USDA

United States Department of Agriculture

Food Safety and
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Dr. Loïc Evain
Chief Veterinary Officer
Direction Générale de l'Alimentation / Ministère de l'Agriculture
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75735 Paris Cedex 15
France

Dear Dr. Evain,

The FSIS onsite audit conducted from March 20 through March 31, 2017, supports that France's raw and processed pork and raw veal inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of France are included as an attachment to the report.

If you have any questions, please feel free to contact me directly.

Sincerely,

Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

FRANCE

March 20 – 31, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

August 25, 2017
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 20 – 31, 2017. The purpose of the audit was to determine whether France's food safety system governing raw and processed pork and raw veal remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. France currently exports the following categories of meat products to the United States: raw and processed pork products; intact veal carcasses; primal and subprimal cuts; veal trimmings; ground veal; and other non-intact veal products.

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

Government HACCP System:

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

FSIS received a written response from the CCA addressing all outstanding concerns identified in the draft final audit report. FSIS will evaluate the adequacy of the proposed corrective actions and base its activities for future equivalence verification on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of France's raw and processed pork and raw veal food safety system from March 20 – 31, 2017. The audit began with an entrance meeting on March 20, 2017, in Paris, France with the participation of representatives from the Central Competent Authority (CCA) – *Direction Générale de l'Alimentation, General Directorate for Food* (DGAL) and the FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing raw and processed pork and raw veal remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The scope of this audit included all aspects of France's inspection system for producing and exporting raw and processed pork and raw veal products to the United States. France is eligible to export raw and processed pork products; intact veal carcasses; primal and subprimal cuts; veal trimmings; ground veal; and other non-intact veal products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, findings of prior audit-related site visits, point-of-entry (POE) 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 a self-reporting process.

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

Administrative functions were reviewed at CCA headquarters in Paris, two departmental offices, and four local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended. A representative sample of four establishments was selected from a total of five establishments certified to export pork and veal to the United States. 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, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat.

Additionally, two government laboratories were audited: a microbiology laboratory located in Périgueux, and a residue laboratory located in Quimper, to verify technical support to the inspection system and to assess the oversight that DGAL maintains over their functions.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• DGAL/Paris
	Departmental Offices	2	• *Direction départementale de la protection des population* (DDPP) 64/Pau • *Direction départementale de la cohésion sociale et de la protection des population* (DDCSPP) 24/Périgueux
Laboratories		2	• *Laboratoire départemental d'analyse et de recherché* (LDAR) – government microbiological laboratory/Périgueux • *Laboratoire Public Conseil, Expertise et Analyse en Bretagne* (LABOCEA) - government residue laboratory/Quimper
Raw pork and veal slaughter and pork processing establishments		2	• FR 24.053.001 CE veal/Boulazac • FR 29.225.001 CE (pork)/Quimper
Pork processing establishments		2	• FR 64.010.003 CE/Aicirits Camou Suhast • FR 64.063.004 CE/Arzacq Arraziguet

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, *et seq*.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq*.); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of France's inspection system for meat 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 Sanitary/Phytosanitary Agreement.

Currently, France has equivalence determinations from FSIS for the following regulations and legislation:

- *Regulation European Commission (EC) No. 852/2004*;
- *Regulation (EC) No. 853/2004;*
- *Regulation (EC) No. 854/2004;*
- *Regulation (EC) No. 882/2004;*
- *Regulation (EC) No. 2073/2005;*
- *Regulation (EC) No. 1099/2009;*
- *Council Directive 93/119/EC;*

- *Council Directive 96/22/EC;*
- *Council Directive 96/23/EC; and*
- *Council Directive 97/747/EC.*

In addition:

- FSIS has determined the use of *Enterobacteriaceae* and Total Viable Count (TVC) in lieu of generic *E. coli* is acceptable for all European Union (EU) exporting countries.
- The use of an alternative laboratory testing method International Organization for Standardization (ISO) 6579:2002 (modified) for *Salmonella* by France is acceptable.
- France suspends an establishment's eligibility to export the first time it fails to meet a *Salmonella* performance standard until compliance with this standard is met.
- France uses the *L mono* COMPASS screening method in conjunction with ISO 11290-1, and the CONFIRM *L mono* Agar test as a confirmation method for *Listeria monocytogenes* (Lm) testing in ready-to-eat (RTE) products.
- The use of private laboratories for the analysis of official samples is acceptable.

III. BACKGROUND

France currently exports processed pork and raw veal products to the United States. From October 1, 2013 to September 30, 2016, FSIS import inspectors performed 100 percent reinspection for labeling and certification of 275,861 pounds of pork meat exported by France to the United States. FSIS also performed reinspection on 90,624 pounds at POE for additional types of inspection (TOI), of which no product was rejected because of food safety issues. France was not eligible to export veal to the United States until December 6, 2016. No veal products have been exported to the United States at the time of the 2017 audit.

In 2015, FSIS conducted an audit of France's pork and veal inspection systems, identifying issues related to the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations, Government Sanitation, and Government HACCP System components, indicating inadequacies in DGAL's oversight at the United States-certified establishments, including a veal establishment. DGAL proffered acceptable corrective actions to address the audit findings.

Subsequent to the 2015 audit, France submitted documentation on its STEC program and slaughter system. France updated its self-reporting tool (SRT) to provide information pertaining to the inspection system, including its microbiological testing program related to the implementation of testing for *E. coli* O157:H7 and other non-O157:H7 STEC. FSIS determined that France's system of controls, as represented in its SRT submission, provided an equivalent level of public health protection as applied domestically in the United States. On December 6, 2016, FSIS notified France that it recognizes France as equivalent to export raw beef products to the United States. Based on this recognition, DGAL certified one veal establishment that slaughters cattle less than 30 months of age.

After January 12, 2017, shipments of raw beef imports from France are subject to FSIS targeted frequency of POE verification testing for *E. coli* 0157:H7 and non-O157:H7 STEC sufficient to gain confidence that the level of public health protection for raw beef from France is equivalent

To that of the United States. Additionally, FSIS requested that France include government data on testing for *E. coli* O157:H7 and non-O157:H7 STEC in its annual SRT to demonstrate that it is continuously assessing and addressing any adverse trends as part of the national control program, not just in product exported to the United States.

Prior to 2015, the last FSIS audit of France's meat inspection system was conducted in June 2013. The FSIS final audit reports for France's food safety system are available on the FSIS website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign 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. The national government must 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. The evaluation of this component included a review and analysis of the information provided by DGAL in the updated SRT and direct observations, onsite records review, and interviews during the onsite audit.

The FSIS auditors verified that the inspection system is organized and administered by the national government of France. There have been no major changes in DGAL's organizational structure since the last FSIS audit in 2015. France is a member of the EU. Agricultural and sanitary matters are shared between the EU and member States. DGAL's authority to enforce inspection laws comes from *Regulation (EC) No. 178/2002* of the European Parliament and of the Council of 28 January 2002 defining the general principles and requirements of food law, establishing the European Food Safety Authority, and defining procedures in matters of food safety. The EC regulations are the primary overarching laws for regulating meat inspection. France is responsible for ensuring that adulterated or misbranded products are not exported to the United States through enforcement of its national legislation and implementing regulations.

