comply with the general criteria applicable to the operation of test laboratories; be accredited by the French Accreditation Committee (COFRAC) or by any equivalent European organization; and commit to continuously maintaining their expertise and competence regarding the approved types of tests.

Law No. 2008-776 established COFRAC as the only national accreditation body. All laboratories conducting official testing are accredited in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards. COFRAC audits recently approved laboratories within their first 12 months of operation and periodically afterwards (i.e., every 15 months for chemical residue testing laboratories and every 18 months for microbiological laboratories). In compliance with Regulation (EU) 2017/625, DGAL relies on audits conducted by COFRAC and on COFRAC's accreditation to select approved laboratories.

The FSIS auditors verified that DGAL maintains oversight of its approved chemical residue and microbiological laboratories, through COFRAC's periodic audits in accordance with the ISO/IEC 17025 standards.

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 and for confirmatory testing. The FSIS auditors interviewed management and technical staff of the Laboratorie des Pyrénées et des Landes (located in Mont-de-Marsan), a public laboratory that serves as an official laboratory conducting analyses of government chemical residue samples for the presence of veterinary drugs and growth promoters in meat products. The audited laboratory is accredited as described above by COFRAC with a scope of accreditation that includes residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The FSIS auditors reviewed documentation to confirm that analysts had successfully completed intra- and inter-laboratory evaluations administered by the NRL and demonstrated 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.

Through records reviews and interviews of the laboratory management, the FSIS auditors verified chemical residue sample handling, delivery, and receipt in the official government chemical residue testing laboratory. After receiving an official sample for analysis, the laboratory verifies that the seal is intact and matches the number assigned by the SIGAL (DGAL's electronic database) on the laboratory submission form. Once the laboratory verifies and documents the temperature of the sample and confirms sample integrity and acceptability, the laboratory assigns a unique laboratory sample number. The laboratory rejects the sample if these requirements are not met. The assigned laboratory's sample number alone accompanies the sample through the analytical process to eliminate any potential bias. The FSIS auditors verified through observation that laboratory personnel store chemical residue samples in accordance with the laboratory's standard operating procedures.

The FSIS auditors also visited the Laboratoire des Pyrénées et des Landes (located in Lagor) and interviewed laboratory officials to discuss the government microbiological testing program. This government microbiological laboratory conducts official microbiological testing for *L. monocytogenes* and *Salmonella* in RTE products. The FSIS auditors reviewed the laboratory training materials, annual audit records, accreditation scope, and the results of laboratory proficiency testing. The FSIS auditors reviewed sample receipt protocol and handling and verified that laboratory personnel perform analysis of samples and reports results to the NRL in a timely manner. The laboratory implements DGAL-approved analytical methods and has a quality assurance program. Through record reviews, FSIS auditors verified that COFRAC audits the laboratory every 18 months, and the laboratory corrects any deficiencies found by COFRAC.

During the onsite audits of these facilities, the FSIS auditors verified the sample receiving procedures, the sample acceptance criteria (including temperature requirements), handling, storage, and traceability and reviewed the reporting criteria. Both facilities utilize a local

Laboratory Information Management System to ensure traceability and proper results reporting to the NRL. The FSIS auditors verified equipment was routinely calibrated and maintained, and that reagents were properly labeled and maintained (e.g., expiration dates for prepared media).

The FSIS auditors reviewed laboratory personnel training records and confirmed that laboratory personnel receive initial and ongoing training regarding FSIS import requirements to maintain competency in analytical methods. The FSIS auditors also verified that both official laboratories participate in proficiency testing to ensure the validity of results and confirm that the laboratories can analyze the samples. Official test results are entered into the SIGAL national information system for food-related products and available to DGAL officials at headquarters as well as the DDPPs. DGAL officials confirmed to the FSIS auditors that violative or unacceptable test results were not retested or resampled.

The FSIS auditors verified that DGAL's food safety inspection system governing meat products has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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 equivalence component 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 all animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

As an EU member, France implements the overarching Regulation (EC) No. 1099/2009 related to the protection of animals at the time of slaughter. That regulation is consistent with FSIS animal welfare requirements. Section II.E.1 of Technical Instruction DGAL/SDASEI/2021-253, the 2012 Ministerial Order (Procedures for the Immobilization, Stunning, and Slaughter of Animals and for Animal Protection in Slaughterhouses), and Article R214-65 of the Rural Code require humane handling and humane slaughter of livestock. As stunning techniques, Article 3 of the 2012 Ministerial Order only authorizes penetrative captive bolt gun, concussion, electric stunning, and exposure to carbon monoxide. At the audited swine and bovine slaughter establishments, the FSIS auditors verified that electric stunning was used and confirmed that government inspection personnel were meeting DGAL's animal protection requirements at the time of slaughter and during slaughter operations.

VOs stationed at certified slaughter establishments are responsible for monitoring compliance with animal protection. Article 7 of Regulation (EC) No. 1099/2009 requires that slaughter and related operations be performed only by persons with the appropriate level of competence and to do so without causing the animals any avoidable pain, distress, or suffering. The FSIS auditors verified that the DDPP officials were also conducting both routine and unannounced inspections

related to animal welfare and documenting what was observed during their inspections in RESYTAL (France's electronic food safety inspection system).

The FSIS auditors verified that if inspections resulted in administrative sanctions (e.g., formal notice, suspension of approval, administrative closure) of an establishment due to noncompliance with animal welfare requirements, an inspection report must be entered into RESYTAL along with the associated follow-up (verification of corrective actions or removal of administrative sanctions).

Section II.2.2 of Technical Instruction DGAL/SDASEI/2023-145 (Requirements for Carrying Out Official Inspections Regarding Live Animals in Meat Slaughterhouses) describes DGAL's requirements for ante-mortem inspection. As a prerequisite for approval to export to the United States, slaughter establishments must include ante-mortem activities in their SCPs. The VO must carry out ante-mortem inspection on all animals before slaughter in accordance with Commission Implementing Regulation (EU) 2019/627. The HTs may also carry out an initial inspection of animals and help VOs with practical tasks. Through interviews and document review, the FSIS auditors confirmed that ante-mortem inspection is to be completed no later than 24 hours after the arrival of animals and within the 24 hours preceding their slaughter, as required by Commission Implementing Regulation (EU) 2019/627.

The FSIS auditors confirmed that two inspection levels are used when conducting ante-mortem inspection. Level 1 inspection is performed by either the VO or the HT and consists of a physical examination of the animal presented for slaughter with a focus on the general health condition of the animal. Level 2 inspection, on the other hand, is solely performed by the VO and includes both a comprehensive physical examination of the animal as well as a documentary review of the food chain information (FCI) that comes with the animal which is set aside during Level 1 inspection.

Through discussion with VOs stationed at the audited slaughter establishments, the FSIS auditors confirmed that animals may be either fit for slaughter or require a Level 2 inspection resulting in a postponement of slaughter. After Level 2 inspection is conducted, animals may be: (a) declared fit for slaughter with conditions or without conditions, (b) isolated while alive for further physical examination and/or documentary review, or (c) declared unfit for slaughter due to poor health. The FSIS auditors also confirmed that dead, non-ambulatory, dying, diseased, or disabled animals are condemned and not used to manufacture meat products eligible for export to the United States. Each animal's FCI is uploaded in a traceability electronic system (Elisa) which is accessible to all VOs.

The requirements for post-mortem inspection are outlined in Section III.b.1, b of Technical Instruction DGAL/SDA SEI/2021-253 and in Commission Implementing Regulation (EU) 2019/627. Through observation of slaughter operations and document review at the bovine slaughter facility, the FSIS auditors verified that government inspection personnel were examining carcasses and parts at the head inspection station, the viscera inspection station, and the carcass inspection station, as required by DGAL. Furthermore, through observation, the FSIS auditors also verified that government inspection personnel were conducting post-mortem inspection under the supervision of VOs and were organoleptically inspecting the head, tail,

tongue, thymus gland, and all viscera of every slaughtered animal. The FSIS auditors confirmed that government inspection personnel were observing disease lesions and were palpating the carcasses and parts to detect abnormal lumps in tissues and abnormal firmness in organs. In addition, at the certified slaughter facilities, the FSIS auditors observed that government inspection personnel were not passing contaminated carcasses or parts until removal of all contamination in a satisfactory fashion. In that regard, the FSIS auditors verified that carcasses needing further examination by the VO were either railed out or placed in a retention area.

