United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW.
Washington, D.C. 20250

March 28, 2024

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

Dear Dr. Larsen,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Denmark's meat inspection system October 30–November 15, 2023. Enclosed is a copy of the final audit report. The comments received from the Government of Denmark are included as an attachment to the final audit report.

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

Sincerely,

MARGARET BURNS RATH

Digitally signed by MARGARET BURNS RATH
Date: 2024.03.28 16:55:04 -04'00'

Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

DENMARK

OCTOBER 30–NOVEMBER 15, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

March 26, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Denmark conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from October 30–November 15, 2023. The purpose of the audit was to verify whether Denmark's food safety inspection system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Denmark currently exports the following categories of pork products to the United States: raw intact, raw ground, comminuted, or otherwise non-intact, not ready-to-eat (RTE) otherwise processed, RTE fully-cooked, RTE dried, RTE acidified/fermented (without cooking), and thermally processed-commercially sterile.

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

The FSIS auditors concluded that Denmark's pork products food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Danish Veterinary and Food Administration (DVFA), as the Central Competent Authority, has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, DVFA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Denmark's food safety system October 30–November 15, 2023. The audit began with an entrance meeting October 30, 2023, in Glostrup, Denmark, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Danish Veterinary and Food Administration (DVFA). Representatives from DVFA accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference November 15, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery (AMR) Product
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed - Commercially Sterile	Thermally Processed, Commercially Sterile (TPCS)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Pork - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Denmark as subject to African swine fever requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Denmark's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews and reviewed records to verify whether Denmark's food safety inspection system governing pork products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a 3-year period, in addition to information obtained directly from DVFA through the SRT.

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

The FSIS auditors reviewed administrative functions at DVFA headquarters, 2 regional offices, and 11 local inspection offices within the establishments. The FSIS auditors evaluated whether the control systems in place that ensure the national system of inspection, verification, and enforcement are being implemented according to DVFA's requirements.

A sample of 11 establishments was selected from a total of 21 establishments certified to export to the United States. This included 7 pork slaughter and processing establishments, 3 pork processing establishments, and 1 TPCS product storage facility. The pork products these establishments produce, and export to the United States include raw intact, raw ground, comminuted, or otherwise non-intact, NRTE otherwise processed, RTE fully-cooked, RTE dried, RTE acidified/fermented (without cooking), and TPCS.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens

food safety. The FSIS auditors assessed DVFA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also visited one microbiological and one chemical residue laboratory to verify that these laboratories can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Danish Veterinary and Food Administration, Glostrup
	Regional Units	2	• Meat Inspection Management Unit, Århus • Food Inspection Unit—Northeast, Aalborg
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 No. 14, Danish Crown, Blans • Establishment No. 25, Danish Crown, Ringsted • Establishment No. 31, Danish Crown, Herning • Establishment No. 320, Danish Crown, Horsens • Establishment No. 338, Tican Fresh Meat A/S & Cold Storage, Thisted • Establishment No. 801, SB Pork A/S, Brørup • Establishment No. 865, Dane Pork A/S, St. Lihme
Pork processing establishments		3	• Establishment No. 65, Danish Crown A/S (Also trading as Danish Crown Foods A/S Tulip Food Company), Vejle • Establishment No. 211, Danish Crown A/S (Also trading as Danish Crown Foods A/S & Tulip Food Company), Svenstrup • Establishment No. 236, BHJ A/S, Hobro
Pork products storage facility		1	• Establishment No. 5963, Hansen & Son A/S – Tricolore, Padborg

FSIS performed the audit to verify that Denmark's pork products food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

The audit standards applied during the review of Denmark's inspection system for 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 Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From June 1, 2020, to May 31, 2023, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 263,811,864 pounds of pork from Denmark. Of these amounts, additional types of inspection were performed on 18,983,098 pounds of pork, including physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). As a result of this additional testing, 8,946 pounds of pork was rejected for issues related to public health, specifically off-condition product. An additional 270,789 pounds of pork were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

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

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

The first equivalence component the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

DVFA is the CCA of Denmark's meat inspection system and is within the Ministry of Food, Agriculture and Fisheries. DVFA has the overall authority and responsibility for the regulation, implementation, and enforcement activities related to the inspection and export certification of pork products through national legislation, including Law Order No 1033 of July 5, 2023, and Order No 1721 of November 30, 2020. DVFA is administered by five officers: the Chief Inspection Officer, the Chief Financial Officer, the Deputy Director General Food Affairs, the Chief Veterinary Officer, and the Chief Legal Officer. The FSIS auditors confirmed that there have been changes with alignment of divisions within DVFA's organizational chart. These changes include having the meat inspection, food inspection, and veterinary inspection divisions now under the purview of the Chief Inspection Officer instead of three officers as they were previously organized.

