

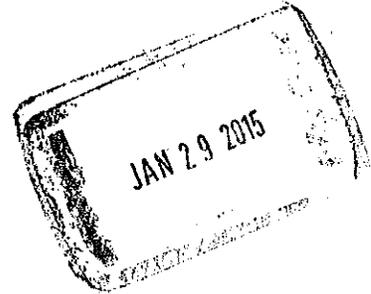


United States Department of Agriculture

Food Safety and  
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Dear Dr. Henriksen,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Denmark's meat inspection system from March 4 through March 19, 2014. 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 report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile number (202) 720-0676, or via electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov)

Sincerely,

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit

Enclosure

**DENMARK**  
**FINAL AUDIT REPORT**

January 29, 2015  
Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 4 - 19, 2014, to determine whether Denmark's food safety system governing the production of meat remains equivalent to that of the United States, with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. Denmark currently exports only pork products to the United States.

The audit focused on six main system components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs. In addition, the FSIS auditor verified that the corrective actions taken by the Central Competent Authority (CCA) in response to the June/July 2009 audit findings were being implemented. The last FSIS audit revealed potential weakness in government oversight, inspection/enforcement, and the inability of inspection personnel to correctly implement the Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), EC Directive 64/433, HACCP verification procedures, and post-mortem inspection procedures. Although corrective actions from the last audit were completed, there were repeat deficiencies associated with SSOP and SPS.

The FSIS auditor reviewed management, supervision, and administrative functions during the on-site portion of the verification audit that included six government offices - CCA Headquarters, two regional and three local offices; two swine slaughter and processing establishments, one thermal processing establishment, and one government laboratory conducting microbiological and residue testing to verify that the national system of inspection, verification, and enforcement were being implemented as required to maintain equivalence.

The 2014 audit results indicate that the Denmark's food safety inspection system is performing at an "adequate" level. The CCA meets most of the core criteria for all six equivalence components. FSIS identified CCA government oversight as a weakness related to the CCA's sanitation verification activity, including the verification of measures to prevent the reoccurrence of sanitation deficiencies, CCA inspection verification activity and recordkeeping, laboratory recordkeeping, and the CCA's microbiological control verification program. These deficiencies were discussed at the exit meeting on March 19, 2014, in Glostrup, Denmark. The CCA understood and accepted the nature of the finding. The audit findings are addressed in the respective sections of the report.

During the exit meeting on March 19, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions. FSIS will evaluate any information provided by the CCA including the submittal of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions. FSIS expects the CCA response within 60 days of the issuance of this report. Additionally, during April and May 2014, FSIS received Danish Veterinary and Food Administration's (DVFA) response to FSIS' preliminary audit findings, contained in this audit report. DVFA's response reaffirmed the implementation of corrective actions discussed at the exit meeting.

It is therefore important that the CCA provide any additional implemented corrective actions to address the reported findings in the audit report and provide to FSIS a report on the adequacy of their implementation within the next sixty days.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site equivalence verification audit of Denmark's meat inspection system from March 4 - 19, 2014. Denmark is eligible to export raw and processed pork products to the United States.

Denmark has 27 establishments that are certified to export only pork products to the United States. Between July 1, 2012 and April 30, 2014, Denmark exported approximately 140,617,083 pounds of raw and processed pork products to the United States, of which 14,678,338 pounds were re-inspected and 107,089 pounds refused by FSIS at a United States Point-of-Entry (POE). An analysis of POE findings between July 1, 2012 and April 30, 2014, showed that 658 of the total 6,390 lots of meat products imported from 16 establishments were re-inspected; of the POE failures, no food safety violations were found.

This audit was conducted pursuant to the specific provisions of the United States laws (U.S. Code, U.S.C.) and regulations (Code of Federal Regulations (CFR)), in particular:

- Federal Meat Inspection Act (21 U.S.C. 601 et seq.);
- Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

The audit standards applied included all applicable legislation and procedures originally determined by FSIS to be equivalent as part of the initial equivalence process for Denmark and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement and the European Community/United States Veterinary Equivalence Agreement were also applied.

- European Commission (EC) Regulations 852/2004; 853/2004; 854/2004; 882/2004; 178/2002; 2073/2005, 2074/2005; 2075/2005; and 2076/2005;
- Commission Decision 97/747/EC;
- European Union (EU) Regulation 2001/471/EC; and
- Assessment of Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23.

Denmark is equivalent to FSIS requirements for generic *E. coli* testing with the following exceptions:

- Use of a gauze pad sampling tool;
- Use of the NMKL or AOAC 991.14 method to analyze samples;
- Use of an alternate method (TEMPO EC) to detect and quantify generic *E. coli* in raw products; and
- Use of Enterobacteriaceae and Total Viable Count in Lieu of Generic *E. coli* Testing.

Denmark is equivalent to FSIS requirements for *Salmonella* testing for pathogen reduction performance standards with the following exceptions:

- The establishments take the samples;

- Private laboratories analyze the samples;
- A continuous, on-going sampling program is used;
- A gauze pad sampling tool is used; and
- NMKL method # 71 and iQ Check method are used to analyze samples.

## II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Denmark's food safety inspection system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled. To achieve this goal, the audit focused on six equivalence components to determine whether each component continues to be equivalent to that of the United States: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

The FSIS auditor verified that the corrective actions taken by the Central Competent Authority (CCA) in response to the June/July 2009 FSIS audit were implemented to address deficiencies in the principal areas of Sanitation control: Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOP), European Commission (EC) Directive 64/433, slaughter/processing controls – HACCP (recordkeeping, corrective actions), post-mortem inspection procedures – sub-maxillary lymph nodes were not incised/examined by an individual Danish Veterinary and Food Administration (DVFA) inspector, and inspection/enforcement controls – SPS, SSOP, and EC Directive 64/433 enforcement and verification.