At the audited swine slaughter facilities, the FSIS auditors verified the implementation of an individual sanitary measure approved by FSIS regarding visual only post-mortem inspection of hog carcasses. Through observation, interview, and record review, the FSIS auditors confirmed that government inspection personnel were conducting visual only post-mortem inspection on market hog carcasses as described in Commission Implementing Regulation (EU) 2019/627 and as per the individual sanitary measure approved by FSIS. Additionally, the FSIS auditors confirmed the following official controls on products intended for export to the United States: (a) FCI was accompanying all animals destined for slaughter, (b) the VOs were reviewing the FCI to determine the extent of visual inspection, (c) all hogs are reared in France, and (d) under the supervision of VOs, government inspection personnel were conducting inspection of every carcass and part by performing visual inspection of all external surfaces, surfaces of body cavities, and offal. The FSIS auditors concluded that government inspection personnel were conducting post-mortem inspection in a manner that is consistent with FSIS requirements.

Through observation, interviews, and record reviews, the FSIS auditors confirmed that government inspection personnel were verifying the adequate identification, removal, and disposal of specified risk materials (SRM) at the audited veal slaughter/processing establishment. DGAL follows Regulation (EC) No. 999/2001, which defines SRMs in a manner that is consistent with FSIS' definition. DGAL requires the removal of all SRMs at the slaughterhouses to ensure SRMs do not enter the food chain. Through record review, the FSIS auditors verified that at the audited veal slaughter establishment, SRMs are identified as a biological food safety hazard in the hazard analysis, and appropriate controls are applied. Section, II.D.1 of Technical Instruction DGAL/SDSSA/2021-253 outlines the modalities for the removal of SRMs and mandates that SRM removal be included in either the certified establishment's prerequisite programs (Sanitation SOPs or Sanitation Performance Standards (SPS)) or the HACCP plan.

France implements the requirements of Regulation (EC) No. 1069/2009 regarding the treatment of animal byproducts for different categories of animal byproducts not intended for human consumption. The FSIS auditors verified that after ante-mortem and post-mortem inspections, all animal byproducts that are deemed unfit for human consumption (condemned animals, parts and inedible materials) pursuant to the requirements of Regulation (EU) 2017/625 are adequately disposed of. The animal byproducts are sorted into categories (1, 2, or 3) and collected for disposal or use, pursuant to Regulation (EC) No. 1069/2009 and the SCP of the establishment. Through document review and discussion, the FSIS auditors confirmed that the management of animal byproducts is assessed at least once per year during the quarterly supervisory visits.

Section II.C.2 of Technical Instruction DGAL/SDASEI/2021-253 prohibits any cross contamination between products intended for export to the United States and other products

destined for other markets. Through observation and interviews, the FSIS auditors confirmed that products destined for export to the United States are properly identified and stored in designated areas, separated in time from other products (processed immediately after pre-operational sanitation activities) where government inspection personnel were not verifying the separation between product eligible for export to the United States, and product designated for other markets. In the maturation chamber, a row of hams hanging from a rail designated for export to the United States was in direct contact with hams destined for domestic and other foreign markets. The product was immediately moved to another rail that provided adequate distance to ensure separation. In addition, certified establishments are required to have an internal traceability system that allows for easy differentiation between products destined for export to the United States and other products.

To remain informed of any update or change in APHIS' animal disease restrictions, the Department of Economic Affairs (DOEA) of the French Embassy in Washington, D.C. actively monitors the APHIS website as well as regulatory updates/changes related to animal disease status. Then DOEA conveys information dealing with animal health back to DGAL so that (a) FranceAgriMer can update the Expadon 2 electronic system and (b) VOs who perform export certification can accurately verify all health information, in particular the eligibility of products (USDA-approval status of the establishment and health status). Should a disease restriction be issued by APHIS, a rapid alert system allows DGAL headquarters to send out the information to the official export e-mail addresses of the DDPPs and to certified establishments through FranceAgriMer.

Section II.J of Technical Instruction DGAL/SDSSA/2021-253 establishes the specific labeling requirements for products destined for export to the United States. The FSIS auditors verified that the DOEA at the Embassy of France in Washington, D.C. has prepared a guidance document entitled "Labeling" for all certified establishments. The document outlines the FSIS labeling requirements including all the required features on a label affixed to products destined for export to the United States. The FSIS auditors confirmed that when conducting their pre-shipment review of records before export certification, government inspection personnel verify the accuracy and truthfulness of the labels that are applied to products designated for export to the United States.

The requirements for supervisory review visits are described in Section III.B.3 of Technical Instruction DGAL/SDA SEI/2021-253 and in the 2021 Instruction about USDA Supervisory Inspection. DGAL requires the performance of supervisory review visits once per quarter by DDPP officials. The supervisory visits include (a) an inspection of the certified establishments' official premises and (b) an inspection of products destined for export to the United States. The facilities inspection consists of a review of inspection records and a physical tour of the establishments. During this visit, the focus is placed on the general upkeep of the facility, the equipment, personnel hygiene practices, and the implementation of the establishments' SCP (HACCP, Sanitation SOPs, SPS). The findings are documented on an official form and kept at the DDPP. The FSIS auditors reviewed supervisory review reports at the visited DDPPs and confirmed that the supervisory reviews were conducted in accordance with DGAL's requirements.

After verifying this component, the FSIS auditors concluded that France's food safety system continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control actions to prevent contamination of products when insanitary conditions or practices are present, which as described, is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

As mentioned earlier, one of the requirements for the approval of an establishment to export meat products to the United States is the development of an SCP that describes the procedures that the establishment operators must implement to ensure the hygiene and safety of the products. The SCP is reviewed and approved by the PVOs before final approval is granted to an establishment. Government inspection personnel are responsible for the verification of the SCP's implementation.

Section II.E.2 of Technical Instruction DGAL/SDASEI/2021-253 requires a zero tolerance critical control point (CCP) for fecal material, milk, and ingesta at all certified swine and bovine (veal) slaughterhouses. The FSIS auditors observed and verified that government inspection personnel were performing livestock zero tolerance verification for fecal material, milk, or ingesta on carcasses, heads, cheeks, and weasand meat at a minimum of one time per slaughter shift. Zero tolerance verification activities are conducted after the post-mortem rail inspection station and before final wash, or any additional trimming, washing, or application of any intervention by the certified establishment personnel. The FSIS auditors reviewed the official zero tolerance and lactic acid (if applicable) verification records as well as noncompliance records issued at the bovine (veal) and swine slaughter establishments and found that government inspection personnel were adequately verifying DGAL's sanitary dressing requirements.

DGAL's requirements for certified establishments to meet the SPS are outlined in Section II.D.1 of Technical Instruction DGAL/SDASEI/2021-253 and in Annex II of Technical Instruction DGAL/SDASEI/2014-393. Prior to approval to export to the United States, an establishment that intends to be certified for export to the United States must ensure that conditions within and around the establishment are sanitary to prevent the contamination or adulteration of products. This includes making sure that the establishment grounds and facilities, equipment and utensils, sanitary operations, and employee practices do not create any insanitary condition conducive to direct product contamination and/or adulteration. Through record review and interviews, the FSIS auditors confirmed that government inspection personnel were verifying the SPS requirements before certifying any export to the United States.

Annex II.3 of Technical Instruction DGAL/SDASEI/2014-393 outlines the expectations by DGAL that government inspection personnel verify through direct observation that the SPS requirements are met. Furthermore, DDPP officials pay particular attention to the cleanliness and upkeep of equipment and facilities as well as the establishment's documentation of compliance with the SPS regulations during the comprehensive yearly documentary review. The FSIS auditors reviewed official government SPS noncompliance records at all the audited establishments and found that government inspection personnel were verifying that conditions in certified establishments were sufficient to prevent product contamination or adulteration.

