United States Department of Agriculture

Food Safety and Inspection Service

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Dr. Soubeyran,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of France's meat inspection system from April 12 through May 12, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of France are included as an attachment to the report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

FRANCE

APRIL 12 – MAY 12, 2021

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 5, 2021
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from April 12–May 12, 2021. Due to the global COVID-19 pandemic the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to determine whether France's food safety inspection system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. France currently exports raw-intact and raw-non intact veal products, and raw-intact; raw-non intact; thermally processed, commercially sterile; and not heat treated – 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors concluded that France's meat products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. La Direction Générale de l'Alimentation – The Directorate General for Food (DGAL) requires sanitary operating procedures and HACCP systems to ensure controls of hazards in raw veal and pork in their meat inspection system. In addition, DGAL has instituted microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of France's food safety inspection system April 12–May 12, 2021. The audit began on April 12, 2021 with an entrance meeting held via videoconference 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 attended all audit sessions.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Veal - All Products Eligible 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, or Otherwise Non-intact Pork	Pork - All Products Eligible 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 - Commercially Sterile	Thermally Processed, Commercially Sterile (TPCS)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible

[1] All source meat and poultry used to produce products must originate from eligible countries and establishments certified to export to the United States. For processed meat products, meat includes pork and veal (as defined in the Federal Meat Inspection Act).

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes France as free of foot-and mouth disease (9 CFR 94.11), free of swine vesicular disease (9 CFR 94.13), free or low risk of classical swine fever (CSF), as part of APHIS-defined European CSF region (9 CFR 94.31), with controlled risk of bovine spongiform encephalopathy, and subject to European Union (EU) designation of African swine fever (ASF) restricted zone in the EU, established by the EU because of detection of ASF in domestic or feral swine (9 CFR 94.8).

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed France's self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed official government records to determine whether France's food safety inspection system governing meat products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components; product types and volumes; frequency of prior audit-related site visits; point-of-entry (POE) reinspection and testing results; specific oversight activities of government offices; and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from DGAL through the SRT.

Determinations concerning program effectiveness during this remote audit 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 official government records associated with administrative functions and oversight. Those records were maintained at DGAL's headquarters in Paris as well as in three local inspection offices and two official laboratories. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of three establishments was selected from a total of 10 establishments certified to export to the United States. This included one bovine (veal) slaughter and processing establishment, one swine slaughter and processing establishment, and one swine processing-only establishment.

This remote audit did not include direct observation by FSIS auditors of conditions and operations at establishments in France nor review by FSIS of establishments' conditions or records, but rather a review of records associated with official government verification activities at the selected establishments. The FSIS auditors assessed DGAL's oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign

food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

The FSIS auditors also remotely audited one official chemical residue testing laboratory and one official microbiological testing laboratory to verify that these laboratories were capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• DGAL headquarters, Paris
	Regional Offices	3	• Departmental Directorate for Protection of Population (DDPP24), Dordogne • Departmental Directorate for Protection of Population (DDPP29), Finistère • Departmental Directorate for Protection od Population (DDPP64), Pyrenees Atlantiques
Laboratories		2	• Laboratoire des Pyrenees et des Landes, government chemical residue testing laboratory, Pyrenees-Atlantiques • Laboratoire Departmental d'Analyse et de Recherche de Dordogne, government microbiological testing laboratory, Périgueux
Swine slaughter and processing establishment		1	• Establishment FR. 29.225.001, Jean Henaff Production, Pouldreuzic
Bovine (veal) slaughter and processing establishment		1	• Establishment FR. 24.053.001, Sobeval, Boulazac Isle Manoire
Swine processing establishment		1	• Establishment FR. 64.010.003, Haraguy-Jambon de Bayonne, Pyrenees Atlantiques

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.) 601, *et seq*.);
- The Humane Methods of Livestock Slaughter Act (7.U.S.C. 1901, *et seq.*); and
- The Meat Inspection Regulations (9 CFR Part 301 to the end).

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

III. BACKGROUND

From December 1, 2017 to November 30, 2020, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 995,503 pounds of meat from France. This included 176,096 pounds of thermally processed, commercially sterile (TPCS) pork; 151,606 pounds of ready-to-eat (RTE) dried pork; 4,944 pounds of RTE acidified/fermented pork (without cooking); 1,347 pounds of raw intact pork; and 661,510 pounds of raw intact veal exported by France to the United States. Of these amounts, additional types of inspection were performed on 133,107 pounds of meat (31,137 pounds of TPCS pork; 18,345 pounds of RTE dried pork; 3,260 pounds of RTE acidified/fermented pork [without cooking]; and 80,365 pounds of raw intact veal). These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). As a result of this additional testing, no meat product was rejected for issues related to public health or other consumer protection.

The previous FSIS audit in 2019 identified the following systemic findings:

Summary of Findings from the 2019 FSIS Audit of France
Component 1: Government Oversight (e.g., Organization and Administration)
• The Central Competent Authority (CCA) did not include provisions to prohibit inspection officials from signing export certificates for product destined for the United States until all inspection laboratory verification sample test results for chemical residue are received and found acceptable.
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
• At all audited slaughter establishments, documented periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by government inspection personnel.
Component 6: Government Microbiological Testing Programs
• The laboratory did not routinely use a positive control in conjunction with its Shiga-toxin-producing *Escherichia coli* (STEC) screening method (GENE-UP®). FSIS considers the use of a positive control necessary for ensuring the validity of each analysis. • The laboratory could not demonstrate (e.g., by written procedure) that the entire N60 sample would be tested in the event that the sample submission is greater than the size of the test portion prescribed by the screening method (375 g).