## III. AUDIT METHODOLOGY

FSIS utilized its established four-phase process to conduct this equivalence verification audit - plan, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase is to document and analyze previous audit findings and other available information. The FSIS auditor examined the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and self-reporting tool (SRT) data collected since the last FSIS audit in 2009. The audit findings identified by FSIS in FY 2009 included the following findings:

- CCA inspection verification and enforcement controls
  - Sanitation control – SPS, SSOP, EC Directive 64/433
  - Slaughter/processing controls – HACCP (recordkeeping, corrective actions), and
- CCA post-mortem inspection procedures – sub-maxillary lymph nodes were not incised/examined by an individual DVFA inspector.

During the FY 2009 audit, the CCA issued a Notice of Intent to Delist (NOID) to one establishment. This NOID was issued for deficiencies concerning SSOP, SPS, and sanitary operations (sanitary dressing defects).

The FSIS auditor conducted on-site verification of corrective actions taken in response to the FY 2009 audit. The auditor also reviewed documents and observed operations to ensure that similar deficiencies did not exist in the audited establishments. The results of these activities are included within their respective components.

FSIS POE verification testing identified three food safety POE violations between August 2011 and March 2012: two for zero tolerance failure – presence of fecal and ingesta on raw product (pork spare ribs), and one for presence of fecal and ingesta on pork chitterlings exported to the United States. Actions implemented in response to these violations and the verification activity by the CCA were received from the CCA during FSIS' ongoing equivalence verification process (OEVP) associated with POE violations concerning food safety issues. There were no POE food safety violations since April 2012. The 2014 audit included two of the establishments that were associated with the product that was implicated in the POE violations for zero tolerance failure. The FSIS auditor verified the implementation and verification, as well as analysis, of those corrective actions taken by establishments and accepted by the CCA and confirmed that they were in place and effective.

The FSIS auditor reviewed information obtained directly from the CCA outlining the structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for planning the on-site audit itinerary.

The second phase was on-site verification. FSIS verified the CCA's oversight activities through on-site document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the audit by representatives from the CCA's Audit Unit (AU), International Trade Division (a division within the DVFA), including members from the regional and local inspection offices. The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters, Meat Inspection Administration, Food Control South Jutland offices, and two swine slaughter and processing and one pork thermal processing establishments to verify that the national system of inspection, verification, and enforcement was being implemented as required to maintain equivalence.

The regulations used to determine equivalence were the Denmark Food Act (*August 20, 2011*), Danish Order on Export of Foodstuffs (*Order no. 914 of September 10<sup>th</sup>, 2012*), which contains the regulatory requirements for establishments exporting meat and meat products to the United States, and the Danish Circular on Meat Inspection, which contains certain provisions of *Articles 4 and 5 of Article 19.9 and 10 and Annex I* of the European Parliament and Council Regulation (EC) No. 854/2004 of April 29, 2004 laying down specific rules for the organization of official controls on products of animal origin for human consumption, as last amended by Commission Regulation (EC) No. 1021/2008 of October 17, 2008, the European Parliament and Council Regulation (EC) No 219/2009 of March 11, 2009. During the establishment visit, the auditor paid particular attention to the extent to which the government and industry interact to control hazards and prevent program deficiencies that may threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories, including a review of the CCA's laboratory audit reports and laboratory-related data compiled for a year preceding the 2014 audit and on-site interviews with inspection personnel. In addition, FSIS examined the DVFA laboratory, located in Ringsted, which was

conducting analytical testing as part of Denmark's national residue program as well as microbiological testing of official samples.

The third phase of the audit is evaluation. FSIS conducts an evaluation of all data collected on-site to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. An extensive analysis of all data was used to determine the equivalence decision.

The final phase of the audit process is feedback, which begins with FSIS providing a draft audit report to the CCA and giving them an opportunity for comment. After reviewing the CCA comments and responses to all findings, FSIS finalizes the report. The CCA develops an action plan to address any issues raised by the audit, and FSIS monitors resolution of all issues.

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT**

The first of the six equivalence components reviewed was Government Oversight. FSIS' import eligibility requirements state that an equivalent foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States' meat inspection system. The evaluation of this component included a review of documentation submitted by the CCA as support for the responses and corrective actions, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and in the audited establishment.

Denmark is a part of the European Union and governed by the EC. The DVFA is Denmark's CCA under the Ministry of Food, Agriculture, and Fisheries (MFAF). The DVFA has one central office with five departmental offices within: Food Safety, Meat Inspection, Veterinary, Administrative and Laboratories, and Communication and Innovation Departments.

The CCA's authority to enforce inspection laws comes from *EC Regulation No. 178/2002* of the European Parliament and of the Council of 28 January 2002 defining the general principles and requirements of food law, establishing the European Food Safety Authority and defining procedures in matters of food safety. This is further supported by Danish Food Act (*August 20, 2011*), Danish Order on Export of Foodstuffs and Danish Circular on Meat Inspection as mentioned above. Other members of the EC are not considered third countries. The CCA has the legal authority and responsibility to enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States.

The Food Safety Department regional level consists of five Food Control Offices: North Jutland, Central Jutland, South Jutland, Sealand/Funen, and Copenhagen across the country and is responsible for establishments that process food products in addition to other food safety responsibilities. Currently, four Food Control Offices: North Jutland, Central Jutland, South Jutland, and Sealand/Funen of these five Food Control Offices have authority over establishments that are certified to export pork to the United States. The Meat Inspection Department has one office that is located in Vejle and is responsible for all establishments that slaughter livestock. The Veterinary Department regional level consists of three Veterinary Control Offices: North, South, and East and is responsible for animal welfare, veterinary medicine, and animal health.