The FSIS auditors also confirmed that government inspection personnel were verifying that establishments certified to export to the United States take corrective actions related to SPS noncompliance by requiring either immediate actions or requesting a deadline for completion of the corrective actions. The deadline is dependent upon the level of urgency and the outcome (warning, formal notice, etc.). Should government inspection personnel observe that installation, equipment, or production requirements are not met, or find a non-compliant product that could cause a health problem, DGAL may temporarily suspend or cancel the certified establishment's eligibility to export products to the United States. In that case, the establishment can no longer produce, sell, or export any products. Furthermore, Articles L237-1, L237-2, and L237-3 of the Rural Code impose penalties ranging from seizure of products to suspension of production activities for noncompliant establishments. The absence or ineffectiveness of self-checks by establishments certified to export to the United States may also result in significant administrative penalties.

Section II.D.2 of Technical Instructions DGAL/SDASEI/2021-253 and DGAL/SDASEI/2014-393 outline DGAL's requirements for certified establishments to develop, implement, and maintain daily pre-operational and operational sanitation procedures sufficient to prevent direct contamination or adulteration of meat products destined for export to the United States. Both documents specify DGAL's expectations in terms of the content and design of the Sanitation SOPs, its implementation and maintenance as well as corrective actions and recordkeeping. On days when products designated for export to the United States are produced, both VOs and HTs verify organoleptically and through records review that pre-operational and operational sanitation procedures are properly implemented. In addition, government inspection personnel also verify the content of the Sanitation SOPs and the documentation attesting the application of the program including corrective actions taken in response to direct product contamination, if any.

At two of the audited establishments, the FSIS auditors assessed the adequacy of pre-operational Sanitation SOPs by observing government inspection personnel conduct pre-operational verification of the establishments' facilities, utensils, and equipment. The FSIS auditors verified that government inspection personnel conducted this activity in accordance with the established procedures, including a pre-operational record review of the establishments' monitoring results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils, as well as an assessment of SPS requirements. The FSIS auditors also observed government inspection personnel perform operational Sanitation SOPs verification in all visited establishments. The inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditors verified that

inspection and establishment records mirrored the actual sanitary conditions of the establishments. The FSIS auditors also examined the government inspection personnel's documentation of Sanitation SOPs noncompliance records and verified that government inspection personnel, when needed, took regulatory enforcement actions sufficient to ensure that sanitary conditions were restored, and product was protected from contamination, as required by Section III.D of Technical Instruction DGAL/SDASEI/2021-253.

Through interview of government inspection personnel, the FSIS auditors confirmed that in the event of noncompliance related to sanitation requirements, Section II.3 of Technical Instruction DGAL/SDASEI/2014-393 requires that DGAL suspend export certification pending corrective actions by the noncompliant establishment. Then the DDPP marks the export authorization as suspended in the SIGAL electronic system and notifies FranceAgriMer of the suspension. After that, FranceAgriMer updates the Expadon 2 database showing the establishment as suspended and unable to export products to the United States.

Except for the isolated sanitation observations documented in the Establishment Checklists in Appendix A, the FSIS auditors concluded that DGAL's inspection system governing meat products 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 equivalence component 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.

In accordance with Annex 3 of Technical Instruction DGAL/SDASEI/2014-393, Section II.D.3 of Technical Instruction DGAL/SDASEI/2021-253, and Regulation (EC) No. 852/2004, each certified establishment is required to develop, implement, and maintain a HACCP system that identifies, prevents, and controls the food safety hazards of concern. The required HACCP system must integrate the seven principles of HACCP outlined by the Codex Alimentarius. In addition, DGAL requires establishments to maintain documents supporting the decisions made in their hazard analysis and HACCP plan, including the initial validation of their HACCP systems.

The certified livestock slaughter and processing establishments are required to establish a zero tolerance CCP for fecal contamination, ingesta, and milk and address STEC pathogens in their hazard analyses (for veal slaughter establishments only). Moreover, DGAL mandates that certified establishments producing RTE products address *L. monocytogenes* and *Salmonella* in their HACCP plans or Sanitation SOPs while certified establishments producing TPCS products are required to destroy *Clostridium botulinum* spores with a sterilization value of 3 or higher and a pH equal to or above 4.5. Nevertheless, the FSIS auditors identified the following finding at multiple establishments:

• Government inspection personnel did not verify that HACCP plans complied with DGAL's requirements for HACCP plan content. Ongoing verification activities

(calibration of the process monitoring instrument; direct observation of monitoring activities; and review of records) or their frequencies were not listed on the HACCP plans.

At all the visited establishments, the FSIS auditors verified that government inspection personnel were conducting verification activities for HACCP requirements according to DGAL's requirements, except for the HACCP design finding identified above. Furthermore, the FSIS auditors reviewed records associated with government inspection personnel's verification of compliance with HACCP requirements and verified that government inspection personnel conduct verification of the establishments' critical limits established for all CCPs to ensure the adequacy of their food safety controls. The FSIS auditors also confirmed that government inspection personnel conduct daily verification of zero tolerance for fecal material, ingesta, and milk. Through records review, the FSIS auditors verified that the establishments eligible to export to the United States identify microbiological hazards associated with fecal material, ingesta, and milk as reasonably likely to occur and implement CCPs to control those hazards. The FSIS auditors confirmed that government inspection personnel were verifying that establishments eligible to export to the United States review records associated with the production of product for export to the United States to ensure that all HACCP requirements are met prior to shipping.

The FSIS auditors also verified the official controls in place for *Trichinella spiralis* in pork products. France has developed an official control plan that consists of testing 1 out of 1,000 pigs in controlled farms for *Trichinella spiralis*. In the past 10 years of testing, no positive results have been recorded. DGAL assigns health veterinarians to all pig farms, and they report the housing conditions at the farms. Only hogs from controlled farms are slaughtered and used for products destined for export to the United States. Each year DGAL issues a technical instruction the health veterinarian must verify at the controlled farm. The verification activities are reported to the DDPP and recorded in the SIGAL database that lists all farms that have a controlled housing environment. Through document review, the FSIS auditors confirmed that government inspection personnel were verifying that establishments producing pork products were evaluating and controlling *Trichinella spiralis* in their hazard analyses.

Except for the HACCP design finding listed above and the isolated observations documented in the Establishments Checklists in Appendix A, the FSIS auditors' onsite verification concluded that DGAL requires each certified establishment to develop, implement, and maintain a HACCP program for each processing category. The FSIS auditors verified that the HACCP program as described is consistent with criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

As an EU member, France implements the requirements of Regulation (EU) 2017/625 regarding official controls. Regulation (EU) 2017/625 frames the surveillance and control of chemical residues into two different regulations which are (a) Commission Implementing Regulation (EU) 2022/1646, and (b) Commission Delegated Regulation (EU) 2022/1644. Under these new regulations, three types of plans are conducted:

- (1) A monitoring plan whose purpose is to assess consumers' exposure to a particular risk and to identify management measures to control that risk. Sampling is representative of the target population and samples are taken randomly within this population.
- (2) A targeted control plan which relates to foodstuffs that represent an increased risk of contamination and will make it possible to assess the effectiveness of the management measures previously implemented. This plan provides a more focused search for non-conformities. Sampling is targeted and samples are taken on a sub-population presenting an increased risk of contamination.
- (3) A control plan for imported products at the EU border control post.

In accordance with Regulation (EU) 2017/625, DGAL develops and implements a national residue program each year. 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.

Technical Instruction DGAL/SDASEI/2022-848 provides that the national residue plan specifies the analytes to be detected, the method of analysis to be used, the matrix to be collected, the maximum residue limit (MRL), and the total number of samples to be collected. Testing of certain chemical residues is required by EU regulations while other residues are assessed through risk evaluation. The National Agency for Food Safety, the Environment, and Labor (Agence National de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail) are responsible for risk evaluations. On-farm controls of veterinary drugs, 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 are met.

At the visited livestock slaughter establishments, the FSIS auditors verified that DRAAF assigned the residue sampling to the DDPPs that, in turn, assign them to the certified establishments. Although DGAL requires that carcasses sampled under the monitoring and targeted control plans be retained until testing results are available, the FSIS auditors found that when an establishment was scheduled for a routine (random) chemical residue sample, only products lots that were not intended for export to United States were being sampled, and thus identified the following finding:

• DGAL did not ensure that livestock animals (veal and swine) whose meat is destined for export to the United States were included in DGAL's official government chemical residue sampling program.