In this current audit, the FSIS auditors verified that the corrective actions for the previously reported systemic findings in Components 1, 2, and 6 were implemented and effective in resolving the findings.

Recent FSIS 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. The organizational structure and management approach of DGAL are described in Memorandum DGAL/SDPRAT/2016-941, the National Quality of the DGAL Organization Manual. The oversight by DGAL of the meat inspection system is based on a continuous chain of command comprising three levels: national level, regional level, and local level.

At the national level, DGAL is the only body responsible for designing policies for primary production of meat products and meat by-products, 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 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 its headquarters are located in Paris.

The Regional Directorate for Food, Agriculture, and Forest links the national level to the local level by coordinating and managing the interactions between the national and local levels. There are 13 regions and five overseas regions.

At the local level, public veterinary offices (PVOs) are responsible for the implementation and enforcement of food safety policies. PVOs are located in either large departments known as the Departmental Directorate for Protection of Populations (DDPP) or smaller departments referred to as the Departmental Directorate for Social Cohesion and Protection of Populations (DDCSPP). There are 96 departments and five 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 the United States 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. Memorandum DGAL/SDSEI/2019-38 requires that before the grant of approval, official services review and evaluate the required food safety management plan (FSMP) submitted by establishments applying for eligibility to export meat products to the United States.

Article L. 231-2-1 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.

The FSIS auditors confirmed that, by the end of 2021, the organizational structure of DGAL will be consolidated from three to two major services with sub-directorates: (1) the International Health Performance Service (IHPS), and (2) the Service for Health Control Policy Design and Implementation (SHCPDI). IHPS will include three sub-directorates. The Sub-directorate for Europe, International and Integrated Risk Management will be responsible for the anticipation of the positions taken at the European and international levels. This sub-directorate will also validate the negotiation mandates through an analysis of risk and extended impact conducive to a transversal programming of the health control policy. The Sub-directorate for Ecological Transition for Quality Food will be responsible for developing and pooling the strategic management of the incentive components of public policies led by DGAL in order to stimulate the ecological transition of agricultural and food production systems and to better meet the civil society's expectations. The final sub-directorate, the Sub-directorate for Information Systems and Business Management of Deconcentrated Services, will be tasked with strengthening the management of the human and budgetary resources, as well as the information systems, and renovating the relationship framework with deconcentrated services.

SHCPDI, on the other hand, will comprise (a) the Sub-directorate for Animal Health and Welfare whose role will be to manage the design, operational programming, and implementation of official control related to animal health and welfare within a framework of responsibilities reaffirmed with partners, and to integrate zoonotic threats; (b) the Sub-directorate for Plant Health and Protection will manage the design, operational programming and implementation of official controls related to plant and forest health; (c) the Sub-directorate for Food Safety will oversee the design, operational programming and implementation of official food safety controls through the integration of biological, chemical, and physical risks; and (d) the Mission for Relations with Partners will be responsible for strengthening consultation with authorities (Health Parliament) and further structuring France's relations with its partners.

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 lays down overarching guiding principles and legitimate objectives for food law in order 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/withdrawal procedures must be included in the FSMP before an establishment is approved for export to the United States. Once the veterinarian services approve the FSMP, the establishment is granted eligibility and government inspection personnel (GIP) are assigned on a continuous basis to certified establishments. 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 the 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 uses a Rapid Alert System described in the Alert Management Guide to notify FSIS that adulterated products have been shipped.

The FSIS auditors confirmed that GIP make sure that product eligible for export to the United States is not commingled with domestic or other products that are not eligible. Additionally, the FSIS auditors confirmed that, in accordance with Memorandum DGAL/SDASEI/2021-253, GIP ensure that source materials used in processing operations originate only from French establishments certified 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 include requirements consistent with 9 CFR 416 sanitation regulations and 9 CFR 417 HACCP regulations. DGAL is the only body with authority to certify and decertify establishments as eligible to export to the United States. DGAL, through the local veterinarian services, ensures that the same laws, regulations, and policies are applied consistently to all establishments certified to export meat products to the United States. The aforementioned technical instruction requires that only establishments certified by DGAL can export meat or meat products to the United States. An establishment that wishes to export meat or meat products to the United States submits a request for approval in the Exp@don 2 automated system. A technical file is assigned to the application, which is then forwarded to the head of the local DDCSPP. Exp@don 2 is an online database for information management regarding export regulation. Exp@don 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. The request for approval must include both a summary of and an all-inclusive FSMP that describe all the procedures implemented by the slaughter establishment and/or processing establishment to ensure hygienic practices, food safety, and compliance with FSIS requirements. Furthermore, the FSMP must also include detailed procedures regarding traceability, withdrawal, and recall. The Veterinary Officers (VOs) 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 facility requirements. Once the DDPP official confirms that all FSIS requirements are met, the establishment is added to the list of approved establishments which is then updated and forwarded to FSIS by DGAL. In addition, Memorandum DGAL/SDSSA/2019-38 states that inspection of the FSMP 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*, *Lm*, 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 also investigated the cause of the failure in the certification process that allowed an ineligible French establishment to export over 38,000 pounds of pork pâté to the United States, resulting in a recall by FSIS in February 2021. According to DGAL officials, the above establishment is located in one of the large departments and the exporter bought the product from the ineligible establishment and then sent it to another department. Therefore, the producer may not have been aware that its products were exported to the United States. DGAL veterinarian officers signed four export certificates without checking the establishment's eligibility to export to the United States. Therefore, the DGAL officials contended that human error was the main cause of the breakdown in the certification process.

