USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Per S. Henriksen
Chief Veterinary Officer
Ministry of Food, Agriculture and Fisheries
Danish Veterinary and Food Administration
Mørkhøj Bygade 19
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Dear Dr. Henriksen,

The Food Safety and Inspection Service onsite audit conducted from May 23 through June 10, 2016, supports that Denmark's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Denmark are included as an attachment to the report.

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

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

DENMARK

MAY 23 TO JUNE 10, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 5, 2016
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 Food Safety and Inspection Service (FSIS) from May 23 to June 10, 2016. The purpose of the audit was to determine whether Denmark's food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Denmark currently exports pork products to the United States.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration), Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling), Government Sanitation, Government Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs.

During the audit, the following findings were identified:

- In six of eight establishments audited, the FSIS auditors identified implementation issues with sanitation requirements in the area of maintenance of equipment, overhead structures, premises, ventilation, sanitary operation, employee hygiene and storage conditions in chilling rooms which obstructed inspection in the coolers.
- When inspectors retain carcasses and parts for veterinary disposition due to pathology, they often discard parts of viscera prior to presentation to the veterinarian. The Central Competent Authority (CCA) procedures for veterinary disposition require all parts and carcasses to be presented to the veterinarian.

An analysis of the findings within each component did not identify any significant findings which represented an immediate threat to public health. However, as noted above a number of audit observations pertaining to sanitation requirements were identified during the audit. The auditors verified that the CCA or establishment's representative addressed most of the noncompliances immediately and provided documented preventative measures. For other noncompliances needing additional time the CCA has instructed establishments to correct them within reasonable timeframe. During the audit exit meeting, the CCA committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of CCA's proposed corrective actions once received.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Denmark's food safety system from May 23 to June 10, 2016. The audit began with an entrance meeting held on May 23, 2016, in Glostrup, Denmark with the participation of representatives from the Central Competent Authority (CCA), the Danish Veterinary and Food Administration (DVFA), and two FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat products maintains equivalence to that of the United States, with the ability to export products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

FSIS applied a risk-based procedure which 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) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA, through a self-reporting process. The FSIS auditors further verified implementation of corrective actions by the DVFA in response to the previous FSIS audit in 2014.

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

Administrative functions were reviewed at CCA headquarters, one food control office, one meat inspection department, and eight local inspection offices, during which the FSIS auditors evaluated the implementation of control systems in place which ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of eight establishments was selected from a total of 21 establishments eligible to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with

FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2 , the FSIS regulations addressing equivalence determinations for foreign country inspection systems.

Additionally, FSIS audited the microbiological and chemical residue testing programs of the Eastern Regional DVFA Laboratory (Ringsted) in order to verify the CCA's ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• The Danish Veterinary and Food Administration, Glostrup
	Regional	2	• Food Control Offices, North Jutland, Aalborg • Meat Inspection Department, Meat Inspection Unit, Lystrup
Laboratories		2	Regional Veterinary and Food Control Authority, Region East, Laboratory, Ringsted • Microbiology Testing Program • Chemical Residue Testing Program
Pork Slaughter and Processing Establishments		4	Sæby, Skærbæk, Sønderborg, and Ringsted
Pork Processing Establishments		4	Svenstrup, Vejle, Kjellerup, and Esbjerg

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

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

The audit standards applied during the review of 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 Sanitary/Phytosanitary Agreement. Currently, Denmark has equivalence determinations in place for the following:

- 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;
- Council Directive 93/119/EC;
- Council Directive 96/22/EC;
- Council Directive 96/23/EC; and
- Council Directive 97/747/EC.

Currently, Denmark has equivalence determinations in place for the following procedures. Denmark performs a full carcass visual post-mortem inspection on indoor raised market hogs.

FSIS' requirements for generic *E. coli* testing are equivalent with the following exceptions:

- Use of a gauze pad sampling tool;
- Use of the NMKL (Nordic Committee on Food Analysis) or AOAC (Association of Official Analytical Chemists) 991.14 method to analyze samples; and
- Use of an alternate method (TEMPO EC- TEMPO *Escherichia coli*) to detect and quantify generic *E. coli* in raw products.

FSIS' requirements for *Salmonella* testing for pathogen reduction performance standards are equivalent with the following exceptions:

- The establishments collect the samples;
- Private laboratories analyze the samples;
- A continuous, ongoing sampling program is used;
- A gauze pad sampling tool is used; and
- NMKL method # 71 and IQ (Innovation & Quality) Check method are used to analyze samples.

A detailed analysis of the CCA's continued ability to meet the original commitments related to these equivalence determinations is provided under Section IX, Government Microbiological Testing Programs.

III. BACKGROUND

Denmark is eligible to export raw and processed pork products to the United States. From January 1, 2013, to December 31, 2015, Denmark exported 236,585,468 pounds of pork products; of this volume, 25,696,753 pounds of the product received re-inspection at the United States POE. Of the re-inspected volume, a total of 414,913 pounds of product was rejected for food safety reasons. Although the last on-site audit of Denmark's meat inspection system conducted in 2014 did not identify any systemic finding, the FSIS auditors did identify isolated concerns in Government Statutory Authority and Food Safety and Other Consumer Protection Regulations, Sanitation, HACCP Systems, and Government Microbiological Testing Program components. The current audit verified that the CCA had implemented all proffered corrective actions in response to FSIS' findings.

The audit also included visits to two establishments involved in POE violations, for one of which FSIS concluded that the CCA had satisfactorily worked with the operator to identify the root causes of the problems and institute appropriate corrective actions. For the other establishment, the CCA is working with FSIS to resolve the product spoilage issue. The CCA has launched a challenge study to support its claim of product safety

under current measures to control all pathogens associated with its heat-treated shelf stable mortadella. The imported mortadella product had failed re-inspection at United States POE. Specific details regarding these follow-up activities are included in the subsequent sections of the audit report where appropriate.

The FSIS final audit reports for Denmark's food safety system are available on the FSIS Web site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

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

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such manner 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 evaluation of this component included a review of documentation submitted by the CCA as support for the responses in the Self-Reporting Tool (SRT) and corrective actions, as well as on-site record reviews, interviews, and observations made by the FSIS auditors at government offices and in the audited establishments.

Denmark, as a member of the European Union (EU), has transposed EU legislation pertaining to food of animal origin, and has based its authority to enforce inspection laws from EC Regulation No. 178/2002. This is reinforced by the Danish Food Act *(*August 20, 2011*)*, Danish Order on Export of Foodstuffs No. 722, and the Danish Circular on Meat Inspection.

The audit of the CCA's headquarters in Glostrup confirmed that the Danish Veterinary Food Administration (DVFA) is the CCA of Denmark. The DVFA is one of five agencies that are overseen by the Ministry of Environment and Food (MEF). The MEF was created in the summer of 2015 as a result of a merger between the Ministry of the Environment and the Ministry of Food, Agriculture, and Fisheries (MFAF). The other four agencies within MEF include the Danish Environmental Protection Agency, the Danish AgriFish Agency, the Nature Agency and the Danish Coastal Authority. The DVFA, which is headed by an Executive Director, bears responsibility in the areas of feed and veterinary legislation, veterinary control, animal diseases, animal welfare, nutritional information, and international cooperation.

