



United States Department of Agriculture

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Food Safety and  
Inspection Service

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

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

Dear Dr. Larsen,

The United States Department of Agriculture Food Safety and Inspection Service conducted a remote ongoing verification audit of Denmark's meat inspection system from March 8 through April 8, 2022. 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 this audit report, please contact the Office of International Coordination at [InternationalCoordination@usda.gov](mailto:InternationalCoordination@usda.gov).

Sincerely,

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF  
DENMARK

MARCH 8 TO APRIL 8, 2022

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
PORK PRODUCTS  
EXPORTED TO THE UNITED STATES OF AMERICA

September 1, 2022

Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Denmark conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from March 8 to April 8, 2022. Due to the global COVID-19 pandemic the audit was conducted remotely using video conferences to conduct interviews and records review. 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 correctly labeled and packaged. Denmark currently exports the following categories of pork products to the United States: Raw-Intact, Raw Non-Intact, Not Heat Treated-Shelf Stable, Heat Treated-Shelf Stable, Fully Cooked-Not Shelf Stable, Heat Treated-Not Fully Cooked-Not Shelf Stable, 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 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 (CCA) has required that establishments certified as eligible to export pork 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 requirements for microbiological and chemical residue testing programs that are organized by the national government to verify its system. An analysis of each component did not identify any findings representing an immediate threat to public health.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Denmark’s food safety system from March 8 to April 8, 2022. The audit began with an entrance meeting held via videoconference March 8, with the Central Competent Authority (CCA)— Danish Veterinary and Food Administration (DVFA). Representatives from DVFA participated throughout the entire audit.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

<b>Process Category</b>	<b>Product Category</b>	<b>Eligible Products<sup>1</sup></b>
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	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
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible

<sup>1</sup> All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

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 remote equivalence verification audit, FSIS reviewed and analyzed Denmark's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine 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 (POE) reinspection and testing results, specific oversight activities of government offices, and testing capabilities capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from 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 records related to administrative functions and oversight from DVFA headquarters, three regional offices, and three local inspection offices within the establishments. The audit involved meetings with government personnel and laboratory staff. FSIS scheduled three meetings each week over a five-week period with an exit meeting at the conclusion of the audit. Through records review, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of three establishments was selected for the audit from a total of twenty-three establishments certified to export to the United States. This included two pork slaughter and processing establishments, and one pork processing establishment. The categories of 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 acidified/fermented (without cooking); RTE dried; RTE fully cooked; RTE fully cooked without subsequent exposure to the environment and TPCS.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. 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 remotely audited one official microbiological laboratory and one official chemical residue laboratory to verify that these laboratories provide adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>Danish Veterinary and Food Administration, Glostrup</li> </ul>
	Unit and Division Offices	2	<ul style="list-style-type: none"> <li>Meat Inspection Management Unit, Århus</li> <li>Food Inspection Unit—Northeast, Aalborg</li> </ul>
Laboratories		2	<ul style="list-style-type: none"> <li>Danish Veterinary and Food Administration Laboratory, Microbiology Unit, Ringsted</li> <li>Danish Veterinary and Food Administration Laboratory, Chemical Residue Unit, Ringsted</li> </ul>
Pork slaughter and processing establishments		2	<ul style="list-style-type: none"> <li>Establishment No. 14, Danish Crown, Sonderborg</li> <li>Establishment No. 25, Danish Crown, Ringsted</li> </ul>
Pork processing establishments		1	<ul style="list-style-type: none"> <li>Establishment No. 211, Danish Crown Foods A/S (also T/A Tulip Food Company), Svenstrup J</li> </ul>

FSIS performed the audit to verify that Denmark’s 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 Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); 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 February 1, 2019, to January 31, 2022, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 212,627,762 pounds of pork products from Denmark. Of these amounts, additional types of inspection were performed on 17,049,476 pounds of pork products, including physical examination, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella*) in pork. As a result of inspection, 8,946 pounds of pork products were rejected due to off condition. An additional 276,835 pounds of pork products were refused for other issues not related to public health including shipping damage, labeling or other miscellaneous issues.