During the on-site visit to the Meat Inspection Administration and Food Control South Jutland offices, the FSIS auditor conducted an examination of their oversight activities, including periodic supervisory reviews, enforcement activities reports and verification activity, and training records for official personnel by interviewing departmental personnel and reviewing documentation.

The International Trade Division within the Communication and Innovation Department of the DVFA is responsible for the official certification or decertification of United States eligible establishments and for maintaining the official list of establishments eligible to export to the United States. The AU of International Trade Division is responsible for conducting periodic supervisory reviews of the inspection personnel in establishments certified as eligible to export to the United States based on the following minimum frequencies:

- Slaughter establishments: Eight reviews/year
- Processing establishments: Six reviews/year
- Cold storage facilities: Four reviews/year
- ID warehouses: One review/year

DVFA can increase the frequency of conducting periodic supervisory reviews of the inspection personnel in establishments certified as eligible to export to the United States based on results from the periodic supervisory reviews conducted by AU.

Periodic supervisory reviews at establishments are conducted by the International Trade Division - AU personnel. These verification reviews are conducted using a standard format check sheet. Each supervisory review emphasizes certain sections of that check sheet, such as SSOP, SPS, HACCP, United States and European Union requirements, veterinary control, etc. Each section has its own checklist with a description of the finding and comment areas on preceding pages. This review report is distributed to the establishment management, the in-plant inspection personnel (IIP), the regional office, and a semiannual summary report to the regional office and the CCA headquarters. The in-plant personnel are responsible for the verification of corrective actions resulting from the review and their results are recorded in the subsequent review. If the corrective actions either do not occur or are not effective, they may request assistance from the regional office.

The FSIS auditor accompanied and observed one of the AU personnel responsible for conducting the periodic supervisory reviews. During the review, the AU personnel verified that in-plant inspection personnel implemented inspection verification requirements for ante-mortem examination, humane handling and slaughter, post-mortem examination, *Salmonella* and generic *Escherichia coli* (*E. coli*) sample collection, verification of pre-operational and operational sanitation verification procedures, and HACCP verification activities including the zero tolerance CCP verification. This included the live animal pens, all areas of slaughter and cutting, storage of products, further processing, and included thermal processing at one of the establishments audited.

The FSIS auditor verified that the CCA implemented the following verification program as described in Denmark's Alternative Post-Mortem Inspection Procedures: "Supply Chain of Inspection System" to check the accuracy of the visual inspection program for the removal of both food safety and non-food safety defects (i.e. other consumer protection defects). The official veterinarians (OV) checks that the official auxiliaries (i.e., in-plant inspection personnel) conduct inspection procedures on a daily basis as

described in "Guidelines on Measuring the Quality of the Inspection of Slaughtered Animals at Pig Slaughterhouses" and document the results on a Quality Measurement Form. The number of verification samples is statistically calculated and depends on the number of pigs slaughtered at a particular slaughterhouse. One sample consists of "one animal," i.e. ante-mortem, post-mortem (carcasses, plucks, intestines, etc.) inspection, and inspection on the rework platform. At a minimum 5 procedures are conducted for each sample. The supervisor verifies the procedures (palpation, incision, behavior); in addition, the supervisor conducts a routine inspection of carcasses that have already been through post-mortem control to make sure the right decisions are made by the inspectors. If food safety is compromised, the supervisor immediately takes corrective action. Additionally, a monthly evaluation is conducted where a 3 percent differentiation is accepted without changing sample size. Document reviewed for the previous 90 days indicated less than a 1 percent differentiation.

The FSIS auditor verified that IIP conduct ante-mortem inspection on the day of slaughter by reviewing the receiving logs and the pen cards. Denmark does not import any swine from outside the country which prevents the introduction of the African swine fever from certain third party countries into Denmark. The inspection personnel observed all animals at rest and in motion in designated holding pens prior to slaughter in order to determine whether they are fit for slaughter and for human food purposes. The designated holding pens for sick or suspect animals were maintained so that further examination of these animals could occur if needed. The FSIS auditor observed and verified that all animals have access to water in all pens, and that provisions are made for animals that are held for more than 12 hours to have access to feed (European Union requirement is 12 hours, whereas the FSIS requirement is 24 hours). The FSIS auditor concluded that the implementation of the ante-mortem inspection complies with European Union regulations deemed equivalent by FSIS.

The FSIS auditor did identify one finding concerning ante-mortem inspection of suspect animals and post-mortem disposition records related to those animals. The review of CCA ante-mortem inspection records for a 60-day period of suspect animals at one establishment identified that they did not correlate with the post-mortem final disposition records for those suspect animals. CCA final disposition information was not recorded for two of seven swine that were identified as suspects during ante-mortem requiring final veterinary disposition according to *EU Regulation 854/2004*. The animals were suspects for abnormalities. The IIP were able to identify those animals by the recorded gamble hook identification number associated with the animal through the electronic inspection system at post-mortem inspection stations, which records any associate pathology with the animal.

The FSIS auditor also assessed post-mortem inspection examinations through on-site record reviews and interviews, and compared the results to the on-site observations of IIP performing post-mortem examinations. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented and concluded that IIP are adequately trained in performing their in-line post-mortem inspection duties.

The FSIS auditor observed the performance of the IIP examining the heads, viscera, and carcasses in which the proper observation and palpation of required organs and lymph nodes are made in accordance with European Union regulations that have been deemed equivalent by FSIS. The design of the post-mortem inspection stations, including proper lighting meets equivalent requirements.

