United States Department of Agriculture

Food Safety and
Inspection Service

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APR 0 1 2020

Dr. Hanne Larsen
Chief Veterinary Officer
Danish Veterinary and Food Administration
Ministry of Environment and Food of Denmark
Stationsparken 31-33
2600 Glostrup
Denmark

Dear Dr. Larsen,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Denmark's meat inspection system from November 4 through November 15, 2019. Enclosed is a copy of the final audit report. The comments received from the Government of Denmark are included as an attachment to the report.

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

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

DENMARK

NOVEMBER 4 – 15, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

April 1, 2020

Food Safety and Inspection Service
United States Department of
Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from November 4 – 15, 2019. The purpose of the audit was to determine whether Denmark's food safety inspection system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Denmark currently exports the following categories of products to the United States: thermally processed, commercially sterile pork; ready-to-eat (RTE) pork fully-cooked without subsequent exposure to the environment; RTE fully-cooked pork; RTE dried pork; RTE acidified/fermented pork (without cooking); raw intact pork; raw non-intact pork; and not ready-to-eat otherwise processed pork.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration, Enforcement Authority, Government Inspection Personnel-Training/Staffing); (2) Government Verification of Food Safety and Other Consumer Protection Requirements (e.g., Humane Handling, Ante-Mortem Inspection, Post-Mortem Inspection, Product Standards and Labeling); (3) Government Sanitation Verification; (4) Government Hazard Analysis and Critical Control Point (HACCP) System Verification; (5) Government Chemical Residue Program; (6) Government Microbiological Pathogen and Process Control Programs.

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

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The Central Competent Authority (CCA) inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing export certificates.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The CCA's national chemical residue program has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

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

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Denmark's food safety system from November 4 – 15, 2019. The audit began with an entrance meeting held on November 4, 2019, in Glostrup, Denmark, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Danish Veterinary and Food Administration (DVFA). During the audit exit meeting on November 15, 2019, the DVFA committed to address the preliminary findings. Representatives from the DVFA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products[1]
Raw – Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Ground product; other non-intact; and sausage.
Raw – Intact	Raw intact pork	Boneless manufacturing trimmings; carcass (including halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primals and subprimals.
Thermally Processed/Commercially Sterile	Thermally processed, commercially sterile	Corned (species); ham; other; sausage; and soups.
Not Heat Treated – Shelf Stable	Not ready-to-eat (NRTE) otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.
Not Heat Treated – Shelf Stable	Ready-to-eat (RTE) acidified/fermented meat (without cooking)	Other – not sliced; other – sliced; sausage/salami – not sliced; and sausage/salami – sliced.
Not Heat Treated – Shelf Stable	RTE dried meat	Ham – not sliced; ham – sliced; jerky; other – not sliced; and other – sliced.

[1] All source meat used to produce meat products must originate from eligible countries and certified establishments eligible to export to the United States. For processed meat products, meat includes the following species: beef, goat, lamb, mutton, pork, and veal.

Process Category	Product Category	Eligible Products[1]
Not Heat Treated – Shelf Stable	RTE salt-cured meat	Not sliced; and sliced.
Heat Treated – Shelf Stable	NRTE otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.
Heat Treated – Shelf Stable	RTE acidified/fermented meat (without cooking)	Other – not sliced; other – sliced; sausage/salami – not sliced; and sausage/salami – sliced.
Heat Treated – Shelf Stable	RTE dried meat	Ham – not sliced; ham – sliced; jerky; other – not sliced; and other – sliced.
Heat Treated – Shelf Stable	RTE salt-cured meat	Not sliced; and sliced.
Fully Cooked – Not Shelf Stable	RTE fully-cooked meat	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Fully Cooked – Not Shelf Stable	RTE fully-cooked meat without subsequent exposure to the environment	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Heat Treated but not Fully Cooked – Not Shelf Stable	NRTE otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; sausage products; smoked parts; and soups.

The USDA's Animal and Plant Health Inspection Service recognizes Denmark as free of African swine fever, foot-and-mouth disease, and swine vesicular disease, and low risk of classical swine fever with restrictions.

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

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

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

Administrative functions were reviewed at CCA headquarters, two regional offices, and ten local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 10 establishments (six pork slaughter and processing establishments and four pork processing) was selected from a total of 24 establishments certified to export to the United States. The products these establishments produce and export to the United States include thermally processed, commercially sterile (TPCS) pork; ready-to-eat (RTE) pork fully-cooked without subsequent exposure to the environment; RTE fully-cooked pork; RTE dried pork; RTE acidified/fermented pork (without cooking); raw intact pork; raw non-intact pork; and not ready-to-eat (NRTE) otherwise processed pork.

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

Additionally, FSIS visited the microbiology and chemical residue units at the DVFA Laboratory to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• DVFA, Glostrup
	Regional	2	• Meat Inspection Unit, Lystrup • Food Inspection Unit, Vejen
Laboratories		2	• DVFA Laboratory, Microbiology Unit, Ringsted • DVFA Laboratory, Chemical Residue Unit, Ringsted

Pork slaughter and processing establishments	6	• Establishment No. 14, Danish Crown, Sonderborg • Establishment No. 25, Danish Crown, Ringsted • Establishment No. 31, Danish Crown, Herning • Establishment No. 71, Danish Crown, Saeby • Establishment No. 320, Danish Crown, Horsens • Establishment No. 801, SB Pork A/S, Brorup
Pork processing establishments	4	• Establishment No. 53, Danish Crown, Esbjerg • Establishment No. 65, Tulip Food Company, Vejle • Establishment No. 170, Agri-Norcold A/S, Vejen • Establishment No. 211, Tulip Food Company, Svenstrup J

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] Section 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR §301 to the end).