Specific procedures for addressing violative test results are described in Section IV of Technical Instruction DGAL/SDSPA/2022-848. This includes specific instructions for reporting of results, product sequestration, on-farm investigation, violation reporting to DGAL, and follow-up

sampling. During the visit to the official chemical residue sampling laboratory, the FSIS auditors confirmed that a test result is considered violative if it exceeds the MRL established by DGAL's Office of Laboratories. DGAL utilizes a rapid alert system to inform another country of residues exceeding established French tolerances if such product is shipped.

The FSIS auditors were able to conclude that the procedures outlined in the technical instruction were followed as intended through the reporting, investigation, and follow-up phases.

The FSIS auditors' review of the official government chemical residue sampling records at the two audited slaughter establishments indicated that DGAL has adhered to the 2023 sampling program schedule, as required by Technical Instructions DGAL/SDASEI/2020-825 and DGAL/SDASEI/ 2021-94. Through interviews and document review, the FSIS auditors verified that chemical residue samples are collected and shipped under inspection seal by government inspection personnel. Samples are shipped to the laboratory in accordance with protocols outlined in DGAL/SDASEI/2019-39, and typically involves direct pick-up by a courier dispatched from the receiving laboratory.

The FSIS auditors confirmed that VOs verify that each animal presented for slaughter is accompanied by documentation that provides information on the animal's breed, age, and farm of origin; the FCI (veterinary examination and treatment history); 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 chemical residue samples are conducted in accordance with required protocols.

Except for the finding listed above, the FSIS auditors' onsite verification concluded that DGAL has met the core requirement of this component. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component 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. This component also addresses requirements for TPCS meat products.

The FSIS auditors verified that DGAL ensures establishments follow Commission Regulation (EC) 2073/2005, regarding process hygiene criteria testing and analysis for carcasses. DGAL requires all slaughter establishments to implement a microbiological control testing program for Enterobacteriaceae to verify process control, in accordance with Commission Regulation (EC) No. 2073/2005. The FSIS audit included record review and interviews of government inspection personnel to verify microbiological process control. The FSIS auditors reviewed

Enterobacteriaceae testing results showing that the audited livestock slaughter establishments routinely met their limits and took corrective actions when there was loss of process control.²

Technical Instruction DGAL/SDASEI/2021-253 outlines the official government microbiological testing program for meat products destined for export to the United States. The document outlines the microbiological testing requirements for process control verification, pathogen reduction standards, RTE products, and STEC for establishments slaughtering veal. Sample collection is performed by government inspection personnel and shipped under government seal on the day of sampling, typically through direct pick-up by a courier dispatched from the receiving laboratory.

DGAL has a *Salmonella* sampling and testing program in raw meat products. This *Salmonella* testing program for chilled livestock (bovine and swine) carcass sampling is consistent with the provisions of Commission Regulation (EC) No. 2073/2005. Annex III.C2 of Technical Instruction DGAL/SDASEI/2021-253 (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 establishments exceed the required number of allowed positive tests. All samples are sent to an approved microbiology laboratory for analysis, and government inspection personnel analyze results to determine the effectiveness of each establishment's *Salmonella* control program. The FSIS auditors observed government inspection personnel collect *Salmonella* samples at two slaughter establishments, reviewed the carcass testing results, and confirmed that DGAL has suspended export certification at one of the swine slaughter establishments due to its failure to meet the *Salmonella* performance standards.

DGAL has microbiological testing programs for *Salmonella* and *L. monocytogenes* in both postlethality exposed and non-post lethality exposed RTE products. The sampling program also includes sampling of food contact surfaces for *L. monocytogenes* or *Listeria* species analysis by establishments producing post-lethality exposed RTE products. These inspections are implemented in establishments certified to export RTE meat-based products to the United States. Annex III of Technical Instruction DGAL/SDASEI/2021-253 requires that RTE establishments consider the hazard of *L. monocytogenes* contamination of RTE products and control the pathogen through their HACCP plans, Sanitation SOPs, or other prerequisite programs. To verify the efficacy of their *L. monocytogenes* control program, establishments use Annex II of Technical Instruction DGAL/SDASEI/2021-253 which contains the requirements for microbiological testing for RTE post-lethality exposed products. The regimen for the testing program includes product testing and testing of food-contact surfaces with frequencies equivalent to those implemented domestically in the United States.

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² DGAL presented draft revised requirements to ensure that swine slaughter establishments exporting to the United States implement equivalent sampling methodologies and analysis for microbiological organisms consistent with FSIS requirements in 9 CFR 310.18. Additionally, DGAL notified local DDPPs that these changes must be implemented pending issuance of the revised requirements.

Annexes II and III of Technical Instruction DGAL/SDASEI/2021-253 describe sampling requirements and analysis for establishments that produce RTE products for export to the United States. At the audited microbiological laboratory, the FSIS auditors verified that 325g of RTE product is tested for the presence or absence of *Salmonella* in RTE products using a method consistent with ISO 6579 and incorporating a screening method validated by AFNOR (IRIS *Salmonella* method). The FSIS auditors verified that the official laboratory tests RTE products for presence or absence of *L. monocytogenes* using a method consistent with the ISO 11290-1 method and incorporating a screening method (the RAPID *L. monocytogenes* method) validated by the French Association of Normalization (AFNOR).

The FSIS auditors confirmed that establishments are required to test for STEC every lot of meat product that is intended for export to the United States. The official government STEC sampling is conducted at least once per year per certified establishment based on the type of product produced for export to the United States (e.g., trim, primals, and subprimals). Per DGAL requirements, government inspection personnel verify that establishments handling raw veal intended for export to the United States address the risk of STEC, including *Escherichia coli* O157:H7 and STEC serogroups (O26, O45, O103, O111, O121, and O145), in their HACCP systems. To control these food safety hazards, the establishment may include measures from the SPS procedures, Sanitation SOPs, or HACCP plans. DGAL provides instructions for establishment sample collection, including the types of samples collected, the sampling method, and sampling frequency.

Through interviews and review of official records at the veal establishment, the FSIS auditors confirmed that the requirements of Technical Instruction DGAL/SDASEI/2021-253 were implemented as required regarding STEC sampling. The FSIS auditors noted that both establishment and government sampling is comprised of 60 uniform pieces (i.e., N60 sampling) collected from an individual day's production of primal and subprimal cuts. The FSIS auditors verified that each lot of products exported to the United States was subject to establishment testing, with government inspection personnel verification testing conducted at least once per year.

Annex II of Technical Instruction DGAL/SDASEI/2021-253 requires laboratories to use the entire N60 sample. Because the audited official laboratory does not conduct testing for STEC in raw veal products, the FSIS auditors discussed the STEC testing methods with officials of the Office of Laboratories and confirmed that to detect the *eae* and *stx* genes belonging to the seven STEC serogroups (O157, O26, O103, O145, O45, O121, and O111), the national reference laboratories used the following methods: (1) a method derived from ISO TS 13136 2:2012 (the LMAP_DGAL_Screening PCR STEC_al_2 method) for screening by real time PCR for virulence genes *stx*1 and 2 and *eae*; and (2) a method derived from ISO TS 13136:2012 (the LMAP_DGAL_confirmation STEC-al.1 method) for confirmation through isolation of target STEC strains. In the event the NRL detects STEC genes in any sample, the producing establishment is required to exclude the sampled lot from export to the United States.

The FSIS auditors reviewed records and interviewed government inspection personnel at the only certified establishment in France eligible to export TPCS products to the United States. DGAL requires establishments producing TPCS product to address the hazards using HACCP

principles according to Regulation (EC) No. 852/2004, which outlines specific requirements for food in hermetically sealed containers. DGAL provides further instructions for establishments producing TPCS products in Technical Instruction DGAL/SDSSA/2015-364, which includes specific requirements for thermal processes, commercial stability tests, and good hygiene practices. The sterilization parameters 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, in accordance with Technical Instruction DGAL/SDSSA/2015-364. At the audited establishment that produces TPCS products, the FSIS auditors confirmed that the establishment's process achieved sterilization parameters consistent with DGAL's requirements.