In a letter from DGAL to FSIS dated February 24, 2021 about this matter, DGAL proposed corrective actions consisting of (1) reminding the entire local inspection team (including all VOs) of the certification rules; (2) reevaluating the local certification procedures to prevent recurrence; (3) training the inspection personnel on the specific rules for exporting meat products to the United States; and (4) issuing a warning to the exporter of the ineligible products. The FSIS auditors verified, through document review and discussion with DGAL officials, that DGAL held a meeting and training session with the VOs to heighten awareness of the FSIS requirement that only establishments certified by DGAL can export meat products to the United States. In addition, DGAL officials stated that, by the end of 2021, an upgrade to the automated system, Exp@don 2, will be deployed with notable changes in the certification process. With the upgraded Exp@don 2, information entered by an applicant must be pre-validated electronically before completing the application process. During the pre-validation phase, applicants will not be able to move further in the certification application process and must ensure they only export products from eligible establishments; DGAL is responsible for ensuring that only eligible establishments can export.

The local DDPP inspection staff (that signed the export certificates) were reminded of certification requirements for United States exports. The FSIS auditors also reviewed the warning that DGAL sent to the exporter for not ensuring that only eligible establishments can export products to the United States. The FSIS auditors concluded that the proposed preventive measures are effective and the forthcoming upgrade to an automated system should further mitigate potential for recurrence considering the fact that this incident only happened once and France has not had any POE violations in the last three years.

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, DC. In the event of a change or update in FSIS requirements, the Agricultural Counselor communicates news of the change to DGAL officials in Paris who, in turn, relay it to the local DDPPs via mail and email. The FSIS auditors confirmed that the GIP stationed at the three audited establishments maintain current and up-to-date knowledge of FSIS requirements.

The FSIS auditors verified that all GIP assigned to certified establishments to perform ante-mortem (AM) and post-mortem (PM) inspection, certify exports; collect official samples, and conduct sanitation and HACCP verification activities are employees of and paid by the French national government. As civil servants, GIP are subjected to administrative policies that apply to all government officials. 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 veterinary degree. On the other hand, non-veterinarian GIP, also referred to as Official Auxiliaries (OAs) must pass a test before being hired. Once hired, all VOs and OAs 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 the GIP. 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.

The FSIS auditors confirmed that one VO and an appropriate number of OAs 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 Memorandum DGAL/SDASEI/2018-635, which requires prior consultation between the establishments and the inspection services on manufacturing schedules. These schedules are planned in advance and recorded before the slaughter and processing of meat products intended for export to the United States.

The FSIS auditors confirmed that GIP 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. Veterinary services operate under the authority of the Minister of Agriculture. Three categories of GIP perform meat inspection: (1) VOs whose function is to provide scientific and technical expertise, communication, and management; (2) OAs who conduct the daily inspection at the certified establishments; and (3) Sanitary Controllers who provide continuous inspection at slaughterhouses. GIP receive training on HACCP, Sanitation Standard Operating Procedures (Sanitation SOP), animal welfare, AM and PM inspection, and microbiology at the National School of Veterinary Services, and/or in association with the National Training Institute for the Ministry of Agriculture. All GIP stationed at certified establishments receive their induction training from FranceAgriMer (an organization under the Ministry of Agriculture that supports

the meat industry on export issues) and newly hired employees shadow their seasoned counterparts to familiarize themselves with the FSIS requirements. In addition, American food safety consultants provide training on the specific FSIS requirements.

In France, there are 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) No. 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 European Commission.

According to Articles 2-5 of the Rural Code, the NRLs responsibilities are to perform confirmatory analysis, to develop and validate methods, to conduct inter-laboratory comparative testing or proficiency testing, to coordinate the activities of the approved laboratories, and to control reagents. The duties of the approved routine laboratories (which include approved 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 (convention) with the private laboratories that perform official tests if public laboratories do not have the capacity to perform those tests. The convention describes the specifications and services that the private laboratories must meet in order 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 vis-à-vis 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 according to International Organization for Standardization (ISO)17025 standards. COFRAC audits the approved laboratories every 15 months while the recently approved laboratories are audited within their first 12 months of operation. In compliance with Regulation (EU) No. 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 residue laboratories, through COFRAC's annual audit of the residue laboratory quality system in accordance with the ISO 17025 standard. EU regulations require testing of certain residues while other residue testing is determined by risk analysis. The National Agency for Food Safety, the Environment and Labor is responsible for risk evaluations. In accordance with Council Directive No. 96/23/EC, France

develops and implements a national residue program each year. This program is furnished to FSIS annually with the previous year's results.