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

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EU) No. 142/2011;
- Council Directive No. 93/119/EC;
- Council Directive No. 96/22/EC; and
- Council Directive No. 96/23/EC.

III. BACKGROUND

From July 1, 2016 to June 30, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 230,265,137 pounds of meat from Denmark. This included 34,259,119 pounds of TPCS pork; 47,166 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 127,679 pounds of RTE fully-cooked pork; 3,496,196 pounds of RTE dried pork; 3,639,476 pounds of RTE acidified/fermented pork (without cooking); 187,194,173 pounds of raw intact pork; 562,016 pounds of raw non-intact pork; and 939,312 pounds of NRTE otherwise processed pork exported by Denmark to the United States.

FSIS also performed additional types of inspection on 20,385,674 pounds of pork (3,177,785 pounds of TPCS pork; 27,132 pounds of RTE fully-cooked pork; 2,145,018 pounds of RTE dried pork; 573,698 pounds of RTE acidified/fermented pork (without cooking); 14,331,800 pounds of raw intact pork; 33,775 pounds of raw non-intact pork; and 96,466 pounds of NRTE otherwise processed pork). These additional types of inspection included testing for chemical residues and microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products).

As a result of this additional testing, 129,310 pounds of pork were rejected for issues related to public health, including one lot (9,735 pounds) of boneless pork bellies for fecal contamination and eight lots (119,575 pounds) of raw intact pork identified as being off-condition. The current audit included visits to the two establishments implicated in these POE violations to verify the corrective actions submitted by the DVFA in response to the notification issued by FSIS. The result of this audit verification activity indicated that the corrective actions had been implemented as communicated.

The previous FSIS audit in March 2018 identified the following finding:

Summary of Findings from the 2018 FSIS Audit of Denmark
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
• Inadequate government verification of corrective actions associated with HACCP requirements for the support of critical control point monitoring frequencies in six of the seven visited slaughter establishments. The DVFA's inspection system did not effectively verify the adequacy of Denmark's HACCP system.

The FSIS auditors verified that the corrective actions for the previously reported findings were implemented and effective in resolving the finding.

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

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

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be

organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; 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 FSIS auditors verified that there have not been any major changes in the CCA's organizational structure since the last FSIS audit conducted in 2018. The DVFA serves as the CCA under the Ministry of Environment and Food and is divided into four departments: the Finance and Meat Inspection Department, the Veterinary Department, the Food Safety Department, and the Export and Innovation Department. The DVFA headquarters office is in Glostrup, with local offices and laboratories located throughout the country. Food safety requirements and veterinary inspections are implemented by the Food Inspection Units (FIUs), Veterinary Inspection Units (VIUs), and Meat Inspection Units (MIUs).

The primary role of a VIU is to inspect farm animals, to develop and maintain emergency response to infectious livestock diseases, and to combat disease outbreaks. The inspection of farm animals includes the inspection of animal welfare, veterinary drugs, and animal transport conditions. The FIU is in charge of the inspection in processing establishments and cold storage facilities. This includes inspection of the establishment's control programs, hygiene control, and labeling issues. The MIU is responsible for inspection in slaughter establishments, as well as for animal welfare and animal health.

The FSIS auditors verified that in-plant inspection personnel consist of government veterinarians and inspectors (official auxiliaries) who are full-time government employees paid by the Danish government. The FSIS auditors reviewed a sample of daily and monthly inspection verification reports at each visited establishment and verified that the DVFA applies uniform standards of inspection across all establishments certified to export to the United States.

The DVFA's Audit Unit (AU) is responsible for conducting periodic supervisory reviews at establishments certified to export to the United States. The AU ensures that establishments certified to export to the United States comply with DVFA and FSIS requirements, evaluates the performance of the inspection personnel, trains the inspection personnel, and assists in updating or developing inspection legislation and guidelines.

The DVFA has adopted the European Union (EU) legislation pertaining to production of food of animal origin to ensure that the same set of laws, regulations, and policies are applied consistently to all food producing establishments. In addition, the DVFA has adopted FSIS regulatory requirements to ensure uniform and standardized implementation of FSIS inspection requirements in all establishments certified to export to the United States. The DVFA develops technical guidance or orders concerning implementation of FSIS requirements and disseminates this information to all levels of inspection. The updated information or revised policies are discussed during supervisory visits with the inspection personnel.

The FSIS auditors verified that inspection personnel were responsible for ensuring that requirements for product exported to the United States were met in accordance with the DVFA's instructions. The inspection personnel's export verification activities included examination of product condition (i.e., type, volume, and source); review of associated documents, including labeling and establishment pre-shipment review records; and issuance of official meat inspection certificates. The final export certificate is signed and issued by FIU veterinarians. FSIS auditors confirmed that the DVFA has procedures in place to ensure the security and integrity of these certificates.

The FSIS auditors' review of records indicated that inspection personnel routinely confirmed (although not a specific CCA requirement at the time of the audit) acceptable test results of government microbiological sampling (i.e., "hold and test") prior to certifying product for export to the United States. However, the FSIS auditors identified a potential weakness regarding the export certification of product tested in conjunction with the government chemical residue monitoring program. The FSIS auditors observed that, while in many cases the visited slaughter establishments elected to retain carcasses at their own discretion pending receipt of satisfactory results, this is not an explicit requirement within Denmark. Furthermore, the FSIS auditors observed that, in the case of those chemical analyses for which it may take several weeks to receive results, the sampled carcass would be fabricated (broken down), boxed, and moved to a cold storage facility under establishment control.