In France, there is a continuous chain of command from the national central level to the local levels via a regional level. At the national level, DGAL is within the Ministry for Agriculture, Agrifood, and Forestry (MAAF) and is responsible for designing policies for primary production, animal welfare, and slaughterhouses. DGAL has the legal authority and responsibility to develop and oversee the implementation of inspection procedures in accordance with national standards, in addition to those standards imposed by importing countries. These laws and regulations are applicable to all certified establishments. The laws and regulations provide DGAL with the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States including suspension of operations and removing the eligibility of establishments to export to the United States.

At the local level, veterinary offices are located in public structures in either large departments called the Departmental Directorate for Protection of Populations (DDPP) or smaller departments called the Departmental Directorate for Social Cohesion and Protection of Populations (DDCSPP) and are responsible for implementation and enforcement of policies. There are 96 departments and 5 overseas departments. Each type of Departmental Directorate has a Veterinary Services Directorate responsible for enforcement, control, and surveillance of animal health and food laws, including United States import requirements. At least two Chiefs of Service, one of which is assigned to the Service of Animal Health and Welfare and the other to the Service of Food Safety, support each Director of Veterinary Services.

The Prefecture of Region links the national level to the local level through the Regional Directorate for Food, Agriculture, and Forest (DRAAF) and is responsible for coordination and management between the national and local levels. There are 13 regions and 5 overseas regions.

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

DGAL is the only body with authority to certify and decertify United States export eligible establishments and has an approval process in place for the certification of establishments. *Memorandum DGAL/Sous direction de la sécurité sanitaire des aliments/sub directorate for food safety (SDSSA)/ No. 2016-355 of 08/19/2016* provides that inspection of the food safety management plan by official services is mandatory before the grant of approval and during scheduled inspections of approved establishments. On July 12, 2016, DGAL issued a Technical Instruction, "*DGAL/Sous direction du pilotage des resources et des actions transversales/sub directorate" (SDPRAT)/ No. 2016-940,* for the management of resources and transversal actions to the field staff for uniform application of inspection procedures for compliance verification at the regulated establishments.

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

The current audit included the review of the administrative functions in two departmental offices, identified as DDPP-64 and DDCSPP-24. These departmental offices provide oversight and are responsible for ensuring that all the FSIS requirements are met at United States-certified establishments within their respective regions. The FSIS auditors verified that the departmental offices provide periodic supervisory reviews at the United States-certified establishments. The FSIS auditors examined a sampling of reviews to determine whether these reviews were conducted to ensure that requirements referred to in relevant subsections of nine CFR 327.2 were met. The FSIS auditors verified that the concerns that arose during the 2015 audit regarding periodic supervisory reports were corrected. No concerns were identified during the audit of either DDPP-64 or DDCSPP-24.

DGAL ensures that source meat products used in processing operations originate only from certified establishments in accordance with *Memorandum DGAL/SDASEI/2017-49,* which describes the process by which meat and meat products can be exported to the United States. The official veterinarian (OV) inspects these procedures before approval is granted to the establishment and continues to be evaluated during future routine inspections of the facility. The FSIS auditors verified that DGAL ensures that source meat products used in processing operations originate only from certified establishments in eligible countries.

The FSIS auditors verified that DGAL prevents fraud or misuse of export health certificates. The OV signs the certificates, which are recorded in the server register with each number being unique and single. There is an embossed stamp on each page. The government seal and security accountability logs are kept in a secured and locked environment. A tracking system is in place at DGAL headquarters and at the establishment level by the OVs who maintain all export certificates, ensuring traceability with each hard copy being kept at the DDPP/DDCSPP.

Annual allocation of resources is determined at the central level, and then distributed to regions, which then split resources between departments. DGAL is an agency funded by the national government and does not receive any other funding. Fees assessed to meat establishments go to the general budget of the state and not directly to DGAL, nor the Ministry of Agriculture. All DGAL personnel are employees of the government of France and subject to administrative policies that apply to all government officials.

All inspectors authorized to perform the controls, whether they are permanent civil servants or salaried government employees, are government inspectors. They are directly paid by the government; hired and fired by the government (through DGAL); have the same obligations regarding training, independence, confidentiality, impartiality, and integrity; and have the authorization to act on behalf of the government and to spend government funds. DGAL has ultimate control and supervision over the activities of all inspectors. The FSIS auditors verified that all inspection personnel conducting government verification activity including ante- and post-mortem inspection are government-paid employees, maintaining competent and qualified personnel to ensure the production of safe, wholesome, and accurately labeled product in certified establishments.

The FSIS auditors verified that DGAL has implemented and conducted ongoing training programs intended to ensure that government inspection personnel are aware of specific food safety and inspection requirements that pertain to France's meat export to the United States. The FSIS auditors determined that the supervisory chain of command of the DDPP/DDCSPP has a mechanism that assesses the inspectors' training needs and provides recommendations as appropriate. There is a well-maintained training on an intranet portal at the central level that offers a series of courses on a wide range of topics, including food safety and animal health. Employees can access the site voluntarily to improve their skills for career advancement or to fulfill requirements to complete specific courses mandated by DGAL. Additionally, United States- based consulting groups have delivered training on a wide variety of food safety subjects, with special emphasis on HACCP, SSOPs, and the FSIS requirements. The FSIS auditors verified the training records of official inspection personnel at DDPP/DDCSPP and local inspection offices, in addition to observing their performance while conducting inspection activities, concluding they have sufficient training to perform their inspection activities.

DGAL maintains administrative and technical support to operate its laboratory system. The official tasks of control are performed according to *Regulation (EC) No. 854/2004*. DGAL ensures that the laboratories possess the personnel, facilities, equipment, and methods necessary to fulfill their mission. Each laboratory is accredited in accordance with *International Organization for Standardization/International Electrotechnical Commission* (ISO/IEC) 17025 standard by the *Comité français d'accréditation* (COFRAC). COFRAC conducts periodic reviews of the activities of the laboratories that DGAL oversees. Official inspection personnel carry out the sampling for official testing programs. DGAL has the authority to suspend any laboratory at any time.

The FSIS audit included onsite visits to the *Laboratoire départemental d'analyse et de recherche*, a government microbiological laboratory located in Périgueux, conducting microbiological testing of samples for establishments certified to export to the United States; and the *Laboratoire Public Conseil, Expertise et Analyse en Bretagne*, a government residue and microbiological laboratory located in Quimper, conducting analytical testing as part of France's national residue program, as well as microbiological testing of official samples. No concerns arose as the result of these reviews.

Testing of certain residues is compulsory by EU regulations while others are determined by risk analysis. The *Agence National de Sécurité sanitaire de l'alimentation, de l'environnement et du travail* (ANSES), is responsible for risk evaluations. Every year a program has to be presented to the EU Commission, which then determines the testing for the residue program. The EU Commission is in charge of each EU member state's residue program, which are adapted according to specific situations.

The FSIS determined that the French government organizes and administers the country's meat inspection system, and that DGAL officials enforce laws and regulations governing production and export of meat at certified establishments.

