United States Department of Agriculture

Food Safety and
Inspection Service

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Washington, D.C.
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JUL 17 2018

Dr. Per S. Henriksen
Chief Veterinary Officer
Danish Veterinary and Food Administration
Ministry of Environment and Food of Denmark
Mørkhøj Bygade 19
DK–2860 Søborg
Denmark

Dear Dr. Henriksen,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site ongoing equivalence verification audit of Denmark's pork products inspection system from March 12 through March 23, 2018. 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.

FSIS acknowledges that the Danish Veterinary and Food Administration (DVFA) provided documentation to address the findings noted during the on-site audit. FSIS is in the process of evaluating your response, and may be requesting additional information regarding Denmark's inspection procedures related to the DVFA's Critical Control Point monitoring procedures for zero tolerance.

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

Sincerely,

Janell Kause
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

DENMARK

MARCH 12 - 23, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 13, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service from March 12-23, 2018. The purpose of the audit was to determine whether Denmark's food safety system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Denmark currently exports the following categories of pork products to the United States: raw intact, primal and subprimal, boneless manufacturing trimmings, raw ground, raw non-intact, not ready-to-eat processed meat, ready-to-eat (RTE) acidified/fermented meat, RTE dried meat, RTE fully cooked meat, thermally processed-commercially sterile, and edible offal.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

Government Hazard Analysis and Critical Control Points System

- Inadequate government verification of corrective actions associated with HACCP requirements for the support of critical control point monitoring frequencies in six of the seven audited slaughter establishments. The DVFA's inspection system did not effectively verify the adequacy of Denmark's HACCP system.

During the audit exit meeting, the Central Competent Authority (CCA) committed to address the preliminary findings as presented. Once FSIS receives the documented proposed corrective actions, FSIS will evaluate the adequacy of the information to determine the scope of future equivalence verification activities.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Denmark's food safety system from March 12-23, 2018. The audit began with an entrance meeting held on March 12, 2018, in Glostrup, Denmark, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Danish Veterinary and Food Administration (DVFA).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Denmark is eligible to export raw and processed pork products to the United States. Denmark currently exports the following categories of pork products: raw intact, primal and subprimal, boneless manufacturing trimmings, raw ground, raw non-intact, not ready-to-eat (NRTE) processed meat, ready-to-eat (RTE) acidified/fermented meat, RTE dried meat, RTE fully cooked meat, thermally processed-commercially sterile, and edible offal.

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

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

The two FSIS auditors were accompanied throughout the 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 (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at CCA headquarters, one regional office, and 11 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 11 establishments to be audited was selected from 25 establishments certified to export to the United States. The selected establishments included seven pork slaughter and processing establishments and four pork processing establishments. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent non-compliances that threaten food safety. The FSIS auditors examined 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.

Additionally, FSIS audited one microbiology laboratory and one chemical residue laboratory to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Danish Veterinary and Food Administration, Glostrup
	Regional	1	• Food Inspection Unit, Lystrup, Aarhus
Laboratories		2	• Danish Veterinary and Food Administration Laboratory, Microbiology Unit, Ringsted • Danish Veterinary and Food Administration Laboratory, Chemical Residue Unit, Ringsted
Pork slaughter and processing establishments		7	• Establishment 14, Danish Crown, Sonderborg • Establishment 22, Danish Crown, Ronne • Establishment 25, Danish Crown, Ringsted • Establishment 31, Danish Crown, Herning • Establishment 71, Danish Crown, Saeby • Establishment 320, Danish Crown, Horsens • Establishment 338, Tican Fresh Meat, Thisted
Pork processing establishments		4	• Establishment 53, Danish Crown, Esbjerg • Establishment 65, Tulip Food Company, Vejle • Establishment 211, Tulip Food Company, Svenstrup J • Establishment 236, BHJ A/S, Hobro

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

- The Federal Meat Inspection Act (FMIA) (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 Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of Denmark's inspection system for slaughter and processed pork 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. This also includes the following:

- Regulation European Commission (EC) No. 178/2002;

- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

From January 1, 2016 to September 30, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 132,114,895 pounds of raw and processed pork products exported by Denmark to the United States. FSIS also performed reinspection on 12,691,984 pounds at point-of entry (POE) for additional types of inspection, including testing for chemical residues and microbiological pathogens, of which a total of 313,580 pounds were rejected for food safety reasons (e.g., ingesta, fecal materials, etc.) other than testing positive for pathogens.

The previous FSIS audit in 2016 identified findings related to the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations and Government Sanitation components. This 2018 audit also included a visit to the one establishment involved in 2016 POE violations. FSIS verification concluded that the CCA worked with the establishment to identify the root causes of the POE violations and instituted appropriate corrective actions. The FSIS auditors verified that the corrective actions for the previously reported findings had been completed.

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 (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; 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 at least once per shift at processing establishments and on the line during all slaughter operations. The evaluation of all six equivalence components included a review and analysis of documentation previously

submitted by the CCA as support for the responses provided in the SRT. The onsite audit included record reviews, interviews, and observations made by the FSIS auditors.

The Danish Veterinary and Food Administration (DVFA) is the CCA under the Ministry of Environment and Food of Denmark (MEFD). MEFD was created in the summer of 2015 from a merger between the Ministry of the Environment and the Ministry of Food, Agriculture, and Fisheries. DVFA is one of five agencies that MEFD oversees. An Executive Director, who has responsibility in the areas of feed and veterinary legislation, veterinary control, animal diseases, animal welfare, nutritional information, and international cooperation, leads the DVFA. The other four agencies within MEFD are the Danish Environmental Protection Agency, the Danish Agrifish Agency, the Danish Nature Agency, and the Danish Coastal Authority. As a member of the European Union (EU), DVFA gets its authority from *Regulation (EC) No. 178/2002, the Danish Food Act (August 20, 2011), the Danish Executive Order on Export of Foodstuffs No. 806 of June 22, 2017, and the Danish Circular on Meat Inspection.*

The FSIS auditors performed onsite observations and reviewed records maintained by inspection personnel at DVFA headquarters, regional food inspection units, and inspection offices within certified establishments. Officials use the authority of the laws of Denmark to enforce the rules of the meat inspection system, identify and document non-compliances, and verify the adequacy of corrective actions and preventive measures. The enforcement strategies in place are based on *Regulation (EC) No. 882/2004* and *Regulation (EC) No. 178/2002*. The CCA has the authority to suspend, or withdraw certification of certified establishments.

The activities that occur at the CCA level include issuing inspection rules and regulations; serving as an advisory body to MEFD for policy making regarding food safety and animal welfare; establishing the guidelines for government inspection and industry; establishing the sampling plans; establishing guidelines for government inspections and sanctions; supervision; audits of enforcement implementation, laboratories and task forces; risk monitoring involving food and feed safety; animal health and welfare; training of inspection staff; and collaborating with universities for risk evaluation or research.

The Audit Unit (AU) is a liaison between the DVFA and the field staff responsible for conducting supervisory audit reviews at all establishments eligible to export pork products to the United States. It has an office located within the Communication and Innovation Department of DVFA. The DVFA requires the AU to ensure that establishments eligible to export to the United States comply with FSIS requirements, evaluate the performance of the local authority, assist in conducting uniform inspection and enforcement, train inspection personnel, and update and develop legislation and guidelines.

Denmark's inspection system at the local level consists of four Food Inspection Units (FIUs) and a Meat Inspection Department (MID) with its associated Meat Inspection Units (MIUs) located at the slaughterhouses. Veterinary Inspection Units (VIUs) support this organizational structure for livestock inspection and emergency response and food and veterinary task forces. Each pork

slaughter and processing establishment eligible to export to the United States is inspected by an MIU, while inspectors in each pork processing establishment exporting to the United States are supervised by an FIU. The FSIS auditors verified the implementation of administrative functions at the FIU located in Lystrup, Aarhus, which include authorization, registration, and approval of new establishments, official sampling, export certification, compliance guidance to new establishments, withdrawal of approval, managing recalls, and handling foodborne outbreaks.