The FSIS auditor also observed the functions of the off-line inspectors who conduct daily inspection verification activities. These daily verification activities include direct observation and review of establishment records, including HACCP, Sanitation - SSOP, and SPS, generic *E. coli* sampling techniques and records, and *Salmonella* sampling techniques conducted by the establishment for their Pathogen Reduction Program and records review. The off-line inspector also collects one *Salmonella* sample weekly from a swine carcass, uses the results to verify the establishment's *Salmonella* sampling Pathogen Reduction Program, and oversees the submission of samples to the laboratory.

The FSIS auditor observed that, at one slaughter and processing establishment, a recent slaughter floor design change had impacted the ability of inspection personnel to adequately conduct verification activities. The redesign changed the location at which CCA off-line inspection personnel would observe and verify the establishment's procedures to ensure that carcasses are not contaminated with fecal material, ingesta, or milk. Though no zero-tolerance issues were identified during the audit, it was observed that the location provided for inspection personnel obstructed them from observing the carcass properly. This observation was also identified by the CCA AU during the audit.

The CCA took immediate actions to address the above issue. The location of the CCA's off-line inspection personnel was moved back to its previous location earlier in the rail system after the post-mortem rail inspection station and prior to entering the cooler.

Products destined for the United States were not being produced on the day of the audit at the thermal processing establishment; however, thermally processed products were being produced according to equivalent policy. All product currently produced for exports to the United States at this establishment audited are thermally-processed, commercially-sterile (TPCS), and packaged in cans. The review included the establishment's written HACCP program for the production of TPCS with an emphasis on adequate thermal processing, including critical limits specified to assure that all products are rendered free of microorganisms capable of growth at non-refrigerated temperatures.

The FSIS auditor reviewed the CCA's verification of monitoring and testing of seals for cans as well as establishment records assuring that the containers are hermetically sealed (airtight) to protect the product from contamination by microorganisms during and after processing. Other programs for the handling and preparation of these containers and food products were also reviewed. The reviews identified no concerns.

Inspection personnel are employed directly by the CCA which is responsible for the initial hiring, training, and payment of inspection personnel. All inspection personnel at establishments are assigned by the regional office that directly oversees them. Inspection personnel at establishments certified to export meat to the United States are full-time government employees and receive a fixed monthly salary plus overtime payment if applicable. They receive no payment from either industry groups or establishment personnel. Payments are managed by the general governmental salary system that handles all salaries for governmental employees. The costs are retrieved by the government from the establishments. The FSIS auditor verified the payment of inspection personnel by a government agency at both the Meat Inspection Administration, and Food Control South Jutland offices through the review of recorded accountable time worked by inspection personnel and their payroll records.

The FSIS auditor reviewed the records of training programs at the CCA headquarters and the regional offices including individual training records of inspection personnel verifying that the inspection system assures adequate and timely training of inspection personnel. The Danish Government has a training program "Campus" for OV and inspectors that is available on the DVFA intranet site. Additionally, DVFA employs the following methods for training of inspection personnel: The AU teaches inspection personnel new and existing FSIS requirements during establishment visits and meetings (*Journal number: 2010-20-7516-00087/Audit Unit dated 2-5-10*); provides Better Training for Safer Food (EU-courses), e.g., Monitoring and audits with SSOP and HACCP on United States approved firms, microbiology regulation and the official controls, exports, audit, risk assessment; at project sites, CCA employees share knowledge on animal welfare, inspection, audits, sampling, and other topics; and provides training on Professional Exercise of Authority. Training records indicated that training is conducted routinely with an emphasis on requirements to export to the United States. The FSIS auditor also interviewed inspection personnel at local inspection offices and observed the appropriate application of the training during the establishment audits. These observations verified that the inspection personnel assigned to certified establishments receive adequate training related to United States export at a level that ensures competency and consistent performance, and that their supervisors provide adequate oversight to ensure the proper implementation of the inspection system in maintaining equivalence.

The CCA has a mechanism in place to effectively convey FSIS requirements to all levels of inspection. Information on changes in the FSIS regulations are transmitted electronically by e-mail from the Headquarters of DVFA (Unit of Export) to the regional offices to the Meat Inspection Unit and then to the IIP. The auditor noted that the CCA oversees the functions of the inspection system by designing and implementing inspection-related procedures in accordance with national standards, in addition to those standards imposed by importing countries. The FSIS auditor verified through the review of supporting documentation provided by the CCA that the CCA maintains a communication system to convey United States inspection requirements throughout its inspection system in a timely manner. The documents reviewed support that the CCA provides instructions to field personnel through the AU during establishment visits and meetings.

During the on-site visit to the Meat Inspection Administration, Food Control South Jutland offices, and the three certified establishments, the FSIS auditor reviewed regional and inspector-generated records and interviewed regional and IIP. The CCA uses a Quality Supervision of Inspectors program, which is described as DVFA's quality program to assess performance of the inspection personnel. The criteria used in connection with quality supervision of inspectors is referenced in Quality Supervision of Data Collection carried out by an Inspection Official in Meat Businesses (*January 2008*). The criteria for the evaluation of the quality of the meat inspection system is in Guidelines on Measuring the Quality of the Inspection of Slaughtered Animals at Pig Slaughterhouses (*September 2009*). The FSIS auditor reviewed the last year of periodic supervisory reviews (quality supervision reviews) and interviewed the AU personnel and supervisory personnel who conduct them. These reviews were complete and well documented, including follow-up on previous findings and on areas where training was requested and provided by supervisor. However, the supervisory reviews did not previously identify the following audit finding concerning the IIP suspect animal disposition documentation and IIP *Salmonella* verification activity.