The activities that occur at the central level include:

- Rulemaking,
- Acting as an advisory body to the ministry for policy making**,**
- Establishing the guidelines for government inspection and industry,
- Establishing the sampling plans,
- Establishing guidelines for government inspections and sanctions,
- Supervision, enforcement audit, laboratories and task forces,
- Risk monitoring involving food and feed safety,
- Animal health and welfare,
- Training of staff,
- International cooperation, and
- Collaborating with universities (risk evaluation, research, etc.)**.**

The Audit Unit (AU), an office located within the Communication and Innovation Department of DVFA, is a conduit between the CCA and the field staff. The AU is responsible for conducting supervisory reviews at all United States-certified establishments. The AU is required to provide the CCA with an overview of the following areas:

- Ensuring compliance of United States-certified establishments with respect to FSIS requirements,
- Evaluating the performance of the local competent authority,
- Assisting to conduct uniform inspection and enforcement,
- Training of inspection personnel, and
- Updating and development of legislation and guidelines.

The structure of the inspection system at the second or local level consists of five Food Control Offices (FCOs) and a Meat Inspection Department (MID) with its associated Meat Inspection Units (MIU). This organizational structure is supported by Veterinary Control Offices (VCOs) for livestock inspection and emergency response, and food and veterinary task forces. The United States-certified slaughter and processing establishments are managed at the second level by the MIU, while all processing establishments exporting to the United States are overseen by FCOs. This audit verified administrative functions at the North Jutland FCO, which include registration and approval of new establishments, official sampling, export certification, compliance guidance to new establishments, withdrawal of approval, managing recalls, and handling foodborne outbreaks and other important functions.

At the North Jutland office located in Aalborg, the FSIS auditors conducted interviews with officials from the North and South Jutland FCOs in conjunction with document review from both offices. The FSIS auditors confirmed that these offices are charged with delivery of supervisory oversight at processing establishments including the United States-certified establishment exporting processed pork products to the United States. In addition to delivery of oversight, the experienced veterinary officers employed at these offices are also responsible for performing a wide array of duties, which include

establishment approval and guidance to new facilities and verification of export certification. These offices organize official sampling in the processing establishments. FCOs also play a critical role in recalls of food products tested positive for foodborne pathogens.

Through document reviews, the FSIS auditors verified the activities of the North Jutland FCOs in response to POE violations originating from an establishment exporting Ready-to-Eat (RTE) products to the United States. The auditors determined that authorities pursued the investigation into the causes of the POE violation and verified the efficacy of corrective actions. No concerns were identified as result of the audit of the North Jutland FCO.

The audit also included a visit to the MID for its oversight activities of slaughter and processing establishments including the United States-certified establishments slaughtering pigs. Structurally, the MID is connected to Meat Inspection Administration headquartered in Glostrup, which is one of the six departments of DVFA and headed by the Chief Meat Inspection Officer (CMIO). The CMIO is responsible for slaughter-related activities in Denmark and reports directly to the Executive Director of DVFA. The CMIO is supported by the Head of each MIU. Each United States-certified establishment visited has its own Deputy Head of meat inspection who leads the inspection team, consisting of veterinarians and lay inspectors (LIs). The MIUs are located in slaughter establishments and are analogues to the local inspection office. The FSIS auditors visited four MIUs, interviewed deputy heads, veterinarians and LIs and reviewed a sample of daily and monthly inspection reports at each MIU and determined that the CCA applies uniform standards of inspection across all United States-certified establishments.

In assessing DVFA's ability to acquire and maintain competent and qualified personnel, the FSIS auditors verified that inspection personnel in slaughter and processing establishments including the United States-certified establishments are employees of DVFA who are paid by the government. The DVFA ensures that there is no conflict of interest as Danish legislation prohibits accepting any cash or in kind items of value from the regulated industry. The FSIS auditors verified that government inspection officials were carrying government-issued identification badges to access the establishments and government facilities.

The structure of field staff deployed at Danish livestock slaughter meat inspection units, meat processing and cold storage including the United States-certified establishments is comprised of a Veterinary Officer (VO) and LIs. A veterinary officer must have a degree in veterinary medicine to be recruited in DVFA, which is consistent with the minimum academic requirement for VOs as laid out in Regulation (EC) No. 854/2004 and in Danish Order No. 1455/2006. LIs are required to have a high school diploma with additional specialized courses in the field of meat hygiene, HACCP, anatomy, physiology, pathology, zoonosis, and microbiology to be employed with DVFA. These requirements are laid out in Danish Order No. 1455/2006 and EU Regulation No. 854/2004.

DVFA has a specialized training program for VOs and LIs. Upon initial appointment, each VO and LI receives formal training in conjunction with on-the-job training with a senior veterinarian prior to being assigned to an independent position. All inspection personnel are required to participate in trainings and continuing education courses offered by the EU – Better Training Safer Food (BTSF). In order to be appointed to the United States-certified establishments, the VO or LI must have a sound knowledge of DVFA-issued legislation and guidance documents on FSIS requirements, in addition to having proficiency in EU regulations and food law.

For ongoing training of inspection personnel, DVFA has organized a training portal on its Web known as "CAMPUS." The site is used by employees for courses mandated by DVFA or for career development. The CCA has mechanisms to regularly assess training needs of employees or to improve their skills to advance in the fields of meat inspection and food safety. The senior auditors of the audit division also contribute to the delivery of training, and while on supervisory visits, hold meetings with inspection staff on performance of establishments with respect to meeting requirements related to United States export. The FSIS auditors reviewed the employees' training records during the audit of the North Jutland FCO and MID in Lystrup and determined that the training program is delivered as intended.

The FSIS auditors also verified at the North Jutland FCO and MID office inspectors' annual performance review and personal development program for the VOs and LIs assigned to United States-certified establishments and concluded that these reviews and development programs are carried out according to DVFA's established standards. Performance reviews are conducted by the Deputy Heads of MIUs for veterinarians, who in turn evaluate the performance of LIs. The tool used for performance assessments include the results of quality supervision, weekly work meetings, and one-on-one meetings with inspectors. The outcome of supervisory visits by the senior auditors also plays a significant role in the determination of the inspectors' performance.

During the audit of the North Jutland FCO, the FSIS auditors also reviewed the CCA's procedures to ensure the security and integrity of export certificates. DVFA has issued the following official documents to control the issuance of the certificate and guidance to inspectors on verification of the requirements of the importing country:

- Danish Order No. 102, Type of Paper for Health Certificate,
- Danish Order No. 722, Export of Foodstuffs,
- Danish Instruction No. 9051, Inspection of Certificate Paper, and
- Guidance on Inspection of Export Establishments, dated April 21, 2016.

A sample of export certificates issued under government seals were verified at the North Jutland FCO.

Technical support for microbiological and chemical residue testing within the CCA's meat inspection system is provided through two government laboratories located in Ringsted and Aarhus. The Ringsted laboratory serves as a National Reference

Laboratory (NRL) for one or more animal diseases or for food safety issues. Each laboratory is International Organization for Standardization (ISO) 17025 accredited through *Den Danske Akkrediteringsfond - DANAK*. DANAK is the national accreditation body in Denmark appointed by the Danish Safety Technology Authority, under the Ministry of Business and Growth.