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

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

The evaluation of this component included a review and analysis of the information provided by DGAL in the updated SRT and direct observations, onsite records review, and interviews during the onsite audit. The FSIS auditors verified that DGAL maintains regulatory authority as outlined in official legislation, regulations, decrees, policies, and guidelines. DGAL's authority is in accordance with the following:

- *Regulation (EC) Nos. 178/2002* and *852/2004* on the hygiene of foodstuffs;

- *Regulation (EC) No. 853/2004* describing specific hygiene rules for the food of animal origin;
- *Regulation (EC) No. 854/2004* describing specific rules for the organization of official controls on products of animal origin intended for human consumption;
- *Regulation (EC) No. 882/2004* on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- *Regulation (EC) No. 1099/2009* on the legal requirements for the humane handling of animals in the slaughter establishments;
- *Decision 98/258/EC* on the conclusion of the Agreement between the European Community and the United States on sanitary measures to protect public and animal health in trade in live animals and animal products;
- *French Rural Code* describing the authority of official controls over regulated food operating business;
- *The Order 4 of June 8, 2006* on laws concerning approval of establishments for marketing products derived from animal for human food;
- *French Regulation of May 4, 2010* describing laws pertaining to withdrawal time of veterinary drugs in animals for human food;
- *The Order of July 29, 2013* on laws on defining first and second category health hazards for animal species;
- *Memorandum DGAL/Sous direction des affaires sanitaires européennes et internationals/sub directorate for international and European sanitary affairs (SDASEI)/2014-393* dated 05/20/2014 describing the terms for the certification of official establishments to export to certain third countries of fresh meat, meat and poultry products, milk products, and fish products, as well as the procedures for certifying official establishments to export to these third countries; and
- *Memorandum DGAL/SDASEI/2017-49* on the provisions for the export of meat and meat products to the United States.

The FSIS auditors interviewed the DGAL personnel, and reviewed records maintained at DGAL headquarters and local inspection offices in each audited establishment. The FSIS auditors verified that DGAL provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for France's meat food safety system. The FSIS auditors, accompanied by the DGAL representatives, observed the performance of verification activities by the government inspection personnel.

The verification activities observed included ante-mortem inspection; humane handling and slaughter verification; post-mortem inspection; zero-tolerance verification of establishment's procedures for controlling feces, ingesta, and milk contamination; N60 sampling; analysis of establishment generic *E. coli* sample results; verification of pre-operational and operational sanitation verification procedures; and HACCP verification activities. Additionally, the FSIS auditors assessed the performance evaluation of government inspection personnel and the completion of supervisory reviews of establishments certified eligible to export to the United States.

The FSIS auditors verified that the government inspection personnel's ante-mortem inspection activities complied with EU regulations and *Memorandum DGAL/SDASEI/2017-49* on instructions for certified establishments eligible to export to the United States. DGAL ensures that only meat

products originating from establishments certified for export to the United States, and currently not restricted by the USDA's Animal and Plant Health Inspection Service, are designated for export to the United States. The inspection personnel reviewed the incoming registration and identification documents with each load/truck. They also observed all animals while at rest and in motion in the unloading and ante-mortem inspection pens prior to slaughter to determine whether the animals are fit for slaughter.

The FSIS auditors observed and verified that all animals had access to water at all times in all holding pens, including the suspect pen, and that if an animal was to be held overnight, feed would be provided. For each inspected lot, DGAL personnel document the results of ante- mortem inspection and numbers of livestock accompanying each lot to slaughter.

Each audited establishment maintained a designated holding pen for further examination of sick or suspect animals. The OV examines any suspect livestock identified with conditions that may preclude slaughter, and documents the results on a form designated for ante-mortem inspection. Additionally, the OV documents livestock condemned on either ante-mortem or post-mortem inspection on a condemnation form and all products are rendered unsuitable for human food. The implementation of ante-mortem inspection complies with United States requirements for ante-mortem inspection of livestock.

France's food safety system provides for the humane handling and slaughter of livestock. DGAL has the legal power to enforce legislation. Relevant training is provided related to the protection of animals at the time of slaughter and related operations. *Regulation (EC) No. 1099/2009* describes the legal requirements for the humane handling of animals in the slaughter establishments. DGAL maintains written requirements to provide for the humane treatment of livestock at slaughter. The OV verifies compliance with relevant EC and national rules on animal welfare (humane handling), such as rules concerning the protection of animals at the time of slaughter and during transport as part of the Veterinary Inspector's daily inspection and documentation of the findings.

The FSIS auditors verified that the inspection system ensures United States requirements are met for livestock facilities and humane handling and slaughter. Government inspection personnel verify that operators comply with humane handling and humane slaughter requirements. Deficiencies noted in the 2015 audit concerning potential injury in receiving pens and unloading docks were corrected and confirmed. The FSIS auditors observed the stunning process and verified the veal and pork slaughter establishments were providing adequate stunning prior to shackling and hoisting. The government inspection personnel verified that the animals were insensible to pain; and through observation, the loss of consciousness and accompanying indicative signs of adequate stunning before being shackled and bled.

The requirements for conducting post-mortem inspection are described in legislation and are documented procedures of DGAL. The OV is responsible for supervising post-mortem procedures. Post-mortem inspection must be conducted for every animal slaughtered, whether for domestic use or export to another country. The post-mortem inspection is conducted by government inspection personnel that must be physically present in the facility during every stage of slaughter.

The FSIS auditors verified continuous post-mortem inspection activities during and after the slaughter of swine and veal through onsite record reviews, interviews, and observations of inspectors conducting post-mortem inspection. This includes zero tolerance verification for fecal material, milk, and ingesta performed by the on-line government inspection personnel on each carcass slaughtered during all slaughter operations. Government inspection personnel are trained in performing post-mortem inspection activities. The FSIS auditors verified that the proper presentation, identification, examination, and disposition of carcasses and parts are being implemented.

The FSIS auditors also verified that audited establishments are providing government inspection personnel with the appropriate facilities to conduct post-mortem inspection (i.e., inspection stations, adequate lighting, etc.). The FSIS auditors observed the performance of examination of carcasses and viscera at each certified establishment and verified government inspection personnel were implementing DGAL's government inspection procedures as written.

During the post- mortem inspection, the government inspection personnel verify there is no fecal, ingesta, or milk contamination. In addition, an official off-line inspection plan must be arranged so that the government inspection personnel can check the absence of contamination by visual inspection, according to predefined procedures, on randomly selected carcasses. The number of carcasses selected for visual inspection of internal and external surfaces depends on the number of animals slaughtered and the random selection procedure is defined in the inspection plan. The sampling location is after the post- mortem inspection station and before cooling. The government inspection personnel will also check that there is no non-fecal contamination (e.g., hair, etc.).

The FSIS auditors observed the off-line OVs conducting daily inspection and verification activities in all four audited establishments and verified that government inspection occurs at least once per shift during the processing of meat products. The OVs are permanently located in all meat and processing establishments and are responsible for the supervision of inspection personnel assigned to those establishments. The inspection system provides for continuous (daily) inspection of preparation of meat products and oversight by official supervision.
Disposition of suspect animals during ante-mortem and post-mortem inspection and verification of acceptability of the final product are the responsibility of the OV, who prepares daily post-mortem disposition reports to document his/her official control actions. The government inspection personnel verification procedures and instructions are documented in *Memorandum DGAL/SDASEI/2017-49*. This document also details specific instructions for verification of United States requirements.

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

At each audited slaughter establishment, the FSIS auditors observed the sanitary dressing processes to verify implementation of practices that maximize the prevention of contamination during

dressing procedures and viscera removal. The FSIS auditors also observed government inspection personnel conducting verification of monitoring of the critical control point (CCP) for zero tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditors verified the controls to ensure the veal product is free from specified risk materials (SRMs) at the veal slaughter and processing establishment.