At the audited establishment producing TPCS products destined for export to the United States, the FSIS auditors conducted additional verification activities that 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 also observed a can teardown and confirmed that it was consistent with DGAL's requirements. The FSIS auditors confirmed that process schedules were developed by the Technical Center for the Conservation of Agricultural Products, an industrial organization recognized by DGAL as a center of reference for the development of thermal processes.

The 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 microbiological sampling and testing programs that meet the core requirements of this component. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held June 21, 2023, with DGAL officials via videoconference. At this meeting, the FSIS auditors presented the preliminary findings from the audit. 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 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

• Government inspection personnel did not verify that HACCP plans complied with the DGAL's requirements for HACCP plan content. Ongoing verification activities (e.g., calibration of the process monitoring instrument, direct observation of monitoring activities, and review of records) or their frequencies were not listed on the HACCP plans at multiple audited establishments.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

• DGAL did not ensure that livestock animals (veal and swine) whose meat is destined for export to the United States were included in DGAL's official government chemical residue sampling program.

During the exit meeting, DGAL committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of DGAL's documentation of proposed corrective actions once received 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

ESTABLISHMENT NAME AND LOCATION 2. AUDIT DA		AIE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Broceliande-AHL 12 Boulevard du 21eme Siècle 06/06/20		23	FR 14.752.020 CE	France	
14310 5. AUDIT S		AFF		6. TYPE OF AUDIT	
			ıl Audit Staff (IAS)	v	\neg
				X ON-SITE AUDIT	DOCUMENT AUDIT
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Part A - Sanitation Standard Operating Procedures ((SSOP)	Audit		rt D - Continued	Audit
Basic Requirements		Results		nomic Sampling	Results
7. Written SSOP		X	33. Scheduled Sample		
Records documenting implementation.		X	34. Species Testing		
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue		
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E -	Other Requirements	
10. Implementation of SSOP's, including monitoring of impleme	entation	X	36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's			37. Import		
12. Corrective action when the SSOPs have failed to prevent d				and Deet Oresteel	
product contamination or adulteration.			38. Establishment Grounds		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construc	tion/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan .			41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective a	ctions.	X	42. Plumbing and Sewage		
Records documenting implementation and monitoring of the HACCP plan.	е		43. Water Supply		
17. The HACCP plan is signed and dated by the responsible			44. Dressing Rooms/Lavato		
establishment individual. Hazard Analysis and Critical Control Point			45. Equipment and Utensils		
(HACCP) Systems - Ongoing Requirements			46. Sanitary Operations		
18. Monitoring of HACCP plan.			47. Employee Hygiene		
19. Verification and validation of HACCP plan.			48. Condemned Product Co	ntrol	
20. Corrective action written in HACCP plan.					
21. Reassessed adequacy of the HACCP plan.			Part F - Ir	spection Requirements	
22. Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event occ			49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Covera	ge	
23. Labeling - Product Standards			51. Periodic Supervisory Revie	ws	
24. Labeling - Net Weights			52. Humane Handling		
25. General Labeling			Oz. Humane Haffulling		О
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)		53. Animal Identification		О
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection		0
27. Written Procedures		O	55. Post Mortem Inspection		О
28. Sample Collection/Analysis		О			
29. Records		О	Part G - Other Regu	latory Oversight Require	ements
Salmonella Performance Standards - Basic Requ	irements		56. European Community Di	rectives	
30. Corrective Actions		О	57.		
31. Reassessment		О	58.		
32. Written Assurance		О	59.		
			-		

Establishment Operations:	Pork processing.
Prepared Products:	

- 60. Observation of the Establishment
- 7. The establishment's SSOP program does not include operational sanitation procedures and frequencies.
- 8. Establishment is not conducting operational sanitation activities to prevent direct product contamination/adulteration.
- 10. Establishment is not generating operational sanitation records during production.
- 14. Ongoing verification activities and frequency are not listed in the HACCP plan.

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE		3. ESTABLISHMENT NO. 4. NAME OF COUNTRY				
Sobeval Zone Industielle Av Louis Lescure	06/12/20	23	24.053.001 CE		France		
Boulazac, 24750 Perigueux	5. AUDIT S				6. TYPE OF AUDIT		
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Part A - Sanitation Standard Operating Procedures (SSOP)	Audit Results			rt D - Continued		Audit Results
Basic Requirements 7. Written SSOP		rtosuits	33	Scheduled Sample	nomic Sampling		results
Records documenting implementation.							
Signed and dated SSOP, by on-site or overall authority.			1	Species Testing			
Sanitation Standard Operating Procedures (SSOP)	1		35.	Residue			
Ongoing Requirements				Part E -	Other Requirements		
10. Implementation of SSOP's, including monitoring of impleme	entation.	X	36.	Export			
11. Maintenance and evaluation of the effectiveness of SSOP's			37.	Import			
 Corrective action when the SSOPs have failed to prevent di product contamination or adulteration. 	irect		38.	Establishment Grounds	and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39.	Establishment Construc	tion/Maintenance		X
Part B - Hazard Analysis and Critical Control			40.	Light			
Point (HACCP) Systems - Basic Requirements 14. Developed and implemented a written HACCP plan .			41.	Ventilation			X
15. Contents of the HACCP list the food safety hazards,		X	42.	Plumbing and Sewage			
critical control points, critical limits, procedures, corrective at 16. Records documenting implementation and monitoring of the			43.	Water Supply			
HACCP plan. 17. The HACCP plan is signed and dated by the responsible			44.	Dressing Rooms/Lavato	ries		
establishment individual. Hazard Analysis and Critical Control Point			45.	Equipment and Utensils			
(HACCP) Systems - Ongoing Requirements			46.	Sanitary Operations			
18. Monitoring of HACCP plan.			47.	Employee Hygiene			
19. Verification and validation of HACCP plan.			48.	Condemned Product Co	ntrol		
20. Corrective action written in HACCP plan.		X					
21. Reassessed adequacy of the HACCP plan.				Part F - In	spection Requirements		
 Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event occ 			49.	Government Staffing			
Part C - Economic / Wholesomeness			50.	Daily Inspection Covera	ge		
23. Labeling - Product Standards			51.	Periodic Supervisory Revie	ws		
24. Labeling - Net Weights			52.	Humane Handling			
General Labeling Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moneless)	oisture)		53	Animal Identification			
	oistare)		JJ.	Allina identification			
Part D - Sampling Generic <i>E. coli</i> Testing			54.	Ante Mortem Inspection			
27. Written Procedures			55.	Post Mortem Inspection			
28. Sample Collection/Analysis				Part G - Other Pegu	latory Oversight Require	monte	
29. Records				i ait o - Other Negu	atory Oversignt Nequile		
Salmonella Performance Standards - Basic Requ	irements		56.	European Community Di	rectives		
30. Corrective Actions			57.				
31. Reassessment			58.				
32. Written Assurance			59.				