Discussions with DVFA representatives indicated that FIU veterinarians were not expected to confirm acceptable government chemical testing results for product originating from cold storage facilities prior to signing export certificates, and that confirmation of acceptable chemical residue test results would only occur during spot checks of records pertaining to the establishment's export control program. However, FSIS requires that acceptable results of government testing be confirmed by government inspection personnel on each shipment of product exported to the United States. Consequently, the FSIS auditors identified the following finding:

- The CCA inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing export certificates.

The FSIS auditors confirmed that in-plant inspection personnel verify that raw meat products originate only from establishments certified to export to the United States. The FSIS auditors verified the source of raw products for further processing by cross-referencing domestic declarations with associated pre-shipment records. The FSIS auditors confirmed through interviews and record reviews that in-plant inspection personnel ascertain by means of the traceability process, space, or time the proper implementation of the establishment's procedures to separate production operations for the U.S. market from product destined for other markets.

The FSIS auditors verified that the DVFA has the legal authority and responsibility to certify, de-certify, or take appropriate enforcement measures in establishments certified to export to the United States. The FSIS auditors reviewed the DVFA approval process for establishments that apply to be designated as certified to export to the United States. Following the submission of an

establishment's application, the inspection personnel review establishment documents and conduct an on-site inspection of the establishment. The DVFA has the authority to approve the application following the acceptable results of the document review, on-site audits, and implementation of appropriate corrective actions. There have not been any major changes in the DVFA's approval process to certify establishments since the last FSIS audit in 2018.

The DVFA's enforcement measures may include taking regulatory control action, withholding actions, or suspension. The FSIS auditors reviewed a sample of noncompliance reports (NRs) generated by government in-plant inspection personnel to verify that in-plant inspection personnel had identified deficiencies during pre-operational and operational verification activities. The in-plant inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditors reviewed documentation on a selection of open and closed NRs, and the auditors determined that in-plant inspection personnel have adequately described noncompliances and verified the effectiveness of the establishment's corrective actions.

The FSIS auditors verified that the audited establishments have developed and implemented traceability and recall procedures in accordance with the DVFA's requirements. The establishments' procedures provide written instructions that include: (a) traceability mechanisms to ensure source materials originate from establishments certified to export to the United States; (b) separation from establishments not certified to export to the United States or ineligible products, and (c) recordkeeping requirements. The in-plant inspection personnel verify the efficacy of these procedures during their inspection verification activities. The FSIS auditors reviewed the in-plant inspection personnel's documented verification records and associated traceability records. These documents met the DVFA's requirements, and the FSIS auditors found no concerns.

The FSIS auditors verified through document reviews and interviews that in-plant inspection personnel possessed the educational credentials, training, and experience to carry out their assigned tasks. Since the last FSIS audit in 2018, the DVFA has organized ongoing training programs on its website known as "CAMPUS" for inspection personnel in establishments certified to export to the United States. Training courses have covered such subjects as pathogen reduction/HACCP, sanitation, traceability, and FSIS import requirements. In addition to reviewing training records from 2018 to 2019, the FSIS auditors interviewed in-plant inspection personnel to assess their knowledge, skills, and abilities. The FSIS auditors confirmed that in-plant inspection personnel assigned to establishments certified to export to the United States have attended the ongoing trainings. The training participation records were adequate and proper documentation was maintained at inspection offices. In addition, the FSIS auditors reviewed inspection documentation concerning performance evaluations of in-plant inspection personnel. The review of these documents did not raise any concerns.

An FSIS auditor visited the microbiology and chemical residue units at the DVFA Laboratory. This is a government laboratory that conducts analyses of meat (pork) products intended for export from Denmark to the United States. These laboratories are accredited by the Danish Accreditation Body (DANAK) in accordance with the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025,

General requirements for the competence of testing and calibration laboratories. The FSIS auditor verified that DANAK conducts the prescribed audit of the laboratory quality systems once every fifteen months and that the laboratory is responding to and implementing corrective actions in response to any audit findings. These laboratories also perform internal audits according to their Quality Assurance Manual once a year.

The FSIS auditor observed a demonstration by laboratory personnel on sample receipt and handling, including checking sample integrity and security, registration of the sample in the Laboratory Information Management System, and assigning the identification and storage of samples in accordance with laboratory standard operating procedures. The FSIS auditor verified that these government laboratories performed a timely analysis of samples; reported the amount of analyzed samples and the results to the DVFA in a timely manner; applied equivalent analytical methodologies; and had effective quality assurance programs. The FSIS auditor reviewed the most recent DANAK audit report of the laboratories and identified no concerns.

FSIS determined that Denmark's government organizes and administers the country's pork inspection system, and that DVFA officials enforce laws and regulations governing production and export of meat at establishments certified to export to the United States. However, the FSIS auditors observed that the inspection personnel are not confirming all acceptable testing results from swine carcasses and parts subjected to routine government chemical residue testing prior to signing export certificates.

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. FSIS requires that the foreign country's inspection system provides for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors reviewed the practices at six swine slaughter and processing establishments and confirmed that inspection personnel verify that humane handling and slaughter of livestock are conducted in accordance with European Commission (EC) regulations. The DVFA has issued the *Notice of the Animal Welfare Act* as the implementing document for *Regulation (EC) No. 1099/2009*, which describes the responsibilities and official controls for humane handling.