During this remote audit, the FSIS auditors interviewed management and technical staff of the Laboratoire des Pyrenees et des Landes, a public residue laboratory that serves as an official laboratory conducting analyses of government samples for the presence of chemical residues in meat products. This laboratory is accredited by the EU and COFRAC for ISO 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The document reviews established that analysts had successfully completed intra- and inter-laboratory evaluations administered by the supervisor and possessed the competencies necessary to conduct the analyses assigned to them. Additionally, sample handling and frequencies, timely analyses, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control are performed in accordance with the laboratory's quality management program.

Through records reviews and interview of the laboratory management and VOs, the FSIS auditors verified chemical residue samples collection, handling, delivery, and receipt in the official government chemical residue testing laboratory. At sample receipt, the laboratory verifies that the seal is intact and matches the number on the laboratory submission form. Once the laboratory verifies and documents the temperature of the sample and confirms sample integrity, the laboratory assigns a unique laboratory's 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 laboratory personnel store the samples in accordance with the laboratory's standard operating procedures.

The FSIS auditors confirmed that GIP have verified the corrective actions related to the systemic finding reported in Component 1 of the 2019 audit were implemented and effective. In that audit, the FSIS auditors found that DGAL was not requiring that livestock carcasses subjected for chemical residue sampling be held by the certified slaughter establishments until an acceptable result was ascertained. The FSIS auditors confirmed that DGAL modified Memorandum DGAL/SDASEI/2018-635 and required that in the event a carcass to be exported to the United States is randomly selected and sampled as part of the national residue control plan, this carcass must be held until the analytical result is obtained. The proffered corrective actions are consistent with FSIS requirements regarding the Agency's chemical residue testing on livestock carcasses.

The FSIS auditors interviewed representatives from DGAL and the Laboratoire Départemental d'Analyse et de Recherche de Dordogne (LDAR) to discuss the government microbiological testing program. LDAR is an official government microbiological laboratory that conducts official microbiological testing on raw pork and beef products for *Salmonella* performance standards and on beef products that require testing for *Escherichia. coli* (*E. coli*) O157:H7 and non-O157 STEC. The FSIS auditors reviewed the laboratory training materials, annual audit records, accreditation scope, and the results of laboratory proficiency testing. The FSIS auditors reviewed microbiological sample receipt protocol and handling by LDAR and verified that

LDAR performs analysis of samples and reports results to DGAL in a timely manner. LDAR applies DGAL-approved analytical methodologies and has quality assurance programs. The FSIS auditors verified that DGAL applied and implemented appropriate and adequate corrective actions in response to the FSIS 2019 audit findings. The laboratory has included a positive control sample in their routine screening method (GENE-UP®) to test for STEC.

Official test results are entered into the SYGAL global information system for food related products and available to DGAL officials at headquarters. Then, DGAL sends the results by mail and email to GIP at the establishment from which the sample was collected. DGAL officials confirmed to the FSIS auditors that violative or unacceptable tests results were not re-tested or re-sampled.

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; AM inspection of animals; PM inspection of each and every carcass and part; 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. Technical Instruction DGAL/SDASEI/2021-253 Section II, E, 1 (Animal Protection), 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. Through records review and discussion, the FSIS auditors confirmed that GIP were verifying the 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 ascertained that the DDPPs were conducting daily, routine, and unannounced inspections related to animal welfare and documenting their finding in RESYTAL (France's electronic food safety inspection system). In the event that inspections result 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).

Memorandum DGAL/SDASEI/2010-8171 (Requirements for Carrying Out Official Inspections with Regard to Live Animals in Meat Slaughterhouses) describes France's requirements for AM inspection. As a prerequisite for approval to export to the United States, slaughter establishments must include AM activities in their FSMP. The VO must carry out AM inspection on all animals before slaughter in accordance with Regulation (EU) No. 2019/627. The OA may also carry out an initial inspection of animals and help with practical tasks. Through interviews, the FSIS auditors ascertained that AM 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 Regulation (EU) 2019/627. In some circumstances, it may be necessary to repeat AM inspection in order to meet this requirement.

The FSIS auditors confirmed that two inspection levels are used when conducting AM inspection. Performed by either the VO or the OA, Level 1 inspection 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 came with the animal set aside during Level 1 inspection. Through discussion with DGAL officials, 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) isolated while alive for further physical examination and/or documentary review, (b) declared fit for slaughter with conditions or without conditions, 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 VOs.

The requirements for PM inspection are outlined in Technical Instruction DGAL/SDA SEI/2021-253, Section III, b, 1, b and in Regulation (EU) No. 2019/627. Through interviews and document review, the FSIS auditors verified that, at the livestock slaughter facilities, GIP 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 interviews with GIP, the FSIS auditors also verified that OAs were conducting PM inspection under the supervision of VOs and were organoleptically inspecting the head, tail, tongue, thymus gland, and all viscera of each slaughtered animal. GIP were observing disease lesions such as abscesses, tumors, injection lesions, etc., and were palpating the carcasses and parts to detect abnormal lumps in tissues and abnormal firmness in organs. In addition, through discussion with GIP stationed at the certified slaughter facilities, the FSIS auditors confirmed that GIP 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. The FSIS auditors concluded that GIP were conducting PM inspection in a manner that is consistent with FSIS requirements.