Official controls are administered through DVFA's Meat Inspection Units (MIU), Food Inspection Units (FIU) and Veterinary Inspection Units (VIU). A local MIU is located within each slaughter establishment and is responsible for the official verification of the food safety

system from the receiving of live animals to final product shipment. There are three FIUs located in Denmark, with each unit assigning inspectors to processing and cold storage facilities on an as needed basis. FIUs are responsible for the official verification of the food safety system from the receipt of product through the completion of processing, storage, and shipment, and including export certification of products. The VIU is responsible for inspection of farms for medication usage, disease surveillance, control of animal transport systems, and assistance with animal welfare investigations and violations. The FSIS auditors verified that DVFA has procedures in place to ensure an effective level of oversight and that supervisory feedback is provided from the officers to the inspection units during or following onsite visits to the inspection units.

The FSIS auditors verified through interviews and record reviews DVFA's process for certification of an establishment as eligible to export pork products to the United States. All exporting establishments must be registered by DVFA according to National Order No. 1520 of December 15, 2022, on authorization of food establishments. An establishment must apply to DVFA, and then DVFA assesses the establishment's own check procedures and production facilities for compliance with both DVFA and any additional FSIS import requirements. If DVFA's review of facilities and establishment programs determines that FSIS import requirements are met, the inspection unit recommends the establishment for certification by DVFA's International Trade Division. DVFA will then formally request that FSIS list the establishment as certified to export to the United States. The certified establishment is then included in communications from DVFA regarding United States topics and subjected to regular Veterinary Officer (VO) or Official Inspector (OI) export verification controls and yearly audits by the VO. DVFA's U.S. Audit Unit of the International Trade Division also conducts routine periodic supervisory visits of the MIUs and FIUs.

The FSIS auditors verified that DVFA supervisory officials ensure staffing levels are adequate, program verification tasks are completed according to schedules on a daily and shift-by-shift basis, and that official sampling tasks are performed as required. The FSIS auditors verified through review of programs and records that DVFA has procedures in place to ensure an effective level of oversight is maintained and official government inspectors are present to conduct inspection of each carcass and its parts and at least once per shift during processing operations. MIUs are staffed by a Head of Meat Inspection, deputy heads of meat inspection units, a Coordinating Veterinary Officer (CVO), VOs, Lay Inspectors (LIs), and secretaries. FIUs are staffed by a head of FIU, two supervisory heads of unit, VOs, OIs, and support staff. VIUs are staffed by supervisory heads of units, VOs, and support staff. The FSIS auditors verified that supervisory staff, CVOs, VOs, OIs, LIs, and all DVFA support staff are employed and paid by DVFA through the official governmental pay system.

The FSIS auditors verified that DVFA conducts audits of certified establishments at a frequency of four times per year, which may be reduced to a minimum frequency of once per year based on outcomes of previous audits or if the establishment has been audited by an accepted third party entity such as a certification audit in accordance with International Organization for Standardization (ISO) standards. The audit frequency of an establishment may also be reduced if the establishment is part of a larger corporate group with overarching control of individual establishments, in which case an audit will be conducted at the corporate level. Audits are designed to verify establishment controls and the establishment's food safety systems and

records, with additional specific topics covered, including U.S. import requirements. After the audit, the DVFA auditor issues a written inspection report. The establishment must respond with corrective actions for any findings, after which DVFA performs follow-up reviews to verify the issue was effectively resolved.

DVFA educational and training requirements for VOs, OIs, and LIs are set within Regulation (EU) 2017/625 and include a veterinary degree for VOs and specialized education for LIs and OIs. The FSIS auditors verified through interviews and review of training records that DVFA has an annual training plan in place and conducts initial training for government personnel upon hiring as well as continual ongoing and refresher training of all government personnel. Government personnel are trained based on their specific job duties, including ante-mortem, post-mortem, animal welfare and humane handling, transport of animals, export certification, sanitation, HACCP, thermal processing, and sampling techniques. Government personnel are also provided training on specific FSIS import requirements, including pre-operational and operational verification of sanitation standard operating procedures (Sanitation SOPs), labeling requirements, hold of products tested for adulterants, and HACCP pre-shipment reviews.

Government personnel are authorized to take enforcement actions in establishments to ensure compliance with DVFA requirements in accordance with DVFA guidelines. There are four types of enforcement actions, and the actions may be escalated based on severity or when a finding is repetitive. The first type of enforcement action is when an observation or noncompliance of lesser concern is documented, and the establishment is allowed the opportunity to address the issue. If the finding is more severe, such as a food safety issue, or the finding is repetitive and has not been adequately corrected, a warning is issued. DVFA may issue an injunction, ban, or prohibition order to stop an establishment process until a more severe issue is corrected. In the most severe cases, DVFA can issue an administrative fine, report an issue to the police for prosecution, or withdraw the establishment's registration, thereby ceasing operations completely. DVFA has not taken any enforcement actions to withdraw the registration of an establishment which was certified to export to the United States.