The previous FSIS audit in 2019 identified the following findings:

<b>Summary of Findings from the 2019 FSIS Audit of Denmark</b>
<b>Component 1: Government Oversight (e.g., Organization and Administration)</b>
<ul style="list-style-type: none"><li>• The Central Competent Authority (CCA) inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing export certificates.</li></ul>
<b>Component 5: Government Chemical Residue Testing Programs</b>
<ul style="list-style-type: none"><li>• The CCA's national chemical residue program has provisions in place that allow for chemical residue samples with violative test results to be re-analyzed at the establishment's request; however, the FSIS auditors' review of records indicated that no retesting occurred on product shipped to the United States in recent history.</li></ul>

During this audit, the FSIS auditors verified through interview and review of records that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent FSIS final audit reports for Denmark's food safety inspection system are available on the FSIS website at: [www.fsis.usda.gov/foreign-audit-reports](http://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 regulation of pork products and activities related to their inspection and export certification through national legislation including Law Order No 8 of January 6, 2022 and Order No 1721 of November 30, 2020. The FSIS auditors confirmed that there has been a change to the DVFA organizational chart; the laboratory is no longer part of the Meat Inspection Department and is now within the Innovation Department.

Official controls are administered through DVFA's Meat Inspection Units (MIU), Food Inspection Units (FIU) and Veterinary Inspection Units (VIU). Each MIU is located within a slaughter establishment and is responsible for control from receiving live animals to product shipment. Each FIU is located within processing and cold storage facilities and is responsible for control from receiving product through processing, storage and shipment 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.

DVFA ensures staffing levels are adequate, program verification tasks are completed according to schedule on a daily and shift-by-shift basis, and that official sampling tasks are performed. 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 carcass-by-carcass inspections continuously and processing inspection activities at least once per shift. MIUs are staffed by Veterinary Officers (VOs) and Lay Inspectors (LIs), while FIUs are staffed by VOs and Official Inspectors (OIs), and VOs comprise the staff of VIUs. The FSIS auditors verified through interview that VOs, OIs and LIs are employed and paid directly by DVFA.

The FSIS auditors verified through interviews and record reviews the process for certification of an establishment as eligible to export pork products to the United States. All exporting establishments must be registered by the DVFA according to National Order No 2247 of January 12, 2021, on authorization of food establishments. An establishment must apply to DVFA which then assesses the establishment's own check procedures and production facilities for compliance. If the establishment meets United States requirements, the DVFA MIU or FIU recommends the establishment for certification by the DVFA International Trade Division. DVFA will then 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, subjected to regular VO or OI export verification controls and yearly audits by the VO. The DVFA U.S. Audit Unit conducts periodic supervisory visits of the MIUs and FIUs.

DVFA schedules audits of certified establishments at a frequency of four times per year which may be reduced to the minimum frequency of once per year. The frequency can be reduced based on outcomes of previous audits, or if the establishment has been audited by a certified third party such as an International Organization for Standardization (ISO) certification audit. Audits are designed to verify establishment controls and the establishment's food safety systems and records with additional specific topics covered including U.S. requirements. After the audit, the DVFA auditor issues a written inspection report. The establishment must respond and correct any findings, after which there are two additional DVFA follow-up reviews to verify the issue was resolved.

DVFA follows an escalating system of enforcement action with four levels of action based on repetitive nature or severity of the finding. A less than ideal observation or non-compliance (MVO) is documented, and the establishment is permitted the opportunity to address the issue. If the initial finding is more severe such as a food safety issue or it is repetitive and not corrected, a warning is then issued. DVFA may issue an injunction or prohibition order to stop an establishment process until a more severe issue is corrected. In the most severe case of findings, DVFA can issue an administrative fine, report an issue to the police for prosecution, or withdraw the establishment's registration thereby ceasing operations completely. There have been no instances of enforcement action since the last FSIS audit where a certified establishment has had their registration withdrawn.

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 in order for the VO to certify and sign the certificate verifying that the pork products meet United States requirements. 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. The VO also conducts random checks of consignments to ensure all United States requirements are met prior to certification of the export. Export certificates are issued at the local control unit level on certificate paper, which has a watermark and holographic security seal and is individually numbered and tracked.

DVFA only permits pigs of Danish origin to be slaughtered in establishments approved to export pork products to the United States. The FSIS auditors verified that DVFA has species verification procedures in place for pork products exported to the United States. VOs or OIs evaluate certified establishment procedures including review of product formulations, review of domestic declarations of source material, and adequate separation of products. In the event of any suspicion about the accuracy of species origin or product formulation, a VO or OI can submit a sample for analysis.