At the FIU in Lystrup, the FSIS auditors conducted interviews with officials from the North and South FIUs and reviewed documents from both offices. The FSIS auditors confirmed that these offices are responsible for delivery of supervisory oversight at processing establishments, including establishments eligible to export processed pork products to the United States. In addition to delivery of oversight, the veterinary officers are also responsible for performing a wide array of food safety inspection duties, which include reviewing establishment surveys of sanitation standards for approval, guidance to inspectors at new facilities, and verification of export certification. These offices also assign official sampling by the inspectors in the processing establishments. Additionally, the FIUs play a critical role in recalls of food products that tested positive for foodborne pathogens and impose sanctions in case of noncompliance.

At the CCA headquarters in Glostrup, the FSIS auditors verified that the MID, which is one of the five departments of DVFA, is headed by the Chief Meat Inspection Officer (CMIO). The MID consists of the MIU in Lystrup and all local MIUs in slaughter establishments. The CMIO is responsible for slaughter-related activities in Denmark, government analytical laboratories in Aarhus and Ringsted, and reports directly to the Executive Director of DVFA. Four Head of Meat Inspection officials support the CMIO. Each official receives support from an average of four Deputy Head of Meat Inspection personnel. Each visited slaughter or processing establishment eligible to export to the United States has its own Deputy Head of Meat Inspection who leads the inspection team, which consists of variable numbers of veterinarians and DVFA in-plant inspection personnel (IIP) depending on the size and number of production line of the establishment. The MIUs are located in slaughter establishments, which are the DVFA inspection offices within the establishments.

The FSIS auditors visited seven pork slaughter and processing establishments and four processing establishments during which they interviewed head of units, deputy heads, veterinarians, and IIP. The FSIS auditors reviewed a sample of daily and monthly inspection reports at each site and verified that the DVFA applies uniform standards of inspection across all establishments eligible to export pork products to the United States.

In assessing DVFA's ability to acquire and maintain competent and qualified personnel, the FSIS auditors verified that inspection personnel in the establishments eligible to export pork products to the United States are employees of DVFA who are paid by the government. 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 DVFA staff in pork slaughter establishments and processing establishments is comprised of at least one veterinarian and IIP. A DVFA veterinarian must have a degree in veterinary medicine in accordance with requirements for veterinarians in *Regulation (EC) No. 854/2004*

and Danish Order No. 1455/2006. IIP 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 by DVFA. These requirements are described in *Danish Order No. 1455/2006 and Regulation (EC) No. 854/2004.*

DVFA has a specialized training program for veterinarians and IIP. Upon initial appointment, each veterinarian and IIP receives formal training in conjunction with on-the-job training with a senior veterinarian prior to being assigned to an establishment. All inspection personnel are required to participate in trainings and continuing education courses offered by the EU. In order to be appointed to an establishment eligible to export pork products to the United States, the veterinarian or IIP must have a sound knowledge of DVFA legislation and FSIS's requirements, in addition to having proficiency in EU regulations.

For ongoing training of inspection personnel, DVFA has organized a training portal on its Web site known as "CAMPUS." Employees use the "CAMPUS" site for courses mandated by DVFA or for career development. DVFA has mechanisms to assess training needs of its 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 DVFA employees' training records during the audit of the FIUs in Lystrup and MIUs and determined that the training program is delivered as intended.

At the FIUs and MIUs, the FSIS auditors also verified the organizations carried out periodic supervisory reviews, annual performance reviews, and personal development programs for veterinarians and IIP assigned to establishments eligible to export pork products to the United States. Through record reviews and interviews, the FSIS auditors determined 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 or Head of FIUs for veterinarians, who in turn evaluate the performance of IIP. The tool used for performance assessments includes the results of quality supervision, weekly work meetings, and one-on-one meetings with inspectors. The outcome of the periodic supervisory audits, conducted by the DVFA senior auditors, also plays a significant role in the determination of the inspectors' performance.

During the audit of the regional FIU, the FSIS auditors also reviewed the DFVA's procedures to ensure the security and integrity of export certificates. The DVFA has issued the following official documents that cover procedures to control the issuance of the certificate and provide guidance to inspectors on verification of the requirements of the importing country: *Danish Executive Order on Export of Foodstuffs No. 806 of June 22, 2017 and Guidance on Inspection of Export Establishments*. The FSIS auditors reviewed and verified the adequacy of samples of export certificates issued under government seals at regional FIUs and at audited establishments.

The FSIS auditors verified that the DVFA provides technical support for microbiological and chemical residue testing for local slaughter establishments and processing establishments through two government laboratories located in Ringsted and Aarhus. The Ringsted laboratory

serves as a National Reference Laboratory (NRL) for animal diseases and 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.

DVFA is responsible for the enforcement of food safety standards and has the authority and the ability to require corrective actions in establishments exporting to the United States and to take additional enforcement measures as appropriate. The enforcement actions taken at establishments approved for export to the United States are examined during the regular audits performed at each establishment. The FSIS auditors verified through interviews and record reviews that enforcement actions range from warnings and injunctions to fines or criminal prosecution. If the production in establishments eligible to export to the United States does not comply with FSIS equivalence requirements, DVFA may withdraw or suspend its approval according to *the Danish Executive Order on Export of Foodstuffs No. 806 of June 22, 2017.* Additionally, all establishments certified to export to the United States have to meet *Article 12 of Regulation (EC) No. 178/2002*, which sets out how compliance will be achieved and what enforcement measures will be used if corrective actions are not taken in case of noncompliance.

The FSIS auditors discussed the 2016-2017 violations of FSIS import requirements detected in the imported pork products at United States POE. The DVFA explained the corrective actions implemented in the establishments, and verified by the inspection personnel to ensure effective corrective actions, and measures implemented to prevent future recurrence of reinspection failures. Additionally, the FSIS auditors discussed the previous audit findings and the corrective actions implemented by the establishments and verified by the DVFA. The FSIS auditors verified and confirmed that the findings of the 2016 audit were corrected.

The audit determined that Denmark's government organizes and administers the country's meat inspection system, and that DVFA officials enforce laws and regulations governing production and export of pork at establishments eligible to export to the United States. The FSIS auditors determined that Denmark's pork inspection system continues to maintain the government oversight framework to implement equivalent requirements that meet the core requirements for this component.

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

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

The FSIS auditors evaluated this component via in-plant record reviews, interviews, and direct observation. This evaluation was in correlation with information provided by the DVFA in the SRT, POE information, and Denmark's history of compliance. The FSIS auditors reviewed the slaughter practices at the audited establishments and confirmed that inspection personnel verify that humane handling and humane slaughter of livestock are conducted in accordance with EU regulations. The DVFA issued Decree No. 140/2012 (XII.22) as the implementing document for *Regulation (EC) No. 1099/2009*, which describes the responsibilities and official controls for humane handling. 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 DVFA.

At each audited slaughter establishment, the FSIS auditors verified that swine brought to slaughter receive ante-mortem examination in accordance with *Regulation (EC) No. 854/2004*. The FSIS auditors further verified that at each audited slaughter establishment, at least one 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 veterinarian applies the relevant provisions of *EC Directive No. 93/119/EC, Regulation (EC)* No. *854/2004, and Regulation (EC)* No. *1099/2009.*

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

Only market swine raised indoors since weaning and raised under controlled circumstances are eligible for visual post-mortem inspection and export to the United States. An integral component of the visual inspection system is the supply chain information. This information contains pre-slaughter data that is to be presented to the slaughter establishment prior to slaughter of the swine. The slaughter establishment must make the food chain information available to the official veterinarian immediately, not less than 24-hours before the arrival of the animal or lot. Official veterinarians at the slaughter establishment are allowed to use their professional judgement to decide if the lot of swine should be allowed to undergo visual inspection or traditional inspection.

In each audited slaughter establishment, the FSIS auditors verified through record reviews, interviews with inspection staff, and observation that each establishment is staffed with DVFA-appointed veterinarians and IIP to conduct ante-mortem and post-mortem inspection activities in accordance with *Regulation (EC) No. 854/2004.* Special provisions to ensure presence of IIP in the eligible processing establishments when products are prepared for the United States export are defined in the DVFA *Export Inspection Guidance, Section II, Chapter 1, dated March 25, 2017.* The FSIS auditors further verified that the DVFA maintains on-line post-mortem inspection of each carcass at all audited slaughter establishments.