The FSIS auditors verified that the government inspection personnel identify tonsils and distal ileum associated with cattle of less than 30 months of age in the product and ensure any veal products they inspect and pass are free of these SRMs. The FSIS auditors did not observe any systemic sanitary dressing concerns.

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

The periodic supervisory review reports are distributed to the audited establishment's management and the related departmental office. The OV is responsible for the verification of corrective actions resulting from the review. The supervisory reviews evaluate the adequacy of the establishments' food safety systems and the capability of government inspection personnel of conducting inspection activities at certified establishments. The FSIS auditors did not identify any negative trends based on the supervisory review records and inspection- related verification activity records reviewed.

The FSIS auditors verified that there is a separation of product eligible for export to the United States from product not meeting requirements. Government inspection personnel verify that United States-eligible establishments comply with the requirement for separation of product destined for the United States and document results. The FSIS auditors verified use of product codes with designated codes to export to the United States and segregation of final boxed product. The FSIS auditors verified that establishments had written programs to define separation of products destined for export to the United States.

The FSIS auditors determined that the DGAL verification procedures ensure United States requirements are met. In addition, DGAL has consistently ensured the implementation of sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that DGAL requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product

contamination or insanitary conditions. The evaluation of this component included a review and analysis of the information provided by DGAL in the updated SRT and direct observations, onsite records review, and interviews during the onsite audit.

The FSIS auditors reviewed the legislation, regulations, official instructions, decrees, and guidelines of DGAL and verified that DGAL uses its legal authority to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The FSIS auditors' verification activity identified in this component demonstrated that DGAL enforces overarching EU sanitary regulations, including *Regulation (EC) No. 852/2004 Article 4 No. 2 cf.; 4 No. 3 and Annex II*; *853/ 2004 Article 3 cf. Annex II Chapter I-VII, and Annex III; 854/2004 Article 4(2)*, which have been determined to be equivalent to the FSIS requirements. In addition to complying with EU hygiene legislation for requiring food operating businesses to maintain sanitary operating conditions and prevent product contamination, DGAL requires all United States-certified establishments to meet the FSIS requirements for sanitation consistent with provisions specified in 9 CFR Part 416. DGAL issued *Memorandum DGAL/SDASEI/2017-49* delineating the procedures into SSOP and SPS.

DGAL demonstrated that it enforces these requirements at United States-certified establishments. DGAL conducts verification of sanitary conditions in accordance with the aforementioned documents, including the evaluation of written sanitation programs, verification of both pre-operational and operational sanitation implementation and monitoring of sanitation procedures, including hands-on verification inspection, and records review. The FSIS auditors confirmed the verification frequency of sanitation requirements. The government inspection personnel conduct verification of SSOP requirements on a daily basis when production for the United States export is occurring.

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

The FSIS auditors observed the government inspection personnel's verification of operational sanitation procedures in all four audited establishments, comparing the overall sanitary conditions of all audited establishments to the government inspection verification documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records at all establishments. The FSIS auditors also examined the government inspection personnel's documentation of noncompliance reports and supervisory reviews of establishments. The FSIS auditors noted that the inspection and establishment records were reflective of the actual sanitary conditions of the establishment.

The FSIS auditors reviewed the government inspection personnel and establishment records and verified that the government inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination. DGAL

further provided the FSIS auditors with evidence that equipment noncompliances had been corrected and verified to ensure compliance with United States requirements. Deficiencies observed in the 2015 audit concerning sanitation and condensation had been corrected, implemented, and confirmed.

The FSIS auditors' analysis and onsite verification activities indicate that the meat inspection system of France requires that all certified establishments develop, implement, and maintain sanitation programs, including SSOPs, to prevent the creation of insanitary conditions and direct product contamination. Government inspection personnel assess the risks posed by conditions that could cause direct product contamination, and when a noncompliance is identified, they require the establishment to implement adequate corrective actions.

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

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system. The evaluation of this component included a review and analysis of the information provided by DGAL in the updated SRT and direct observations, onsite records review, and interviews during the onsite audit.

France's meat inspection system follows EU requirements for United States-eligible establishments, *Regulation (EC) Nos. 854/2004* and *852/2004*, in which HACCP regulatory requirements are prescribed and found equivalent to 9 CFR Part 417. DGAL ensures that HACCP- based procedures are satisfactory in all United States-eligible establishments and inspections are performed accordingly. All certified establishments are required to implement HACCP system. When any modification is made in the product, process, or any step, certified establishments must review the procedure and make the necessary changes. Chapter III of *Memorandum DGAL/SDASEI/2017-49* states that the HACCP plan is mandatory.

The FSIS auditors conducted an onsite review of each audited establishment's HACCP system, including hazard analyses, HACCP plans, and CCP records. The FSIS auditors observed the government inspection personnel conducting HACCP hands-on verification activities. In addition, the FSIS auditors reviewed the government inspection personnel's HACCP verification records associated with CCPs. The review of the establishments' corrective actions in response to a few deviations from critical limits indicated that the establishments' corrective actions were adequately documented and verified by the government inspection personnel as meeting all HACCP corrective action requirements in 9 CFR 417.3(a).

The FSIS auditors' review of documents pertaining to the hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments, as well as onsite observation of the inspection personnel conducting inspection tasks and associated inspection verification records, revealed an adequate HACCP food safety system in the audited establishments. The only concern arose in the veal slaughter and processing establishment. The DGAL did not provide adequate guidelines to their inspection personnel on how to evaluate the establishment's HACCP system, as evidenced by the inability to provide support for decisions made in the hazard analysis and adequately address *E. coli* O157:H7 and non-O157:H7 STECs. The DGAL did not

provide instructions to inspection personnel to evaluate the supporting documentation required to support decisions made in the hazard analysis, as evidenced by the veal establishment using an antimicrobial intervention for which it was unable to demonstrate effectiveness of reducing or eliminating *E. coli* O157:H7 and non-O157:H7 STECs. At the exit meeting, DGAL stated that it would include guidelines on how to evaluate an establishment's intervention and control programs for veal in a directive to government inspection personnel.

The FSIS auditors verified the completion of corrective actions based on the 2015 audit. In addition, the FSIS auditors' analysis and onsite verification activities indicate that DGAL requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category. FSIS has concerns regarding the veal slaughter establishment and the lack of instructions from DGAL to the government inspection personnel to effectively evaluate veal intervention and control programs.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The 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 and poultry inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed France's National Residue Control Program for 2016, 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 last FSIS audit.

France, in accordance with *EC Directive 96/23*, develops and implements a national residue program each year. This program is furnished to FSIS annually with the previous year's results. France, as a member of the EU, has residue plans that are acceptable by EU standards and therefore equivalent to the FSIS criteria. DGAL uses a system of laboratories that includes public laboratories located in France and other laboratories located throughout the EU. Many of these laboratories are designated as reference laboratories for specific residue areas. Other samples go to other government and public laboratories, as no one laboratory conducts analyses for all residues. The laboratories are accredited by the EU and the French accreditation body for ISO/IEC 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. DGAL maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The requirement of *Article 5 of the EC Directive 96/23* mandates that the country update the national residue control plan for the following year based on the results of the previous year in order to consider changes in chemical group and detection measures. The annual monitoring plan takes into consideration the assessment of sampling results obtained from past sampling tests, including regulated use of veterinary drugs. The plan specifies the analytes to be detected, the method of analysis to be used, the matrix to be collected, the tolerance, and the total number of samples to be collected. According to the chemical residue-monitoring plan in slaughter animals,

there are previously determined targeting criteria that must be respected. They are detailed in the specific instructions for each control plan. On-farm controls of veterinary pharmacies, along with controls carried out in slaughterhouses, ante-mortem, and post-mortem inspections, and chemical residue control plans, ensure that all requirements regarding veterinary drugs and their extra-label use are met.