The FSIS auditors verified through interviews that products not eligible for export to the United States are identified and kept physically separated from eligible pork products. DVFA VOs verify slaughter establishment controls and are continuously present each day during slaughter and cutting operations. Products moved from one certified establishment to another must be accompanied by a domestic declaration, a DVFA signed and issued document providing declarations of origin and tracking information of the products identified on the document. Therefore, a consignment located at a certified cold storage facility for export could have several domestic declarations, each signed by a DVFA official at the corresponding certified slaughter establishment and each certified processing establishment.

DVFA's document Special Requirements Regarding the Export of Meat and Meat Products to the United States, dated May 15, 2021, requires all food business operators to prepare and maintain a written recall procedure. The VO or OI audit the certified establishment's recall plan on a yearly basis for completeness and maintenance including a test recall. Certified establishments are required to immediately inform DVFA of the shipment of adulterated product according to Order No 727 of May 29, 2020. DVFA has a mechanism in place to notify FSIS of the shipment of non-compliant or adulterated products. There have been no recalls of pork products exported from Denmark to the United States since the last FSIS audit.

DVFA uses Regulation European Union (EU) No 2017/625 as the basis for designation of an accredited or official laboratory. The DVFA chemical residue and microbiological laboratories are accredited by the Danish Accreditation Fund (DANAK). DANAK accredits laboratories according to ISO/International Electrotechnical Commission (IEC) 17025 standards. DANAK reviews and accredits each specific method of analysis for which a laboratory has applied for approval. During the audit, the FSIS auditors verified through records review and interviews that DVFA laboratories performing analyses of official samples are accredited by DANAK.

The FSIS auditors confirmed through record review that DANAK conducts an accreditation audit of the laboratories on a yearly basis and requires laboratories to meet ISO/IEC 17025 standards. 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 results of analyses are reported according to DVFA procedures and systems. The FSIS auditors also reviewed internal employee training and proficiency requirements and the results of the most recent internal audits.

DVFA educational and training requirements for VOs, OIs and LIs are set within Regulation (EU) No 2017/625. The FSIS auditors verified through interviews and review of records that DVFA has an annual training plan in place and has conducted initial training for employees upon hiring as well as continual ongoing and refresher training of all employees. Employees 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. Employees are also provided training about specific FSIS requirements including labeling, test and hold, and pre-shipment review.

The auditors verified that Denmark's pork 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.

**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 establishments certified to export to the United States.

The FSIS auditors verified through interviews and record reviews 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. 9504, dated June 25, 2021. Ante-mortem inspection must take place within 24 hours of an animal's 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 will determine if the health and welfare of the animal is compromised, any abnormality or disease condition which may affect the suitability of the animal for human consumption, and any use of prohibited or unauthorized substances. The VO also reviews food chain information of the animals being inspected 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. DVFA VOs verify food chain information and transport documents for each arrival of a load of animals and documents information including where and when animals were received, any animals dead on arrival, and health status of all animals.

DVFA follows EU legislation and Danish orders regarding animal protections during transport, protection of animals during slaughter, and animal welfare to verify humane handling occurs from the initial starting point of moving animals from the farm through the process until animals are slaughtered. DVFA VOs verify each certified establishment meets requirements through one yearly audit and four spot check reviews 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. DVFA VOs use a checklist for performance of verification activities and create a control report to document results. Any findings of non-compliance result in immediate issuance of injunctions or are reported to the police for prosecution dependent on the specific observation.

The FSIS auditors verified through interviews and record reviews that post-mortem inspection of every swine carcass, head and viscera is conducted according to Guideline of Meat Inspection No. 9504. Under supervision of VOs, the LIs perform carcass-by-carcass inspection by performing visual inspection of all external surfaces, surfaces of body cavities, and offal. DVFA LIs identify carcasses for trimming or further inspection according to the Danish code system for classification and communication of carcass findings being either major or minor findings. Carcasses with major findings including signs of animal health issues, animal welfare issues or food safety issues such as contamination must be further inspected by a VO or LI for evaluation and after establishment actions. Carcasses with minor findings, such as local or minor slaughter errors requiring trimming, are randomly re-inspected by a VO or LI after establishment actions. DVFA has also instituted daily evaluations of the quality and accuracy of carcass assessments by the LI team at the slaughter line and of establishment personnel performing corrections to carcasses to verify the code system is working as intended.