Through interviews and record reviews, the FSIS auditors confirmed that GIP were verifying the adequate identification, removal, and disposal of specified risk material (SRM) in veal slaughter/processing establishments. DGAL follows Regulation (EC) No. 999/2001, which defines SRMs as the tonsils, the last four meters of the small intestines, the caecum, and the mesentery of animals of all ages. Moreover, Technical Instruction DGAL/SDSSA/2021-253 Section II, E, 4 (Cattle Abattoirs: Special Requirements for Bovine Spongiform Encephalopathy [BSE]) requires that veal from slaughtered non-ambulatory veal calves be excluded from exports to the United States. DGAL requires the removal of all SRMs at the slaughterhouses to ensure SRMs do not enter the food chain. Through discussion with DGAL officials during the remote audit, 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. Memorandum DGAL/SDSSA/2021-253 Section, II, D, 1 (Health Performance Standards) outlines the modalities for the removal of SRMs and mandates that SRM removal be included in either the certified establishment's prerequisite programs (SSOPs or Sanitation Performance Standards [SPS]) or the HACCP plan.

France implements the requirements of Regulation (EC) No. 1069/2009 regarding the treatment of animal by-products for different categories of animal by-products not intended for human consumption. The FSIS auditors verified that after AM and PM inspections, all animal by-products that are deemed unfit for human consumption (condemned animals, parts and inedible materials) pursuant to the requirements of Regulation (EU) No. 2017/625 are subject to administrative seizure (an administrative act that restricts the right to use a food product of animal origin in order to protect public health). The animal byproducts are sorted in categories (1, 2, or 3) and collected for disposal or use, pursuant to Regulation (EC) No. 1069/2009 and the FSMP of the establishment. GIP stationed at the certified slaughter establishments carry out daily random checks of inedible and condemned materials throughout the year while the management of animal by-products is assessed at least once per year during the quarterly supervisory visits.

Memorandum DGAL/SDASEI/2021-253, II, C, 2 prohibits any cross contamination between products intended for export to the United States and other products that do not meet United States standards. Through interviews with GIP, 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). 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.

In order to remain informed of any update or change in APHIS' animal disease restrictions, the Department of Economic Affairs of the Embassy of France in Washington, DC actively monitors the APHIS website as well as regulatory updates/changes related to animal disease status and conveys information dealing with animal health back to DGAL so that FranceAgriMer can update the Exp@don 2 electronic system and the 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 email addresses of the DDPPs and to certified establishments through FranceAgriMer.

Technical Instruction GAL/SDSSA/2021-253 Section II, J (Implementation of Exports) lays down the specific labeling requirements for products destined for export to the United States. The FSIS auditors verified that the Economic Department of the Embassy of France in Washington, DC 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, GIP 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 Technical Instruction DGAL/SDA SEI/2021-253, Section III, B, 3 (Supervisory Inspections) 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 establishment's health control plan (HACCP, Sanitation SOPs, SPS). The findings are documented either in RESYTAL or on a local record that is kept in the inspection office.

Product inspection supervisory visits, on the other hand, are performed by VOs at the certified slaughter establishments and consist of verifying that GIP are properly conducting AM and PM inspection on carcasses and parts. The findings are recorded in a dedicated electronic or paper medium. The FSIS auditors reviewed supervisory review reports and confirmed that all the FSIS import requirements were verified throughout the year. Moreover, the FSIS auditors confirmed that evaluation of AM and PM inspection were included in the supervisory review reports. This was a correction of a systemic finding reported during the previous FSIS audit in 2019. Deficiencies found during supervisory visits are corrected and verified during the following visit by a DGAL supervisor.

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 DGAL requires each official establishment to develop, implement, and maintain written SSOPs to prevent direct product contamination or insanitary conditions,

and to include requirements for SPS and sanitary dressing. The evaluation of this component included a review and analysis of the information provided by DGAL in the updated SRT, review of GIP verification records, and interviews of DGAL officials.

As noted earlier, one of the requirements for a slaughter establishment's approval to export meat products to the United States is the development of an FSMP. In the FSMP, the establishment operators must describe all the procedures the establishment will implement to ensure the hygiene and safety of the products. The FSMP is reviewed and approved by the veterinary services before final approval is granted to the establishment. GIP stationed at the slaughterhouses are responsible for the verification of the FSMP's implementation.

Technical Instruction DGAL/SDASEI/2021-253 Section II, E, 2 (HACCP Plan) also 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 ascertained that GIP 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 PM 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 verification records as well as noncompliance records issued at the veal slaughter establishment and found that GIP were verifying the CCA's sanitary dressing requirements in accordance with DGAL's instructions.

DGAL's requirements for certified establishments to meet the SPS are outlined in Memorandum DGAL/SDASEI/2021-253, Section II, D, 1 (Hygiene Performance Standards) and in Annex II of Memorandum 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 enough 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.

Annex II, 3 of Memorandum DGAL/SDASEI/2014-393 lays down the expectations by DGAL that GIP verify through direct observation that the SPS requirements are met. Furthermore, GIP 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 by DGAL. The FSIS auditors reviewed official government SPS noncompliance records from two certified establishments and found that GIP were verifying that conditions in those two certified establishments were sufficient to prevent product contamination or adulteration.

The FSIS auditors also confirmed that GIP were verifying that certified establishments take corrective actions related to SPS noncompliances by requiring either immediate actions or requesting and validating 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 GIP 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 certified establishments may also result in significant administrative penalties. In addition, retail facilities and consumers may file lawsuits when the product does not meet food safety requirements.