At each audited slaughter establishment, the FSIS auditors verified that swine brought to slaughter receive ante-mortem examination in accordance with *Regulation (EC) No. 854/2004*. The FSIS auditors further verified that at each audited slaughter establishment, at least one government veterinarian conducts ante-mortem inspection of all swine on the day of slaughter.

The FSIS auditors observed government veterinarians as they monitored the unloading of swine livestock; toured the animal pens, driveways, ramps, and floors; and viewed the procedures of stunning and methods to verify effective stunning. All the slaughtering facilities utilized carbon dioxide gas to stun animals.

In each audited slaughter establishment, the FSIS auditors verified through record reviews, interviews with inspection personnel, and observation that each establishment is staffed with DVFA-appointed government veterinarians and inspectors to conduct ante-mortem and post-mortem inspection activities (respectively) in accordance with *Regulation (EC) No. 854/2004*. The FSIS auditors further verified that the DVFA maintains on-line post-mortem inspection of each carcass at all audited slaughter establishments.

The FSIS auditors observed that the audited establishments were operating under an alternative post-mortem inspection system for the visual inspection of carcasses, heads, viscera, and associated lymph nodes of market hogs presented for slaughter. FSIS previously reviewed Denmark's request to use this alternative procedure (as an individual sanitary measure) and determined that Denmark's submission for visual inspection in market hogs met established equivalence criteria.

The FSIS auditors verified implementation of the alternative procedure and verified that only market hogs raised indoors since weaning and raised under controlled circumstances are eligible for visual post-mortem inspection and export to the United States. An integral component of the visual inspection system is the supply chain information. This information contains pre-slaughter data that are to be presented to the slaughter establishment prior to slaughter of the swine. The slaughter establishment must make the food chain information available to the government veterinarian immediately, not less than 24 hours before the arrival of the animal or lot.

The FSIS auditors verified that the DVFA provides inspection at least once per shift during processing operations. The inspection verification tasks are scheduled ahead of time at DVFA headquarters and are tabulated in the *Annual Meat Inspection Plan*. The DVFA veterinarians use this document for planning the audits and the daily or weekly inspections. The results of inspections are documented in daily or weekly inspection reports, which are warehoused in the intranet sites known as the Digital Control System (DIKO) and Work Zone. The range of enforcement actions conducted by the inspectors depends on the nature, extent, and compliance history of establishments. Results may range from no remarks to monetary fines, criminal prosecution, and/or withdrawal of approval.

The control of animal by-products, including condemned materials, is accomplished through the application of *Regulation (EC) No. 1069/2009* and the *Regulation (EU) No. 142/2011*. In addition, the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213, Annex 6, Chapter 2*, provides procedures for the supervision of denaturing of condemned carcasses. During the audit, the FSIS auditors verified that the relevant portions of this regulation were applied, including: (a) appropriate identification in accordance with the categories described therein; (b) segregation in specially-marked or otherwise secure containers; and (c) documented final disposal of these materials at nearby rendering facilities. Receipts

documenting the weights of final disposal were maintained by each establishment and routinely reviewed by inspection personnel.

As indicated previously, periodic supervisory reviews are conducted by members of the Audit Unit (AU). The DVFA AU ensures that establishments certified to export to the United States comply with FSIS requirements, evaluate the performance of the local authority, assist in conducting uniform inspection and enforcement, train inspection personnel, and update and develop legislation and guidelines. Through record reviews and interviews, the FSIS auditors determined that these supervisory reviews and development programs are carried out according to the DVFA's established standards. In addition to periodic supervisory reviews conducted by the AU, performance reviews are conducted by the Deputy Heads of MIU or Head of FIU for veterinarians, who in turn evaluate the performance of government inspection personnel. The tool used for performance assessments includes the results of quality supervision, weekly work meetings, and one-on-one meetings with inspection personnel.

The FSIS auditors concluded that the CCA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (SOPs) to prevent direct product contamination or insanitary conditions.

Through record reviews, interviews, and observations, the FSIS auditors verified that the DVFA ensured that each certified establishment operates in a sanitary manner. The in-plant inspection personnel verify that the establishment implements sanitary dressing procedures throughout the slaughter process on a daily basis. The DVFA provides guidance to inspection personnel on official control procedures for slaughter hygiene verification and ongoing assessment of the establishment's compliance with food hygiene requirements from acceptance of animals for slaughter through carcass dressing and chilling.

Government veterinarians and inspectors ensure that carcasses with visible fecal, ingesta, or milk contamination are railed out for further trimming and reinspection before entering the carcass cooler, thus verifying an establishment's ability to implement corrective actions and compliance with *Regulation (EC) Nos. 852/2004, 853/2004,* and *178/2002.* The slaughter hygiene verification system monitors contamination at final inspection as a key point to comply with DVFA requirements in the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213, Annex 6, Chapter 6,* and focuses on the need for establishments to take the necessary actions to correct and prevent recurrence.

The FSIS auditors verified that the construction, facilities, and equipment of the establishments certified to export to the United States are designed to prevent the contamination or adulteration of pork products destined for export to the United States. The DVFA's inspection system has

official controls over establishment construction, facilities, and equipment, and the DVFA has the authority to take formal enforcement action to direct an establishment to rectify both hygiene and structural deficiencies. The DVFA requires a facility to be of sound construction prior to issuing approval to operate as a slaughter or processing establishment. The DVFA's government inspectors ensure that the establishment maintains the facility in good functioning order as part of the daily inspection of hygiene by performing regular audits and recording any noncompliances in the daily inspection records and a monthly summary.