The FSIS auditors verified through interviews and record reviews that the VOs verify certified establishments meet the requirements of DVFA's document Special Requirements Regarding the Export of Meat and Meat Products to the United States, May 15, 2021, which provides requirements for the control of condemned animals. Certified establishments are responsible for the handling, marking and storage, with controls to ensure that carcasses are clearly identified. VOs verify establishment controls of condemned material handling as part of their routine inspection verification procedures.

DVFA United States Audit Unit of the International Trade Division conducts supervisory visits to certified establishments at a minimum frequency of three times annually at slaughter establishments, two times annually at processing establishments and once annually at cold storage facilities. DVFA Head of Unit officials meet with VOs four to six times per year to review the control system including inspection trends, new requirements, and POE violations. VOs also serve as supervisors in each certified establishment and conduct a Quality Supervision

review of how each individual DVFA employee performs the duties of their position. Findings from the supervisory reviews, head of unit reviews and quality supervision reviews are documented with training or follow-up activities conducted as needed. Any observations of non-compliance during reviews are also documented, requiring the certified establishment to document corrective actions which are subject to verification. The FSIS auditors verified these DVFA procedures during the audit through interviews and review of records.

The FSIS auditors verified through interviews and record reviews that DVFA requires certified establishments to properly label products according to the DVFA document Special Requirements Regarding the Export of Meat and Meat Products to the United States. VOs and OIs must audit specific United States labeling requirements yearly and verify labeling during the export procedures verification process. Labels must include product name, company authorization number, shipping identification mark, country of origin, name and address of the manufacturer or distributor, net weight of the product and safe handling instructions. Additional requirements are specified for consumer packages, multi-ingredient products, heat treated products and non-heat-treated products. Any labels with claims must be approved by FSIS prior to their use by a certified establishment.

The FSIS analysis and remote verification 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 DVFA requires each certified establishment to develop, implement, and maintain written sanitation standard operating procedures (SOP) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

The FSIS auditors verified through interviews and record reviews that DVFA requires certified establishments to comply with the document 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. The document 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 SOP programs. Certified establishments must also maintain daily sanitation SOP records of implementation, monitoring, and corrective actions.

The DVFA official verifies SPS and sanitation SOP requirements are met by each certified establishment according to DVFA's document Guidance on Controls on Companies Exporting Food to Third Countries (Export Control Guidelines) dated February 22, 2022. DVFA 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 9 CFR 416.1 to 416.5. DVFA Export Control Guidelines also require the VO or OI to verify implementation of sanitation SOP programs once per shift. Pre-operational inspection is performed by the VO or OI observing the designated establishment employee perform their cleanliness check, by inspecting establishment equipment prior to operations, or by directly observing cleaning procedures conducted by establishment employees. The FSIS auditors verified these DVFA procedures during the audit through interview and review of records.

The DVFA document Special Requirements Regarding the Export of Meat and Meat Products to the United States 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. Certified establishments must maintain daily records sufficient to document implementation and monitoring of procedures which must be incorporated in their HACCP plan, sanitation SOP program or another self-monitoring procedure. The FSIS auditors verified through interview and review of records that the VOs and OIs routinely perform verification of sanitary dressing procedures.

The FSIS auditors verified through interviews and review of records that DVFA requires the VOs or OIs to verify certified establishments follow zero tolerance requirements for fecal material, ingesta and milk as required by DVFA's Export Control Guidelines. DVFA VOs or LIs perform zero tolerance checks and document results during each shift. LIs also perform inspection of every carcass for fecal material, ingesta and milk during the post-mortem carcass by carcass inspection. Any carcass with contamination is 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 prior to moving back onto the production line.

The FSIS analysis and remote verification activities indicate that DVFA requires operators of 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 certified establishment develop, implement, and maintain a HACCP system.

A DVFA VO or OI conducts an audit on an annual basis 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 through interviews and record reviews that DVFA requires certified establishments to develop and implement a HACCP system in accordance with DVFA's document Special Requirements Regarding the Export of Meat and Meat Products to the United States. An officer from the DVFA International Trade Division, U.S. Audit Unit verifies that the VO or OI evaluates the

HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records and pre-shipment reviews as part of the audits at each certified establishment.

Certified establishments are required to meet the HACCP requirements stipulated in Executive Order on Exports no. 213/2019, specific U.S. requirements published on the DVFA website and the DVFA guidance on export. DVFA VOs follow the DVFA Inspection Guidelines dated January 13, 2021, and DVFA Export Control Guidelines as the basis for performance of DVFA verification activities in certified establishments. The FSIS auditors verified through interviews and record reviews that the VO develops an annual inspection plan to schedule audits, and daily and weekly inspections. Results of inspections and verifications are documented on a daily control report and later summarized on a monthly inspection review report.