The FSIS auditors verified through a review of records that DVFA currently only allows pigs of Danish origin to be slaughtered in establishments approved to export pork products to the United States. The FSIS auditors also verified that DVFA has requirements for species verification procedures in place to ensure only products containing pork are approved for export to the United States. VOs or OIs are required to evaluate procedures within certified establishments, including review of product formulations and domestic declarations of source material, and to verify adequate separation of pork products from other meat products. In the event of any suspicion or doubt of the species content of product formulation of a meat product, the VO or OI can submit a sample of the product for laboratory analysis.

DVFA ensures that only products that have been inspected and certified as eligible for export to the United States are issued an export certificate. An exporter is responsible for providing all information required for the VOs to certify and sign the certificate verifying that the pork products meet U.S. import requirements. OIs or VOs conduct a weekly export control review of relevant documents for export consignments to ensure there are records of product status, traceability, testing results, and pre-shipment review records. OIs or VOs also conduct random

checks of consignments to ensure all U.S. requirements are met prior to certification of the export. Government personnel verify completeness of consignment information, including shipping marks and container identification, and apply a DVFA seal to the shipping containers of pork products exported to the United States, with the exception of TPCS products, which do not require a DVFA seal. Export certificates are stamped by a certifying officer at a DVFA local control unit office. These certificates are printed on security paper that has a watermark, holographic security seal, and is individually numbered for traceability.

The FSIS auditors verified through interviews and direct observations that pork products eligible for export to the United States were identified and kept physically separated from products that were not eligible. VOs and LIs verify slaughter establishment controls and are continuously present each day during slaughter and cutting process operations. Products moved from one certified establishment to another are controlled by the certified establishments with additional DVFA oversight through the use of a DVFA domestic declaration, which provides declarations of origin and tracking information of the products identified on the document. Through the issuance and verification of domestic declarations, DVFA ensures that only eligible products from certified establishments are exported to the United States.

DVFA's Special Requirements Regarding the Export of Meat and Meat Products to the United States, dated May 11, 2022, requires all establishments to prepare and maintain a written recall procedure. The FSIS auditors verified that the VO or OI perform an annual audit of the certified establishment's recall plan, which includes a review for completeness and maintenance activities, including the requirement for the establishment to conduct a test recall. Additionally, certified establishments are required by law to immediately inform DVFA of the shipment of adulterated product according to Order No. 1433 of November 1, 2022. The FSIS auditors verified that DVFA has a mechanism in place to notify FSIS of the shipment of noncompliant or adulterated products. There have been no recalls of pork products exported from Denmark to the United States since the previous FSIS audit in 2022.

DVFA implements requirements in Regulation (EU) 2017/625 for designation of an accredited or official laboratory. The DVFA official government chemical residue and microbiological laboratory and the Danish Technical University (DTU) laboratory are accredited by the Danish Accreditation Fund (DANAK) according to ISO/International Electrotechnical Commission (IEC) 17025 standards. The FSIS auditors verified that analysis of all official DVFA samples occurs at the Ringsted microbiology unit or chemical residue unit laboratories, with DTU providing confirmatory analysis for a limited scope of chemical residue samples when required. During the audit, the FSIS auditors verified through records review and interviews that DVFA laboratories performing analyses of all official samples are accredited by DANAK.

The FSIS auditors confirmed that DVFA relies on the accreditation audit conducted by DANAK to ensure that laboratories operate competently and generate valid results. The FSIS auditors interviewed staff and reviewed documents from laboratories to verify adequate controls are in place for package and sample integrity, including DVFA sample seals at receiving, use of recognized and approved DANAK-accredited analysis methods, calibration of laboratory equipment, ongoing control testing to verify methods, proficiency testing, and that results of analyses are reported through the laboratory reporting system directly to DVFA headquarters

personnel and to the government personnel where the sample originated. The FSIS auditors also reviewed internal personnel training and proficiency requirements and the results of the most recent internal audits.

The FSIS audit verification activities indicate that Denmark's pork products inspection system is organized and administered by the national government, and that DVFA inspection officials are assigned to enforce the laws and regulations governing pork products, providing ultimate control, supervision, and enforcement of regulatory requirements.

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

The second equivalence component the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that DVFA requires a VO to perform ante-mortem inspection of each animal prior to slaughter. Ante-mortem inspection is carried out according to EU regulations implemented through procedures in the Guideline of Meat Inspection No. 10380, dated December 16, 2022. Ante-mortem inspection must take place within 24 hours of an animals' arrival at a slaughterhouse, and less than 24 hours prior to slaughter. The VO may require an additional inspection at any other time as deemed necessary. The VO reviews food chain information, including health status of the animal, region of origin, any prior veterinary treatments and associated withdrawal periods, and production data that may provide information on disease status of the animals. The VO inspection of animals and review of the food chain information of each shipment of animals allows for confirmation of animal health status regarding applicable APHIS requirements. Through review of documentation and the ante-mortem inspection of animals, the VO determines the health and welfare of the animals, any abnormalities or disease conditions which may affect the suitability of the animals for human consumption, and any use of prohibited or unauthorized substances. The FSIS auditors verified that the VO performs ante-mortem inspection and follows DVFA procedures for the identification of suspect animals for segregation and further examination at post-mortem, ensures adequate control over condemned animals, and that only animals which meet DVFA requirements for slaughter are released.