In order to establish requirements that are equivalent to the requirements of the FSIS inspection system, especially those not covered in the EU-issued hygiene regulations and directives, the DVFA has issued the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213*, of which Annex 6, Chapter 3 is devoted to sanitation SOPs. The sanitation SOP requirements in the *Order* are consistent with sanitation standards applied in the United States in accordance with 9 CFR §416.11 – 416.16. This *Order* requires each establishment to develop and implement a written sanitation SOP program. The establishments must have written procedures to require that food contact surfaces (FCS) are cleaned prior to the start of operation and to maintain sanitary conditions throughout the operation to prevent product adulteration.

The FSIS auditors evaluated the adequacy of pre-operational sanitation by observing in-plant inspection personnel conducting pre-operational verification of the establishment's sanitation program. The inspection personnel conducted this activity in accordance with the DVFA procedures, including a pre-operational record review of the establishment monitoring results and an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity). The FSIS auditors verified the ability of inspection personnel 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 requirements for sanitation in all ten audited establishments, comparing the overall sanitary conditions of these 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 visited establishments. The FSIS auditors examined the inspection personnel's documentation of NRs and supervisory reviews of establishments. The inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination. The FSIS auditors observed that the inspection and establishment records were reflective of the actual sanitary conditions of the establishment.

In addition to the basic requirements outlined above, the DVFA has developed specific requirements for sanitation in establishments producing RTE, post-lethality exposed (RTE-PLE) product as listed in the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213*, Annex 6, Chapter 14. Establishments are required to verify sanitation by sampling and testing FCS for *Lm* or indicator organisms, and also develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, sanitation SOPs, or other prerequisite program. Guideline documents on export control outline government sampling regimens to be instituted at the establishments producing RTE-PLE products. For those establishments

addressing *Lm* hazards only through sanitation, all RTE-PLE products destined for export to the United States are subjected to government testing.

The FSIS auditors identified isolated noncompliances related to the inspection verification of sanitation requirements. These findings are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS auditors' analyses and on-site verification activities indicate that the DVFA requires operators of establishments certified to export to the United States to develop, implement, and maintain sanitation programs. FSIS concludes that the DVFA continues to meet the core requirements for this component.

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

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

The DVFA adopted requirements consistent with 9 CFR §417 for the implementation of HACCP. The DVFA, through the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213,* Annex 6, Chapter 4, outlines the regulatory requirements that are consistent with FSIS requirements, requiring establishments exporting to the United States to develop, implement, and maintain HACCP programs.

At the ten audited establishments, the FSIS auditors conducted an on-site review of the establishments' HACCP systems, including hazard analyses, HACCP plans, and critical control point (CCP) records as well as reviewing inspection verification records and direct observation of in-plant inspection verification activities. The actions to be taken by in-plant inspection personnel at establishments certified to export to the United States are identified in the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213* and the *DVFA Export Inspection Guidance*. The inspection personnel conducted verification of HACCP plans consistent with FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*. The inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping. In-plant inspection personnel adequately documented and verified the adequacy of the establishments' corrective actions. The establishments' corrective actions in response to deviations from critical limits, identified by the establishment or the government inspectors, met all four parts of corrective action requirements cited in 9 CFR §417.3(a), which have been adopted by Denmark.

The *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213,* Annex 6, Chapter 6 requires that the HACCP plan for slaughter establishments must contain a zero tolerance CCP to ensure the absence of visible contamination of fecal matter, ingesta, or milk. The FSIS auditors reviewed the zero tolerance CCP at six swine slaughter and processing establishments. The FSIS auditors also verified the physical CCP locations by observing government inspection personnel conducting HACCP hands-on verification activities.

The audit scope included four processing establishments: one that produces TPCS product, one that produces raw edible offal products (e.g., pork chitterlings), one that produces flash-frozen pork products, and one that produces RTE fermented product. The FSIS auditors conducted on-site observations and reviewed both in-plant inspection personnel verification, as well as establishment-generated monitoring and verification records for CCPs at all four audited processing establishments.

At the establishment producing TPCS product, the FSIS auditor visiting this location verified that the canned product is produced under the establishment's HACCP plan that addressed all food safety hazards, including microbiological hazards associated with TPCS products. The establishment utilizes processing schedules set out by its process authority.

At the establishment producing RTE products, the FSIS auditor visiting this location confirmed that the DVFA requires the establishment to conduct a hazard analysis for the product, which is post-lethality exposed (PLE) to the production environment, and to address the microbiological hazards either in the HACCP plan or through a prerequisite program or sanitation SOPs. This included inspection verification that the appropriate validation documents to support lethality for *Salmonella* in these products were maintained. In addition, the FSIS auditor confirmed that, to ensure that *Lm* is prevented from contacting any RTE-PLE product regardless of whether the product supports growth or not (i.e., a zero tolerance for *Lm*), there is ongoing testing for *Lm* in the finished product, on FCS, and in the processing environment as mandated by the DVFA.

The FSIS auditors identified isolated noncompliances related to the inspection verification of HACCP requirements. These findings are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS auditors' analyses and on-site verification activities indicate that the DVFA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs. FSIS concludes that the DVFA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. To be equivalent to FSIS's inspection program, the food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS's residue experts thoroughly reviewed Denmark's Residue Control Program for 2019, associated methods of analysis, and additional SRT responses outlining the structure of Denmark's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit conducted in 2018.