In each audited processing establishment, the FSIS auditors verified that DVFA provides inspection at least once per shift during processing operations and on-line inspection during slaughter operations. The inspection verification tasks are scheduled ahead of time at DVFA headquarters and are tabulated in the *Annual Meat Inspection Plan*. The DVFA veterinarians use this 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 monetary fines, criminal prosecution, and/or withdrawal of approval.

The FSIS auditors determined that Denmark's pork inspection system continues to maintain equivalent statutory authority requirements that meet the core requirements for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

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

Official veterinarians and IIP ensure that carcasses with visible fecal contamination are railed out for further trimming and reinspection before entering the chiller, verifying an establishment's ability to implement corrective actions and compliance with *Regulation (EC) Nos. 853/2004, 852/2004, and 178/2002.* The slaughter hygiene verification system monitors contamination at final inspection as a key point to comply with DVFA requirements in Chapter 6, Annex 6 of the *Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017,* and focuses on the need for establishments to take the necessary actions to correct and prevent recurrence.

The FSIS auditors verified that the certified establishments' construction, facilities, and equipment are designed to prevent the contamination or adulteration of pork products destined for export to the United States. DVFA's inspection system has official controls over establishment construction, facilities, and equipment and has the authority to take formal enforcement action to direct an establishment to rectify both hygiene and structural deficiencies. DVFA requires a facility to be of sound construction prior to issuing approval to operate as a slaughter or processing establishment. DVFA's IIP ensure that the establishment maintains the facility in good functioning order as part of the daily inspection of hygiene by performing

regular audits and recording any non-compliances in the daily inspection records and monthly summary.

The FSIS auditors reviewed the following documents during the verification of this component: meat inspection plan; inspection daily checklist for sanitation-related tasks; a sample of the daily inspection reports; EU-required HACCP-based audits conducted by trained veterinarians; periodic supervisory review reports; written sanitation SOPs and monitoring records for the last 90 days at each audited establishment; documents relating to Sanitation Performance Standards (SPS) and Good Manufacturing Practices (GMPs); and reports on sanitation and pathogen testing programs at processing establishments.

In order to maintain requirements equivalent to requirements under FSIS's inspection system, especially those not covered in the EU-issued hygiene regulations and directives, the DVFA has issued the *Danish Executive Export Order of foodstuffs, No. 806 of June 22, 2017*, of which Chapter 3, Annex 6 is devoted to sanitation SOPs. The sanitation SOP requirements in the order are consistent with sanitation standards applied in the United States in accordance with 9 CFR 416.11 - 416.16. This order requires each establishment to develop and implement a written sanitation SOP program. The establishments must have written procedures to ensure that cleaning of food contact surfaces (FCSs) 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 audited establishments, the FSIS auditors verified the actual pre-operational inspection by observing the IIP conducting pre-operational sanitation verification of the pork production facility. The FSIS auditors identified findings related to SPS and sanitation SOPs during the pre-operational verification, which were immediately corrected.

DVFA's authority to exert official control at each regulated establishment, including those eligible to export to the United States, is drawn from *Regulation (EC) Nos. 882/2004 and 854/2004*. While *Regulation (EC) No. 882/2004* ensures the verification of compliance with feed and food law and animal health and animal welfare rules, *Regulation (EC) No. 854/2004* specifically stresses organization of official control on product derived from animals intended for human consumption. Additionally, DVFA issued the *Export Inspection Guidance* to the inspection staff to ensure that all elements related to sanitation are implemented in accordance with the *Danish Executive Order on Export of Foodstuffs, No. 806.* Section II (a) of Chapter 1B3 of the *DVFA Export Inspection Guidance* defines the instructions for DVFA's IIP assigned at establishments eligible to export to the United States to follow when verifying the establishment´s pre-operational and operational sanitation SOPs.

The risk-based verification frequencies ensure that all food safety programs of an establishment are covered. Pre-operational and operational sanitation SOPs are covered on a daily basis whereas SPS tasks in establishments eligible to export to the United States are completed on a weekly basis.

In addition to the basic requirements outlined above, the DVFA has developed specific requirements for sanitation in establishments producing RTE, post-lethality exposed (RTE-PLE) product as listed in the *Danish Executive Order on Export of Foodstuffs, No. 806*. Establishments are required to verify sanitation by sampling and testing FCSs for *Listeria monocytogenes (Lm)* or indicator organisms, and also develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, sanitation SOPs, or other prerequisite program. Guideline documents on export control outline official sampling regimens to be instituted at the establishments producing RTE-PLE products. For those establishments addressing *Lm* hazards only through sanitation, all RTE-PLE products destined for export to the United States are subjected to official testing.

The government inspectors sample RTE-PLE product every month for analytical testing to detect *Lm* and *Salmonella*. The FCSs are also sampled for *Listeria* at the frequency of two samples per production line per year for non-deli products and four samples per production line per year for deli products. The same testing frequencies are applied for sampling of the production environment. All products destined for export to the United States are subjected to official testing.

The FSIS auditors determined that Denmark's pork inspection system continues to maintain equivalent regulatory sanitation requirements that meet the core requirements for this component.

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

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

The DVFA adopted FSIS requirements consistent with 9 CFR Part 417 for the implementation of HACCP. The DVFA, through the *Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017, Annex 6, Chapter 4,* contains the regulatory requirements that are consistent with 9 CFR 417.1- 417.5 and 417.7, requiring establishments exporting to the United States to develop, implement, and maintain HACCP programs.

Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017, Annex 6, Chapter 6 requires the HACCP plan for slaughter establishments must contain zero tolerance critical control point (CCP) to ensure the absence of visible contamination of fecal matter 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."

At the eleven audited establishments, the FSIS auditors conducted an onsite review of the establishments' HACCP systems, including hazard analyses, HACCP plans, and CCP records as well as inspection verification records and direct observation of in-plant inspection verification activities. The actions to be taken by IIP of establishments certified to export to the United

States are identified in the *Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017* and the *DVFA Export Inspection Guidance*. The IIP at establishments certified to export to the United States conducted verification of HACCP plans consistent with FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, and HACCP requirements. The inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping.

In each of the seven audited slaughter establishments, the FSIS auditors, together with the IIP, observed the establishments' employees conducting direct observation of HACCP monitoring and verification activities for the zero tolerance CCP. In addition, FSIS auditors observed IIP conducting direct observation of HACCP verification activities associated with zero tolerance CCP verification for visible milk, ingesta, and feces on swine carcasses. During this audit, neither the FSIS auditors nor the IIP observed any deviations from the critical limits.

The establishments' corrective actions in response to deviations from critical limits identified by the establishment and the IIP indicated that the IIP adequately documented and verified the adequacy of the establishments' corrective actions; therefore, meeting all four parts of corrective action requirements cited in 9 CFR 417.3(a), which have been adapted by Denmark. However, the FSIS auditors identified that the DVFA's verification activity associated with corrective actions related to zero tolerance deviation failed to evaluate the adequacy of establishment's reassessment of the HACCP plan. The establishment failed to adequately support the monitoring frequency of the zero tolerance CCP. Evidence indicated that the DVFA had documented multiple CCP deviations for zero tolerance and that the DVFA was identifying fecal contamination on carcasses at a higher frequency than the establishment.

During further interviews with establishment and DVFA's inspection personnel and review of the establishment's supporting documents as part of the decision-making process for the HACCP plan zero tolerance CCP monitoring frequency, the FSIS auditors identified the following:

- Inadequate government verification of corrective actions associated with HACCP requirements for the support of CCP monitoring frequencies in six of the seven audited slaughter establishments. The DVFA's inspection system did not effectively verify the adequacy of Denmark's HACCP system.

The audit scope included four processing establishments, one of which produces thermally processed-commercially sterile (TPCS) product, one of which produces raw edible offal products (e.g., pork chitterlings), one of which produces NRTE dried processed pork powder for further processing, and the other exports RTE fermented product that is post-lethality exposed to the production environment. The FSIS auditors conducted onsite observations and reviewed both in-plant inspection verification, as well as establishment generated monitoring and verification records for CCPs at all four audited processing establishments.

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

confirmed that IIP verify the establishment's compliance in accordance with DVFA issued guidance documents.