DVFA implements animal welfare requirements in accordance with EU legislation and Danish orders, including protections during transport, protection of animals during slaughter, and humane handling requirements from the farm through the slaughter process. VOs take action according to DVFA requirements if signs of animal welfare violations are identified through observation of animals during ante-mortem. VOs verify each certified establishment meets requirements through annual audits and quarterly inspections of the humane handling system.

Additionally, the VO observes and verifies daily operations for conditions and construction of holding pens, animal spacing to prevent overcrowding, ventilation, water and feed availability in pens, movement of animals to slaughter, and stunning effectiveness. The FSIS auditors verified that VOs are performing these verification activities regarding animal welfare and documenting all observed results as required by DVFA. Any findings of noncompliance result in immediate enforcement actions according to DVFA procedures with an issuance of injunctions or are reported to the police for prosecution dependent on the specific observation.

The FSIS auditors verified through observations and interviews that post-mortem inspection of each carcass and its parts is conducted according to Guideline of Meat Inspection No. 10380. Under supervision of VOs, the LIs perform post-mortem inspection of each carcass and its parts by performing visual inspection of all external surfaces, surfaces of body cavities, and offal. LIs identify carcasses for trimming or further inspection according to the Danish code system for classification with findings classified as major or minor. Carcasses with major findings, such as signs of animal health issues, animal welfare issues or food safety issues, including contamination, must be further inspected by a VO or LI when identified. Carcasses with minor findings, such as local or minor slaughter defects requiring trimming, are randomly reinspected by a VO or LI after establishment corrective actions. DVFA has also instituted daily evaluations of the quality and accuracy of carcass assessments by the LIs on the slaughter line and of establishment personnel performing corrections to carcasses in order to verify the system is working as intended. The FSIS auditors observed inspection and identification of carcasses by LIs and further observed establishment actions and DVFA reinspection of affected carcasses as effective during the post-mortem inspection process.

The FSIS auditors verified through observations that VOs ensure certified establishments control condemned materials and meet DVFA's requirements as described in Special Requirements Regarding the Export of Meat and Meat Products to the United States, dated May 11, 2022. Certified establishments are responsible for handling, marking, and storage of condemned materials. Establishments must implement controls to ensure carcasses of animals that arrive dead or that are euthanized and condemned are clearly identified and marked with a colored denaturant. VOs verify establishment controls of condemned material handling from the point of animals being received at the facility and throughout the facility as part of their audit and routine weekly inspection verification procedures. The FSIS auditors observed condemned carcasses after the post-mortem inspection stand being clearly marked with a green colored denaturant in accordance with DVFA's requirements. Additionally, the FSIS auditors verified that inedible materials throughout certified establishments were placed within containers that were easily identified and controlled by establishment marking systems according to DVFA requirements, thereby preventing their use for human consumption.

DVFA requires certified establishments to properly label products according to DVFA's Special Requirements Regarding the Export of Meat and Meat Products to the United States. VOs and OIs are required to audit specific FSIS labeling requirements annually and verify labeling of a shipment during the export certification verification process. The FSIS auditors verified through observations that DVFA ensures labeling meets FSIS requirements and that all labels with claims and special statements must be directly approved by FSIS prior to their use by a certified establishment.

The FSIS auditors verified that supervisory visits to certified establishments are conducted at a minimum frequency of three times annually at slaughter establishments, two times annually at processing establishments, and once annually at cold storage facilities by the DVFA U. S. Audit Unit of the International Trade Division. Additionally, VOs serve as supervisors in each certified establishment and conduct a quality supervision review of how each individual government inspection employee performs the duties of their position. Findings from DVFA's U. S. Audit Unit supervisory reviews and VO quality supervision reviews are documented, and training or follow-up activities are conducted as needed. Any noncompliance observed at certified establishments during reviews are also documented and are subject to verification reviews by government personnel after establishment corrective actions. The FSIS auditors verified implementation of DVFA review procedures during the audit through interviews and review of records of both the supervisory reviews and quality supervision reviews.