The FSIS auditors reviewed documents to verify that VOs and OIs verify critical control points (CCPs) according to the annual meat inspection plan. Documents reviewed included performance of daily zero tolerance checks, reviews of establishment pre-shipment reviews and verification of certified establishment CCPs by either review of records, own observations by the VO or OI, or over the shoulder direct observation of establishment monitoring of the CCP. DVFA guidelines also provide further instructions on how VOs are to verify the product flow chart and description, hazard analysis, HACCP plan, monitoring, verification, corrective actions, recordkeeping, and pre-shipment reviews. The FSIS auditors verified that if a non-compliance was observed the certified establishment is provided notification, the findings are documented, and the certified establishment must take corrective actions which are then reviewed by the VO or OI.

The FSIS analysis and remote verification activities indicate that DVFA requires operators of 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 meat products inspection authorities or by FSIS as potential contaminants.

Prior to the audit, and as part of the annual SRT review for ongoing equivalence determination, FSIS reviewed Denmark's National Residue Control Plan (NRCP), associated methods of analysis, reported results of the testing program, and additional SRT responses outlining the structure of Denmark's official chemical residue testing program.

The FSIS auditors verified that the NRCP is developed and administered by DVFA to plan and manage the testing of carcasses and parts for chemical residues and contaminants in pork products. The Ringsted laboratory in coordination with DVFA central authorities and the Danish

Technical University are responsible for planning, implementation, and coordination of the NRCP on a yearly basis in accordance with Council Directive No 96/23/EC. The yearly 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 requests based on the NRCP to DVFA personnel at each MIU.

The FSIS auditors verified through interviews with VOs that sample schedules are received from the laboratory providing the specific details for every sample to be submitted. Sample tissues are then collected according to test instructions and packaged by the LIs who are under direct supervision of the VOs. Information of the requested sample is entered into the DVFA laboratory system by the LI and included with the sampled tissues which are packed, sealed, and shipped through a DVFA courier to the laboratory for analysis. The VOs indicated during interviews that any carcass sampled for chemical residue testing is identified and segregated to ensure that the specific carcass and its parts are held pending acceptable test results.

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. The Ringsted laboratory determines if a residue sample result is violative if there are levels detected which do not meet EU requirements. DVFA then requires that each certified establishment evaluate test results to determine if product meets all United States requirements prior to requesting export certification. The FSIS auditors verified through interview that based on these DVFA requirements, all 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 the VOs at both 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 of the VIU may also schedule additional testing to verify that no further violations occur.

The FSIS analysis and remote verification activities indicate that DVFA has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in pork products destined 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. This component also addresses requirements for TPCS pork products.

The FSIS auditors determined DVFA has made changes in microbiological testing programs of carcasses in slaughter establishments since the last audit including starting an official DVFA sampling program for generic *Escherichia Coli* (*E. coli*) in March of 2022 and ending the official DVFA *Salmonella* Performance Standard program as of January 1, 2022. DVFA began implementation of generic *E. coli* program sampling which requires DVFA sampling of five carcasses once per month. Results of analysis are reported to in plant DVFA personnel for evaluation and action at each certified establishment.

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. Certified establishments are required to sample carcasses at one point in the slaughter process for aerobic colony count and *Enterobacteriaceae* and evaluate results based on an upper limit (M), or a trend is determined based on test results above the lower limit (m).<sup>2</sup> 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. The VOs perform a review of the certified establishment's test program four times per year and routinely review test results and records of the testing program.

The DVFA requires certified establishments to test carcasses for *Salmonella* in accordance with the Danish Order on *Salmonella* in Pigs No. 1079 dated June 1, 2021. Frequency of sampling is dependent on the number of animals slaughtered with five carcasses swabbed daily when 30,000 pigs are slaughtered per day. Results are 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 positive per 12-month average, which is computed monthly. DVFA verifies sampling and establishment corrective actions in response to positive samples and collects information on the results in accordance with Commission Regulation (EC) No 2073/2005.