Additionally, there is a regulatory definition for RTE products in the *EU Regulation 2073/2005 of November 15, 2005*, that requires countries to fulfill the microbiological requirements of importing countries. FSIS' equivalence criteria for *Listeria monocytogenes (Lm)* in RTE products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States. The CCA is to conduct verification sampling of post lethality exposed RTE products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective.

The FSIS auditor reviewed information provided by the CCA through the SRT and conducted interviews during the audit with the CCA and government laboratory's microbiological department in Ringsted. An analysis of all information obtained determined that the CCA's RTE *Lm* verification sampling of post lethality exposed RTE product used to verify the effectiveness of control measures of establishments certified for export to the United States is solely based on the official finished product sampling of the product destined to be exported to the United States. It does not include ongoing verification sampling of food contact surface and environmental (non-food contact) surface and is not equivalent to FSIS' RTE *Lm* verification sampling program. Denmark does not export post lethality exposed RTE products to the United States, however.

On March 25, 2014, DVFA contacted FSIS' Office of Policy and Program Development (OPPD) - International Equivalence Staff (IES) to further engage in discussions concerning Denmark's RTE *Lm* verification sampling program and the equivalence criteria Denmark is required to meet for the export of RTE product to the United States.

The DVFA is responsible for direct oversight of government laboratories that conduct chemical residue and microbiological testing of product exported to the United States. In accordance with *EU Regulation 882/2004 - Article 33*, Denmark has designated the Food Institute, a part of the Technical University of Denmark as National Reference Laboratory (NRL). According to agreement between DVFA and the NRL, the overall purpose of the NRL activity is to ensure the analytical quality of the analyses carried out by DVFA's laboratories. The relationship between DVFA and the Food Institute is addressed in two agreements, Performance and Framework. The reports of these laboratory reviews are shared at the central and regional levels. The FSIS auditor reviewed both supervisory and laboratory reviews generated for the previous year at the CCA, regional level, and at the audited laboratory.

The DVFA allows establishments to use private laboratories for testing their own samples. The regional offices of DVFA oversee that the United States-certified establishments provide documentation that they use private laboratories that comply with the Order on Authorization of Food Establishments (*Order no.83 of February 2nd 2011*) Chapter 32 that stipulates the laboratory must be accredited or have an equivalent quality assurance system. In Denmark, accreditation of laboratories is carried out by the Danish Accreditation and Metrology Fund, DANAK, under the Danish Ministry of Economics and Business Affairs and appointed by the Danish Safety Technology Authority as the national accreditation body in Denmark.

FSIS' audit of the government laboratory's microbiological department in Ringsted identified two findings associated with the temporary (i.e., less than one hour) sample storage refrigerators.

- Temperature monitoring was only conducted weekly and not daily.

- Microbiological laboratory personnel failed to provide documented comment/action taken when a deviation in the temperature was recorded during temperature monitoring activities to bring the unit back into compliance as the laboratory control program requires.

The on-site audit findings indicate a need for the CCA to improve its oversight activities concerning the above findings related to the CCA government microbiological laboratory department.

During April and May 2014, FSIS received DVFA's response to FSIS' preliminary audit findings, contained in this audit report. DVFA's response provided implemented immediate corrective actions for the short-term and long-term prevention of recurrence of these findings.

The audit verification, including observations, document reviews, and interviews in combination with FSIS' review of the SRT and pre-audit document analysis of the CCA's control measures, indicated that Denmark's meat inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce laws and regulations governing meat inspection in official establishments. The CCA has applied these standards uniformly at the three certified establishments that were audited, indicating that FSIS' requirement of ultimate control and supervision over inspectors and inspection verification activities was met. The verification activities of Denmark's inspection system as designed and implemented indicated that the CCA continues to demonstrate the ability to satisfy the equivalence requirements for this component that are articulated in FSIS import regulations (9 CFR 327.2) with the exception of Denmark's verification sampling of post lethality exposed RTE product control program.

The FSIS' identified audit findings that require the CCA's attention are related to the following three components: Government Oversight; Sanitation; and Microbiological Testing Programs equivalence components. FSIS determined that Denmark's inspection system does support the finding that the CCA operates at an "adequate" level for this component.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to the establishments certified eligible to export to the United States. The evaluation of this component included an analysis of information provided by the CCA, the SRT, interviews, and observations during the on-site portion of the audit. The FSIS auditor verified that official inspection and verification activities were conducted in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified the regulatory authority maintained by the CCA as outlined in official legislation, regulations, and other instructions issued in accordance with the *EC Regulations 178/2002* (as above); *852/2004* on the hygiene of foodstuffs; *853/2004* describing specific hygiene rules for the food of animal origin; *854/2004* describing-specific rules for the organization of official controls on products of animal origin intended for human consumption;

882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; Decision 98/258/EC on the conclusion of the Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products; Denmark Food Act (*August 20, 2011*), Danish Order on Export of Foodstuffs (*Order no. 914 of September 10th 2012*), which contains the regulatory requirements for establishments exporting meat and meat products to the United States and the Danish Circular on Meat Inspection.

The auditor confirmed that the CCA provided the regional offices and establishment offices with the appropriate regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to establishments certified eligible to export to the United States.

The mandatory implementations of HACCP requirements that establishments certified to export to the United States have to meet are listed in the Danish Order on Export of Foodstuffs (*Order no. 914 of September 10th 2012 Annex 6, Chapter 4*). This chapter in the order addresses how HACCP is to be developed, implemented, and maintained for any Danish establishment to be eligible for export to the United States in accordance with 9 CFR 417.1-417.5 and 417.7.

The FSIS auditor verified that the CCA exercises its legal authority to require the certified establishments to develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination and the creation of insanitary conditions. This authority is in accordance with Denmark Food Act and Danish Order on Export of Foodstuffs for the regulatory requirements for establishments exporting meat and meat products to the United States.