The FSIS audit activities indicate that DVFA maintains the legal authority and a regulatory framework that is consistent with the criteria for this component and therefore continues to meet the core requirements.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component 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 SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

The FSIS auditors verified that DVFA requires certified establishments to comply with the requirements described in DVFA's Special Requirements Regarding the Export of Meat and Meat Products to the United States. Certified establishments are required to develop, implement, and maintain Sanitation SOPs to ensure operations occur under sanitary conditions. DVFA requires certified establishments to have written programs and include procedures conducted before and during production and to identify the frequency of procedures. DVFA also requires certified establishments to take corrective actions, including disposal of contaminated product, restoration of hygienic conditions, and measures to prevent recurrence of product contamination, including evaluation and modification of the written Sanitation SOPs, as needed. Certified establishments must also maintain daily Sanitation SOP records of implementation, monitoring, and corrective actions. The FSIS auditors verified that certified establishments maintained daily Sanitation SOP records of implementation, monitoring, and corrective actions in accordance with DVFA requirements.

Government inspection personnel verify SPS and Sanitation SOP requirements are met by each certified establishment according to DVFA's Guidance on Controls on Companies Exporting Food to Third Countries (Export Control Guidelines), dated February 22, 2022. The Export Control Guidelines provide instructions that the VO or OI must carry out weekly inspections of basic hygiene, interior design, and maintenance requirements consistent with FSIS requirements in 9 CFR 416.1-416.5. The VO or OI is also required to verify implementation of Sanitation

SOPs once per shift. For pre-operational inspection, the VO or OI observes the designated establishment employees perform their cleanliness check, inspect establishment equipment prior to operations, or directly observe cleaning procedures conducted by establishment employees. The FSIS auditors assessed the adequacy of DVFA verification activities by observing in-plant government inspection personnel conducting pre-operational sanitation in two of the certified establishments included in the scope of the audit. The FSIS auditors also verified that government inspection personnel document all results of sanitation inspections, including when observations are identified. When an observation occurs, government inspection personnel reviews establishment responses and verifies corrective actions are taken to adequately address the observed deviations.

DVFA's requirements for certified establishments to implement sanitary dressing procedures of carcasses are described in DVFA's Special Requirements Regarding the Export of Meat and Meat Products to the United States. DVFA requires certified establishments to develop, implement, and maintain written procedures to prevent contamination of carcasses, organs, and other parts throughout the slaughter and dressing process. The FSIS auditors verified that certified establishments have procedures in place and maintain daily records sufficient to document implementation and monitoring of procedures that must be incorporated in their HACCP plan, Sanitation SOPs or another self-monitoring procedure. The FSIS auditors also observed DVFA personnel perform and document their routine verification of sanitary dressing procedures.

The FSIS auditors verified through observations that DVFA requires VOs or LIs to verify certified establishments meet zero tolerance requirements for fecal material, ingesta, and milk as required by DVFA's Export Control Guideline. VOs or LIs perform zero tolerance checks and document results during each shift. LIs also perform inspection of each carcass for fecal material, ingesta, and milk during post-mortem inspection. Any carcass with contamination is identified as a major finding according to the Danish post-mortem inspection code system and is required to be sent to the side rail for trimming. Each carcass coded in this way is subject to reinspection by LIs assigned to the side rail prior to returning to the production line. The FSIS auditors observed the post-mortem inspection, LIs use of the Danish code system, and side rail operations during site visits to certified establishments and did not identify any findings.

The FSIS audit activities indicate that DVFA requires certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs and sanitary dressing procedures. FSIS concluded that DVFA continues to meet the core requirements for this component.

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

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

The FSIS auditors verified that DVFA requires certified establishments to develop and implement a HACCP system in accordance with DVFA's Special Requirements Regarding the Export of Meat and Meat Products to the United States. VOs or OIs, conduct annual audits to evaluate the HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records, and pre-shipment reviews at each certified establishment. The FSIS auditors verified the annual audit results during site visits to certified establishments. DVFA also requires supervisory reviews by the U. S. Audit Unit of the International Trade Division to evaluate VO or OI performance and the establishment's HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records, and pre-shipment reviews. The FSIS auditors verified that DVFA performed supervisory reviews in accordance with documented requirements.

Certified establishments are required to implement HACCP systems based on DVFA's specific U.S. requirements published on the DVFA website and the DVFA guidance on export, which are consistent with FSIS requirements in 9 CFR part 417. VOs and OIs verify implementation of HACCP in certified establishments in accordance with requirements in DVFA's Inspection Guidelines, and the Export Control Guidelines. The FSIS auditors verified that the VO develops and implements an inspection plan to schedule annual audits and both daily and weekly inspection verification activities in accordance with DVFA requirements. Results of verification activities are documented on a daily control report and summarized on a monthly inspection review report.

The FSIS auditors observed that VOs and OIs verify critical control points (CCPs) according to the annual meat inspection plan developed at each certified establishment. VOs and OIs verify implementation of daily zero tolerance checks at slaughter facilities, pre-shipment reviews, and verification of CCPs through review of records, own observations and monitoring by the VO or OI, or over the shoulder direct observation of establishment monitoring of the CCP. The FSIS auditors verified that when findings are observed, the certified establishment is notified, the findings are documented, and the certified establishment must take corrective actions, which are then reviewed by the VO or OI for effectiveness and compliance, consistent with DVFA requirements.