The FSIS auditors evaluated the DVFA's program for RTE product by reviewing the information contained in the SRT. The DVFA has adopted the definition of RTE product as specified in *Regulation (EC) No. 2073/2005* in its national legislation. At the establishment producing RTE products, the FSIS auditors confirmed that the DVFA requires establishments to conduct a hazard analysis for the product, which is post-lethality exposed to the production environment, and to address the microbiological hazards either in the HACCP plan or through a prerequisite program or sanitation SOPs. In addition, the FSIS auditors confirmed that in order to ensure that *Lm* is prevented from contacting any post-lethality exposed RTE product regardless of whether the product supports growth or not (i.e., a zero tolerance for *Lm*), there is ongoing testing for *Lm* in the finished product, on FCSs, and in the processing environment as mandated by the DVFA. The FSIS auditors noted that both RTE establishments audited apply sanitation measures alone (Alternative 3) to address *Lm* hazards in their post-lethality exposed product destined for United States export.

Accordingly, the CCA's verification of effectiveness of sanitation are conducted by employing microbiological testing of product, FCSs and environmental surfaces (non-food contact) with a frequency supported and documented in accordance with the provisions in the *Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017*. The FSIS auditors confirmed that the IIP verified the establishment's compliance with Danish legislation and regulatory requirements governing the RTE products for *Lm* and *Salmonella* spp. through verification sampling and testing by validated analytical methods at the government laboratories. No concerns arose as a result of this audit verification.

The FSIS auditors' analysis and onsite verification activities indicate that the DVFA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs. The FSIS auditors determined that Denmark's pork inspection system continues to maintain regulatory HACCP requirements that meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the onsite visit, FSIS's residue experts thoroughly reviewed Denmark's Residue Control Program for 2017, associated methods of analysis, and additional SRT responses outlining the structure of Denmark's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

FSIS based its verification of Denmark's chemical residue testing program on information contained in Denmark's 2017 National Residue Control Plan (NRCP), the 2017 NRCP results, and an onsite audit of a chemical residue laboratory. The provisions in EC Directive No. 96/23/EC govern the DVFA's NRCP, which covers the frequency and sample allocations among species and the group of compounds that must be analyzed and requirements in *Regulation (EC) No. 882/2004*. Denmark is responsible for the control and analysis of chemical residues present in meat and processed meat products. The DVFA has the legal authority for surveillance of chemical residues that exceed the maximum levels accepted nationally and internationally.

The DVFA is responsible for the development and administration of the NRCP. 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, which is a reference laboratory for food, and chemists from their residue laboratories forecast the annual residue testing program for the subsequent year. The annual NRCP takes into consideration the assessment of sampling results obtained from the previous years' sampling results in order to consider changes including regulated use of veterinary drugs. The plan specifies the detection method, the method of analysis to be used, the matrix to be collected, the maximum residue limits, if applicable, and the total number of samples to be collected; in this case, FSIS's concern is swine since it is the only species of export to the United States. The DVFA laboratories complete detailed planning, and then the final plan is submitted to the EU commission for approval.

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

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

The FSIS auditors' review of documentation at the seven audited slaughter establishments' local inspection offices verified that IIP were collecting samples of the required matrices for detection and adhered to the prescribed sample collection schedule. The FSIS auditors' review of the

monitoring results for the last 90 days at these establishments indicates that no violative samples were detected.

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

The FSIS auditors observed a demonstration by laboratory personnel on sample receipt and handling, including checking sample integrity and security, registration of the sample in Laboratory Information Management System, assigning the identification and storage of samples in accordance with the laboratory's standard operating procedure. The FSIS auditors verified that the government laboratory: performs a timely analysis of samples; reports the number of analyzed samples and the results to the DVFA in a timely manner; provides the DVFA with a quarterly report on the progress of the plan; applies approved analytical methodologies; and has quality assurance programs. No concerns arose from these observations and reviews.

The FSIS auditors verified that the DVFA has implemented the NRCP in accordance with *EC Directive No. 96/23/EC.* The CCA has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet FSIS criteria. The program contains provisions that ensure any product with residues exceeding established tolerances, if applicable, is condemned and ineligible for use as human food. The FSIS auditors determined that Denmark's pork inspection system continues to maintain equivalent regulatory requirements for their chemical residue program that meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth 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 pork products prepared for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis of *Regulation (EC) No. 2073/2005*, which contains specific rules for testing and minimum sampling, and the CCA guidance document *Microbiological Criteria for Foodstuffs No. 9044 dated January 27, 2015,* that contains the regulatory requirements on the implementation of provisions of *Regulation (EC) No. 2073/2005,* for establishments exporting pork and pork products to the United States.

The DVFA requires all slaughter establishments to implement a microbiological testing program to assess the effectiveness of process control. Establishments either implement sampling and testing for generic *E. coli* in raw carcasses consistently with procedures established in 9 CFR Part 310.25 or by sampling and testing for *Enterobacteriaceae* and total viable count in raw pork product, a procedure acceptable for all EU exporting countries and found equivalent by FSIS.

Denmark requirements are consistent with FSIS regulatory requirements cited in 9 CFR Part 310.25(a) for generic *E. coli*. However, they have an exception of the following equivalent measures: Danish establishments use a gauze pad sampling tool and accredited private microbiology laboratories use a laboratory analytical method approved by the Nordic Committee on Food Analysis (NMKL) or Association of Analytical Chemists (AOAC) 991.14 to analyze samples for generic *E. coli*. In addition, they use an alternate method (TEMPO EC – TEMPO *E. coli*) to detect and quantify generic *E. coli* in raw products. No concerns arose from these observations and reviews.

The DVFA conducts verification activities that verify written generic *E. coli* testing programs meet requirements, including the location of sampling, randomness of sampling, and sample integrity. The DVFA uses these test results to verify that establishments' slaughter dressing controls for fecal contamination are adequate. Furthermore, the IIP verify that each establishment documents and correctly evaluates test results, and takes appropriate corrective actions if the upper control limits are exceeded. The DVFA requires that test results for product that is presented for export to the United States be found compliant prior to the export health certificate being approved. Additionally, the DVFA mandates that all establishments have a recall program in place and a trace back system for product produced.

The FSIS auditors verified through document reviews, direct observation, and interviews of IIP that the seven audited slaughter establishments had implemented a microbiological testing program to verify process control; and *E. coli* testing of livestock carcasses with requirements consistent with 9 CFR Part 310.25(a). The FSIS auditors reviewed testing results for the last 60 days showing that the establishments routinely met their limits, and that there has not been any identified loss of process control. The FSIS auditors' review of the establishments' microbiological testing programs and records did not reveal any noncompliance or concerns.

The DVFA applies a sampling and testing program to verify that the establishments certified to export to the United States meet the requirements consistent with 9 CFR Part 310.25(b) and the FSIS *Salmonella* performance standard for hogs. The specific requirements are provided in the *Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017, Annex 6 Chapter 8, titled "Salmonella Testing*." The FSIS auditors reviewed the implementation of the program within certified slaughter establishments along with results and records documenting performance standards. 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. Establishments can utilize either FSIS methods as outlined in the Microbiology Laboratory Guidebook applicable to *Salmonella* in raw products or alternative analytical methods determined to be equivalent by FSIS. Denmark uses VIDAS, NMKL No. 71, and IQ-Check *Salmonella* Kit for the purpose of *Salmonella* testing in raw products that meets the established criteria.

The FSIS auditors verified that the DVFA sample collection procedures at all establishments certified to export to the United States are in accordance with the sample collection protocols provided in the *Order of Export of Foodstuffs, No. 914 dated September 10, 2012*, on the topic of sample handling and analysis. The planning of the in-plant inspection verification is made in accordance with the DVFA *Export Inspection Guidance.* The DVFA performs documented analyses of the results of microbiological testing programs (including baseline/prevalence/ pathogen reduction studies) to determine the ongoing effectiveness of the inspection system for *Salmonella* performance standards.

The FSIS auditors reviewed records, including *Salmonella* spp. results, for the last 60 days at the seven audited slaughter establishments. Results showed no *Salmonella* set failures during the period reviewed. In addition, the FSIS auditors observed and verified the IIPs' collection procedures are in accordance with the sample collection protocols described in the aforementioned regulatory requirements. FSIS verification activities confirm aseptic techniques, and procedures for sample collection from market hog carcasses for *Salmonella* testing. The demonstrated methodology is consistent with FSIS's method.