Denmark had previously requested from FSIS an equivalence determination of two alternative post-mortem inspection procedures for "Supply Chain of Inspection System." FSIS determined that the submitted request for the following two alternative post-mortem inspections procedures met FSIS' established criteria and granted Denmark's request for each of these issues.

1. Omission of incising the mandibular lymph nodes as well as the omission of incising the hearts of slaughtered market hogs (December 18, 2008).
  - The heart incision aspect is not pertinent because FSIS does not perform heart incision as a post-mortem inspection procedure.
2. Visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs (December 1, 2012).
  - This alternative inspection procedure was not observed. The CCA stated that at this time they are not ready to implement this alternative inspection procedure.

The FSIS auditor verified that written procedures are in place instructing inspection personnel how post-mortem inspection is to be performed, including visual inspection, palpation, and incision of relevant portions of the animal described in *EU Regulation 854/2004*. In accordance with the Danish Circular on Meat Inspection, *Section 20, Subsection 2-3*, fattening pigs housed under controlled housing conditions in integrated production systems since weaning need only to undergo visual inspection (supply chain inspection). The Danish Product Standard (*January 2013*) defines the requirements for the production

of swine for the pig meat market. It focuses primarily on the key areas affecting animal welfare, meat safety, and traceability in the primary production of pigs. The FSIS auditor verified through at least 90 days of documentation that all market swine slaughtered under the "Supply Chain of Inspection System" are born and raised in the country and raised indoors meeting the criteria of the standard. Additionally, the OV verifies that pre-slaughter data information on the origin and health of the animals is presented to the slaughter establishment prior to slaughter of swine. Both of these met the criteria of the system and FSIS' equivalence determination for alternative post-mortem inspections procedures.

Denmark's meat inspection system outlines requirements in the Order on Export of Foodstuffs that the establishment must ensure that products destined for a country with specific import requirements are separated from products not destined for that country. The FSIS auditor verified that establishments that produced product for the United States and product for countries not destined for the United States had a written procedure according to Order on Export of Foodstuffs. It was further verified that all stages of production with an eventual United States destination are separated by time or space from any domestic production or production for another export market.

The audit shows that Denmark's meat inspection system has the legal authority and a documented regulatory framework to implement requirements equivalent to those governing the system of meat inspection organized and maintained by the United States. FSIS analysis and audit of Denmark's inspection system indicates that the CCA continues to demonstrate the ability to satisfy the equivalence requirements for this component that are articulated by FSIS import regulations (9 CFR 327.2). FSIS determined that Denmark's inspection system does support the finding that the CCA operates at an "average" level for this component.

## **VI. COMPONENT THREE: SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. An equivalent inspection system provides requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the on-site portion of the audit, the auditor reviewed documentation provided by the CCA concerning sanitation requirements including *EU regulations 852/2004 article 4 no 2 cf. Annex II, 853/ 2004 article 3 cf. Annex 2 chapter I-VII, and Annex 19 - Guidance on Inspection of Export Establishments (March 26, 2013)*. These documents provide instructions to the official inspection personnel to conduct a daily assessment of inspection activities during routine verification of sanitation issues. There are no fundamental differences between the United States and European Union sanitary risk control systems. The FSIS auditor verified that the in-plant personnel conduct verification of sanitary conditions in accordance with the above requirements.

The frequency of the SPS inspection verification task is risk-based, but in the United States-certified establishments, SPS-related subjects are inspected on a weekly basis according to the Guidance on Inspection of Export Establishments *Annex 19, page 6 (d)*: "weekly control of basic hygiene and maintenance requirements." For the United States-certified establishments, the requirements on SSOP (416.11-416.16) are listed in the Order on Export of Foodstuffs *Chapter 20 Annex 6, Chapter 3*. The planning of the SSOP and SPS inspections verification task is made using the Meat Inspection Plan described in *Annex 29*. The Meat Inspection Plan scheduling sheet lists the sanitation requirements, rules, and dates for the entire year to plan and execute verification tasks.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at the audited establishments. The FSIS auditor verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification inspection. The IIP's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification activities. The IIP conducted this activity in accordance with the established equivalent procedures.

The FSIS auditor followed and observed in-plant inspection verification of operational sanitation procedures. These verification activities included direct observation of operations and review of the establishment's associated records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection verification records. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishment maintained sanitation records sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. The SSOP in the establishments audited were found to meet the basic FSIS regulatory requirements, with the following exceptions.

The FSIS auditor observed findings concerning the CCA's ability to exercise regulatory control over SSOP pre-operational and operational related tasks in establishments eligible to export to the United States. The observations are as follows:

- In one establishment, on the slaughter floor during pre-operational inspection verification,
  - Meat product residue from the previous day's production and unidentified black colored particles were observed on several stainless steel conveyor pans that carry the intestines to the casing department. Additionally, the black metal hangers had residue build-up from previous production days.
  - Several air knives on the slaughter floor were observed to have rust on the blades. These blades come in direct contact with the product creating an insanitary condition and the possibility of product adulteration.
- In one establishment, in the deboning area at break time, several employee stainless steel mesh gloves and finger attachments were observed hanging on their equipment rack at the employee's station in contact with either a non-product contact surface (metal platform) or hanging 1-2 inches above that surface. Although no actual product contamination was observed, this creates an insanitary condition and a potential source of product contamination.