The FSIS audit activities indicate that DVFA requires certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that DVFA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

The FSIS auditors verified that Denmark's national residue control program (NRCP) is developed and administered by DVFA for testing of carcasses and parts for chemical residues in pork products. The Ringsted laboratory, in coordination with DVFA central authorities and DTU, is responsible for planning, implementation, and coordination of the NRCP annually in accordance with Commission Delegated Regulation (EU) 2022/1644 supplementing Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2022/1646 and Commission Regulation (EU) 2023/915, Commission Delegated Regulation (EU) 2022/931 supplementing Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2022/932. The annual sampling plan is developed based on the number of animals slaughtered during the previous year with a distribution of analyses performed for several categories, including substances having an anabolic effect, unauthorized substances, veterinary drugs, and environmental contaminants. The Ringsted laboratory sends sample collection requests based on the NRCP to DVFA personnel at each MIU.

The FSIS auditors verified that sample schedules providing the specific details for each sample to be submitted are received at the MIU from the laboratory. Samples are collected according to test instructions and packaged by LIs under direct supervision of VOs. In addition to scheduled testing requests, VOs may also submit samples when animals are identified as suspect for possible residue violations. Sample information is entered directly into the DVFA laboratory system by the LI and included with the sample that is packed, sealed, and shipped through DVFA personnel and vehicles to the laboratory for analysis. The FSIS auditors verified DVFA controls for sample integrity, temperature controls of the packaged samples from pick up to drop off at the laboratory, and reception procedures at the laboratory. The FSIS auditors also verified that any carcasses or parts that are tested for chemical residues are held pending acceptable test results or excluded from eligibility for export to the United States.

The FSIS auditors verified through interviews and record reviews that the Ringsted laboratory reports results of analyses directly to DVFA headquarters personnel and to the VO in the MIU where the sample originated through the laboratory reporting system. The Ringsted laboratory determines residue sample results to be violative when levels detected exceed EU maximum residue levels. If the laboratory detects non-violative levels of chemical residues, the levels detected are also included on the laboratory report, which is sent to the MIU and certified establishment. The FSIS auditors verified that DVFA then requires that each certified establishment evaluate the reported test results to determine if product meets all U. S. requirements prior to requesting export certification of tested product. The FSIS auditors verified through interviews that based on these DVFA requirements, establishments currently certified to export to the United States have procedures in place to separate and exclude all carcasses and parts tested for residues until the tested product result is determined to be acceptable for export to the United States.

The FSIS auditors verified that in the event a result is violative, the laboratory must inform DVFA headquarters and VOs at the MIU and the VIU where the producing farm is located. The VO of the VIU performs an investigation at the producing farm and takes any required actions to prevent further violations from occurring, including changes in animal management, or sanctions and penalties for the farmer as warranted. The VO may also schedule additional testing to verify that no further violations occur.

The FSIS audit activities indicate that DVFA has overall authority of a chemical residue testing program designed and implemented to prevent and control the presence of veterinary drugs and other chemical contaminants in pork products intended for export to the United States. FSIS concludes that DVFA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that pork products prepared for export to the United States are safe and wholesome.

The FSIS auditors verified through interviews and record reviews that DVFA requires certified establishments follow Commission Regulation (EC) No. 2073/2005 regarding process hygiene criteria testing and analysis for carcasses or requirements consistent with 9 CFR 310.25. Certified establishments are required to sample carcasses at one point in the slaughter process for aerobic colony count and may choose to sample for either Enterobacteriaceae or generic *Escherichia coli (E. coli)*.[2] Results are reviewed and evaluated using statistical process control for a window of 13 results and certified establishments must take actions based on test results. VOs review the establishment's test program four times per year and on a weekly basis review test results and records of the testing program. Additionally, government verification testing of 5 carcasses is conducted by DVFA once per month and analyzed for generic *E. coli* to verify establishment hygiene procedures of the slaughter process. Results of analysis for DVFA testing are reported to in-plant DVFA personnel for evaluation and action, as needed, at each certified establishment.

The FSIS auditors verified that certified establishments are required to test swine carcasses for *Salmonella* in accordance with EU requirements in Commission Regulation (EC) No. 2073/2005, which is implemented by DVFA Order No. 597. Frequency of sampling is dependent on the number of animals slaughtered during a production day at each certified establishment. Established DVFA criteria requires results to be analyzed versus a short-term window of no more than one positive in a period of eleven slaughter days, and a long-term window of less than two percent of positive results per 12-month timeframe, which is computed on a monthly basis. VOs verify establishment sampling and corrective actions in response to positive in accordance with DVFA requirements.