Page 2 of 2

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Raw intact veal

60. Observation of the Establishment

- 10. Government inspection personnel did not identify multiple pieces of meat from the previous days' production on the floor underneath the weighing station and dried blood on the wall at the weasand banding station at pre-operational sanitation inspection.
- 15. Government inspection personnel did not verify that the hazard analysis did not identify chemical hazards at the lactic acid application step.
- 20. Government inspection personnel did not identify that the HACCP plan did not include all parts of corrective actions for the lactic acid CCP (identifying and eliminating the cause of the deviation and establishing measures to prevent recurrence).
- 39. Government inspection personnel did not identify peeling silicone caulking around the rail at the chiller entrance to the chiller at preoperational sanitation inspection.
- 41. Government inspection personnel did not identify condensation at the entrance to the packaged product room at pre-operational sanitation inspection

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

		2. AUDIT DA			4. NAME OF COUNTRY		
	ean Henaff Production	06/08/20)23	29.225.001 CE France		France	
Pouldreuzic 5. AUDIT ST.			AFF			6. TYPE OF AUDIT	
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Part	A - Sanitation Standard Operating Procedures (Basic Requirements	SSOP)	Audit Results			rt D - Continued onomic Sampling	Audit Results
7.	Written SSOP			33.	Scheduled Sample		
8.	Records documenting implementation.			34.	Species Testing		
9.	Signed and dated SSOP, by on-site or overall authority.			35.	Residue		
Sa	anitation Standard Operating Procedures (SSOP)				Part E -	Other Requirements	
	Ongoing Requirements	ntation		36	Export	· · · · · · · · · · · · · · · · · · ·	
	Implementation of SSOP's, including monitoring of implement Maintenance and evaluation of the effectiveness of SSOP's.			-	Import		
	Corrective action when the SSOPs have failed to prevent disproduct contamination or adulteration.			1	Establishment Grounds	and Pest Control	
13.	Daily records document item 10, 11 and 12 above.			39.	Establishment Construc	tion/Maintenance	
	Part B - Hazard Analysis and Critical Control			40.	Light		
	Point (HACCP) Systems - Basic Requirements			41.	Ventilation		
	Developed and implemented a written HACCP plan .			12	Dlumbing and Cowago		
	Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective ac			_	Plumbing and Sewage Water Supply		
16.	Records documenting implementation and monitoring of the HACCP plan.	!			Dressing Rooms/Lavato	ries	
17.	The HACCP plan is signed and dated by the responsible establishment individual.				Equipment and Utensils		
	Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46.	Sanitary Operations		
18.	Monitoring of HACCP plan.			47.	Employee Hygiene		
19.	Verification and validation of HACCP plan.			48.	Condemned Product Co	ontrol	
20.	Corrective action written in HACCP plan.						
21.	Reassessed adequacy of the HACCP plan.				Part F - In	spection Requirements	
22.	Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occurrence.			49.	Government Staffing		
	Part C - Economic / Wholesomeness			50.	Daily Inspection Covera	ge	
23.	Labeling - Product Standards			51.	Periodic Supervisory Revie	ws	
24.	Labeling - Net Weights			_	Humane Handling		
25.	General Labeling			52.	Humane Handling		0
26.	Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)		53.	Animal Identification		О
	Part D - Sampling Generic <i>E. coli</i> Testing			54.	Ante Mortem Inspection		О
27.	Written Procedures		О	55.	Post Mortem Inspection		О
28.	Sample Collection/Analysis		О	<u> </u>			
29.	Records		О		Part G - Other Regu	latory Oversight Requirements	
S	Salmonella Performance Standards - Basic Requi	irements		56.	European Community Di	rectives	
30.	Corrective Actions		О	57.			
31.	Reassessment		О	58.			
32.	Written Assurance		О	59.			
				-			

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Establishment Operations:	Pork processing.
Propored Products:	

60. Observation of the Establishment

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

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32. Written Assurance O 59.	31. Reassessment		О	58.			
	32. Written Assurance		О	59.			

Page 2 of 2

Establishment Operations:	Pork processing
Prepared Products:	Not heat treated, shelf stable pork

60. Observation of the Establishment

19. Government inspection personnel did not identify that the establishment did not include frequencies for verification activities (direct observation, calibration of process monitoring instruments, and record review) for CCP 1 (15% weight loss of hams).

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT D		3. ES	TABLISHMENT NO.	4. NAME OF COUNTRY		
Fipso Industrie Rte De Bellocq 54270	06/06/2023			64.305.002 CE	France		
Lahontan	5. AUDIT STAFF				6. TYPE OF AUDIT		
	OIEA Internationa		al Audit Staff (IAS)		X ON-SITE AUDIT	DOCUMEN.	T AUDIT
Place an X in the Audit Results block to in	dicate non	compl	lianc	e with requireme	ents. Use O if not	applicable.	
Part A - Sanitation Standard Operating Procedures	(SSOP)	Audit		Pai	rt D - Continued		Audit
Basic Requirements		Results		Eco	nomic Sampling		Results
7. Written SSOP			33.	Scheduled Sample			
8. Records documenting implementation.			34.	Species Testing			
9. Signed and dated SSOP, by on-site or overall authority.			35.	Residue			
Sanitation Standard Operating Procedures (SSOP Ongoing Requirements	")			Part E -	Other Requirements		
Implementation of SSOP's, including monitoring of implementation of SSOP's, including monitoring of implementation.	entation.		36.	Export			
11. Maintenance and evaluation of the effectiveness of SSOP's	S.		37.	Import			
Corrective action when the SSOPs have failed to prevent or product contamination or adulteration.	direct		38.	Establishment Grounds	and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39.	Establishment Construct	tion/Maintenance		X
Part B - Hazard Analysis and Critical Control			40.	Light			
Point (HACCP) Systems - Basic Requirements			41.	Ventilation			
Developed and implemented a written HACCP plan . Sometimes of the HACCP list the food safety hazards,		X	42.	Plumbing and Sewage			
critical control points, critical limits, procedures, corrective a		Λ		Water Supply			
HACCP plan.			44.	Dressing Rooms/Lavator	ries		
17. The HACCP plan is signed and dated by the responsible establishment individual.			45.	Equipment and Utensils			
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46.	Sanitary Operations			
18. Monitoring of HACCP plan.			47.	Employee Hygiene			
19. Verification and validation of HACCP plan.			48.	Condemned Product Co	ntrol		
20. Corrective action written in HACCP plan.							
21. Reassessed adequacy of the HACCP plan.				Part F - In	spection Requirements	5	
 Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event oc 			49.	Government Staffing			
Part C - Economic / Wholesomeness			50.	Daily Inspection Coverage	ge		
23. Labeling - Product Standards			51.	Periodic Supervisory Review	ws		
Labeling - Net Weights General Labeling			52.	Humane Handling			
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/M	loisture)		53.	Animal Identification			
Part D - Sampling	,			Ante Mortem Inspection			
Generic E. coli Testing			54.	Ante Worten Inspection			
27. Written Procedures			55.	Post Mortem Inspection			
28. Sample Collection/Analysis 29. Records				Part G - Other Regu	latory Oversight Requi	rements	
29. Necolds							
Salmonella Performance Standards - Basic Requ	uirements		56.	European Community Dir	rectives		
30. Corrective Actions			57.				
31. Reassessment			58.				
32. Written Assurance			59.				

Establishment Operation	s: Pork slaughter and processing.
Prepared Produ	ss: Raw intact pork

60. Observation of the Establishment

- 15. Government inspection personnel did not identify that the hazard analysis did not include chemical hazards at the singeing step in the where an anti-foaming agent was introduced.
- 39. Government inspection personnel did not identify peeling paint on a cooling unit above the trimming line for raw pork legs. No product adulteration was observed.