Memoranda DGAL/SDASEI/2021-253, Section II, D, 2 (SSOPs) 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 memoranda specify DGAL's expectations in terms of content and design of the Sanitation SOP program, 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 OAs verify organoleptically and through records review that pre-operational and operational sanitation procedures are properly implemented. In addition, GIP also verify the content of the Sanitation SOP program and the documentation attesting the application of the program including corrective actions taken in response to direct product contamination.

Through discussion with GIP and document review, the FSIS auditors confirmed that GIP were performing and documenting sanitation verification activities during days when products destined for the United States were produced by certified establishments. Furthermore, the reviewed Sanitation SOP noncompliance records indicated that GIP were making sure that any time product contamination occurred, the certified establishment took corrective actions to restore sanitary conditions, provide appropriate disposition of products, and prevent recurrence, as required by Memorandum DGAL/SDASEI/2021-253, Section III, D (Official Checks).

In the establishments that produce RTE products, Memorandum DGAL/SDASEI/2021-253, Section II, G (Special Requirements for Establishments that Manufacture RTE products) requires the development of a control plan that addresses *Lm* and *Salmonella* within the HACCP plans or Sanitation SOP programs. In addition, France adopted requirements consistent with 9 CFR 430. The requirements for establishments that export products to the United States are described in the following document: DGAL/SDASEI/2021-253.

The FSIS auditors reviewed the official sample results for *Salmonella* and *Lm* at certified establishments producing RTE products and found that GIP were implementing the sampling program as expected and were reviewing the sample results before signing the export certificates. Through records review, the FSIS auditors confirmed that GIP were ensuring that one of the certified establishments producing post-lethality exposed RTE products was following one of the *Lm* alternatives in 9 CFR 430 and was meeting all the requirements specified in that alternative to control *Lm* in its products.

In the event of noncompliance related to sanitation requirements, Memorandum DGAL/SDASEI/2014-393, Section II, 3 (Expectations in Case of Noncompliances with

European, French or Specific Requirements) 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 Exp@don 2 database showing the establishment as suspended and cannot export products to the United States.

The FSIS analysis and remote verification activities indicate 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 Memorandum DGAL/SDASEI/2014-393 and Section II, D, 3 (HACCP) of Memorandum 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 in the Codex Alimentarius Commission. This includes a flow chart, hazard analysis, HACCP plan, intended use of product, monitoring and verification activities, corrective actions, reassessment, and records supporting the implementation of the HACCP system. 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 system. The certified livestock slaughter and processing establishments are required to establish a zero tolerance CCP for fecal contamination, ingesta, or milk and address STEC pathogens in their hazard analyses (for veal slaughter establishments only). Moreover, DGAL mandates that certified establishments producing RTE products address *Lm* 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.

The FSIS auditors verified that GIP were conducting verification activities for HACCP requirements according to the CCA's requirements. Furthermore, the FSIS auditors reviewed records associated with GIP's verification of compliance with HACCP requirements and verified that GIP conduct daily verification of the establishments' critical limits established for all CCPs to ensure the adequacy of their food safety controls. The FSIS auditors also ascertained that GIP 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 GIP 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 reviewed the records associated with the official government sampling of STEC, *Lm,* and *Salmonella* in raw and RTE meat products and found that they were being conducted at the required frequency and reviewed by the VOs prior to signing export certificates.

Memorandum DGAL/SDASEI/2021-253 stipulates that any lot associated with a non-negative result, or potentially in contact with a lot with a non-negative result, is ineligible for export to the United States. Annex 6 of the above-mentioned memorandum also requires that, as part of their HACCP system, certified establishments hold any production lot that was sampled for STEC (as part of the self-control program) until an acceptable result is ascertained. Furthermore, the certified establishments' FSMP must include and define all the corrective and preventive actions taken in the event of a positive result. Certified establishments are required by law to report any positive sample results to DGAL. The FSIS auditors also confirmed that the establishment's pre-shipment review included checks for acceptable results from self-control testing.

The FSIS auditors also verified the official controls in place for *Trichinella* in pork products. France has developed an official control plan that consists of testing 1 out of 1,000 hogs in controlled farms for *Trichinella*. In the past 10 years, no positive results were obtained. DGAL assigns health veterinarians to all hog 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 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 GIP were verifying that the establishment producing RTE pork products was evaluating and controlling *Trichinella* in its hazard analysis.

The FSIS auditors' analysis and remote verification activities indicate that DGAL requires each certified establishment to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditors determined that the HACCP program as described is consistent with criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth 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, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or FSIS as potential contaminants. Prior to the remote audit, FSIS' residue experts thoroughly reviewed France's 2020 National Residue Control Plan submission, associated methods of analysis, and additional SRT responses outlining the structure of France's chemical residue testing program. There have not been any POE violations related to this component since the previous FSIS audit in 2019.

In accordance with Council Directive No. 96/23/EC, DGAL develops and implements a national residue program each year. DGAL uses a system of laboratories that includes public laboratories located in France and other laboratories located throughout the EU. Many of these laboratories are designated as reference laboratories for specific residue areas. DGAL maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption. The laboratories are ISO 17025 accredited by the EU and COFRAC for ISO 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications.