The FSIS auditors verified that DVFA implements official government verification sampling of RTE products for *Salmonella* and *Lm* according to DVFA's Export Control Guideline. VOs or OIs collect RTE product samples in finished packaging according to the scheduled frequency based on product types. Samples are analyzed for *Salmonella* and *Lm* by the DVFA microbiology laboratory using validated methods. VOs or OIs also collect *Lm* surface swab

[2] FSIS continues to work with DVFA to ensure that microbiological sampling and analysis programs for monitoring process control throughout slaughter and dressing operations consistent with U.S. requirements in 9 CFR 310.18 are implemented at certified establishments that export products to the United States.

samples from each production line annually with an increased number of samples on production lines if deli-type RTE products are produced. The Export Control Guidelines provide requirements for official DVFA follow-up testing in the event of a *Lm* positive test result.

The FSIS auditors verified that VOs and OIs review and verify that certified establishments meet requirements to ensure control and prevention of adulteration by *Lm* in the post-lethality production environment as described in DVFA's Special Requirements Regarding the Export of Meat and Meat Products to the United States, which is consistent with FSIS requirements in 9 CFR part 430. DVFA requires that *Lm* cannot be detected in RTE product and that RTE products that are in direct contact with surfaces contaminated with *Lm* are considered adulterated. Additionally, the FSIS auditors verified certified establishments are required to perform corrective actions in response to *Lm* positive test results and perform follow-up sampling of food contact surfaces and environmental (non-food contact) surfaces to ensure sanitary conditions have been restored prior to resuming export of RTE products to the United States.

The FSIS auditors verified the DVFA requirement that certified establishments producing TPCS products must specifically comply with FSIS requirements in 9 CFR part 431 in accordance with DVFA's Guide to Specific Requirements for the Export of Meat and Meat Products to the United States. The FSIS auditors verified that VOs or OIs verify compliance with a subset of requirements for TPCS products on a monthly rotating schedule so that all requirements are verified each year. Additionally, an annual audit is conducted by DVFA to ensure the certified establishment's procedures specifically comply with FSIS requirements in 9 CFR part 431.

The FSIS audit verification activities indicate that DVFA conducts microbiological sampling and testing programs to ensure that pork products are safe and wholesome. FSIS concludes that DVFA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on November 15, 2023, by videoconference with DVFA. The FSIS auditors concluded that Denmark's pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. DVFA has required that establishments certified as eligible to export pork products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, DVFA has implemented microbiological and chemical residue testing programs that are organized by the national government to verify its food safety system. An analysis of each component did not identify any findings representing an immediate threat to public health.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Blans	11/03/2023	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	
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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

22; During the site visit, it was determined that the establishment did not document corrective actions taken when they had previously identified fecal contamination of a carcass in the carcass breaking/cutting room. No adulterated product identified due to the observation of this recordkeeping issue.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/03/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Ringsted	10/31/2023	25	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	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. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw pork intact

60. Observation of the Establishment

45-
A belts surface that carries spare-ribs to packing was deteriorated, making it hard to clean on the surface.

39-
In cutting room one a ceiling was observed leaking water. The water appeared to be coming for the outside roof. No product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	10/31/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Herning	11/07/2023	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.	
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	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw pork intact

60. Observation of the Establishment

45-

A belt in cut up area was observed with foreign material that appeared to be grease.

A belt was deteriorated, making it hard to clean on the surface. A small piece (fibrous string) of the belt was observed breaking off from the belt.

No product was observed contaminated, and the establishment took corrective actions to include re-inspection of products potentially affected.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/07/2023

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 A/S (Also trading as Danish Crown Foods A/S Tulip Food Company), Vejle	11/01/2023	65	Denmark
	5. AUDIT STAFF: OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

16 & 57; During the site visit, the following was observed; establishment corrective action records for the occurrence of two critical limit deviations did not include documentation of all actions according to DVFA HACCP requirements of Chapter 4.7 for corrective actions. Additionally, the establishment did not maintain records of the two aforementioned process deviations and subsequent corrective action taken in a separate process deviation file or log as required in accordance with DVFA requirements 431.9. No adulterated product was identified as a result of these observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/01/2023

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 A/S (Also trading as Danish Crown Foods A/S & Tulip Food Company), Svenstrup	11/08/2023	211	Denmark
	5. AUDIT STAFF: OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

19; During the site visit it was determined that the establishment did not consider come up time and temperature stabilization of the fermentation chamber as part of their calculation of total degree hours for each scheduled process as part of the development of the critical limit. Through review of records, it was determined that no product was affected despite a lack of adequate validation and support of the critical limit.

46; During the site visit, it was observed that an employee apron (permitted food contact surface) in the ready to eat packaging area was coming into contact with a portion of the bin lifter/tipper which is not maintained in a fully cleaned and sanitized condition. The CCA and establishment took immediate corrective actions to ensure sanitary conditions were restored with no product affected.