The FSIS auditors performed an onsite audit of the *Laboratoire Public Conseil, Expertise et Analyse en Bretagne* (LABOCEA), a public residue laboratory in Quimper, which serves as the official laboratory conducting analyses of government samples for the presence of chemical residues in meat products. This laboratory is accredited by the EU and COFRAC for ISO/IEC 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The FSIS auditors reviewed the accreditation and found not issues. . COFRAC last audited LABOCEA in December of 2016. Each audit is valid for 24 months; within 15 months, there is a follow- up before the renewal audit.

The document reviews establish that analysts had successfully completed intra- and inter-laboratory evaluations administered by the supervisor and possessed the competencies necessary to conduct the analyses assigned to them. Additionally, sample handling and frequencies, timely analyses, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control are performed in accordance with the laboratory's quality management program.The FSIS auditors verified receipt of samples in LABOCEA. At sample receipt, the laboratory verifies the seal is intact and matches the number on the laboratory submission form. The laboratory verifies and documents the temperature of the sample and, once verification confirms sample integrity, the laboratory assigns a unique laboratory sample number. LABOCEA rejects the sample if requirements are not met or sample integrity is not maintained. The laboratory sample number alone accompanies the sample through the analytical process to eliminate any potential bias. The FSIS auditors observed the laboratory personnel at the sample receipt area check sample integrity and security, assign the identification, and store the samples in accordance with the laboratory's standard operating procedure.

The FSIS auditors verified that DGAL has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet the FSIS criteria. DGAL requires carcasses to be retained for residue sampling of suspect animals; however, it does not require retention of carcasses for routine residue sampling. DGAL utilizes a Rapid Alert System that informs another country of residues exceeding established tolerances in the event that such product is shipped. The program contains provisions that ensure any product with residues exceeding established tolerances is condemned and ineligible for use as human food. In addition, to prevent the violations from recurring, DGAL investigates the cause of the residue violation and initiates intensified sampling from the same supplier.

The FSIS auditors found no concerns with DGAL's chemical residue control program. The analysis and onsite audit verification indicated that this component includes a national program that is managed and implemented by DGAL as intended.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat, poultry, and egg products produced to export to the United States are safe and wholesome.

The evaluation of this component included an analysis of information provided by DGAL in the SRT and accompanying documents, as well as interviews and observations made during the onsite equivalence verification audit. There have not been any POE violations related to this component since the last FSIS audit.

The evaluation of this component included a review and analysis of *Regulation (EC) No. 2073/2005 of November 15, 2005*, on Microbiological Criteria for Foodstuffs, which contains the regulatory requirements for establishments exporting meat and meat products to the United States. Specific rules for testing and minimum sampling are provided in *Regulation (EC) No. 2073/2005*. DGAL issued *Memorandum DGAL/SDASEI/2017-49* to facilitate the correct implementation of Microbiological Criteria on meat products destined for United States export. This memorandum outlines the microbial testing requirements derived from the aforementioned EU regulation for process control verification; pathogen reduction standards; RTE post-lethality exposed product; and *E. coli* O157:H7 and other non-O157:H7 STECs for establishments slaughtering cattle. DGAL provides a guidance document entitled "Sample Collection Instructions" concerning the maintenance of sample integrity during sample collection and dispatch.

The government inspection personnel conducts verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample integrity. The government inspection personnel verify establishment sampling collection methodology through direct observation and its secure submission of each sample to the public microbiological laboratory for analysis. The government inspection personnel use the test results to verify establishment slaughter dressing controls for fecal contamination. Furthermore, the government inspection personnel verify that each establishment documents and correctly evaluates test results, and takes appropriate corrective actions if the upper control limits are exceeded. The government inspection personnel require that test results for product that is presented for export to the United States be found compliant prior to the export health certificate being approved.

DGAL mandates that all establishments have a recall program in place and a trace back system for product produced. France requires all slaughter establishments to implement an establishment-conducted microbiological testing program for *Enterobacteriaceae* to verify process control. The inspection system provides for a sampling and testing program for generic *E. coli* or *Enterobacteriaceae* in raw meat product. *Enterobacteriaceae* testing has been accepted as equivalent to generic *E. coli* by FSIS. The FSIS audit included direct observation, record review, and interviews of government inspection personnel and private microbiological laboratory personnel to verify microbial process control. The FSIS auditors verified that the audited pork and veal slaughter establishments were testing for *Enterobacteriaceae* and TVC. 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. No concerns were identified.

DGAL has a *Salmonella* spp. sampling and testing program in raw product to meet *Salmonella* Performance Standards requirements. A *Salmonella* testing program for chilled livestock (cattle and swine) carcass sampling is consistent with the provisions of Annex I, Chapter 2 of *Regulation (EC) No. 2073/2005.* Appendix 3 of *Memorandum DGAL/SDASEI/2017-49*, entitled "Reduction of pathogens: *Salmonella*," establishes performance standards for all slaughter species. The attachment provides details on the acceptable limit, method of analysis, and action to be taken when samples test positive for the presence of *Salmonella*. The establishments submit all samples to the public microbiology laboratory for analysis for presence of *Salmonella* spp. Government inspection personnel verify that all certified establishments' sample collection procedures are in accordance with the sample collection protocols; and analyze results to determine the effectiveness of the establishments' *Salmonella* control programs.

Regulatory *Salmonella* sampling is performed by government inspection personnel with samples analyzed using the ISO 6579 method for which an equivalence determination by FSIS has been granted. Establishment approval is suspended for failure to comply with *Salmonella* performance criteria. Continuing failure despite the implementation of corrective actions by the establishment leads to withdrawal of establishment approval. The FSIS auditors determined that the *Salmonella* testing program instituted by DGAL meets the FSIS criteria for microbiological testing for this pathogen.

DGAL has microbiological testing programs for *Salmonella* in RTE products and *Lm* in RTE products, product-contact surfaces, and non-product-contact surfaces (environmental). These inspections are implemented in establishments certified to export RTE meat-based products to the United States. The technical instruction *Memorandum DGAL/SDSSA/2017-49* requires that RTE establishments consider the hazard of *Lm* contamination of RTE products and control the pathogen through their HACCP plans, SSOP, or other prerequisite programs. Appendix 2 of *Memorandum DGAL/SDSSA/2017-49* contains requirements for microbiological testing that establishments producing RTE post-lethality exposed product are to implement to verify the efficacy of their *Lm* control program. The regimen for the testing program includes product testing, testing of FCS, and testing of the production environment with frequencies similar to those utilized domestically in the United States.

The government inspection personnel perform systematic random sampling and testing of RTE products, with the exception of commercially sterile products. The samples are collected to be tested for *Salmonella* spp. and *Lm*; and testing RTE post-lethality exposed product likely to be re-contaminated with *Lm* by the environment. The sampling frequency depends on the risk analysis. Samples are collected throughout the year depending on the production. These tests are done in addition to the random sampling program and are only aimed at detecting *Lm* on FCS. Through interviews with government inspection personnel and review of official records maintained at the local inspection office, the FSIS auditors verified that DGAL routinely conducts official sampling of RTE post-lethality exposed product, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective.