The FSIS auditors performed verifications through document reviews and direct observation at the audited establishment producing RTE products. The FSIS auditors verified that the DVFA had adopted and implemented procedures and requirements consistent with FSIS regulatory requirements related to the control of *Lm* in the post-lethality exposed RTE environment of the processing facilities as outlined in 9 CFR Part 430.

The DVFA regulatory microbiological verification program in the *Danish Executive Order on Export of Foodstuffs, No. 806 of June 22, 2017, Annex 6,* includes the application of microbiological criteria for *Salmonella* and *Lm* in RTE products. It includes additional post-lethality exposed RTE product sampling by DVFA at pork processing establishments that are certified to export to the United States. The DVFA provided evidence that product destined to the United States is not simply tested to ensure the absence of detectable *Lm* and *Salmonella,* but that controls are in place to prevent adulteration with *Lm* and *Salmonella*.

FSIS further verified that the DVFA has a written enforcement action plan for the official microbiological verification sampling program that outlines the DVFA's response when *Salmonella* or *Lm* are detected in RTE products. Based on requirements that Denmark adopted, RTE product is considered adulterated if it contains *Lm* or *Salmonella,* or if it comes into direct contact with an FCS that is contaminated with *Lm*. The FSIS auditors reviewed testing results for establishments producing RTE product for the last year showing that DVFA verification testing and establishment verification testing produced no positive test results in products tested for *Lm* or *Salmonella* or in FCSs or non-food contact surfaces for *Lm.*

The FSIS auditors performed an onsite audit of the DVFA Laboratory Microbiological Unit, a government laboratory in Ringsted, which is located on the same premise as the DVFA Laboratory Chemical Residue Unit. The laboratory is designated as an EU reference laboratory. The laboratory performs DVFA verification analyses for RTE product that includes *Lm* and *Salmonella* analysis of finished product that is post-lethality exposed to the environment and *Lm*

analysis of FCSs and non-food contact surfaces (environmental). The FSIS auditors verified that DANAK has accredited the laboratory as equivalent to the ISO 17025 standard. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support DVFA's inspection program for certified establishments eligible to export to the United States. The laboratory uses the following analytical confirmatory methods: Rapid' *L. mono* for *Lm* and VIDAS, NMKL No. 71 (ISO 6579 standard) for *Salmonella*.

The FSIS auditors verified that DANAK conducts the prescribed audit of the laboratory quality system to ensure FSIS requirements are met. DANAK audits the laboratory once every fifteen months. The laboratory also performs internal audits according to their Quality Assurance Manual once a year. The laboratory has procedures for Proficiency Testing (PT), participated in 25 inter-laboratory PTs in 2017, and has planned 26 PTs for 2018. The DVFA verifies that equivalent methods are used in government laboratories to analyze samples that have been collected by the IIP in establishments certified to export to the United States. The FSIS auditors reviewed the most recent DANAK audit report of the laboratory. The audit had reported minor non-conformances, which were addressed and corrected by the laboratory's quality assurance department.

The FSIS auditors observed a demonstration by laboratory personnel on sample receipt and handling, including checking sample integrity and security, registration of the sample in the Laboratory Information Management System, and assigning the identification and storage of samples in accordance with the laboratory's standard operating procedure. The FSIS auditors verified that the government laboratory: performs a timely analysis of samples; reports the amount of analyzed samples and the results to the DVFA in a timely manner; applies equivalent analytical methodologies; and has effective quality assurance programs. No concerns arose because of these observations and reviews.

The FSIS auditors verified that Denmark's pork inspection system is organized and administered by the national government to verify that pork products destined for export to the United States are unadulterated, safe, and wholesome in accordance with FSIS requirements. There have not been any POE violations related to this component since the last FSIS audit.

The FSIS auditors determined that Denmark's pork inspection system continues to maintain equivalent regulatory requirements for its government microbiological testing program that meets the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 23, 2018, in Glostrup, Denmark with DVFA. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

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

Government Hazard Analysis and Critical Control Points System

- Inadequate government verification of corrective actions associated with HACCP requirement for the support of CCP monitoring frequencies in six of the seven audited slaughter establishments. The DVFA's inspection system did not effectively verify the adequacy of Denmark's HACCP system.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown . Langbro 7, DK-6400 Sonderborg	03/19/2018	14	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	X
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.	X
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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

7/51/56 Written SSOP

Establishment's written SSOP plan states that operational SSOP monitoring will be conducted weekly and not on a daily bases. Document review of operational SSOP monitoring indicates that all departments of both shifts within the facility were monitored on a daily. This is only a deficiency in the written frequency of the SSOP plan

19/51 HACCP Verification/Validation

The establishment failed to provide adequate support for the frequency they have established to monitoring their Zero-Tolerance CCP.

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

39/51/56 Establishment - Maintenance

The following non-compliances were identified;

1) Excess of grease including the forming of grease droplets (non-dripping) were identified on overhead carcass and primal part moving chain that supplies product to and from various rooms and areas of the establishment. These included but were not limited to deboning room, primal cut up room and various chill coolers for primal cuts and carcasses from the slaughter floor
2) Moving chain motor (overhead) with excess of grease in the deboning room over exposed primal cuts

46/51/56 Sanitary Operations

The following non-compliances were identified;

1) Excess long hairs were observed on several primal cuts of pork product (skin portion of bellies) stored on tree hooks in the chill cooler where primal cuts are placed before the deboning process
2) In the deboning room several employees had their knife holder with knives and gloves used in the deboning process of primal pork cuts within several inches of the stand that they were working off

The FSIS auditor did not observe any product contamination at the time of the observation.

Each of these identified incidents creates a potential cross contamination condition of exposed raw pork product. These observations indicate ineffective maintenance and monitoring of equipment and overhead structures and verification of establishment's SPS programs and verification of sanitary operations in the handling of exposed pork product by CCA inspection personnel which are crucial to an establishment’s ability to produce a clean, safe, and wholesome product.

A review of establishment and inspection verification documents provided no evidence that these deficiencies were previously identified within the records reviewed.

Corrective actions were taken by the establishment and verified by DVFA with additional measures to prevent the reoccurrence to be provided to inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/19/2018

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 . Haslevej 19, DK-3700 Ronne	03/13/2018	22	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.	X
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	
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Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
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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	
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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	X
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

19/51 HACCP Verification/Validation

The establishment failed to provide adequate support for the frequency they have established to monitoring their Zero-Tolerance CCP.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/13/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
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	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	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

19/51 HACCP Verification/Validation

The establishment failed to provide adequate support for the frequency they have established to monitoring their Zero-Tolerance CCP.

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

39/51/56 Establishment – Construction/Maintenance

The following non-compliances were identified;

1) Deterioration of casement coating (concreate) around ceiling structure beams causing cracks that exposed support beam causing rust and crumbling of casement coating throughout various areas of the establishment. These areas included but were not limited to packaging room, cure injection room, deboning room, primal cut up room and various chill coolers for primal cuts and carcasses from the slaughter floor
2) Overhead refrigeration unit with rust and peeling paint that coated rust areas on the unit in the cure injection room
3) Receiving area for dry good and packaging material – trailer to building connection when unloading left extensive opening to the outside creating a situation for an effective pest control. This area was open to the dry goods and box storage are and further down from this open area to the brine mixing room.

45/51/56 Equipment - Maintenance

The following non-compliance was identified;

1) The interlinking white conveyer belt used to sort and move exposed raw pork loins in the fabrication process had extensive links broken off and cracked jagged edges on other areas of the belt

The FSIS auditor did not observe any product contamination at the time of the observation.

Each of these identified incidents creates a potential cross contamination condition of exposed raw pork product. These observations indicate ineffective maintenance and monitoring of equipment and overhead structures and verification of establishment's SPS programs and verification of sanitary operations in the handling of exposed pork product by CCA inspection personnel which are crucial to an establishment’s ability to produce a clean, safe, and wholesome product.

A review of establishment monitoring documentation provided documents provided no evidence that these deficiencies were previously identified within the records reviewed. Additionally, a review of inspection verification provided documents provided evidence that these deficiencies were previously identified within the records reviewed on at least one occasion.