1. E	STABLISHMENT NAME AND LOCATION	2. AUDIT D	ATE	3. ESTABLISHMENT NO. 4. NAME OF COUNTRY			
	A Salaisons De L'Adour	06/08/20	023		65.284.001 CE	France	
	i Est Pyrene Aeropole 65290 ouey	5. AUDIT ST	ΓAFF			6. TYPE OF AUDIT	
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	and Windle And to Decide black to to de	 		ı:		ON ON TEXABELL BOCOMIEN	II AUDII
	ce an X in the Audit Results block to ind		· ·	land	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	
Part	: A - Sanitation Standard Operating Procedures (S Basic Requirements	SSOP)	Audit Results			rt D - Continued onomic Sampling	Audit Results
7. \	Written SSOP			33.	Scheduled Sample	<u></u>	
8. I	Records documenting implementation.			34.	Species Testing		
9. \$	Signed and dated SSOP, by on-site or overall authority.				Residue		
Sa	anitation Standard Operating Procedures (SSOP)					Other Requirements	
	Ongoing Requirements					Other Requirements	
	Implementation of SSOP's, including monitoring of implement	ntation.	X	+	Export		
	Maintenance and evaluation of the effectiveness of SSOP's.	4		37.	Import		
12.	Corrective action when the SSOP's have failed to prevent disproduct contamination or adulteration.	rect		38.	Establishment Grounds	and Pest Control	
13.	Daily records document item 10, 11 and 12 above.			39.	Establishment Construc	tion/Maintenance	
	Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements				Light		
	Developed and implemented a written HACCP plan .			41.	Ventilation		
15.	Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective ac	tions.		42.	Plumbing and Sewage		
16.	Records documenting implementation and monitoring of the HACCP plan.			43.	Water Supply		
17.	The HACCP plan is signed and dated by the responsible establishment individual.				Dressing Rooms/Lavato		
	Hazard Analysis and Critical Control Point				Equipment and Utensils Sanitary Operations	•	
18	(HACCP) Systems - Ongoing Requirements Monitoring of HACCP plan.			1	<u> </u>		
19. Verification and validation of HACCP plan.			47.	Employee Hygiene			
	Verification and Validation of FACCE plan.			48.	Condemned Product Co	ontrol	
	Corrective action written in HACCP plan.				Port E II	concetion Requirements	
21.	Reassessed adequacy of the HACCP plan.				Part F - II	nspection Requirements	
22.	Records documenting: the written HACCP plan, monitoring or critical control points, dates and times of specific event occur	of the urrences.		49.	Government Staffing		
	Part C - Economic / Wholesomeness			50.	Daily Inspection Covera	age	
23.	Labeling - Product Standards			51.	Periodic Supervisory Revie	ews	
24.	Labeling - Net Weights			52	Humane Handling		
	General Labeling			JZ.	Trainanc Trainaing		0
26.	Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	isture)		53.	Animal Identification		О
	Part D - Sampling Generic <i>E. coli</i> Testing			54.	Ante Mortem Inspection	ı	О
27.	Written Procedures		О	55.	Post Mortem Inspection		О
28.	Sample Collection/Analysis		0				
29.	Records		О		Part G - Other Regu	llatory Oversight Requirements	
S	almonella Performance Standards - Basic Requi	rements		56.	European Community D	rectives	
30.	Corrective Actions		О	57.			
31.	Reassessment		О	58.			
32.	Written Assurance		О	59.			

06/08/2023 | Establishment No. 65.284.001 CE | | France Page 2 of 2

FSIS 5000-6 (04/04/2002)

Establishment Operations:	Pork processing
Prepared Products:	Not heat treated, shelf stable pork

60. Observation of the Establishment

10. Government inspection personnel were not verifying the separation between product eligible for US export and product designated for other markets. In the maturation chamber, a row of hams hanging from a rail designated for US export was in close proximity to hams for domestic and other foreign markets. The product was immediately moved to another rail that provided adequate distance to ensure separation.

ESTABLISHMENT NAME AND LOCATION	2. AUDIT DA	ATE	3. ES	STABLISHMENT NO.	4. NAME OF COUNTRY		
Cooperl Arc Atlantique Zone Industrielle de Verdeil	06/12/2023		I	FR 79.246.002 CE France			
79800	5. AUDIT STAFF		6. TYPE OF AUDIT				
Sainte-Eanne	OIEA Internationa			al Audit Staff (IAS) X ON-SITE AUDIT DOCUM		DOCUMENT AUDI	ıŦ
Place an X in the Audit Results block to inc	licata nan	compl	iono	o with requirem	GN-GN E AGBIT		-
Part A - Sanitation Standard Operating Procedures (ianic I	•	rt D - Continued		_
Basic Requirements	3301)	Audit Results			nomic Sampling	Audit Result	
7. Written SSOP		X	33.	Scheduled Sample			
8. Records documenting implementation.			34.	Species Testing			
9. Signed and dated SSOP, by on-site or overall authority.			35.	Residue		X	
Sanitation Standard Operating Procedures (SSOP)				Part E -	Other Requirements		
Ongoing Requirements 10. Implementation of SSOP's, including monitoring of implement	ntation		36.	Export			
11. Maintenance and evaluation of the effectiveness of SSOP's.				Import			
 Corrective action when the SSOPs have failed to prevent disproduct contamination or adulteration. 	rect		38.	Establishment Grounds	and Pest Control		
13. Daily records document item 10, 11 and 12 above.		X	39.	Establishment Construc	tion/Maintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40.	Light			
Developed and implemented a written HACCP plan .		X	41.	Ventilation			
Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective ac	ctions.	X	42.	Plumbing and Sewage			
Records documenting implementation and monitoring of the HACCP plan.			43.	Water Supply			_
The HACCP plan is signed and dated by the responsible establishment individual.				Dressing Rooms/Lavato	ries		
Hazard Analysis and Critical Control Point			45.	Equipment and Utensils			_
(HACCP) Systems - Ongoing Requirements			46.	Sanitary Operations			
18. Monitoring of HACCP plan.			47.	Employee Hygiene			
19. Verification and validation of HACCP plan.			48.	Condemned Product Co	ntrol		
20. Corrective action written in HACCP plan.							
21. Reassessed adequacy of the HACCP plan.				Part F - In	spection Requirements		
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur.			49.	Government Staffing			
Part C - Economic / Wholesomeness			50.	Daily Inspection Covera	ge		
23. Labeling - Product Standards			51.	Periodic Supervisory Revie	ws		
24. Labeling - Net Weights			52.	Humane Handling			_
25. General Labeling	.:-4)						_
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)		53.	Animal Identification			
Part D - Sampling Generic <i>E. coli</i> Testing			54.	Ante Mortem Inspection			
27. Written Procedures			55.	Post Mortem Inspection			
28. Sample Collection/Analysis				Part G. Other Page	laton, Oversight Beguinne	onto	
29. Records				Part G - Other Regu	latory Oversight Requireme	ents	
Salmonella Performance Standards - Basic Requi	irements		56.	European Community Di	rectives		
30. Corrective Actions			57.				
31. Reassessment			58.				
32. Written Assurance			59.				
	_						-

Establishment Operations:	Pork slaughter and processing establishment
Prepared Products:	

- 60. Observation of the Establishment
- 7. The frequency of operational sanitation procedures was not listed in the SSOP program.
- 13. The recorded SSOP corrective actions related to product contamination did not include measures to prevent recurrence.
- 14. The establishment accepts returned products but has not addressed returned products on the flow chart and hazard analysis of the slaughter/deboning process.
- 15. The ongoing verification activities (calibration of the process monitoring instrument; direct observation of monitoring activities; and review of records) and/or their frequencies are not listed on the HACCP plan.
- 35. Livestock animals (pig) whose meat is destined for export to the United States were not included in the national residue sampling program and inspection personnel were not collecting residue sample from carcasses whose meat were destined for export to the United States.

ESTABLISHMENT NAME AND LOCATION	2. AUDIT DA	TE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY	
SOFRIMAIX	06/12/202	23	79.246.003 CE	France	
Zone Industrielle de Verdeil 79800	5. AUDIT STA	AFF		6. TYPE OF AUDIT	
Sainte-Eanne	OJE A I A	,.	1 A 1': C: CC (TAC)		
	OIEA Inte	ernationa	l Audit Staff (IAS)	X ON-SITE AUDIT	OCUMENT AUDIT
Place an X in the Audit Results block to inc	dicate nond	compl	iance with requirem	ents. Use O if not app	icable.
Part A - Sanitation Standard Operating Procedures ((SSOP)	Audit		rt D - Continued	Audit
Basic Requirements		Results		nomic Sampling	Results
7. Written SSOP		О	33. Scheduled Sample		О
8. Records documenting implementation.		О	34. Species Testing		О
9. Signed and dated SSOP, by on-site or overall authority.		0	35. Residue		О
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements)		Part E -	Other Requirements	
10. Implementation of SSOP's, including monitoring of impleme	entation.	О	36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's		0	37. Import		
Corrective action when the SSOP's have failed to prevent d product contamination or adulteration.	lirect	О	38. Establishment Grounds	and Pest Control	
13. Daily records document item 10, 11 and 12 above.		О	39. Establishment Construc	tion/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan .		О	41. Ventilation		
Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective a	actions.	О	42. Plumbing and Sewage		
Records documenting implementation and monitoring of the HACCP plan.		О	43. Water Supply		
The HACCP plan is signed and dated by the responsible establishment individual.		О	44. Dressing Rooms/Lavato45. Equipment and Utensils		
Hazard Analysis and Critical Control Point			45. Equipment and Otensiis		
(HACCP) Systems - Ongoing Requirements			46. Sanitary Operations		
18. Monitoring of HACCP plan.		О	47. Employee Hygiene		
19. Verification and validation of HACCP plan.		О	48. Condemned Product Co	ontrol	
20. Corrective action written in HACCP plan.		O			
21. Reassessed adequacy of the HACCP plan.		О	Part F - Ir	spection Requirements	
22. Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event occ		О	49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Covera	ge	
23. Labeling - Product Standards			51. Periodic Supervisory Revie	ws	
24. Labeling - Net Weights					_
25. General Labeling			52. Humane Handling		О
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)	О	53. Animal Identification		О
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection		О
27. Written Procedures		О	55. Post Mortem Inspection		0
28. Sample Collection/Analysis		0			
29. Records		0	Part G - Other Regu	latory Oversight Requireme	nts
Salmonella Performance Standards - Basic Requ	irements		56. European Community Di	rectives	
30. Corrective Actions		О	57.		
31. Reassessment		0	58.		
32. Written Assurance		О	59.		