The FSIS auditors performed an onsite audit of the *Laboratories départemental d'analyse et de recherche* (LDAR), a public microbiological laboratory at Périgueux. LDAR conducts official microbiological testing on raw pork and beef products for *Salmonella* performance standards; and on beef products that require testing for *E. coli* O157:H7 and non-O157 STECs. The FSIS auditors verified the following: COFRAC last audited LDAR in December of 2016; LDAR holds the accreditations for the analytical methods for *E. coli* O157:H7 and non-O157 STECs; and LDAR is accredited as equivalent to ISO/IEC 17025. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support DGAL's inspection program for certified establishments eligible to export to the United States. The FSIS auditors reviewed the training materials, records, and the results of laboratory proficiency testing. The FSIS auditors observed and verified sample receipt and handling by LDAR. The FSIS auditors verified that LDAR performs a timely analysis of samples, that they report the number of analyzed samples and the results in a timely manner, apply approved analytical methodologies, and have quality assurance programs. No concerns arose as a result of these observations and reviews.

The FSIS auditors' document analysis and onsite verification activities demonstrate that France's meat inspection system includes requirements for a microbiological sampling and testing program. It is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The microbiological testing program as described is consistent with the criteria established for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 31, 2017, in Paris, France with DGAL. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

The current audit did not identify any concerns that represented an immediate threat to public health. During the audit exit meeting, DGAL committed to begin addressing the preliminary finding as presented and provided additional evidence that the isolated finding related to HACCP described on the individual establishment checklist (Appendix A) had been addressed. The FSIS auditors identified the following systemic findings:

Government HACCP System:

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

FSIS received a written response from the CCA addressing all outstanding concerns identified in the draft final audit report. FSIS will evaluate the adequacy of the proposed corrective actions and base its activities for future equivalence verification on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Haraguy-Jambon De Bayonne RTE De Sauveterre 64120 Aicirits Camou Suhast	03/21/17	FR 64.010.003 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/21/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pyragena Abiopole Rte De Samadet 64410 Arzacq Anaziguet, Pau	03/22/17	FR 64.063.004 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/22/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sobeval Zone Industielle Av Louis Lescure Boulazac, 24750 Perigueux	03/27/17	FR 24 .053.001	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment FR 24 .053.001

15. **The FSIS auditors identified the following:**

•The veal slaughter establishment was not able to support the decisions made in the hazard analysis that *E. coli* O157:H7 was not reasonably likely to occur in the slaughter process due to insufficient control mechanisms demonstrating effective monitoring and intervention. The zero tolerance CCP is not sufficient to control the microscopic pathogen *E. coli* O157:H7. If the pathogen *E. coli O*157:H7 is likely to occur, then it must be addressed in the HACCP plan through one or more CCPs to control the pathogen and should put into place one or more validated CCPs to reduce or eliminate *E. coli* O157:H7.

•The veal slaughter establishment used lactic acid as a preventative measure prior to chilling. The lactic acid was mixed at the beginning of the shift and was not monitored throughout the shift. An establishment needs to manage lactic acid by measuring the out-going concentration and temperature; anything over 5 % needs to be declared an ingredient. An establishment also needs to be able to support its decisions in the hazard analysis, the veal establishment had no supporting documentation.

Explanation: A beef (veal) slaughter establishment's "zero tolerance" CCP is designed to identify visible fecal, ingesta, and milk contamination and is not sufficient to control the microscopic pathogen *E. coli* O157:H7. A beef (veal) slaughter establishment's CCP for the identification of visible fecal contamination is an indication of the establishment's control of its sanitary dressing procedures during the slaughter process. If an establishment determines that *E. coli* O157:H7 contamination is a food safety hazard reasonably likely to occur in the production process, then it must be addressed in a HACCP plan. FSIS has indicated that the beef (veal) slaughter establishments need to put one or more validated CCPs in place that are designed to eliminate or reduce *E. coli* O157:H7 and other pathogens. Section 417.2(a) (1) of the HACCP regulations states that a food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish control measures because the hazard historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. In addition to a CCP to address the microbiological food safety hazard, the establishment needs to have other controls in place to limit the cross-contamination and spread of the pathogen in subsequent steps in the slaughter process.

Summary: The establishment did not provide supporting documentation for its interventions to control *E. coli* O157:H7 and non-O157:H7 STECs, using zero tolerance as its only CCP, even though lactic acid was being used as an antimicrobial intervention control measure. The establishment was unable to identify critical control points designed to control food safety hazards that could be introduced into the establishment. The DGAL did not provide adequate instructions to the government inspection personnel to effectively evaluate how the beef (veal) establishment was supporting the control of *E. coli* O157:H7 and non-O157:H7 STECs at the end of their slaughter process.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/27/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Jean Henaff Production Ker Hastell 29710 POULDREUZIC Quimper	03/29/2017	FR 29.225.001 CE	France
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/29/2017

Appendix B: Foreign Country Response to Draft Final Audit Report

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REPUBU®E F'RANc;AISE

MINISTERE DE L'AGRICULTURE
ET DE L1ALIMENTATION

Direction Generale de l'**Alimentation**

Sous direction des affaires sanitaires europeennes et internationales

Service de la gouvernancc ct de ['international dans Jes domaines snnitaire ct alimcntairc

Bureau export pays tiers (BEPT)

251, rue de Vaugirard
75732 Paris Ccdex 15
FRANCE

Madame Jane Doherty
International Coordination Executive

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

ETATS-UNIS D[1]AMERIQUE

Paris Je **1 7 AOUT 2017**

Objet: Reponse au rapport d'audlt provlsoire du FSJS concemant les filleres porcine et veau

References : SDASEI EXP 1708013

Affalre sulvle par : Amelie SCHELL
Tel.: +33 (0)1 49 55 81 55 - Fax: +33(0)1 49 55 81 82
Courriel : export.sdasef.dgal@agriculture.gouv .fr

PJ: 18

Madame la Directrice,

J'ai l'honneur de vous adresser en annexe les commentaires de la Direction generale de l'alimentation relatifs au rapport d'audit provisoire du FSIS, faisant suite a la mission qui s'est deroutee en France du 20 au 31 mars 2017.

Vous trouverez ainsi en annexe :

- les commentaires generaux ;
- les actions correctives aux constats formulas a t'encontre de l'un des etablissements audites.

Je vous informe que !'instruction technique pour les exportations depuis la France vers les Etats-Unis d'Amerique de viandes et produits a base de viande de pore et de veau est en cours de mise a jour pour y inclure les remarques de votre rapport d'audit.

Je vous prie d'agree,r Madame la Directrice, !'expression de mes salutations distinguee

Le directeur general .adjoint de l'alimentation
Chef du service de la gouvernance
et de l'internatio:ial
CVO
Lo"ic EVAIN

p,
L'lildjointe'tJ Its sous-directrice des affaires sanitaires eur,peennes et internationales

Sophie PALIN

Informal translation

Object: response to the draft audit report by FSIS on pork and veal

Dear Mrs Doherty,

I am honored to present you with the attached comments of French General Directorate for Food on the draft audit report by FSIS, following the audit conducted in Franc from March, 20 – 31, 2017.

Thus, please find enclosed:

- General comments;
- Corrective actions to answer the observations made on an audited facility.