Corrective actions or planned actions were taken by the establishment and for those corrective actions taken verified by DVFA with additional measures to prevent the reoccurrence to be provided to inspection personnel.

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 Danrnarks gade 22, DK-7400 Heming	3/20/2018	31	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.	
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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 .	
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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.	X
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	X
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

19/51 HACCP Verification/Validation

The establishment failed to provide adequate support for the frequency they have established to monitoring their Zero-Tolerance CCP.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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 . Gammelby Ringvej 1, DK-6700 Esbjerg	03/20/2018	53	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.

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Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
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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)	03/20/2018

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, 7100 Vejle	03/16/2018	65	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.

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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	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	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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

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

39/51/56 Establishment – Maintenance

In the thermal container closure department on one can closure line a motor that propels the movement of the belt that moves the cans along the can closure line had extensive rust on the housing of the motor. This motor was stationed directly over an area were movement of line operators and rework product would passes.

45/51/56 Equipment - Maintenance

In the thermal container department on can closure line #5 the line had extensive rust throughout the entire mechanical belt and surrounding hardware (guides) of the line. It should be noted that the line was not in use on the day of the establishment audit however, inspection personnel previously indicated that the establishment has a SOP program that a sign is placed on all equipment that is not in used when demonstrating this action in another part of the establishment. This equipment identified had no sign indicating it was not in use which indicates additionally that the establishment failed to follow their own SOP program.

The FSIS auditor did not observe any product contamination at the time of the observation. It should be further noted that the establishment was not producing any product for export to the United States during the day of this establishment audit.

Each of these identified incidents creates a potential cross contamination condition of exposed raw pork product. These observations indicate ineffective maintenance and monitoring of equipment and overhead structures and verification of establishment's SPS programs and verification of sanitary operations in the handling of exposed pork product by CCA inspection personnel which are crucial to an establishment’s ability to produce a clean, safe, and wholesome product.

A review of establishment and inspection verification documents provided no evidence that these deficiencies were previously identified within the records reviewed.

Corrective actions were taken by the establishment and verified by DVFA with additional measures to prevent the reoccurrence to be provided to inspection personnel.

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 Sreby	3/16/2018	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
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.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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.	
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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.	X
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	X
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

10/51 Implementation of Sanitation SOP:

- During pre-operation sanitation in the meat processing department, FSIS auditor observed rusty overhead light structure between processing lines and rusty supply pipes adjacent to the ceiling.
- During operational sanitation, FSIS auditor observed meat trimming of back loin line tainted with black grease (three spots about ½ inch in diameter).

19/51 HACCP Verification/Validation:

The establishment failed to provide adequate support for the frequency they have established to monitoring their Zero-Tolerance CCP.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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 . Mosevangen 1, 9230 Svenstrup J +4589105000	3/15/2018	211	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		X ON-SITE AUDIT DOCUMENT AUDIT

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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	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
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	
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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	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 findings identified by the auditor during this audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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
BHJA/S Komvej 1 **DK** 9500 Hobro	3/19/2018	236	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.

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28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	
32. Written Assurance	

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49. Government Staffing	
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51. Enforcement	
52. Humane Handling	
53. Animal Identification	
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 findings identified by the auditor during this audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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 . 0stbirkvej 2 DK-8700 Horsens +4589192900	03/13/2018	320	Denmark
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		X ON-SITE AUDIT DOCUMENT AUDIT

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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	X
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

SSOP- 10/51
At the raw processing department, FSIS auditor observed white tray, designated for edible products, filled with raw ground pork placed directly on the floor.

19/51 HACCP Verification/Validation
The establishment failed to provide adequate support for the frequency they have established to monitoring their Zero-Tolerance CCP.

22/51 HACCP Plan (flow chart)
The auditor observed that the flow chart of slaughter operation does not clearly illustrate the three lines of post mortem inspection and the two lines of extended slaughter (rework stations) where retain carcasses are isolated for salvage, re-inspection, and introduced back to normal processing line before the zt CCP.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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
Tican Fresh Meat A/S . Strandvejen 6 DK-7700 Thisted	3/21/2018	338	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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	X
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment #338

Ante Mortem inspection:

54/ 51:
Official Food Chain Information to support that received swine lots were raised indoor and eligible for visual PM inspection were not available for verification.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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

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

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

File: 2018-30-1040-00010
Ref. ALPE
Date: 06-07-2018

Information on follow up activities and corrective actions taken by the DVFA.

Dear Todd Furey,

By letter of May 23, 2018 FSIS invited the Danish Veterinary and Food Administration (DVFA) to inform about corrective actions taken by Denmark to address the audit findings.

The DVFA would like to provide FSIS with information about follow up activities and corrective actions taken by the establishments and the DVFA.

Executive summary and page 12, section 4.
"Inadequate government verification of corrective actions associated with HACCP requirements for the support of CCP monitoring frequencies in six of the seven audited slaughter establishments. The DVFA's inspection system did not effectively verify the adequacy of Denmark's HACCP system"

The DVFA performed an audit at the Chain Office/Corporate establishment. The industry informed that they initiated studies to adequately support the CCP monitoring frequency including a guideline to the establishments. Each establishment will thoroughly implement validation of the HACCP-system to make sure it is adequate. At establishment level the CCP operators have been trained and a new documentation system has been implemented to increase the responsibility of the CCP operators. The DVFA will perform further follow up audits at the Chain Office and at each establishment.

Furthermore the DVFA is conducting a training day in September for all Official Veterinarians with focus on USA relevant issues e.g. CCP corrective actions and prerequisite programs.

Specific follow up at each establishment

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

Findings, follow up and verification at the slaughterhouses are attached as annex 1 and findings, follow up and verification at the processing establishments are attached as annex 2.

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Systematic follow up

Meat Inspection Department

To follow up on the comment on ineffective verification of the establishment's SPS and SSOP procedures the MID initiated a systematic follow up.

The draft report from the FSIS is also sent to slaughterhouses not inspected by the FSIS to ensure that similar findings do not occur in these slaughterhouses.

Food Inspection Units

The Food Inspection Units has also initiated a general follow up. For further information about the general follow up please see annex 2.

We hope these comments fulfil your requirements.

Please do not hesitate to contact the International Trade Division (16@fvst.dk) if you need further information or clarification.

Yours sincerely,

Per Henriksen
Chief Veterinary Officer
Danish Veterinary and Food Administration

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

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

File: 2018-30-1040-00010
Ref. ALPE
Date: 06-07-2018

Comments on the draft final report of an on-site audit carried out in Demark March 12 – 23, 2018.

Dear Todd Furey,

The Danish Veterinary and Food Administration (DVFA) highly appreciate the ongoing dialogue and constructive cooperation between our administrations.

By letter of May 23, 2018 FSIS has invited the DVFA to provide comments to the draft report of an audit carried out in Denmark March 12 through March 23, 2018.

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

Page 4, section 3, line 5:

"The enforcement strategies in place are based on *Regulation (EC) No. 882/2004* and *Article 57 of Act 46 of 2008*, which authorizes the CCA to approve and certify establishments to export to the United States. *Act 46 of 2008* further provides the CCA the legal authority to conduct inspection activities in certified establishments and assess penalties for violation of food safety laws. The CCA has the authority to suspend, or withdraw certification of certified establishments."

The DVFA is in doubt about the referral to Article 57 of Act 46 of 2008 and suggest "The enforcement strategies in place are based on *Regulation (EC) No. 882/2004* and *Article 17 of Regulation (EC) No. 178/2002. Article 17 of Regulation (EC) No. 178/2002* further provides the CCA the legal authority to conduct inspection activities in certified establishments and assess penalties for violation of food safety laws. The CCA has the authority to suspend or to approve and certify establishments to export to the United States."

Page 4, section 4, line 1:

"The Audit Unit (AU) is a liaison between the DVFA and the field staff responsible for conducting supervisory audit reviews at all establishments eligible to export pork products to the United States."
The Audit Unit is responsible for conducting periodic supervisory visits. The DVFA suggests "The Audit Unit is responsible for conducting periodic supervisory visits and

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is a liaison between the DVFA and the field staff at all establishments eligible to export pork products to the United States."