06/12/2023 | Establishment No. 79.246.003 | Sofrimax | France Page 2 of 2

FSIS 5000-6 (04/04/2002)

Establishment Operations:	Cold storage facility.
Prepared Products:	NA

60. Observation of the Establishment

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

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



Liberté Égalité Fraternité Direction générale de l'alimentation

Paris, le

0 2 NOV. 2023

Dossier suivi par : Maria-Jessica Plaza

Sous-direction Europe, international et gestion intégrée du risque/Bureau des exportations pays-

tiers

Réf. : SDEIGIR 2310080 Tél. : +33 1 49 55 74 30

Mèl.: export.dgal@agriculture.gouv.fr

La Directrice générale adjointe, CVO

à

Dr. Michelle CATLIN

International Coordination Executive

Office of International Coordination Food Safety and Inspection Service U.S. Department of Agriculture 1400 Independence Avenue SW

Washington, D.C. 20250-3700

ETATS-UNIS D'AMERIQUE

Objet: Réponses aux recommandations du rapport d'audit du système d'inspection des produits carnés.

Madame la Directrice,

C'est avec grand intérêt que j'ai pris connaissance de votre rapport, reçu le 05 septembre dernier, concernant l'audit de plusieurs établissements de la filière des produits carnés, en France.

Les réponses à chacune des recommandations émises pour l'autorité compétente, figurent dans le tableau joint en annexe A.

Les plans d'actions correctives de chaque établissement sont fournis en annexes, numérotées de 1 à 6 et nommées par nom d'entreprise.

Je reste à votre disposition pour toute demande d'information complémentaire que vous viendriez à émettre.

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

La directrice générale adjointe de l'alimentation CVO

Emmanuelle SOUBEYRAN

Annexes:

Annexe A_Réponses aux recommandations pour l'autorité compétente

- Annexe 1_Plan d'action_Brocéliande_14
- Annexe 2_Plan d'action_Sobeval_24
- Annexe 3_Plan d'action_Fipso_64
- Annexe 4_Plan d'action_Pyragena_64
- Annexe 5_Plan d'action_Salaison de l'Adour_65
- Annexe 6_Plan d'action_Cooperl_79

Directorate General for Food



Liberté Égalité Fraternité

<u>Dossier followed by</u>: Maria-Jessica PLAZA Sub-directorate for Europe, International and Integrated Risk Management Office of the Exports to Third Countries

Ref.: SDEIGIR 2310080 Tel.: +33 (0)1 49 55 74 30

Email: export.dgal@agriculture.gouv.fr

The Deputy Director General for Food, CVO to

Dr. Michelle CATLIN

International Coordination Executive

Office of International Coordination Food Safety and Inspection Service U.S. Department of Agriculture 1400 Independence Avenue SW Washington, D.C. 20250-3700 UNITED STATES OF AMERICA

Paris, on November 2, 2023

Subject: Responses to the recommendations of the audit report on the meat products inspection system.

Dear Director,

It was with great interest that I read your report, received on 05 September, concerning the audit of several establishments in the meat products sector in France.

The responses to each of the recommendations made to the competent authority are set out in the table in Appendix A.

The corrective action plans for each establishment are provided in the appendices, numbered 1 to 6 and named by company name.

I remain at your disposal should you require any further information.

Yours sincerely,

The Deputy Director General for Food CVO
Emmanuelle SOUBEYRAN

Annexes:

- Annex A Responses to recommendations for the competent authority
- Appendix 1_Action plan_Brocéliande_14
- Annex 2 Sobeval 24 Action Plan
- Annex 3 Plan d'action Fipso 64
- Annex 4_Plan of action_Pyragena_64
- Annex 5 Action plan Salaison de l'Adour 65
- Annex 6 Action plan Cooperl 79

Annexe A_Réponses aux recommandations pour l'autorité compétente

Composante	Recommandations du FSIS	Réponse de la DGAL
1.Supervision du gouvernement	Conforme: Les auditeurs du FSIS concluent que le système d'inspection de la sécurité alimentaire de la DGAL, régissant les produits à base de viande dispose de la structure organisationnelle nécessaire pour assurer le contrôle, la supervision et l'application des exigences réglementaires pour cette composante.	
2. Autorité statutaire du gouvernement, et règlementations relatives à la protection du consommateur	Conforme: Les auditeurs du FSIS concluent que le système de sécurité alimentaire de la France continue à disposer d'un cadre réglementaire et de procédures de vérification adéquates pour garantir des mesures de contrôle réglementaire officielles suffisantes pour prévenir la contamination des produits en cas de conditions ou de pratiques insalubres, ce qui, comme décrit, est conforme aux critères établis pour cette composante.	
3.Surveillance des SSOP par le gouvernement	Conforme: les auditeurs du FSIS concluent que le système d'inspection de la DGAL régissant les produits à base de viande continue à maintenir des exigences réglementaires sanitaires qui satisfont aux exigences de base de cette composante.	

4.Surveillance de l'HACCP par le gouvernement 5. Programme	personnel d'inspection local n'a pas correctement vérifié que les plans	Un rappel a été fait aux autorités locales sur ce point et il a aussi été organisé un échange de pratique juste avant l'audit et d'autres seront prévus en 2024 afin de s'assurer de la bonne prise en compte de ce commentaire par les services d'inspection locaux. L'instruction technique DGAL/SDASEI/2021-253: « Conditions d'agrément des établissements exportant des viandes et produits carnés vers les États-Unis d'Amérique (USA) » précise très bien les attendus pour cette composante, un point d'attention sera tout de même ajouté à la mise à jour, à venir en 2024, de cette instruction. Pour l'année 2024, les plans d'échantillonnage nationaux sont
gouvernemental d'analyse des résidus chimiques	DGAL ne s'est pas assurée à ce que les animaux d'élevage (veau et porc) dont la viande est destinée à l'exportation vers les États-Unis soient inclus dans le programme officiel d'échantillonnage des résidus chimiques.	déjà finalisés et prêts à être diffusés auprès des autorités locales de contrôle. Cependant, le bureau en charge de la programmation des plans de surveillance et de contrôle, au sein de la direction générale de l'alimentation, va engager une réflexion afin d'envisager au mieux l'intégration de cette exigence, dans les instructions techniques de prélèvement, en les articulant avec les prescriptions de la réglementation européenne. En attendant, un rappel a été fait aux autorités locales, compétentes pour cibler les carcasses à prélever, de bien inclure les journées de production dédiées à l'exportation vers les Etats-Unis dans leur échantillonnage. Cela sera rappelé dans la mise à jour, à venir, de l'instruction technique DGAL/SDASEI/2021-253: « Conditions d'agrément des établissements exportant des viandes et produits carnés vers les États-Unis d'Amérique (USA) ».
6. Programme gouvernemental d'analyses microbiologiques	Conforme: les auditeurs du FSIS concluent que le système français d'inspection des viandes dispose d'un programme de tests microbiologiques organisé et administré et que la DGAL a mis en œuvre les programmes d'échantillonnage et de tests microbiologiques nécessaires qui répondent aux exigences de cette composante	