During the entrance meeting, the FSIS auditors discussed the recent violations of FSIS import requirements detected at the United States POE in the imported product. The CCA explained the corrective actions implemented in the establishment which are verified by the inspection personnel to ensure the efficacy of the measure in preventing future re-inspection failures. Additionally, the FSIS auditors discussed the previous audit findings and the corrective actions implemented by the establishments and verified by the CCA. During the site visits to the establishments, the FSIS auditors verified and confirmed that the findings of the 2014 audit were corrected; however, new concerns were identified which are mostly limited to the sanitation component.

FSIS concluded that the CCA continues to organize and administer its meat inspection system in a manner which meets the core requirements for this component.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS AND OTHER CONSUMER PROTECTIONS (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 Regulations.

The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

To verify the core requirements for this component, the FSIS auditors evaluated the information provided by the CCA in the SRT, POE data, and also reviewed Denmark's prior audit compliance history.

The FSIS auditors selected a sample of four slaughter establishments to verify the CCA's controls for humane handling of livestock, ante-mortem and post-mortem inspection of carcasses and parts. At each slaughter establishment audited, the FSIS auditors verified that the livestock (swine) brought to slaughter receive ante-mortem examination in accordance with Regulation (EC) No. 854/2004. The FSIS auditors further verified that at each slaughter establishment visited, a veterinarian conducts ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion prior to slaughter. When verifying the establishment's compliance with humane handling and slaughter of livestock, the inspector applies the relevant provisions of Council Directive 93/119/EC,

Regulation (EC) 854/2004, and Regulation (EC) 1099/2009. The FSIS auditors verified the corrective action implemented by the establishment in response to the 2014 audit noncompliance. The audit had identified that an ante-mortem suspect identification did not match with the final disposition records for post-mortem. The CCA corrected the finding by issuing a notice on correlation of suspects and post-mortem disposition of carcasses and parts. The FSIS auditors selected a set of records of ante-mortem suspects and correlated each suspect with post-mortem disposition and determined that the procedures were followed in accordance with the guidance in the notice.

Pertaining to post-mortem inspection examination, the FSIS auditors made an assessment of the CCA's compliance through on-site record reviews, interviews and observations of inspectors conducting post-mortem inspections. From a total of eight eligible slaughter establishments, a sample of four was selected for this audit. The FSIS auditors noted that three of the four market hog slaughter establishments were operating under alternative post-mortem inspection involving visual inspection of lungs and liver and their associated lymph nodes of market hogs presented for slaughter. As mentioned earlier, FSIS had determined that Denmark's request for an equivalence determination for an alternative post-mortem inspection, i.e., visual inspection, instead of palpation of lungs and liver and their associated lymph nodes of slaughtered market hogs met the established criteria. The decision to grant equivalence to the alternative post-mortem inspection system was communicated to Denmark in a letter dated October 21, 2015.

The project to modernize market hog slaughter in Denmark is embedded in Regulation (EC) No. 854/2004, which allows transition from a conventional to more efficient inspection system if supported by extensive risk assessments and desired outcomes. The project to phase in the visual inspection system in Denmark was launched in 2008. At that time, the heart and mandibular node were inspected visually instead of incising the nodes. This was followed in 2009 to include visual inspection of mesenteric nodes. In 2013, visual inspection extended to cover lungs and livers. At each phase Denmark submitted to FSIS a request for equivalence determination and provided data on its risk assessments studies. The CCA has provided extensive training to the inspectors and supervisory staff on visual inspection, verification of performance standards of carcasses and parts, and on how to verify food chain information. The visual inspection applies only to market hogs raised in Denmark, weighing 220-240 pounds and approximately six months of age. The alternative post-mortem inspection procedure is not applicable to sows, boars, and roaster pigs. This audit covered one establishment slaughtering sows and boars that was receiving conventional post-mortem inspection.

The FSIS auditors observed the performance of the inspection personnel conducting visual examination of carcasses and viscera at three slaughter establishments under alternative post-mortem inspection, and verified that inspectors were examining the heads, viscera, and carcasses under routine post-mortem inspection procedures at the sows and boars slaughter establishment. No concerns arose except as noted below:

- When the inspectors retain carcasses and parts for veterinary disposition due to pathology, they often discard parts of viscera prior to presentation to the veterinarian.

The CCA's procedures for veterinary disposition require all parts and carcasses to be presented to the veterinarian.

The slaughter establishments are staffed with DFVA-appointed LIs and veterinarians to oversee ante-mortem and post-mortem activates in accordance with Annex I, Section III, Chapter II of Regulation (EC) No. 854/2004. Special provisions to ensure presence of inspectors in the United States-certified processing establishments when products are prepared for the United States export are grounded in Section II, Chapter 1 of the document entitled "Guidance on Inspection of Export Establishments." Through document reviews and interviews with inspection staff at all four slaughter establishments audited, the FSIS auditors verified the CCA maintains continuous inspection at the United States-certified slaughter establishments during all hours of operation.

In each processing establishment audited, the FSIS auditors verified that the CCA provides daily inspection when product for United States export is prepared. The inspection verification tasks are planned ahead of time at DVFA headquarters and are tabulated in the Annual Meat Inspection Plan. The veterinary officers use this plan 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 Digital Control System (DIKO) and Work zone. The range of enforcement actions exerted by the inspectors depends on the nature, extent, and compliance history of establishments. Results may range from no remarks to fines, criminal prosecution, and/or withdrawal of approval.

There are no regulatory changes associated with the export of meat products to the United States since the last FSIS audit that would have required changes by the CCA.

Denmark's meat inspection system continues to maintain the legal authority and a regulatory framework to implement requirements equivalent to those governing meat inspection in the United States, although there was some need for improvement of oversight related to post-mortem inspection procedures.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Government Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures (SSOPs).

To verify the requirements for Government Sanitation, the FSIS auditors conducted an assessment of the CCA's provided information and documents in conjunction with interviews conducted with inspection and supervisory staff and site visits to a sample of eight slaughter and processing establishments. The basic sanitation requirements are stipulated in EC Regulations 852/2004 Article 4 No. 2 Annex II, and 853/ 2004 Article 3, Annex 2 Chapters I-VII, and Annex 19.

The FSIS auditors reviewed the following documents during the verification of this component:

- Meat Inspection Plan for 2016,
- Inspection daily checklist for sanitation-related tasks,
- A sample of the last 90 days' daily inspection reports. The daily inspection reports are not published on the DVFA Web site, while monthly reports are published and available for review,
- EU required HACCP-based audit conducted by trained veterinarians,
- Periodic supervisory reviews conducted by the headquarters-based audit division staff,
- Written SSOP plan and monitoring records for the last 90 days at each audited establishment,
- SPS and Good Manufacturing Practices (GMPs) related documents, and
- Sanitation and pathogen testing program at processing establishments producing RTE-PLE product when addressing *Listeria* hazard through sanitation (Alternative 3) only.