Page 4, section 4, line 3:

"It has an office located within the Communication and Innovation Department of DVFA".
There has been a change in the organization of DVFA. The DVFA suggests "The Audit Unit is part of the International Trade Division located in the Veterinary Department."

Page 4, section 4, line 6:

"The DVFA requires the AU to ensure that establishments eligible to export to the United States comply with FSIS requirements, evaluate the performance of the local authority, assist in conducting uniform inspection and enforcement, train inspection personnel, and update and develop legislation and guidelines."
The DVFA suggests "The DVFA requires the Audit Unit to verify the quality, effect and uniformity of the performance of the inspections including verifying whether the planned arrangements are suitable to reach the set goals and to verify the effectiveness of enforcement and sanctions. Besides the supervisory visits the unit contributes with training of inspectors, courses about FSIS requirements and update and develop legislation and guidelines."

Page 5, section 3, line 2:

"The MID consists of the MIU in Lystrup and all local MIUs in slaughter establishments."
The central authority Meat Inspection Department is located in Lystrup. DVFA suggests "The MID consists of the MID in Lystrup and all local MIUs in slaughter establishments."

Page 6, section 2, line 3:

"All inspection personnel are required to participate in trainings and continuing education courses offered by the EU."
Participation in courses offered by the EU is in general voluntary.
DVFA suggests "All inspection personnel are offered to participate in trainings and continuing education courses offered by the EU."

Page 6, section 3, line 4:

"The senior auditors of the audit division also contribute to the delivery of training".
DVFA suggests "The senior auditors of the audit unit also contribute to the delivery of training".

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Page 6, section 4, line 1:

"At the FIUs and MIUs, the FSIS auditors also verified the organizations carried out periodic supervisory reviews,"
Supervisory visits are performed by the Audit Unit, the FIUs and MIUs are performing quality supervisions. DVFA suggests "At the FIUs and the MIUs, the FSIS auditors also verified the organizations carried out periodic quality supervisions,"

Page 7, section 1, line 1:

"The Ringsted laboratory serves as a National Reference Laboratory (NRL) for animal diseases and food safety issues."
The Ringsted Laboratory is not NRL for animal diseases. The Technical University of Denmark (DTU) is responsibility for animal diseases. The Ringsted Laboratory serves as a NRL for legal Veterinary Drug Residues in Food and for Feed in general. The DVFA therefore suggest that the sentence is changed to "The Ringsted laboratory serves as a National Reference Laboratory (NRL) for food and feed safety issues. DTU is National Reference Laboratory for animal diseases."

Page 8, section 3, line 1:

"The FSIS auditors noted that the seven audited slaughter establishments were operating under an alternative post-mortem inspection system for the visual inspection of..."
Swine received at establishment 31 are inspected conventionally, because they come from herds that have been breaded out door. DVFA suggests "The FSIS auditors noted that the six of the seven audited slaughter establishments were operating under an alternative post-mortem inspection system for the visual inspection of..."

Page 9, section 1, line 5:

"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."
DVFA performs daily inspections in US approved slaughterhouses and meat product establishments. DVFA suggests "The results of inspections are documented in daily inspection reports, which are warehoused in the intranet sites known as Digital Control System (DIKO) and Work Zone."

Page 11, section 6, line 5:
"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."
Milk is not mentioned in this section but in *Regulation (EC) No. 853/2004, appendix III, chapter 4* it is stated that removal of the utter may not cause milk contamination of the carcass. DVFA suggests "Carcasses, viscera and other parts must be treated in a hygienic manner so contamination with fecal material, urine, bile, hair, dirt or other foreign material is avoided. If contamination occurs, it must be removed as soon as possible."

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Page 15, section 2, line 5:

"The Ringsted laboratory is designated as an EU reference laboratory for animal diseases."
The Ringsted laboratory is not designated as an EU reference laboratory for animal diseases. The DVFA suggest the line is removed.

Page 17, section 6, line 3:

"The laboratory is designated as an EU reference laboratory."
The Ringsted laboratory is not designated as an EU reference laboratory. The DVFA suggest the line is removed.

Final comments

The DVFA has used the information and findings from the inspection to initiate follow up at the establishments and systematically at all US approved establishments.

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.

Systematic follow up

The Meat Inspection Department and the Food Inspection Units have furthermore initiated a general follow up on all US-approved establishments.

Follow up activities and corrective actions taken by the DVFA at each establishment and other DVFA activities are described in a cover letter for the FSIS.

Please do not hesitate to contact the International Trade Division (16@fvst.dk) if you have any questions.

Yours sincerely

Per Henriksen
Chief Veterinary Officer
Danish Veterinary and Food Administration

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Follow-up on observations at the establishments:

The observation of 6 slaughterhouses failing to provide adequate support for the frequency they have established to monitor their Zero-Tolerance CCP is addressed in the letter.

Establishment 14	**Danish Crown, Blans**	
Observation	**Corrective actions performed by the slaughterhouse**	**DVFA (CCA) action**
Grease and grease droplets (non-dripping) on overhead constructions	No product contamination. Measures to prevent reoccurrence: The procedure for monitoring and wiping down of grease and condensation has been evaluated and adjusted, the frequency has been increased. Follow up during monitoring of operational SSOP in the department.	Verified without any remarks
Moving chain motor (overhead construction) with excess of grease.	Motor was immediately wrapped with plastic and the excess grease was wiped down. Measures to prevent reoccurrence: The procedure for monitoring and wiping down of grease and condensation has been evaluated and adjusted, the frequency has been increased. Follow up during monitoring of operational SSOP in the department	Verified without any remarks
A holder for the knives and gloves was placed too close to the floor.	The holder was moved and the placing of the other knife holders was evaluated. Measures to prevent reoccurrence: All knife and glove holders will be placed at least 30 cm from a non-SSOP surface. Follow up during monitoring of operational SSOP in the department.	Verified without any remarks
Excess long hairs on several primal cuts of pork product	Products were trimmed. Measures to prevent reoccurrence: Procedure has been evaluated and adjusted. Follow up during monitoring of operational SSOP in the department.	Verified without any remarks
Establishment 25	**Danish Crown, Ringsted**	
Observation	**Corrective actions performed by the slaughterhouse**	**DVFA (CCA) action**
Deterioration of casement coating (con-	Areas covered with plastic.	The covering with plastic was verified

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create) around ceiling structure beams causing cracks that exposed support beam causing rust and crumbling of casement coating throughout various areas of the establishment. All through the establishment.	Action plan will be prepared by technical department. Deadline will be a topic at next weekly meeting between the slaughterhouse and the CA.	by the inspector. The CA sanctioned the slaughterhouse with an injunction order regarding action plan. The slaughterhouse has made an action plan for, when the damaged ceiling will be repaired throughout the plant. Verified without any remarks
Overhead refrigeration unit with rust and peeling paint that coated rust areas on the unit in the cure injection room	Repaired and painted	Verified without any remarks
Receiving area for dry good and packaging material – trailer to building connection when unloading left extensive opening to the outside creating a situation for an effective pest control. This area was open to the dry goods and box storage are and further down from this open area to the brine mixing room.	Gateway has been repaired by professional company medio April.	Tight lists at the gate and a new door between the salt department and the warehouse area Verified OK 06-06-2018
The interlinking white conveyer belt used to sort and move exposed raw pork loins in the fabrication process had extensive links broken off and cracked jagged edges on other areas of the belt	Conveyer belt was replaced with new.	Belt changed immediately – verified by DVFA. MVO SPS
Establishment 71	**Danish Crown, Sæby**	
Observation	**Corrective actions performed by the slaughterhouse**	**DVFA (CA) action**
Rusty overhead light structure and rusty supply pipes adjacent to the ceiling	Grinding and polishing of the pipe. The establishment will evaluate the durability of this treatment and decide whether future treatment should consist of regular grinding and polishing or if the pipe should be replaced or removed altogether instead. General: There will be focus on more effective maintenance and monitoring of equipment for rust. Long term: replacing with parts that do not rust.	The Meat Inspection Unit has verified and will follow the establishment's decision closely. Once a good solution is found, it is essential that it is applied to all the piping in the establishment. In the meantime, the Meat Inspection Unit will, during the daily SSOP inspections, ensure that the piping in the establishment does not in any way compromise products by rusty flakes or debris. The local Meat Inspection Unit made the follow-up inspection the 9th of May: - In the shoulder department, no flaking rust was seen. - In other departments with similar structures (the cutting and the ham department), no flaking rust was seen. The establishment is currently discussing the possibility of removing the pipe entirely. However, since the