I also inform you that the rule on exports from France to the US for pork and veal meats and products is being revised to include the observations made in the report.

Please be assured of my most distinguished salutations,

Loic EVAIN , Chief Veterinary Officer

Deputy General Directorate
Head of Governance and International Affaires
French General Directorate for Food

Page	Extract from report	France's comments
2	Pork processing establishments FR 64.063.004 CE / **Pau**	The city isn't "Pau" but "**ARZACQ ARRAZIGUET**"
3	"In addition: … • **Establishments employees collect the official samples for *Salmonella***"	This isn't correct: - employees collect the samples for the establishment's self-inspection – in accordance with appendix 2 of US-Memorandum 2017-49 of January 12th, 2017; - official inspectors collect the official samples for the official inspection – in accordance with appendix 3 of US-Memorandum
5	Memorandum DGAL … (SDSSA)/No. **2012-8119 part II- A A1** …	This Memorandum has been updated and the references changed: - Memorandum 2012-8119 has been replaced by Memorandum DGAL/SDSSA/2016-355 of 19/08/2016; - The food safety management plan has to be inspected by official services before the grant of approval: part 2.2.2 of Memorandum 2016-355; - The food safety management plan has to be inspected by official services during scheduled inspections: part 3 of Memorandum 2016-355.
5	On **February 26, 2015**, DGAL issued a Technical Instruction …	This instruction has been updated and the references are : Technical Instruction DGAL/SDPRAT/2016-940 of 07/12/2016.
6	DGAL is an agency funded by the national government and **whose revenue includes** fees assessed to meat establishments that are adjusted according to the level of Sanitation of the establishment.	DGAL is funded by the government only and do not perceive any other funding. The fees exist but go to the general budget of the State and not directly to DGAL or the Ministry of Agriculture.
6	All fees go to the treasury office within the **MAAF**.	All fees go to the general budget of the State and not directly to a Ministry.
6	The **part-time veterinary practitioners** used within the service **may be paid by the holdings or assembly centers where they perform duties**. These duties include clinical inspection, assessing the fitness for transport of animals intended for intra-community trade, and issuing the relevant documents.	It seems to be confusion between Official Veterinarians and private veterinarians carrying out some specific missions on behalf of the holder of the animals or on behalf of the Government (See Appendix 1 for the missions that can be performed by private veterinarians). In the establishments (slaughter, cutting, process, warehouse, etc.), there are only OVs, paid by the government. They never perform any mission for the establishment and they are never paid by the establishment.
7	Decree No 2011-2090 of 30 December 2011 describes the conditions to be met for the issuance of such authorization, along with the modalities for the assessment of the employees by the OV.	Decree No 2011-2090 describes the modalities for the participation of slaughterhouse staff in the control of the production of **poultry meat and lagomorphs**. This doesn't concern pig or veal meat production. In pig and cattle slaughterhouses, the slaughterhouse staff is not involved in any official control.
7	The FSIS audit included onsite visits to the *Laboratoire départemental d'analyse et de **recherché***	« de recherche » *(no « é »)*
8	The Agence National de Sécurité sanitaire **del'alimentation,** de l'environnement et du travail (ANSES)	« de l'alimentation » *(space missing)*
9	Only swine and veal that originate in France are slaughtered at establishments that are eligible to export to the United States. This ensures that only meat products currently not restricted by the USDA's APHIS are designated for export to the US.	This is accurate but we do not forbid the use of non-French animals. Actually US-Memorandum 2017-49 is being updated and we add: "*2 - Origin of animals* *The animals must come from countries / areas recognized as being free from the main livestock diseases or avian diseases by the US authorities (see I. C :*

		https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status)"
11	The FSIS auditors observed the off-line **OVs** conducting **daily** inspection and verification **activities in all four audited establishments** and verified that government inspection occurs **at least once per shift during the processing of meat products.** The **OVs** are **permanently** located in all meat and processing establishments and are responsible for the supervision of inspection personnel assigned to those establishments. The inspection system provides for **continuous (daily) inspection** of preparation of meat products and oversight by official supervision.	Official inspection personnel (OVs and OAs/technicians) are permanently present in **slaughterhouses**, on- and off-line. In **meat processing establishments**, on USDA-production days, official inspectors (OV or technician) are present at each stage where exposed products are handled directly as well as during the CCP controls (in accordance with US-Memorandum 2017-49 – III B 3 b). Furthermore, in all establishments (slaughter & process), official "supervision" inspections are carried out quarterly and cover the layout of the rooms, equipment, personnel, records, etc. (in accordance with US-Memorandum 2017-49 – III B 3 c).
11	… each establishment OV is responsible for drafting monitoring plans …	… each establishment OV is responsible for drafting **official** monitoring plans …. *(performed by the official inspection personnel, not the establishment)*
13	The government inspection personnel conduct verification of SSOP requirements **daily**.	The government inspection personnel conduct verification of SSOP requirements every time an USDA-production is performed.
19	The FSIS auditors performed an onsite audit of the *Laboratoire départemental d'analyse et de **recherché***	« de recherche » *(no « é »)*
19	The DGAL did not provide adequate guidelines to their inspection personnel on how to evaluate the establishment's HACCP system, as evidenced by a veal establishment that was unable to provide support for decisions made about their hazard analysis in adequately addressing *E. coli* O157:H7 and non-O157:H7 STECs.	- Corrective actions have been taken by the establishment and validated by the local veterinary office (see attachments) ; - Furthermore, US-Memorandum 2017-49 will be updated as follows: *"The risk of E. coli STEC (O157: H7 and 6 non-O157: O26, O45, O103, O111, O121 and O145 serogroups) **must** be taken into account by any establishment handling raw beef or veal. For the control of this hazard, the facility must include measures in the SPS, SSOP and HACCP plan (and, if appropriate, manage a CCP)."*
19	The DGAL did not provide adequate guidelines to their inspection personnel on how to evaluate the supporting documentation required to support decisions made in the hazard analysis, as evidenced by the veal establishment using an antimicrobial intervention for which it was unable to demonstrate the effectiveness of the intervention on reducing or eliminating *E. coli* O157:H7 and non-O157:H7 STECs.	- Corrective actions have been taken by the establishment and validated by the local veterinary office (see attachments) ; - Furthermore, US-Memorandum 2017-49 will be updated as follows: *"Conditions for the use of lactic acid to reduce microbiological surface contamination of carcases, half-carcases or bovine quarters satisfy the requirements of Part I of the Annex to Regulation (EU) No 101/2013 of the Commission of 4 February 2013.* *The minimum criteria and parameters for HACCP controls are as follows:* *- The concentration of lactic acid during the treatment is verified by periodic monitoring, documented and recorded under the HACCP plan;* *- The temperature of the lactic acid solution during the treatment is monitored continuously by means of measuring instruments, documented and recorded as part of the HACCP plan."*