Additional requirements are enforced in all United States-certified establishments to meet FSIS requirements which are not covered in the EU-issued hygiene regulations and directives. Accordingly, DVFA has issued the Order on Export of Foodstuffs, No. 722 of May 26, 2015. Chapter 3 of Annex 6 of the aforementioned order is devoted to SSOPs. The SSOP requirements in the order are consistent with sanitation standards applied in the United States in accordance with 9 CFR 416.11 - 416.16.

According to provisions in Section 20, Chapter 3 of Annex 6 of the aforementioned order, each establishment must develop and implement a written SSOP program. The establishments must have written procedures to ensure that cleaning of food contact surfaces is occurring prior to the start of operation and to maintain sanitary conditions throughout the operation to prevent product adulteration.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at all of the audited establishments. In two of the audited establishments, the FSIS auditors verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of processing areas. The FSIS auditors identified findings related to sanitation performance standards (SPS) during the pre-operational verification which were immediately corrected.

The authority to exert official control at each regulated establishment including United States-certified establishments is drawn from Regulations (EC) 882/2004 and 854/2004. While the provision of the former regulation ensures the verification of compliance with feed and food law and animal health and animal welfare rules, the latter regulation specifically stresses organization of official control on product derived from animals intended for human consumption. To ensure that all elements related to sanitation are implemented in accordance with the Order on Export of Foodstuffs, No. 722, DVFA has

issued Export Inspection Guidance (updated on April 21, 2016) to the inspection staff assigned to the United States-certified establishments.

The scope, method and the range of verifications of each legislative area are clearly delineated in the inspection guidance document. For example, Section II (a) of Chapter 1B3 of the guidance document laid out the instructions for in-plant personnel to follow when verifying the establishment´s pre-operational and operational SSOPs daily and on each shift during production.

Inspection planning and the frequency of inspection tasks for Unites States-certified establishments are contained in the document titled, "Guidance on inspection of Exporting Establishments" dated April 21, 2016. The risk-based verification frequencies ensure that all food safety programs of an establishment are covered. With this objective, pre-operational and operational SSOPs are covered on a daily basis. Verification of SPS-related tasks in the United States-certified establishments and cold storage facilities are completed on a weekly basis. These frequencies can be increased if warranted.

The EU required HACCP-based audits conducted by trained veterinarians also encompass review of establishment compliance with sanitation regulatory requirements. The veterinary officer uses the meat inspection plan for planning the audits and the daily or weekly inspections.

In addition to the basic requirements outlined above, the CCA has developed specific requirements for sanitation in establishments producing Ready-to-Eat, Post-Lethality Exposed (RTE-PLE) product as listed in the Order on Export of Foodstuffs, No. 722. Establishments are required to verify sanitation by testing food contact surfaces for *Listeria monocytogenes (Lm)* or indicator organisms, and also develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, SSOP, or other prerequisite program. Guideline documents on export control outline official sampling regimens to be instituted at the establishments producing RTE-PLE products. For those establishments addressing *Listeria* hazards only through sanitation (Alternative 3)[1], all products destined for United States export is subjected to official testing.

The government inspectors sample RTE product every month for analytical testing to detect *Lm* and *Salmonella*. Under official verification, food contact surfaces (FCS) are also sampled for two samples per production line per year for non-deli products and four samples per production line for deli products. The same testing frequencies are applied for sampling of the production environment.

[1] 9 CFR part 430 (The *Listeria* Rule) lays out three alternative approaches establishments can take to control *Listeria* in their environment. These include:
Alternative 1: use of a post-lethality treatment and an antimicrobial agent.
Alternative 2a: use of a post-lethality treatment.
Alternative 2b: use of an antimicrobial agent.
Alternative 3: use of sanitation alone.

The FSIS auditors' verification of official controls and enforcement activity regarding development and implementation of SSOP programs included document reviews maintained by establishments and official verification records generated and maintained at the inspection offices located in the establishments.

Although no direct product adulteration was observed during the verification activities, the FSIS auditors reported the following findings concerning the CCA's ability to exercise official controls for sanitary operations:

- In one establishment audited the FSIS auditors noted that there was no actual signature to authenticate the monitoring records since the monitoring records were maintained on a computer printout, however 9 CFR 416.16 requires initials and a date for authentication.
- In six of eight establishments audited, concerns with sanitation requirements were identified. The FSIS auditors identified concerns related to the implementation of sanitary operations, equipment, maintenance, premises, ventilation, and employee hygiene.
- In one establishment, boxes were stacked directly against walls, which precluded official personnel and establishment employees from properly assessing storage conditions along the floor-to-wall junction.

The audit observations noted above indicate that requirements for sanitation are not being adequately enforced at the United States-certified establishments which raise concerns about the effectiveness of supervisory reviews as it pertain to implementation of sanitation.

At the audit exit conference, the CCA provided the FSIS auditors with evidence that the facility sanitation non-compliances had been corrected. FSIS' ongoing assessment of Denmark's inspection system indicated that it maintains clearly defined requirements and controls that meet the core equivalence requirements for this component; however, there is a need to improve sanitation verification and enforcement activity in the United States-certified establishments.

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

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

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The following documents related to HACCP requirements were reviewed:

- Order on Export of Foodstuffs, No. 722 of May 26, 2015,
- Annex 29 of the Meat Inspection Plan for 2016,
- Guidance on own-check in food-establishments, and
- Guidance on inspection of export establishments.

The requirements that each Danish establishment must develop, implement, and maintain a HACCP plan are embedded in Article 5 of Regulation (EC) No. 852/2004. However, establishments exporting pork products to the United States are subjected to additional requirements achieved through compliance with provisions pertaining to HACCP in the Order on Export of Foodstuffs No. 722 updated on May 26, 2015. Annex 6, Chapter 4, of the aforementioned document contains the regulatory requirements in accordance with 9 CFR 417.1- 417.5 and 417.7. By these regulations, DVFA enforces requirements for the development, implementation, and maintenance of HACCP programs in the establishments eligible to export to the United States.

The primary provision in Section 20, Annex 6, Chapter 6 of Order 722 requires the HACCP plan must contain a critical control point (CCP) to ensure the absence of visible contamination of either fecal and/or ingesta. The requirement exclusively states, "Carcasses, viscera and other parts must be treated in a hygienic manner so contamination with fecal material, urine, bile, milk, hair, dirt or other foreign material is avoided. If contamination occurs, it must be removed as soon as possible."

Annex 29 of the Meat Inspection Plan for 2016 is a scheduling sheet that lists all food safety tasks, applicable rules, and dates for the task to be verified during 2016. The Meat Inspection Plan for 2016 covers all HACCP requirements as outlined in the Order on Export of Foodstuffs, No. 722. The planning of the HACCP-based audit conducted by a trained veterinarian and his lay inspector is also made using the Meat Inspection Plan.

At the eight establishments audited, the FSIS auditors verified through interviews of in-plant personnel, record reviews and observations that the in-plant inspection personnel routinely verify HACCP plans in observations that the in-plant inspection personnel routinely verify HACCP plans in accordance with the guidance documents mentioned above.