The FSIS auditor observed findings concerning the CCA's ability to exercise regulatory control over SPS related activities for construction and maintenance, ventilation, dressing rooms, and equipment and utensils of establishments eligible to export to the United States. The observations are as follows:

In one establishment:

- Overhead rails and switches above exposed product had extensive and excessive rail grease creating an insanitary condition and the possibility of product adulteration;

- Maintenance of equipment that comes in direct or indirect contact with product had been neglected as product transport containers were observed to have rough frayed edges (plastic) and cracked, jagged, and rolled edges (stainless steel containers);
- Maintenance and cleaning of overhead structures and walls above areas of equipment had been neglected, with evidence of rust, cracked and dislodged plastic wrapping around pipes, and buildup of production residue and scaled soap residue on overhead structures; and
- The head of a long swine carcass was contacting a non-product contact surface on the slaughter floor.

In one establishment:

- A number of small holes and loose mortar were observed along the wall in a room adjacent to the cooler for storage of raw material;
- An air exchange unit vents directly out in the vicinity of the conveyor belt system product line that carries product, creating the possibility for potential product contamination. Additionally, one vent was located directly over where exposed product passed through to another department; and
- Some employees were storing clean establishment work clothes in their locker with their personal belongings.

The FSIS auditor did not note any direct evidence of pest activity or product contamination related to these findings. In-plant inspection personnel and supervisory officials at the local and regional level enforce the regulatory requirements and verify the ability of the establishments to maintain sanitary conditions. The enforcement by the CCA of immediate corrective actions and verification of those actions to the deficiencies in this component were verified by the FSIS auditor. Additionally, the CCA will verify the establishment's measures to prevent further reoccurrence of the identified and similar deficiencies.

The FSIS auditor's review of CCA IIP in inspection system reports and supervisory review audits identified that similar deficiencies stated above for SSOP and SPS had been previously documented by IIP, supervisors and DVFA's audit unit. The review of these reports was reflective of the overall sanitary condition of the audited establishments. Documentation included corrective actions and measures to prevent reoccurrence by the establishment were included in the inspection reports and verified by inspection and audit unit personnel. Sanitation deficiencies were identified in the FSIS 2009 audit and again in this 2014 audit. The deficiencies are not the same. The records indicate that the CCA does promptly identify and correct sanitation deficiencies; however, additional emphasis is warranted for verifying that corrective measures adequately prevent the reoccurrence of these types of deficiencies.

The Denmark meat inspection system verifies that operators of certified establishments' implement its' requirements for sanitation, the development and implementation of sanitation standard operating procedures, and requirements for sanitary handling of meat products intended for export to the United States. The FSIS auditor's analysis determined that the CCA continues to demonstrate the ability to satisfy the core equivalence requirements for this component as articulated by the FSIS import regulations (9 CFR 327.2). Denmark has a system in place that verifies requirements for all areas of sanitation, and the sanitary handling of products and takes enforcement action when those requirements are not met. Denmark's meat inspection system does support the finding that the CCA's meat

inspection system continues to maintain equivalence and is operating at an “adequate” level for this component.

## **VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. An inspection system requires a HACCP plan or similar type of preventive control plan to maintain equivalence. Denmark’s meat inspection system follows the European Union requirements (especially *EC Reg. 852/2004*) for HACCP for all exporting establishments along with adding the specific requirements for HACCP that must be followed to maintain an equivalent system with that of the United States’ meat inspection system. The mandatory implementation of HACCP requirements are specified in the Order on Export of Foodstuffs (*Order no. 1170 of October 13th 2010*) Annex 6, Chapter 4, which contains the regulatory requirements for establishments exporting meat and meat products to the United States in accordance with 9 CFR 417.1-417.5 and 417.7. By these regulations, DVFA imposes regulatory requirements for the development, implementation, and maintenance of HACCP programs on the establishments certified eligible to export to the United States.

Agency verification (9 CFR 417.8) is described in the Guidance on Inspection of Export Establishments Annex 19, page 6; section C under daily and weekly inspection: Verification of the establishment’s HACCP system. The planning of the inspections verification task is made using the Meat Inspection Plan described in Annex 29. The Meat Inspection Plan scheduling sheet lists the HACCP requirements, rules, and dates for the entire year to plan and execute the verification task. Inspection personnel also must verify, at a minimum annually, that the self-control program of the establishment comply with the current requirements to HACCP in accordance with the Order on Export of Foodstuffs (*Order no. 1170 of October 13th 2010*), including risk analysis, monitoring, corrective actions, verification, validation, documentation, and annual revision. This verification is conducted as an audit. The planning of the audit is also made using the Meat Inspection Plan scheduling sheet. In addition, on a daily basis, the absence of fecal contamination is verified by inspection personnel, by way of inspection of 22 half carcasses/11 carcasses. (*Annex 19, section II (a) Chapter 1 (B) (1)*).

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The FSIS auditor verified through record review and observation that the IIP at the certified establishments conducted daily verification of HACCP plans in accordance with the methodology described in the above regulations and Order, which included the evaluation of written HACCP programs, monitoring, verification, corrective actions, recordkeeping, and hands-on verification inspection. The in-plant daily inspection verification included Critical Control Points (CCP) verification with results entered in in-plant inspection records; the Meat Inspection Plan sheet and DVFA daily Inspection Report and monthly Inspection Summary.

The 2009 FSIS audit identified HACCP deficiencies related to the design, implementation, verification, and recordkeeping at some of the establishments that were audited. FSIS was assured by the inspection officials and/or establishment management that all deficiencies found in the 2009 audit would be corrected.

The FSIS auditor reviewed the establishment's HACCP plans and records and verified that the corrective actions taken following the 2009 FSIS audit had been successfully implemented and maintained. No HACCP plan or recordkeeping deficiencies were identified during this audit. The FSIS auditor also reviewed IIP records and supervisory reviews for any findings for HACCP recordkeeping; there were no reports of deficiencies in this area. No non-compliance trends were detected as a result of the document reviews. The FSIS auditor verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities.