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		pipe is a fire hydrant, the question of removal awaits an answer from the insurance company. The local Meat Inspection Unit will continue follow-up inspection regarding these pipelines. The topic has always been a part of the SSOP checklist and the importance hereof was emphasized on a meeting with the local inspectors.
Meat trimming of back loin line tainted with black grease	Further investigation has showed, that these taintings are formed as a result of friction between the products and the bones. The establishment explained during the audit, that these sawdust residues always are discarded. However, the labelling of the box collecting these residues was not labelled accordingly. The establishment has labelled the box correctly.	Meat Inspection Unit made this an area of extra focus, in order to eliminate similar trouble in other departments. The checklist was modified the 19. March to encompass this new focus area. The local Meat Inspection Unit made the planned follow-up verification the 9. May: - In the ham department no discolored specks were found and the box had been labelled correctly. - The shoulder department was also inspected the 9. May, seeing that the same type of equipment and procedure takes places there. In this department no discoloration was found.
Establishment 320	**Danish Crown Horsens**	
Observation	**Corrective actions performed by the slaughterhouse**	**DVFA action**
White tray, designated for edible products, filled with raw ground pork placed directly on the floor.	Changed this tray into red an checked for other places/departments, where the same problem could occur, to make sure the problem is solved throughout the establishment	Verified by inspection.
The flow chart of slaughter operation does not clearly illustrate the three lines of post mortem inspection and the two lines of extended slaughter (rework stations) where retain carcasses are isolated for salvage, re-inspection, and introduced back to normal processing line before the zt CCP.	Flowchart changed	Verified by inspection personnel
Establishment 338	**Tican Fresh Meat**	
Observation	**Corrective action**	**Verification by DVFA**
Official Food Chain Information to support that received swine lots were raised indoor and eligible for visual PM inspection were not	**Pigs from uncontrolled housing conditions (Raised out-door)** The Regulation for Export of Food and Food Contact Materials No.	**NA**

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available for verification.	806 of 22 June 2017, Annex 6, Chapter 13, states the following: The establishment must, by individual written agreement, conclude with the local Meat Inspection, present carcasses and offal of pigs from uncontrolled housing conditions for Meat Inspection in such a way that the extended post-mortem inspection can be organized, adapted and carried out in accordance with applicable requirements, cf. Council Regulation (EC) No. 854/2004, Annex I, Section IV, Chapter IV, Item. B, No. 3. In order to ensure conventional meat control of pigs from uncontrolled housing conditions, the Meat Inspection Unit and the establishment company have concluded the following agreement: • Pigs from uncontrolled housing conditions are slaughtered under normal conditions on Fridays. If there are changes in relation to slaughter on Friday, this must be clarified with the Meat Inspection before the change can be approved / made. • Meat Inspection is advised no later than Thursday about the current number of slaughter pigs from farms with uncontrolled housing conditions. • Farms that provide pigs from uncontrolled housing conditions are also present in the daily list of status on Food Chain Information. The list is available for AM inspection	

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The Food Inspection Units have initiated a general follow up after the FSIS inspection on 12-23 March 2018, the FIU has also initiate a follow up at Est.: 65.

General follow up:	**Topics**
Instruction/course/update for all FIUs US inspection personnel on the 16. May 2018	- Findings from the FSIS inspection 12-23. March 2018. Findings and photo-documentation of findings were discussed. Focus on maintenance including rust was emphasized. - Corrective actions SSOP and HACCP – by Nina Vejbaek from the US Audit Unit, with emphasis on rules and regulations and the responsibility of the establishments plus the instruction and guidelines and the responsibility of the inspection personnel. - Inspection of all 11 SPS topics were discussed in groups to inspire the inspections personnel and uniform the inspection. - Photo cases of different cases/findings were discussed in groups with emphasis on regulation, reaction and evaluation/sanctions. - Inspection of export documents and supporting background documents
Meeting in the FIU US-inspection group on the 24. May 2018 News letter from meeting 24. May to all FIUs US inspection personnel	- Conclusion from the FSIS inspection 12-23. March 2018: Focus on inspection of maintenance including rust. - Conclusion from the self-evaluation on SSOP: Focus on over the shoulder inspections, relating observations to the establishment procedures and documentation, inspection of implementation of procedures, using precise descriptions of findings on the inspection reports, using the MVO system (minors and trend analysis of findings). - Conclusion from The Audit Unit visits: Inspection methods when inspecting CCPs. - POEs: Focus on inspection of temperatures and keeping the quick flow and the chill-chain on both cold stores and productions plants. Include inspection of temperatures in the daily SSOP inspection instead of the less frequent SPS inspections. - Conclusion from the course on 16. May 2018: Emphasis on planning of following up on corrective actions of SSOP and CCP. The Follow-up-planning-table will be updated with column for follow up planning.

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Findings at FIU Est:	Follow up
Est. No. 53: There were no significant findings to report after consideration of the nature, degree and extent of all observations.	See general follow up
Est. No. 65: The following non-compliances were not identified by Denmark's inspection officials during the establishment walkthrough review: <u>39/51/56 Establishment – Maintenance</u> In the thermal container closure department on one can closure line a motor that propels the movement of the belt that moves the cans along the can closure line had extensive rust on the housing of the motor. This motor was stationed directly over an area were movement of line operators and rework product would passes. <u>45/51/56 Equipment - Maintenance</u> In the thermal container department on can closure line #5 the line had extensive rust throughout the entire mechanical belt and surrounding hardware (guides) of the line. It should be noted that the line was not in use on the day of the establishment audit however, inspection personnel previously indicated that the establishment has a SOP program that a sign is placed on all equipment that is not in used when demonstrating this action in another part of the establishment. This equipment identified had no sign indicating it was not in use which indicates additionally that the establishment failed to follow their own SOP program. The FSIS auditor did not observe any product contamination at the time of the observation. It should be further noted that the establishment was not producing any product for export to the United States during the day of this establishment audit. Each of these identified incidents creates a potential cross contamination condition of exposed raw pork product. These observations indicate ineffective maintenance and monitoring of equipment and overhead structures and verification of establishment's SPS programs and verification of sanitary operations in the handling of exposed pork product by CCA inspection personnel which are crucial to an establishment's ability to produce a clean, safe, and wholesome product. A review of establishment and inspection verification documents provided no evidence that these deficiencies were previously identified within the records reviewed. Corrective actions were taken by the establishment and verified by DVFA with additional measures to prevent the reoccurrence to be provided to inspection personnel.	The motor and the mechanical belt with rust were replaced immediately after the inspection from FSIS. The establishment had changed their procedures for maintenance to be more observant for maintenance problems during their inspections – including during their ssop-inspections. They have made an especially program for prioritizing and improve their maintenance in all departments of the factory. DVFA have increased the focus on maintenance-issues – especial on problems with rust. About the missing sign on the line, the establishment has made clearer procedures, so everyone is aware of, whether the equipment and lines is in use or not. To increase the skills for the inspection personnel to identify maintenance issues the veterinarian officer and the daily inspectors have controlled maintenance together on focused inspections. The maintenance and the working procedures have been discussed at meetings in the local inspection group. Beside that se the general follow up.
Est. No. 211: There were no findings identified by the auditor during this audit.	See general follow up
Est. No. 236: There were no findings identified by the auditor during this audit.	See general follow up

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Planned actions	Planned follow up
At the next meeting in the US inspection group on the 22. August	The FSIS final report will be on the agenda and the group will decide on whether further follow up activities need to be initiated and implemented. As a part of the general follow up, the Food inspection units have an on-going work with training and education of the inspection personnel.
Est. No.: 65	The frequency of FIU inspections with focus on maintenance have been raised to 10 times a year. The FIU has, since the inspection, given several enforcement actions due to other inspection findings regarding rust. FIU has verified, that the establishment has implemented an improved their maintenance program. The FIU has initiated an ongoing verification of the efficiency of this program.

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