57; During the site visit it was observed that the *Listeria* control testing program did not identify two potential food contact surfaces on the required listing.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/08/2023

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
BHJ A/S, Hobro	11/07/2023	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.

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

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

No findings.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/07/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Danish Crown, Horsens	11/06/2023	320	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.	
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw pork intact

60. Observation of the Establishment

No findings observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/06/2023

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 & Cold Storage, Thisted	11/08/2023	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.	
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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.	
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	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw pork intact

60. Observation of the Establishment

41-

Condensate was observed dripping from an air blower in the carcass cooler. No carcasses were in the proximity, no product affected. The establishment took immediate corrective actions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/08/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
SB Pork A/S, Brørup	11/01/2023	801	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	
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Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
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Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw pork intact

60. Observation of the Establishment

10-
The establishment was not following the SSOP procedure for maintaining all knife/equipment sterilizers at the required temperature during production.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/01/2023

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
Dane Pork A/S, St. Lihme	11/02/2023	865	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
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8. Records documenting implementation.	
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12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork

60. Observation of the Establishment

48-
A container holding inedible category 3 product was not labeled correctly.

45-
On the flap door entering the blast chiller grease was observed accumulating at the top and right side. No product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/02/2023

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
Hansen & Son A/S – Tricolore, Padborg	11/02/2023	5963	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	O
8. Records documenting implementation.	O
9. Signed and dated SSOP, by on-site or overall authority.	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O
11. Maintenance and evaluation of the effectiveness of SSOP's.	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O
13. Daily records document item 10, 11 and 12 above.	O
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
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)	O
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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	
55. Post Mortem Inspection	O
	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Canned product storage facility.
Prepared Products:	NA

60. Observation of the Establishment

No findings.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/02/2023

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

Ministry of Food, Agriculture and Fisheries of Denmark
Danish Veterinary and Food Administration

Margaret Burns Rath
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue
Washington, D.C.

File: 2023-16-1040-00010
Ref. DVFA
Date: 21-03-2024

Comments regarding the final audit report on Denmark´s meat inspection system October 30 through November 15, 2023

Dear Margaret Burns Rath,

The Danish Veterinary and Food Administration (DVFA) acknowledges the receipt of FSIS´s draft final report from the ongoing equivalence verification audit of Denmark´s food safety inspection system governing pork products.

By letter of February 5, 2024 FSIS invites DVFA to provide comments to the draft report. DVFA would like to state the following comments to the information in the draft audit report:

Component one: Government oversight.
Page 9:
VOs conduct a weekly export control review of relevant documents for export consignments to ensure there are records of product status, traceability, testing results, and pre-shipment review records. VOs also conduct random checks of consignments to ensure all U.S. requirements are met prior to certification of the export.

Weekly export control reviews and random checks are mainly conducted by OIs.

Component five: Government chemical residue testing programs.
Page 13:
The Ringsted laboratory, in coordination with DVFA central authorities and DTU, is responsible for planning, implementation, and coordination of the NRCP annually in accordance with Commission Delegated Regulation (EU) 2022/1644 supplementing Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2022/1646. The annual sampling plan is developed based on the number of animals slaughtered during the previous year with a distribution of analyses performed for several categories, including substances having an anabolic effect, unauthorized substances, veterinary drugs, and environmental contaminants.

Environmental contaminants are regulated under Commission Regulation (EU) 2023/915, Commission Delegated Regulation (EU) 2022/931 supplementing Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2022/932.

Component six: Government microbiological testing programs.
Page 14:
Certified establishments must take actions based on test results and immediately notify the VO of any single test result or a trend of test results requiring action.

Establishments must take actions but not immediately notify the VO of any single test result or a trend of test results requiring action. DVFA must verify the establishment´s test results as part of the weekly verification of the establishment´s written procedures to prevent contamination of carcasses and parts by enteric pathogens.

Danish Veterinary and Food Administration • Stationsparken 31-33 • DK-2600 Glostrup
Tel +45 72 27 69 00 • Fax +45 72 27 65 01 • CVR 62534516 • EAN 5798000986008 • www.dvfa.dk/contact • www.dvfa.dk

Additionally, government verification testing of carcasses is conducted by DVFA five times per month and analyzed for generic E. coli to verify establishment hygiene procedures of the slaughter process.

DVFA conducts verification testing of 5 carcasses once per month.

On behalf of Tejs Binderup, Deputy Director General,

Yours sincerely,

Lilian Noer
Head of International Trade Division

Danish Veterinary and Food Administration • Stationsparken 31-33 • DK-2600 Glostrup
Tel +45 72 27 69 00 • Fax +45 72 27 65 01 • CVR 62534516 • EAN 5798000986008 • www.fvst.dk/contact • www.fvst.dk