FSIS based its verification of Denmark's chemical residue testing program on information contained in Denmark's 2019 National Residue Control Plan (NRCP), the 2018 NRCP results,

and an on-site audit of a chemical residue laboratory. The provisions in *Council Directive No. 96/23/EC* govern the DVFA's NRCP, which covers the frequency and sample allocations among species and the group of compounds that must be analyzed and requirements in *Regulation (EC) No. 882/2004*. DVFA is responsible for the control and analysis of chemical residues present in meat and processed meat products. The DVFA has the legal authority for surveillance of chemical residues that exceed the maximum levels both nationally and as well as those established by importing countries.

The DVFA is responsible for the development and administration of the NRCP. The annual NRCP takes into consideration the assessment of sampling results obtained from the previous years' sampling results in order to consider changes on the regulated use of veterinary drugs. The plan specifies the detection methods, the methods of analyses to be used, the matrices to be collected, the maximum residue limits, if applicable, and the total number of samples to be collected. The DVFA laboratories complete detailed planning, and then the final plan is submitted to the EU commission for approval.

Denmark, as a member of the EU, has residue plans that are acceptable by EU standards and recognized as equivalent to FSIS's criteria. The FSIS auditors verified that the DVFA's official control measures and enforcement actions of the implementation of the NRCP are in accordance with *Council Directive No. 96/23/EC*. If a positive or violative result occurs, the laboratories notify the DVFA via email. The DVFA takes the following actions when notified of positive or violative results: identify the animal and farm of origin; investigate the cause of the violation at the farm; safeguard the public health by requiring adequate product disposition; intensify the checks on the animals and products from the farm; and impose criminal or administrative penalties against any person who is responsible.

The Veterinary Control Office, which has jurisdiction over violative entities, conducts the follow-up on a noncompliant product investigation. While on-site, the FSIS auditors verified the follow-up procedures performed in conjunction with a residue violation for doxycycline (an antibiotic) identified in a market hog as part of the 2018 NRCP. The follow-up activities also included on-site investigations of the farms involved in the violation.

During the audit of DVFA headquarters, the FSIS auditors clarified the CCA's application of Article 11 (items 5-7) of *Regulation (EC) No. 882/2004*, as it pertains to government chemical residue testing. This particular portion of the EC regulation provides establishments with the opportunity to obtain a supplementary expert opinion (i.e., retesting of product) in the face of a violative test result. However, FSIS does not permit retesting samples in conjunction with government verification programs. Furthermore, the DVFA has not developed clear written instructions to indicate that products retested under this provision would not be exported to the United States, for which the FSIS auditors identified the following finding:

- The CCA's national chemical residue program has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

The FSIS auditors verified implementation of the NRCP at the six audited slaughter and processing establishments. The auditors confirmed that government inspectors conduct random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues. The official monitoring examinations are conducted according to the NRCP, which is defined every year. The plan lists the residue group, the number of samples for the group, and the matrix for each month. The government inspectors randomly select the carcass to sample. The FSIS auditors verified that the DVFA-assigned government inspectors at establishments collected samples under the NRCP project following sampling guidelines and sample integrity procedures. The government inspectors completed the laboratory submission form, and a copy was packaged in the sample shipment cooler, which the government inspectors secured with a numbered seal to maintain integrity.

The FSIS auditors' review of documentation at the local inspection offices of the six audited slaughter establishments verified that government inspectors were collecting samples of the required matrices for detection and adhered to the prescribed sample collection schedule. The FSIS auditors' review of the NRCP monitoring results for the current year at these establishments indicates that no violative samples were detected. The DVFA requires carcasses and parts of suspect animals to be maintained under government control pending sampling results; however, as indicated under Component One of this report, it does not explicitly require retention of carcasses and parts for routine residue sampling.

Two DVFA Laboratory Chemical Residue Units perform Denmark's NRCP analysis. An FSIS auditor visited the DVFA Laboratory Chemical Residue Unit, the government central laboratory in Ringsted, which is located on the same premise as the DVFA Laboratory Microbiological Unit. The laboratory unit in Ringsted tests the vast majority of substance groups for all of Denmark. Some contaminants (heavy metals) are tested at the laboratory unit in Aarhus. The FSIS auditor reviewed the Ringsted laboratory unit's chemical residue testing program and verified that DANAK has accredited the laboratory as equivalent to the ISO 17025 standard in the specific areas of testing. The laboratory also performs internal audits according to their Quality Assurance Manual and has procedures in place for proficiency testing.

The result of the on-site audit activities indicates that the DVFA continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in meat products destined for human consumption. However, the national program has provisions in place that allow for samples with violative test results to be re-analyzed at the establishment's request, for which FSIS requests further information regarding how the DVFA ensures that this does not occur in conjunction with meat products exported to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. To be equivalent to FSIS's inspection program, the food safety inspection system is required to implement certain sampling and testing programs to verify that meat products prepared for export to the United States are safe and wholesome.

The FSIS auditors verified that the DVFA requires certified slaughter establishments to implement written generic *Escherichia coli* plans. Through review of establishment records, the FSIS auditors verified that the swine slaughter establishments are collecting one sample per 1,000 carcasses and documenting results in process control charts. The FSIS auditors observed that this program was conducted in conjunction with the microbiological control testing program for *Enterobacteriaceae* established within the EU to verify process control in slaughter establishments, as per *Regulation (EC) No. 2073/2005*. The FSIS auditors did not have any concerns during the review of these programs.