The FSIS auditors also verified at four slaughter processing establishments that in-plant daily inspection verification also included CCP verification with results entered in the inspection records. The FSIS auditors reviewed the last 90 days' records pertaining to the CCP for zero tolerance and noted that the audited slaughter establishments were monitoring the CCP and taking corrective actions as specified in the plan.

The FSIS auditors also verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities. The review of daily inspection records indicated that inspection personnel were verifying the CCP for zero tolerance for fecal and/or ingesta contamination by way of inspecting 22 half carcasses 11 carcasses at a location after the establishment verification and prior to carcasses entering into chillers. The FSIS auditors further verified the 2014 audit finding related to the change of the CCP monitoring location that was inhibiting verification activity. This finding was corrected.

The FSIS auditors evaluated the CCA's program for RTE product by reviewing the information contained in the SRT. During the on-site visit, the FSIS auditors conducted interviews with the CCA's officials at the North Jutland FCO, inspection personnel assigned to United States-certified establishments, and document reviews. The CCA has adopted the definition of RTE product as specified in Regulation (EC) No. 2073/2005 in its national legislation. The audit scope included three RTE establishments, one of which produces Thermally Processed Commercially Sterile (TPCS-canned) product, and the other two export RTE product which is post-lethality exposed to the production environment.

The FSIS auditors verified that the canned product is produced under the establishment's HACCP plan that addressed all microbiological hazards associated with TPCS products. The FSIS auditors further verified that the in-plant inspector in-charge and the staff verify the plant's compliance in accordance with DVFA-issued guidance documents.

At the two establishments producing RTE products, the FSIS auditors confirmed that the DVFA requires establishments to conduct hazard analysis for the products exposed to post-lethality environment and address the microbiological hazards either in the HACCP plan or through prerequisite program or sanitation. The FSIS auditors noted that both RTE establishments audited apply sanitation measures alone (Alternative 3) to address *Listeria* hazards in their post-lethality exposed product destined for United States export.

Accordingly, the verification of effectiveness of sanitation are conducted by employing microbiological testing of product, food contact surface (FCS) and non-FCS with a frequency supported and documented in accordance with the provisions in the Order on Export of Foodstuffs No. 722. The FSIS auditors verified the DVFA-assigned inspectors verify the establishment's compliance with Danish legislation and regulatory requirements governing the RTE products. No concerns arose as a result of audit verification of the HACCP component except as noted in the relevant establishment checklist in Appendix A.

While on-site, the FSIS auditors conducted follow-up activities at two establishments implicated in POE violations to verify responses provided by the CCA in response to the violations. The FSIS auditors determined that corrective actions in response to fecal/ingesta contamination implemented by the establishments and verified by the CCA were effective in preventing recurrence.

The second POE violation involved heat treated-shelf stable (HT-SS) mortadella product exported from a Danish establishment in June 2015. During routine re-inspection at the POE, the vacuumed package containing the product was inflated, showing evidence of product spoilage.

The risk assessment conducted by the FSIS determined the scientific support provided by DVFA will not prevent potential growth of *Staphylococcus aureus* and other spoilage microorganisms in finished RTE products throughout the identified shelf-life of the product. In order to continue classifying this product under the HT-SS category,

additional support is needed, either in the form of an inoculation challenge study, other scientific support, or a change in process HACCP critical limits sufficient to prevent the potential growth of *Staphylococcus aureus* and spoilage microorganisms in finished RTE products throughout the identified shelf-life of the product.

During the audit of the establishment, the FSIS auditors confirmed that establishments are nearing the completion of a challenge study to provide adequate evidence that the current process and measures are indeed sufficient to ensure food safety of the product as HT-SS.

On July 13, 2016, FSIS received additional information and supporting document from establishment DK -211 from DVFA. Based on the evaluation of documents received, FSIS determined the information provided does not support shelf stability of product produced. On August 19, 2016, FSIS in a letter to DVFA communicated the outcome of its evaluation and requested additional information if establishment wishes to continue classifying this product under the HT-SS category. As stated above the additional support may be an inoculation challenge study or other scientific support. Alternatively, the establishment may choose to change in the process to include HACCP critical limits sufficient to prevent the potential growth of *Staphylococcus aureus* and spoilage microorganisms in finished RTE products throughout the identified shelf-life of the product. Pending DVFA response, FSIS will continue to inspect Heat Treated- Shelf Stable sausages from Denmark establishment 211 at an increased frequency.

FSIS determined that the HACCP program as described is consistent with the criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

In preparation for the on-site visit, the FSIS auditors reviewed and analyzed the information on the 2016 residue sampling plan provided by the CCA. The FSIS auditors further evaluated the information provided regarding the program structure, methods of analysis, and any additional SRT responses outlining the structure of Denmark's chemical testing program. The evaluation of the United States POE data for the duration since the last FSIS audit indicates that there have not been any chemical residue violations involving pork products imported from Denmark. The verification of this component consisted of interviews conducted at all audit locations, document reviews, and an audit of a chemical residue laboratory.

The National Residue Control Plan (NRCP) in Denmark is governed by the provisions in Council Directive 96/23/EC with respect to frequency and sample allocations among species, and the group of compounds that must be analyzed. The requirement of Article 5 of Council Directive 96/23/EC mandates that the country update the NRCP for the following year based on the results of the previous year in order to consider changes in chemical group and detection measures. DVFA, part of MEF, is the CCA responsible for the development and administration of the NRCP.

DVFA also manages and controls the use of veterinary medicinal products in poultry and livestock. The Unit of Animal Welfare and Veterinary Medicine within DVFA prepares the plan and solicits input from experts on chemical residues within Denmark Technical University (DTU) and the chemists from residue laboratories to forecast the annual residue testing program for the subsequent year based on the results from the current year. The final plan submitted to the EU commission for approval takes into consideration critical aspects of planning in areas such as:

- Scheme on distribution of chemicals to be tested among different animal species and product volume in accordance with Council Directive 96/23/EC,
- Additional sampling frequencies for milk, eggs, honey, rabbits and game meat pursuant to Council Directive 97/747/EC,
- Experience from analytical results and research,
- Input provided by the EU commission and Central Reference Laboratory on the NRCP,
- Scheme on uniform sample distribution though the year,
- Target sampling for drugs known to have high seasonal usage,
- Sampling of authorized veterinary medicine is based on statistics from the VetStat database (discussed below),
- Target sampling according to seasonal slaughtering of some species, and
- Resources including field staff and analysts and efficiency of analytical testing equipment.

Regular meetings among DVFA, laboratories and DTU experts take place on the implementation of the NRCP and projects describing sampling instructions, equipment and laboratory sample submission forms. The laboratories oversee sample collection and delivery and issue reminders when samples are overdue. Samples received at laboratories are checked for compliance with sampling instructions, including sample integrity and security. Sample collection including sampling of eggs at packing stations, as well as enforcement, is carried out by DVFA. The laboratories provide quarterly reports to DVFA on the progress of the plan.