In accordance with Article 5 of the Council Directive No. 96/23/EC, EU member countries are required to update their national residue control plan for the following year based on the results of the previous year to consider changes in chemical group and detection measures. The annual monitoring plan takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. Technical Instruction DGAL/SDASEI/2020-150 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 tolerance, 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 Agence National de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail, is responsible for risk evaluations. On-farm controls of veterinary drugs, along with controls carried out in slaughterhouses, AM and PM inspections, and chemical residue control plans, ensure that all requirements regarding veterinary drugs are met.

Specific procedures for addressing violative test results are described in Section IV of Technical Instruction DGAL/SDSPA/2019-39. This includes specific instructions for reporting of results, product sequestration, on-farm investigation, and follow-up sampling. 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, and that ultimately, no adulterated product was identified in exports to the United States.

The FSIS auditors' review of the official government residue sampling records for the two audited slaughter establishments indicated that DGAL has adhered to the 2021 sampling program schedule, as required by Technical Instructions DGAL/SDASEI/2020-825 and DGAL/SDASEI/ 2021-94. Through interviews with GIP and document review, the FSIS auditors verified that monitoring residue samples are collected and shipped under inspection seal by GIP. 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 a DGAL VO verifies that each animal presented for slaughter is accompanied by the animal's passport (document that provides information on the animal's breed, age, farm of origin, etc.); 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 tissue

samples are conducted in accordance with standard protocols that meet the FSIS criteria. DGAL requires carcasses of suspect animals to be retained for sampling at slaughter facilities. The FSIS auditors verified that DGAL has implemented corrective action related to the 2019 onsite audit findings and requires slaughter establishments to hold carcasses selected for routine residue monitoring sampling until all inspection laboratory verification sample test results for chemical residue are received and found acceptable, as required by DGAL/SDASEI/2021-253.

The FSIS auditors reviewed technical documents pertaining to official government chemical residue monitoring programs and verified that DGAL reviews chemical residue test results to ensure that meat products exported to the United States do not contain a chemical residue that exceeds an established United States tolerance or contain a chemical compound with no approved use in the production class tested.

The remote audit activities indicate that DGAL continues to maintain the legal authority to regulate, plan, and execute activities of the food safety inspection system that are designed to prevent and control the presence of residues of veterinary drugs and contaminants in meat products destined for human consumption.

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.

Prior to this remote audit, FSIS microbiologists reviewed France's national microbiological sampling and testing programs, laboratory methods of analysis, and additional SRT responses outlining the structure of DGAL's microbiological verification sampling and testing programs. Since the previous FSIS audit in 2019, the FSIS auditors noted that there have not been any POE violations for STEC in beef (veal), *Salmonella*, or *Lm* in processed RTE meat products, or for failing to produce normal-appearing TPCS products. DGAL-approved laboratories meet the general criteria required from test laboratories that are accredited and audited by COFRAC or any equivalent European body, are ISO 17025 accredited, and take part in interlaboratory proficiency tests (ring tests).

The FSIS auditors verified that DGAL ensures establishments follow Regulation (EC) No. 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 Regulation (EC) No. 2073/2005. FSIS accepts *Enterobacteriaceae* testing as equivalent to testing for generic *E. coli*[2]. The FSIS remote audit included record review and interviews of GIP and microbiological

[2] FSIS notified eligible foreign countries of new regulations for U.S. swine slaughter establishments and continues to ensure that the countries implement equivalent sampling and analysis for microbial organisms for monitoring process control throughout slaughter and dressing operations consistent with U.S. requirements in 9 CFR 310.18.

laboratory personnel to verify microbiological process control. The FSIS auditors reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any identified loss of process control.

Memorandum DGAL/SDASEI/2021-253 outlines the official government microbiological testing program for meat products destined for export to the United States. The memorandum outlines the microbial testing requirements derived from the aforementioned EC regulation for process control verification, pathogen reduction standards, RTE post-lethality exposed product, and STEC for establishments slaughtering cattle. Sample collection is performed by GIP 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 product. This *Salmonella* testing program for chilled livestock (cattle and swine) carcass sampling is consistent with the provisions of Regulation (EC) No. 2073/2005. Annex III, C2 of Memorandum 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 samples test positive for the presence of *Salmonella*. All samples are sent to an approved microbiology laboratory for analysis for presence of *Salmonella*, and GIP analyze results to determine the effectiveness of each establishment's *Salmonella* control program. The FSIS auditors reviewed the carcass testing results for the last year at selected slaughter establishments, noting that the *Salmonella* performance standards were met at each location.

DGAL has microbiological testing programs for *Salmonella* in RTE products and *Lm* in post-lethality exposed RTE products and product contact surfaces. These inspections are implemented in establishments certified to export RTE meat-based products to the United States. Memorandum DGAL/SDASEI/2021-253, Annex III requires that RTE establishments consider the hazard of *Lm* contamination of RTE products and control the pathogen through their HACCP plans, sanitation SOP, or other prerequisite programs. To verify the efficacy of their *Lm* control program, establishments use Annex II of Memorandum DGAL/SDASEI/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 (FCS) with frequencies equivalent to those utilized domestically in the United States. Memorandum DGAL/SDASEI/2021-253 Annex II and III describes sampling requirements and analysis for establishments that produce RTE products for export to the United States. Criteria for official sample evaluation is absence of *Lm* in 25g using ISO 11290-1 and absence of *Salmonella* in 325g using ISO 6579.