The DVFA also applies a sampling and testing program to verify that establishments certified to export to the United States meet the generic *E. coli* requirements above and the former *Salmonella* performance standard for hog carcasses. The specific requirements are provided in the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213*, Annex 6 Chapter 7, entitled *Salmonella Monitoring*. Sampling is conducted by establishment personnel, with periodic verification provided by government inspectors. Periodic verification includes spot-checks of the establishment's sampling procedure, as well as weekly government sampling and testing of a single carcass. The evaluation criteria used in conjunction with establishment test results are 8.7%, with the maximum allowable *Salmonella* positive samples being 6/55 samples.

The FSIS auditors' review of *Salmonella* testing results at the six audited slaughter establishments identified no *Salmonella* set failures during recent history. In addition, the FSIS auditors observed and verified that the establishment's collection procedures and inspection verification activities were in accordance with the sample collection protocols described in the aforementioned requirements.

The DVFA regulatory microbiological verification program in the *Executive Order on Export of Foodstuffs and Food Contact Material, No. 213,* Annex 6, Chapter 14, includes the application of microbiological criteria for *Salmonella* and *Lm* in RTE products. It includes additional RTE-PLE product sampling by the DVFA at certified pork processing establishments. The DVFA provided evidence that product destined for the United States is not simply tested to ensure the absence of detectable *Lm* and *Salmonella,* but that controls are in place to prevent adulteration with *Lm* and *Salmonella*.

Government inspectors sample RTE-PLE product every month for analytical testing to detect *Lm* and *Salmonella*. The FCS are also sampled for *Listeria* spp. at the frequency of two samples per production line per year for non-deli products and four samples per production line per year for deli products. The production environment is tested at a frequency set by the local inspection unit. All products destined for export to the United States have an opportunity for government testing.

The FSIS auditors further verified that the DVFA has a written enforcement action plan for the government microbiological verification sampling program that outlines the DVFA's response when *Salmonella* or *Lm* are detected in RTE products. Based on requirements that Denmark adopted, RTE product is considered adulterated if it contains *Lm* or *Salmonella,* or if it comes

into direct contact with an FCS that is contaminated with *Lm*. The FSIS auditors reviewed testing results for establishments producing RTE product for the last year showing that DVFA verification testing and establishment verification testing produced no positive test results in products tested for *Lm* or *Salmonella,* or on FCS or non-food contact surfaces (environmental) for *Lm.*

An FSIS auditor performed an on-site audit of the DVFA Laboratory Microbiological Unit, a government laboratory in Ringsted. The laboratory performs DVFA verification analyses for RTE product that includes *Lm* and *Salmonella* analysis of finished product that is post-lethality exposed to the environment and *Lm* analysis of FCS and non-food contact surfaces. The FSIS auditor verified that DANAK has accredited the laboratory as equivalent to the ISO 17025 standard. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support the DVFA's inspection program for establishments certified to export to the United States. The laboratory uses the following equivalent analytical confirmatory methods: Rapid L. mono for *Lm* and BAX/Nordic Committee on Food Analysis (NMKL) No. 71 for *Salmonella* (validated to ISO 6579:2006, *Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of Salmonella - Part 1 detection of Salmonella spp.*). Positive *Salmonella* results are subject to further serotyping.

An FSIS auditor visited one establishment producing TPCS products. Within Denmark, establishments producing TPCS product are required to address the hazards using HACCP principles, according to *Regulation (EC) No. 852/2004*, Article 5. Annex II, Chapter XI of this regulation lays down specific requirements for food in hermetically sealed containers, by stating that the heat treatment process used to process an unprocessed product or to process further a processed product is: (a) to raise every part of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process. The sterilization value (F_o) set by the establishment must meet the requirements in *Regulation (EC) No. 852/2004*, which clarifies that the heat treatment used should meet the requirements of an internationally recognized standard.

Specific on-site verification activities conducted by the FSIS auditor included the review of process schedules for products exported to the United States; procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; incubation records; retort heat-distribution tests; and procedures to ensure proper closure of containers, including training of closure technicians. The FSIS auditor's review of the process schedules showed that they were developed by a process authority and included critical factors such as fill weight, height space, as well as come-up and venting times. Final incubation procedures were conducted in accordance with the frequencies, times, and temperatures outlined in the Codex Alimentarius *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979)*. Government inspector verification activities are evaluated in Component 4 (Government HACCP System Verification).

There have not been any POE violations related to this component since the last FSIS audit in 2018. The FSIS auditors' analysis and on-site verification activities indicate that the DVFA continues to maintain the legal authority to implement its microbiological sampling and testing

programs to ensure that meat products are unadulterated, safe, and wholesome. FSIS concludes that the DVFA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

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

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The CCA inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing export certificates.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The CCA's national chemical residue program has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.

During the audit exit meeting on November 15, 2019, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Blans Sonderborg	11/07/2019	14	Denmark
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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. Periodic Supervisory Reviews	
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.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (cuts, edible offal, primals and subprimals).

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 Branch (IAB)	11/07/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Ringsted	11/05/2019	25	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (cuts, other intact, primals and subprimals).

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 Branch (IAB)	11/05/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Herning	11/11/2019	31	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (cuts, primals and subprimals).

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 Branch (IAB)	11/11/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Esbjerg	11/07/2019	53	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Pork processing.
Prepared Products:	Raw intact pork (cuts, edible offal, and other intact).