Since implementation of "VetStat- Monitoring of Usage of Antimicrobials in Animals" in 2001, Denmark continues to play a pivotal role in monitoring use of antibiotics in livestock and poultry under the program. DVFA contributes by implementing initiatives in the monitoring of antibiotics. Some noteworthy features of the DVFA initiative include:

- Higher thresholds for tolerance for the use of antibiotics,

- Higher taxes for selected antibiotics, and simultaneous removal of the existing tax on vaccines, since the use of vaccines may reduce the need for antibiotic use,
- More frequent veterinary medical visits to pig lots, and
- Regular testing of herds where evidence of treatment is present.

For monitoring of residues, official samples are collected in accordance with the Council Directive 96/23/EC requirement. DVFA is targeting 13,643 samples for 2016 which include chemical compounds:

- Dioxin (250 samples),
- Metals (278 samples),
- Mycotoxin (440 samples),
- Fluorinated compounds (56 samples),
- Pesticides (248 samples), and
- Veterinary Drugs (12371 samples).

The follow-up on a noncompliant product or at livestock farm leads to an investigation by the Veterinary Control Office having jurisdiction on violative entity. In accordance with National Order No. 423 of 2016, some of the deterrents applied to violators include farm closure, in conjunction with follow-up samples, or sanctions against violators of confirmed illegal drug use in animals for human food.

During the verification at the establishment level, the FSIS auditors verified the DVFA-assigned government inspectors in MIUs collect the samples under the NRCP project for 2016 following guides for sampling. The inspector simulated the entire process from sample collection to sample sealing. The FSIS auditors further confirmed that the NRCP is on target as intended.

For analysis of samples collected under the NRCP, DVFA uses the chemical residue unit of a central laboratory in Ringsted "*Fodevarestyrelsen, Laboratoriet i Ringsted"* and a field laboratory located in Aarhus. The FSIS auditors reviewed the Ringsted laboratory for its chemical residue testing program. The audit of the laboratory included interviews with the officials, document reviews, and concluded with a site visit to the chemical testing portion of the laboratory. This laboratory is ISO 17025 accredited by DANAK in the specific areas of testing. The FSIS auditors reviewed the most recent accreditation audit of the laboratory that took place in April 2016. DANAK accreditation identified minor issues which the laboratory remedied and submitted the corrective actions pending approval from DANAK.

The FSIS auditors interviewed the analysts to assess their technical competency, training, and knowledge of the analytical methods used on the samples to detect chemical residues. The document review also included an evaluation of management system documents, and internal audit reports. The review of proficiency testing records revealed that all results reviewed were acceptable. During the visit to the facility, the FSIS auditors observed the laboratory personnel at the sample receipt area who were receiving samples, checking sample integrity and security, assigning the identification, and storing the samples in

accordance with the laboratory's standard operating procedure. No concerns arose as a result of the laboratory audit.

Based on the evaluation of information contained in the SRT and pre-audit analysis of supporting documents in conjunction with the information gathered during the on-site audit, FSIS determined that the Government Chemical Residue Control Programs component includes a national program that is managed and implemented by DVFA as intended.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT. The CCA has issued a Guidance Document No. 9044 dated January 27, 2015 on implementation of provisions of Regulation (EC) No. 2073/2005 on "Microbiological Criteria for Food For Certain Microorganisms and Rules" that need to be complied by establishments. Articles 3 and 4 of Regulation (EC) No. 852/2004 provide the legal basis for implementation of Regulation (EC) No. 2073/2005.

Denmark requires all slaughter establishments to develop and implement sampling and testing program for the indicators of fecal contamination in order to assess the effectiveness of its slaughter and dressing process control during the production of raw meat. The requirements that the establishment has to evaluate the results are listed in Annex 6 of the Order on Export of Foodstuffs, Chapter 9. The FSIS auditors verified that all four slaughter establishments audited had developed and implemented *E. coli* testing programs consistent with the standards applied domestically and as specified in 9 CFR 310.25. Inspection personnel routinely verify that results related to statistical process control are correctly evaluated. The FSIS auditors further verified the analytical results and test methods for tests conducted in the last 90 days. No concerns arose as result of verification of the CCA's *E. coli* testing program.

While verifying the testing programs for *Salmonella* species, the FSIS auditors confirmed that FSIS granted the following equivalence determinations for Denmark which DVFA continues to apply in meeting criteria for *Salmonella* testing program at the United States-certified establishments.

- Establishment employees collect the samples for *Salmonella* testing of raw product,
- Private laboratories analyze samples for *Salmonella*,
- A continuous, ongoing sampling program is used,
- A gauze pad sampling tool is used, and
- NMKL method # 71 and IQ Check method are used to analyze samples.

DVFA has captured the requirements on the *Salmonella* testing program in Annex 6 Chapter 8 of Order on Export of Foodstuffs titled "*Salmonella* testing." The performance standards described in the document are consistent with the provisions specified in 9 CFR 310.25. The national prevalence of *Salmonella* in swine carcasses is estimated to be 8.7%; therefore, the Danish standards are consistent with provisions specified in 9 CFR 310.25.

The FSIS auditors verified that the testing program is implemented as intended at all slaughter establishments audited. Establishments are permitted to fail six samples from a set of 55 consecutive samples. Failing a set requires the establishment to implement corrective actions which are verified and evaluated by the in-plant personnel. Additionally, at each United States-certified establishment, the DVFA-assigned inspector collects one verification sample each week as described in the DVFA-issued Export Inspection Guidance. The sample is collected using the instructions provided in Order of Export of Foodstuffs, No. 914 of September 10, 2012 on the topic of sample handling and analysis. Establishments can utilize either FSIS methods as outlined in the Microbiological Laboratory Guide applicable to *Salmonella* in raw products or alternative approved methods.

If establishments chose alternative methods, one of the following FSIS-approved methods can be employed to conduct analytical methods:

- VIDAS,
- NMKL No. 71, and
- IQ-Check *Salmonella* Kit.

Chapter 14 in Annex 6 of Order on Export of Foodstuffs, No. 722 of May 26, 2015, is devoted on application of microbiological criteria for *Salmonella* and *Lm* in RTE products. This document mandates that all United States-certified establishments must develop and implement a microbiological testing program that ensures zero-tolerance for *Lm* on product and product contact surfaces. The measures the CCA requires establishments producing RTE-PLE product to control *Lm* in post-lethality exposed ready-to-eat meat products are consistent with provisions specified in 9 CFR 430.4.

Two of the three RTE establishments audited were producing RTE-PLE products and were applying sanitation measures (Alternative 3) to control *Listeria* hazards in their product. The FSIS auditors verified that the two establishments were required to develop microbiological testing programs to detect *Lm* and *Salmonella spp*. in the product. The FSIS auditors further verified that the establishments had identified in their testing program the plan for test and hold in the event if the product or food contact surface tested positive for *Lm* or *Salmonella spp.*

The FSIS auditors noted that in the two establishments producing RTE-PLE products, testing of FCS, non-FCS, and product were conducted at frequencies outlined in Chapter 14 in Annex 6 of the Order on Export of Foodstuffs, No. 722. Establishment records indicated that product is routinely held until all (FCS, non-FCS, and product) testing results are received. Furthermore, it was noted that establishment testing results were

routinely verified by government inspectors, as well as during periodic supervisory reviews. No concerns arose from the review of these programs.