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

The FSIS auditors confirmed that establishments are required to test every lot of product that is intended for export to the US. 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 US (e.g., trim, primals/subprimals). DGAL requires and GIP verify that establishments handling raw veal intended for export to the United States to address the risk of STEC (O157:H7 and six non-O157 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, sanitation SOP, or HACCP plan. DGAL provides instructions for establishment sample collection, including the types of samples collected, the sampling method, and frequency of sampling.

Through interviews with GIP and review of official records at the veal establishment, the FSIS auditors confirmed that the requirements of Memorandum DGAL/SDASEI/2021-253 were implemented as intended. 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 product exported to the United States was subject to establishment testing, with GIP verification testing conducted at least once per year.

Memorandum DGAL/SDASEI/2021-253 Annex II requires laboratories to use the entire N60 sample. The FSIS auditors confirmed that the GENE-UP Top 6 PCR analysis method and the Pall and ISO 13136 derived methods are the only STEC analysis methods approved for analyses of product destined for export to the United States. The GENE-UP Top 6 PCR method is the only method currently used for testing veal product destined for export to the United States. However, the laboratory representatives acknowledged that their approved laboratory uses a GENE-UP PCR screening method which has been validated by an external entity (Microval) for four STEC subgroups (O26, O103, O111, and O145) only, but not for subgroups O45 and O121. As part of the STEC analyses, if a DGAL-approved laboratory detects the presence of the *stx* virulence gene and O-antigen (with or without the presence of the *eae* gene) in a sample, then the laboratory is required to send the sample to an NRL. In the event the NRL detects the O45 and O121 serogroup, the establishment is required to exclude the sampled lot from export to the United States.

The FSIS auditors reviewed records and interviewed GIP 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*,* Article 5, Annex II, Chapter XI, which lays down specific requirements for food in hermetically sealed containers. DGAL provides further instructions for establishments producing TPCS products in Memorandum DGAL/SDSSA/2015-364, which includes specific requirements for thermal processes, commercial stability tests, and good hygiene practices. The sterilization value (F_o) set by the establishment must meet the requirements in Regulation (EC) No. 852/2004, which clarifies that the heat treatment used should meet the requirements of an internationally recognized standard. Memorandum DGAL/SDSSA/2015-364 specifies a minimum sterilization value of $F_o = 3$, which corresponds to a 10^{12} reduction in the number of *Clostridium botulinum* spores.

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 noted 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. Furthermore, the FSIS auditors noted that sterilization values afforded by these processes were typically around $F_o = 10$, that is more than three times the minimum sterilization value of $F_o = 3$. There have not been any POE violations related to this component since the previous audit in 2019.

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 sampling and testing programs to verify the effectiveness of its system.

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held May 12, 2021 with DGAL officials. 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. Accordingly, the FSIS auditors concluded that DGAL's food safety inspection system governing meat products for export to the United States continues to meet the established FSIS equivalence criteria.

Appendix: Foreign Country Response to the Draft Final Audit Report

MINISTÈRE
DE L'AGRICULTURE
ET DE L'ALIMENTATION
Liberté
Égalité
Fraternité

Direction générale de l'alimentation

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

La directrice générale adjointe de l'alimentation, CVO

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Référence : SDEIGIR EXP 2111001

A Paris, le = 4 NOV. 2021

Objet : Produits carnés – Retour sur le rapport d'audit préliminaire

Madame la Directrice,

En réponse à votre courrier du 10 août relatif à la transmission du rapport préliminaire du visio-audit en objet qui s'est déroulé du 12 avril au 12 mai 2021 dans le cadre du maintien des exportations de produits carnés français vers les Etats-Unis, j'ai l'honneur de vous confirmer mes propos exprimés lors de notre entretien du 15 octobre dernier.

C'est avec satisfaction que j'ai pris bonne note des conclusions positives qui sont formulées dans ce rapport. Ainsi je n'ai pas de commentaires à y apporter.

Je vous renouvelle aussi le plaisir que j'ai eu d'échanger avec vous dernièrement et suis disposée à renouveler ces entretiens régulièrement.

Dans l'attente de la réception du rapport définitif, je vous prie d'agréer, Madame la Directrice, l'expression de mes salutations distinguées.

La directrice générale ~~adjointe de l'alimentation~~
CVO
Emmanuelle SOUBEYRAN

Direction générale de l'alimentation
Ministère de l'agriculture et de l'alimentation
251, rue de Vaugirard
75732 PARIS Cedex 15

Unofficial Translation of DGAL's response

Subject: Meat products - Feedback on the preliminary audit report

Madam Director,

In response to your letter of 1 O August relating to the transmission of the preliminary report of the visio-audit in question which took place from April 12 to May 12, 2021 within the framework of the maintenance of exports of French meat products to the United States , I have the honor to confirm my words to you during our interview on October 15.

It is with satisfaction that I have taken due note of the positive conclusions which are formulated in this report. So I have no comments to make.

I also renew to you the pleasure that I had to exchange with you recently and am ready to renew these meetings regularly.

Pending receipt of the final report, please accept, Madam Director, the expression of my best regards.