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 Branch (IAB)	11/07/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tulip Food Company Vejle	11/08/2019	65	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork processing.
Prepared Products:	Thermally processed, commercially sterile pork (corned (species), ham, other, and sausage).

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 Branch (IAB)	11/08/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Saeby	11/12/2019	71	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw non-intact pork (other non-intact); and raw intact pork (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

The following non-compliances were not identified by Denmark's inspection officials during the establishment review:

Sanitation Standard Operating Procedures (SSOP)

10. Numerous totes containing edible product (pork cuts) presented frayed edges around their borders and internal surfaces which would impact their ability to be cleaned properly and could result in direct product contamination via shredding of plastic fragments.

10. A conveyor belt used to transport exposed product (pork ribs) presented frayed edges and a pitted surface which would render it difficult to clean properly.

10. The overhead rail exiting the carcass cooler was not high enough to provide adequate clearance of the anterior portion of swine carcasses transiting this area. The heads of several carcasses were observed in close proximity (~1 inch / 2.54 cm) with the floor. In one instance, the snout of a carcass was in direct contact with a pile of trimmed meat scraps which had collected on the floor.

10. Excessive grease was observed on the rails of the carcass cooler. Several swine carcasses presented blotches of grease on their hindquarters.

Sanitation Performance Standards (SPS)

42. A clogged floor drain in the corridor which runs parallel to the slaughter line resulted in pooling blood and the creation of insanitary conditions for employees transiting this area.

45. A container designated for edible product was used to collect condemned materials (EC “Category II”) in a pork processing (fabrication) area.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/12/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agri-Norcold A/S Vejen	11/06/2019	170	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Cold Storage Facility

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 Branch (IAB)	11/06/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tulip Food Company Svenstrup J	11/12/2019	211	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork processing.
Prepared Products:	RTE acidified / fermented pork (without cooking) (other - not sliced, sausage/salami - not sliced, and sausage/salami - sliced); RTE dried pork (ham - not sliced, other - not sliced, and other - sliced); RTE fully-cooked pork (sausage products); and RTE pork fully-cooked without subsequent exposure to the environment (sausage products).

60. Observation of the Establishment

22: The establishment's HACCP verification record (record review component) did not include the result of the verification activities.
22: The establishment's HACCP plan did not include returned product in the flow chart or hazard analysis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/12/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown Horsens	11/11/2019	320	Denmark
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	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (cuts, other intact, and primals and subprimals).

60. Observation of the Establishment

The following non-compliances were not previously identified by Denmark's inspection officials at this establishment:

22. The ongoing verification activity of records review for CCP1 (zero tolerance for feces, ingesta, or milk) was not documented in accordance with the frequency outlined in the establishment's written HACCP plan. Where the HACCP plan specified a *daily* frequency for this ongoing verification activity, the review of records conducted by the FSIS auditor indicated that this was documented only on a *monthly* basis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/08/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
SB Pork A/S Brorup	11/06/2019	801	Denmark
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	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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32. Written Assurance	

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Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (cuts, other intact, and primals and subprimals).

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 Branch (IAB)	11/06/2019

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

Ministry of Environment and Food of Denmark
Danish Veterinary and Food Administration

File: 2019-30-1040-00002
Date: 10-03-2020

Michelle Catlin
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, D.C. 20250

Comments on the draft final report of an on-site audit carried out in Demark November 4 – 15, 2019.

Dear Michelle Catlin,

The Danish Veterinary and Food Administration (DVFA) acknowledges the receipt of FSIS's draft final report from an on-site audit of Denmarks's meat inspection system carried out November 5 through November 15, 2019.

By letter of January 13, 2020 FSIS has invited the DVFA to provide comments to the draft report.
DVFA would like to state the following comments to the information in the draft audit report:

Audit objective, scope, and methology:

Page 3:
Administrative functions were reviewed at CCA headquarters, two regional offices, and ten local inspection offices within the establishments.
FSIS visited three regional offices: the Meat Inspection Department, Food Inspection Unit Southwest and Food Inspection Unit Northeast. The food inspection units presented their joint inspection system at the southwest location in Vejen.

Component 1: Government oversight:

Page 7:
The FSIS auditors´ review of records indicated that inspection personnel routinely confirm acceptable test results of government microbiological sampling prior to certifying product for export to the United States.
DVFA inspection personnel was at the time of the FSIS audit not required to routinely confirm acceptable test results prior to certifying product for export to the United States. However DVFA is currently changing procedures for certifying product for export to the United States. DVFA personnel will verify, that the establishments implement procedures to ensure, that only products with acceptable test results are exported to the US.

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Component 5: Government chemical residue testing programs:

Page 16:
The Ringsted laboratory is also designated as an EU reference laboratory for animal diseases.
The Ringsted laboratory is not designated as an EU reference laboratory for animal diseases. Ringsted laboratory is a NRL for residues of veterinary drugs in animal and animal product (EU Dir. 96/23).

Component 6: Government microbiological testing programs:

Page 17:
The FCS are also sampled for Listeria spp. at the frequency of two samples per production line per year for non-deli products and four samples per production line per year for deli products. The same testing frequencies are applied for sampling of the production environment.
The production environment is tested at a frequency set by the local inspection unit.

Page 18:
An FSIS auditor performed an on-site audit of the DVFA Laboratory Microbiological Unit, a government laboratory in Ringsted. The laboratory is designated as an EU reference laboratory.
The Ringsted laboratory is not designated as an EU reference laboratory.

Sincerely,

Hanne Larsen
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