The FSIS auditors verified that the CCA implemented the 2016 official surveillance plan for monitoring *Lm* and *Salmonella* in pork products to be exported to the United States as outlined in Guidance on Inspection of Exporting Establishments, dated April 21, 2016. This plan includes the random and risk-based sampling of all RTE products for *Lm* and *Salmonella*; and a plan that includes the monitoring of FCS and NFCS establishments eligible to export to the United States annually. DVFA's assigned government inspectors sample RTE product one sample every month for analytical testing to detect *Lm* or *Salmonella spp*. Under official verification testing, FCS are also collected at a frequency of two samples per production line per year, and for deli product four samples per production line times are collected for deli products. The same testing frequencies are also applicable for sampling of the production environment.

Through review of certificate of analyses for official verification testing conducted by DVFA, the FSIS auditors determined that analytical methods employed to analyze samples for detection of *Lm* and *Salmonella spp*. are in accordance with the Export Inspection Guide for product testing. The testing methods employed for FCS and NFCS are in accordance with "Guidelines on Sampling the Food Processing Area and Equipment for the Detection of *Listeria moncytogenes*."

Lastly, in order to determine if the CCA has adequate administrative and technical support to operate the inspection system, among other verification activities, the FSIS auditors also included a review of a microbiological laboratory in the scope of the audit.

The DVFA-controlled laboratory consists of a microbiological unit and chemical unit in the same premises located in Ringsted. This laboratory is designated as an EU reference laboratory, participates in inter-laboratory proficiency testing (PT), and has already participated in 16 tests under the program for the year 2015. The FSIS auditors reviewed all test results under the program and concluded that the PT met the tests' standards. Although in Denmark there are two laboratories currently involved in testing for chemical residues under the national residue testing plan, the laboratory audited is the only laboratory which conducts analytical testing on samples for detection of pathogens of foodborne origin. The FSIS auditors verified that the laboratory conducts analytical testing on samples for official verification on product destined for United States export.

The FSIS auditors reviewed the recent ISO 17025 accreditation report issued by DANAK. The laboratory has corrected the concerns identified by DANAK and presented the corrective actions for review to DANAK for its acceptance. The FSIS auditors interviewed analysts and reviewed their training records. The review determined that all analysts received required training to conduct analytical testing. No concerns were identified as a result of the laboratory audit except some minor issues with the requirements of ISO 17025 noted below:

- During the laboratory audit, the FSIS auditors identified minor issues with the requirements of ISO 17025 pertaining to disposal of expired media and calibration of a pH meter.

FSIS determined that the CCA's microbiological testing program as described is consistent with the criteria established for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 10, 2016, in Glostrup, Denmark with DVFA. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The CCA understood and accepted the findings. During the audit, the following findings were identified:

- In six of eight establishments audited, the FSIS auditors identified implementation issues with sanitation requirements in the area of maintenance of equipment, overhead structures, premises, ventilation, sanitary operation, employee hygiene and storage conditions in chilling rooms which obstructed inspection in the coolers.

- When inspectors retain carcasses and parts for veterinary disposition due to pathology, they often discard parts of viscera prior to presentation to the veterinarian. The CCA's procedures for veterinary disposition require all parts and carcasses to be presented to the veterinarian.

An analysis of the findings within each component did not identify any significant findings which represented an immediate threat to public health. However, as noted above a number of audit observations pertaining to sanitation requirements were identified during the audit. The auditors verified that the CCA or establishments representative addressed most of the noncompliances immediately and provided documented preventative measures. For other noncompliances needing additional time the CCA has instructed the establishments to correct them within reasonable timeframe. During the audit exit meeting the CCA committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of CCA's proposed corrective actions once received.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Langbro 7 Blans 6400 Soenderborg	06/06/2016	Est. DK 14	Denmark
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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. Enforcement	
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. Monthly Review	
58.	
59.	

60. Observation of the Establishment
46/51
During pre-operational sanitation the auditors identified:
- A multiple conveyor belts had jagged edges and cuts with discolored surfaces needs replacements.
- A couple of scabbards observed were not cleaned prior to the start of processing/boning operation for the day.
During the operational sanitation tour of facility the auditor noted:
- The chemical storage room had broken floor and/or corner, floor appeared stained due to chemical spillage, badly rusty cabinet needed repair. Overall rooms appeared neglected for a long time.
- The floor in fat melting room was littered with the dirt. A chemical room adjacent to the room had dirt accumulated on the floor and chemical spillage on floor surface.
- At several work station platform in evisceration room had waste water from slaughter accumulated due to lack of drain.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/06/2016

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 Bragesvej 18, DK-4100 Ringsted	06/08/2016	Est. DK 25	Denmark
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

41/51 In two of the three chilling rooms the auditors inspected had visible over the product condensate, however, condensate was not seen coalescing or falling on the product.

45/51 The auditors observed rusty railing and bolts were in some of the chilling rooms inspected.

46/51 Lightly grease laden overhead railing was observe at multiple locations in smoking/curing room. At one location grease from overhead railing had fallen on the product which was stored underneath. Affected product was reworked and verified by the inspection personnel. A couple of small holes in the wall were also observed in the same production area which were immediately filled and patched.

47 An employee in boning room observed sweating profusely while he was deboning pork product. The product suspected of being affected was condemned and employed reassigned to the other work not involving handling of product.

55/51 When inspectors retain carcasses and parts for veterinary disposition due to pathology, they often discard parts of viscera prior to presentation to the veterinarian. The Central Competent Authority (CCA) procedures for veterinary disposition require all parts and carcasses to be presented to the veterinarian.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/08/2016

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 Gammel I Ringvej DK-6700 Esbjerg	06/02/2016	Est. DK 53	Denmark
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/02/2016

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 Tulipvej 10 DK 7100 Vejle,	06/01/2016	Est. DK 65	Denmark
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

46/51 -Dry ingredient room was poorly maintained and was allowed buildup of spices and dust indicating neglected maintenance in the room.

-Dirt and grease build collected around rolling machine for can lids posing potential for lids contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/01/2016

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, Wenbovej 11, DK-9300 Saeby,	05/25/2016	Est. DK 71	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	X	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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

9/51 No actual signature to authenticate the monitoring record as monitoring recorded is maintained on computer printout, however per 9 CFR 416.6 requires initials and date for authentication;

46/51 The following noncompliance related to implementation of sanitation requirements were observed during pre-operational verification of the establishment:
- Two sterilizers with blood and debris in them,
- Blood collecting machine contained pieces of fat,
- Hair build up on paddles in the hair removal machine,
- Some scalders had large buildup of residue and hair,
- Loose paint and two holes in the corner of a wall,
- Debris on plastic boxes,
- Several pieces of fat on hoof cutter,
- Some sterilizers had rusty discolorations,

The CCA and Plant management addressed all the issues identified during the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/25/2016

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 lCompany Mosevangen I, DK 9230 Svenstrup J	05/26/2011	Est. DK 211	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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. Monthly Review	
58.	
59.	