Appendix 1 - Role of private veterinarians in the official Veterinary Services

Le vétérinaire sanitaire	**Le vétérinaire mandaté**
= called “sanitary veterinarian” or “health veterinarian” or “accredited veterinarian” - the veterinarian receives a «clearance» subject to conditions, by the DDPP/DDCSPP - he is designated by the breeder - he can exercise the clearance in no more than 5 *départements* (special cases: for very specialized fields like aquaculture = he can exercise in the whole territory) - he carries out mandatory missions on behalf of the holder of the animals Around 17 000 veterinarians registered by the Order of veterinarians: over 90% are accredited veterinarians. The accredited veterinarian designated by the breeder will be the same one contracted/mandated by the DDPP/DDCSPP to ensure the animal health measures in that farm.	= mandated veterinarian or contracted veterinarian - the veterinarian has a «mandate», subject to conditions, with the DDPP/DDCSPP (a contract) - for a specific mission in a specific *département* - to carry out missions on behalf of the Government
Clearance Obligations of the holder (mandatory prophylaxis, health inspection of the farm, epidemio-surveillance, fairs...) The Government is not responsible for any damage caused or sustained by the veterinarian	**Mandate** Missions commissioned by the Government (EU-trade certification, Animal health restrictions…) The Government is responsible for any damage caused or sustained but the veterinarian
Missions In animal health: - epidemio-surveillance (at the expenses of the Government and/or of the breeders), - inspections and measures taken for screening, immunization or treatment of the animals / prophylaxis led by the Government at the expenses of the breeder, - mandatory health inspections at the rearing house (at the expenses of the Government), - health monitoring (in zoo, breeding establishments), at the expenses of the establishment. In animal welfare (at the expenses of the establishment): - pet stores inspections - monitoring at animal exhibits. No compliances or any notifiable disease suspicion are reported to the DDPP/DDCSPP. In case of export of live animals, if an exam of the animal is required before departure or during quarantine, it will be performed by an accredited veterinarian. He will report to the Official veterinarian at the DDPP/DDCSPP who signs on the basis of the inspection performed by the accredited veterinarian	**Missions** Veterinarians (accredited or not) can be mandated for 3 types of missions : - some specific animal health measures; - some official inspection / official certification regarding food safety or animal trades (EU only); - some inspection or expertise regarding animal welfare. To this day, mainly missions of animal health measures are mandated (the accredited veterinarian of a breeder is de facto mandated in a case of a notifiable disease suspicion or outbreak). Furthermore and following a call for applications, circa 238 veterinarians have been mandated by the DDPP/DDCSPP to officially certify the EU-trade of some specific live animals and 136 have been mandated for specific health measures in bee-keeping.

Mission USA - USDA-FSIS / Viande porcine et viande de veau / 20-31/03/2017

SOBEVAL - Boulazac
FR 24.053.001 CE

Audit: 27/03/2017

PLAN D'ACTIONS CORRECTIVES / *CORRECTIVE ACTION PLAN*			
N°	**NON CONFORMITES / *NON CONFORMITIES***	**ACTIONS CORRECTIVES / *CORRECTIVE ACTIONS***	**DOCUMENTS ASSOCIES / *DOCUMENTS ASSOCIATED***
1	The veal slaughter establishment was not able to support the decisions made in the hazard analysis that E. coli O157:H7 was not reasonably likely to occur in the slaughter process due to insufficient control mechanisms demonstrating effective monitoring and intervention. The zero tolerance CCP is not sufficient to control the microscopic pathogen E. coli O157:H7. If the pathogen E. coli O157:H7 is likely to occur, then it must be addressed in the HACCP plan through one or more CCPs to control the pathogen and should put into place one or more validated CCPs to reduce or eliminate E. coli O157:H7.	En se basant sur des données bibliographiques, nous avons mis à jour le plan HACCP, et notamment la partie analyse des dangers et étude du risque concernant *Escherichia coli* et plus particulièrement *E. coli* O157:H7. Le CCP 1B (absence de souillures visibles par la matière fécale, ingestats, lait ou poils) est complété par le CCP 2B (application de l'acide lactique pour la maitrise, réduction ou élimination du pathogène) développé dans l'item ci-dessous. *Based on the bibliography, we have updated the HACCP plan, and in particular the part concerning the dangers analysis and the risks study in regard of Escherichia coli and more precisely E. coli O157:H7.* *The CCP1B (no visible soiling of fecal material, ingesta, milk or hair) is completed with the CCP 2B (lactic acid application to control, reduce or eliminate the pathogen) developed in the under item.*	Bibliographies / *Bibliography* : Annex 1. Isolation of *E.coli* from retail fresh meats and poultry Mise à jour du plan HACCP / *HACCP update* : Annex 2. EN.US-AB-Risks assessment V5_slaughter Annex 3. EN.US-2T-Risks assessment V3_cutting Annex 4. EN.US-AB-Production DiagramV2_slaughter Procédures / *Procedures* : Annex 5. FR_Procedure_Risk management E. coli & Salmonella

PLAN D'ACTIONS CORRECTIVES / *CORRECTIVE ACTION PLAN*			
N°	**NON CONFORMITES / *NON CONFORMITIES***	**ACTIONS CORRECTIVES / *CORRECTIVE ACTIONS***	**DOCUMENTS ASSOCIES / *DOCUMENTS ASSOCIATED***
2	The veal slaughter establishment used lactic acid as a preventative measure prior to chilling. The acid lactic was mixed at the beginning of the shift and was not monitored throughout the shift. An establishment needs to manage lactic acid by measuring the out-going concentration and temperature, anything over 5% needs to be declared an ingredient. An establishment also needs to be able to support its decisions in the hazard analysis, the veal establishment had no supporting documentation.	En se basant sur des données bibliographiques et la réglementation européenne et américaine, nous avons retenu l'utilisation d'acide lactique à une concentration de 4% (≥ 2 % et ≤ 5%) et à une température ≥ 30°C et ≤ 45°C pour la décontamination des carcasses. Pour cela, nous avons effectué des tests d'efficacité sur plusieurs carcasses et avons constaté la diminution significative de la population des entérobactéries. Une cinétique de refroidissement de la solution au cours de son utilisation a été réalisée ainsi qu'une cinétique de maintien de la concentration dans le temps. L'utilisation d'acide lactique est gérée en tant que CCP (nommé CCP2 B dans les documents). Nous avons mis à jour la procédure et les documents d'enregistrements en prenant en compte ces éléments. *Based on the bibliography and the European and American regulations we choose lactic acid using at a concentration of 4% (≥ 2 % et ≤ 5%) and a temperature ≥ 30°C et ≤ 45°C for carcasses decontamination.* *In this purpose, we realised efficiency tests on several carcasses and we have noted a significant decrease of enterobacteries population.* *A temperature kinetics of the solution during the application has been realised as well as a solution concentration kinetics.* *The use of lactic acid is considered as a CCP (CCP 2B in included documents).* *We updated the procedure and the records taking in account these factors.*	Bibliographies / *Bibliography* : Annex 6. Commission Regulation (EU) No 101-2013 Annex 7. Effects of acid adaptation of E.coli Annex 8. FR_Directive_Use of lactic acid in cattle slaughterhouses (AFSCA - Belgium CCA) Contôle efficacité / *Efficiency control* : Annex 9. Verification of effectiveness Annex 9b. FR_Verification of effectiveness & test results Cinétiques / *Kinetics* : Annex 10. FR_Kinetic study of temperature of lactic acid solution Annex 11. Kinetic study of concentration of lactic acid solution Procédures / *Procedures* : Annex 12. FR_MOPALABUS_Procedure_How to make and use the lactic acid solution Annex 4. EN.US-AB-Production DiagramV2_slaughter Enregistrements / *Records* : Annex 13. FR_AB ENR CCP2B Ind 00_Record_CCP2B_temperature & concentration of lactic acid solution Annex 14. FR_EQEXPED_Record_Pre-shipment control