The FSIS auditors verified through interviews and record reviews that DVFA conducts sampling of RTE products for *Salmonella* and *Lm* according to DVFA's Export Control Guidelines. VOs or OIs collect product samples at a frequency of two samples per month. Samples are analyzed for *Salmonella* and *Lm* by the DVFA microbiology laboratory. VOs or OIs also collect *Lm* surface swabs from production lines on a yearly basis with an increased number of samples on a production line if deli type 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 through interviews that DVFA VOs and OIs review and verify that certified establishments institute testing programs to ensure control and prevention of adulteration by *Lm* in the post-lethality production environment. Certified establishments must meet requirements described in the Special Requirements Regarding the Export of Meat and

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<sup>2</sup> FSIS notified eligible foreign countries of new regulations for U.S. swine slaughter establishments and continues to ensure that the countries implement equivalent sampling and analysis for microbial organisms for monitoring process control throughout slaughter and dressing operations consistent with U.S. requirements in 9 CFR 310.18.

Meat Products to the United States. DVFA requires that *Lm* cannot be detected in product and that products do not come in contact with surfaces contaminated with *Lm*.

The FSIS auditors verified that DVFA requires certified establishments producing TPCS products must comply with 9 CFR 431 in accordance with DVFA's Guide to Specific Requirements for the Export of Meat and Meat Products to the United States dated December 7, 2020. The FSIS auditors verified through interviews and record reviews that VOs or OIs verify compliance with United States canning regulations on a monthly basis. Additionally, an annual audit is conducted by the DVFA to ensure the certified establishment's procedures comply with the requirements of 9 CFR 431.

The FSIS analysis and remote 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 April 8, 2022, 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.

## **Appendix: Foreign Country Response to the Draft Final Audit Report**



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

File: 2022-16-1030-00157  
Ref. DVFA  
Date: 26-08-2022

## **Comments regarding the final audit report on Denmark's meat inspection system March 8 through April 8, 2022**

Dear Michelle Catlin

The Danish Veterinary and Food Administration (DVFA) acknowledges the receipt of Food Safety and Inspection Service's (FSIS) draft final report from the remote ongoing equivalence verification audit of Denmark's food safety inspection system governing pork products. The audit was carried out March 8 to April 8, 2022.

By letter of June 29, 2022 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 5:

*The certified establishment is then included in communications from DVFA regarding United States topics, subjected to regular VO or OI export verification controls, and the DVFA U.S. Audit Unit conducts audits according to the schedule based on the type of certified establishment.*

The VO and OI conducts export verification controls (daily/weekly inspection of the establishment's own check program). VO conducts the yearly audits. DVFA U.S. Audit Unit conducts periodic supervisory visits of the MIU and FIU.

Component four: Government hazard analysis and critical control point (HACCP) system.

Page 10-11:

*An officer from the DVFA International Trade Division evaluates the HACCP system design, implementation, validation, recordkeeping, supporting documentation, reassessment records and pre-shipment reviews as part of an audit at each certified establishment.*

An officer from the DVFA International Trade Division does not audit the establishments. VO evaluates the establishment's HACCP-system as part of the yearly audits of the establishment.

Page 11:

*Certified establishments are required to meet the HACCP requirements set forth within the DVFA Export Control Guidelines. DVFA VOs follow the DVFA Inspection Guidelines dated January 13, 2021, as the basis for performance of DVFA verification activities in certified establishments.*

Certified establishments are required to follow the HACCP requirements stipulated in order of export (no 213), specific US-requirements published on the DVFA website and the DVFA guidance on export. VO and OI follow the DVFA Inspection Guideline (general inspection guidelines) dated January 13, 2021 and DVFA Export Control Guide (specific US inspection requirements) dated February 22, 2022.

Component five: Government chemical residue testing programs.

Page 12:

*The VO's indicated during interviews that any carcass sampled for chemical residue testing is identified and segregated to ensure that the specific carcass and its parts are held pending acceptable test results and these carcasses and parts are excluded from export to the United States.*


and

*The FSIS auditors verified through interview that based on these DVFA requirements, all establishments currently certified to export to the United States have procedures in place to separate and exclude all carcasses and parts tested for residues and to ensure the tested product is not exported to the United States.*

All sampled carcasses are held pending acceptable test results. Some establishments exclude carcasses sampled for chemical residues from export to the United States, other export carcasses sampled for chemical residues to the United States in case of acceptable sampling results.

Please do not hesitate to contact the International Trade Division, e-mail: [16@fvst.dk](mailto:16@fvst.dk) if you need any additional information.

Yours sincerely



Per Krogsgaard Preisler Christiansen  
Deputy Director General  
Danish Veterinary and Food Administration