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/26/2011

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 Aabenraavej 11 DK 6780 Skaerbaek,	06/03/2016	Est. DK 311	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	X
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	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

8/51. The Sanitation corrective actions form requires the time when nonconformity is corrected to be recorded. The review of corrective action form for 90 days revealed that at numerous occasions the time was not recorded.

38/51 Outside premises next to entrance to ante-mortem pens had standing water and blood due to clogged drain which attracted flies in the affected area and the entrance door. No flies were observed in any of the production area. Establishment took immediate corrective action.

39/51 Packing area was observed with multiple rusty pipes, loosely applied duct tape around exhaust pipes. Chilling room floor needed cleaning as evidenced from dirt/debris collected around doors and corners.

45/51Same type and colored containers were in use to store for equipment and edible product. The use of the same type and color containers for equipment and product can pose a potential for contamination.

55/51 Carcasses with visible hair all around rear hock joint were being loaded on the truck to intra-community trade. A procedure to ensure that product for the US export will free of visible hair was not available for the auditors review. Later, during the audit the establishment management revised the procedure to address the concern.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/03/2016

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
DK Foods Bommen 9, Thorning, DK8620 Kjellerup	05/31/2016	Est. DK 4658	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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	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	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	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. Monthly Review	
58.	
59.	

60. Observation of the Establishment

15/51 The hazard analysis (HA) for microbiological hazards did not identify the specific pathogens known for the product or the steps which may be introduced during the process. For example, Lm is a known pathogen in RTE product exposed to the post-lethality production environment. The officials presented a separate document that listed all known pathogens, however, HA did not make reference to the presented document. The finding was immediately corrected during the audit.

45/51Multiple storage totes to store edible product were observed cracked or poorly maintained needed either to be discarded or repaired to prevent cross contamination of product.

46. Synthetic casing containers at the peeling step were unmanageable due to mechanical failure of the device were creating insanitary condition at the CCP-2 location.

Corrective actions initiated by either establishments or the DVFA officials addressed the concerns while audit was in progress. The corrective actions were verified by the inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/31/2016

Appendix B: Foreign Country Response to Draft Final Audit Report

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

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

File: 2016-30-1030-00140
Ref. alpe
Date: 04-11-2016

Comments on the draft final report of an on-site-equivalence verification audit carried out in Denmark May 23 to June 10, 2016.

Dear Jane H. Doherty,

The Danish Veterinary and Food Administration (DVFA) acknowledges the receipt of FSIS's draft final report of an audit carried out in Denmark May 23 to June 10, 2016.

By letter of September 6, 2016 FSIS has invited the DVFA to provide comments to the draft report.

The DVFA would like to state the following comments to the draft report:

Page 2, section 2, 2nd line
"Eastern Regional DVFA Laboratory (Ringsted)". There is no eastern/western region. The DVFA suggests "DVFA Laboratory (Ringsted)".

Page 3, section 6, 5th line:
"The CCA has launched a challenge study". It is not the DVFA that has launched a challenge study, but the establishment. The DVFA suggests "The establishment has launched a challenge study".

Page 4, second 6, 9th line
" bears responsibility in the areas of feed and veterinary legislation ..." The DVFA also bears responsibility for food legislation. The DVFA suggests "bears responsibility in the areas of food, feed and veterinary legislation".

Page 6, section 3, 3rd line
"Structurally, the MID is connected to Meat Inspection Administration headquartered in Glostrup". The MID is not connected to a specific department in Glostrup, the MID is one of the six administrative headquarters; however they are located in Lystrup. The DVFA suggests "Structurally, the MID is one of the six departments in the DVFA, but is located in Lystrup".

Page 7, section 1, 3rd line
"All inspection personnel are required to participate in trainings and continuing education courses offered by the EU – Better Training Safer Food (BTSF)". It is not a requirement to participate in the BTSF courses. Some inspection personnel are offered participation in the courses when relevant and possible. Denmark is only able to send one or two personnel to each course. The DVFA suggests "Inspection personnel are offered to participate in trainings and continuing education courses offered by the EU – Better Training Safer Food (BTSF) when relevant and possible".

Page 9, section 3
DVFA explanation: Visual inspection of lungs and livers is under implementation in Denmark. The imple-

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mentation has to be finished in all relevant slaughterhouses by the end of 2016. The visual inspection in US approved establishments will only be conducted on pigs raised indoors.

Page 9, section 4, 6th line and page 10 section 1

- When the inspectors retain carcasses and parts for veterinary disposition due to pathology, they often discard parts of viscera prior to presentation to the veterinarian.
- The CCA's procedures for veterinary disposition require all parts and carcasses to be presented to the veterinarian.

DVFA's comment:

According to Danish legislation the following tasks concerning post-mortem inspection have to be performed by a veterinarian:

- Animals that have been slaughtered because of emergency.
- Suspicion of offence of regulations concerning animal welfare.
- Suspicion of contagious diseases and zoonosis.
- Animals that have been marked by a veterinarian at the ante-mortem inspection.
- Animals showing signs of poisoning or suspicion of residues.

During the inspection at Est. 25 the FSIS inspector observed that intestines from a pig, which had been marked at the ante-mortem, were not presented to the veterinarian. That was a failure. On June 9 the Meat Inspection Department sent an e-mail to all inspection units stating in which situations it must be a veterinarian, who has to inspect all parts of a slaughtered animal (as stated in the The Danish Circular on Meat Inspection, annex 9, chapter 3).

Page 12, section 1, 1st line and section 3, 2nd line
The two documents referred to as "Export Inspection Guidance" (updated on April 21, 2016) and "Guidance on inspection of Exporting Establishments" (dated April 21, 2016) are the same, called "Export Inspection Guidance".

Page 18, section 5, 2nd line and 3rd line
The laboratory in Ringsted is not a central laboratory and the laboratory in Aarhus in not a field laboratory. They are both Laboratories, the one in Ringsted mainly dealing with microbiology and residues and the one in Aarhus mainly dealing with chemical tests.

Final comments

The DVFA has used the information and findings from the inspection to initiate follow up at three different levels; specific follow up at each establishment, systematic follow up at all US approved establishments and initiatives to improve sanitation verification and enforcement activity.

Specific follow up

All findings from the inspection were addressed immediately during the inspection and the DVFA has performed follow up inspections and verified the corrective actions done by the establishments.

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Systematic follow up

The Meat Inspection Department and the Food Control Offices have furthermore initiated a general systematic follow up on all US-approved establishments to investigate if findings discussed under the inspection are present at other establishments and to ensure that findings are dealt with at all establishments.

Improvement of the sanitation verification and enforcement activity

The DVFA is working with competences, uniformity and enforcement through training, guidelines, uniform checklists etc.

The USA Audit team also initiated an evaluation of their methods and reporting, including follow up and the effectiveness of the reviews to improve the effectiveness of supervisory reviews. This is done in close cooperation with the Meat Inspection Department and the Food Control Offices.

Follow up activities and corrective actions taken by the DVFA at each establishment and DVFA activities for improvement of the sanitation verification and enforcement activity is described in a cover letter for the FSIS.

Please do not hesitate to contact the International Trade Division (30@fvst.dk), if you have any further questions.

Yours sincerely,

Annelise Fenger

Deputy Director General

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