The FSIS auditor verified that the certified establishment had designed, implemented, and maintained an equivalent HACCP system in accordance with the above regulations and Danish Order. In-plant inspection personnel and regional supervisors monitor, verify, and enforce the implementation of the HACCP regulatory requirements in the audited establishment. There were no HACCP deviations identified.

The Denmark meat inspection system requires that operators of certified establishments' maintain regulatory requirements to develop, implement, and maintain HACCP programs for each operation as set forth in the CCA's "Order on Export of Foodstuffs" and the FSIS regulations.

The FSIS auditor's analysis determined that the CCA continues to demonstrate the ability to satisfy the equivalence requirements for this component that are articulated by the FSIS import regulations (9 CFR 327.2). FSIS determined that Denmark's inspection system does support the finding that the CCA's meat inspection system continues to maintain equivalence and is operating at an "adequate" level for this component.

## **VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM**

The FSIS auditor reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that conducts effective regulatory activities to prevent chemical residue contamination of food products. An equivalent system includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The CCA must provide a description of its residue plan and the process used to design the plan; a description of the actions taken to address unsafe residues as they occur; and oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

In accordance with EU regulations, *EC Directive 96/23*, Denmark has developed and implemented a national residue program. Program documentation is furnished to FSIS annually with the previous year's results. Denmark, as a member of the European Union, has residue plans that are acceptable by European Union standards and therefore equivalent to FSIS' criteria. Based on a review of FSIS' records, Denmark has had no POE residue violations in the past three (3) years.

The auditor's review of the SRT and supporting CCA documentation demonstrates that Denmark has a chemical residue control program that is organized and administered by the national government and that includes random sampling of internal organs and fat of carcasses for chemical residues that have been identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

The FSIS auditor verified that the design of the National Residue Testing Plan includes the required criteria, including a description of the basis for the residue plan and the process used to design the residue plan. The residue plan also describes the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for the choice of chemical compounds. It is administered and issued by the CCA and includes a separate sampling guide that provides detailed instructions for field personnel on the collection of samples of specific tissues (i.e., muscle, fat, liver, kidney, retina, urine, and blood [serum, plasma]). The FSIS auditor verified that the official veterinarian performs government sampling by packing all tissues separately and sending them to the government residue laboratories in Ringsted and Arhus in accordance with the DVFA Laboratory Project and Sampling Guidance documents.

The FSIS auditor reviewed the DVFA laboratory located in Ringsted, which conducts most of the residue analysis of government samples from establishments certified to export to the United States. Heavy metal samples are analyzed at the DVFA laboratory located in Arhus; however, this laboratory was not audited during this audit. These are the only two laboratories that conduct residue analysis of government samples for DVFA. These laboratories are designated as reference laboratories for specific residue areas. These laboratories are accredited by the Danish Accreditation and Metrology Fund, DANAK accreditation body for ISO 17025 in the specific areas of residues of pesticides and organic contaminants, anabolic steroids, metals, and residues from veterinary medications. The FSIS auditor reviewed the accreditation and third-party review and audit documents of the DVFA laboratory in Ringsted and had no concerns. Proficiency testing is proceeding as designed and all results reviewed were acceptable.

The FSIS auditor verified that the implementation of Denmark's National Residue Testing Plan at CCA headquarters, regional, and in-plant level offices, and the audited laboratory proceeded in the manner outlined in the plan. A review of Denmark's 2014 National Residue Testing Plan met FSIS' expectations for government verification testing programs.

The audit indicated that Denmark's Chemical Residue Control Program is managed by the CCA. It was established to carry out equivalent activities to prevent chemical residue contamination of food products. The inspection system identified the laws, regulations, and other decrees that serve as the legal authority for the implementation of this program. The CCA includes a description of the process used to design the residue testing plan. The plan describes the actual operations of its residue testing plan and provides a description of the actions taken to deal with unsafe residues as they occur. The CCA had access to and oversees analytical laboratories that have the capability of providing reliable testing results. The CCA has applied sampling standards uniformly at the certified establishments that were audited.

FSIS analysis and audit verification activities of Denmark's chemical residue testing program as designed and implemented indicated that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated in FSIS import regulations (9 CFR 327.2). The FSIS auditor found no concerns with the CCA's chemical residue control program. Therefore, FSIS determined that Denmark's chemical residue control program does support the finding that the CCA's meat inspection system continues to maintain equivalence and is operating at an "average" level for this component.

## IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The evaluation of this component included a review and analysis of *EU Regulation 2073/2005 of November 15, 2005*, on Microbiological Criteria for Foodstuffs and *Order No. 914 of September 10, 2012* of Export of Foodstuffs and *Guideline No. 976 of December 23 to EU Regulation 2073/2005* and *Export of Foodstuffs (Order no. 914 of September 10th 2012)* which contain the regulatory requirements for establishments exporting meat and meat products to the United States. According to *EU Regulation 852/2004*, all establishments producing products for human consumption must implement and maintain a permanent procedure based on HACCP principles. Specific rules for testing and minimum sampling are written in *EU Regulation 2073/2005*.

Denmark has an establishment-conducted microbiological testing program for *Enterobacteriaceae* that requires implementation by all slaughter establishments to show process control. *Enterobacteriaceae* testing has been accepted as equivalent to generic *E. coli* by FSIS. However, establishments that are certified eligible for export to the United States have the option of conducting generic *E. coli* testing instead. Denmark has adopted the FSIS regulatory requirements for testing for generic *E. coli*, which are set out in 9 CFR 310.25, with the exception of the following equivalent measures: Danish establishments use a gauze swab sampling tool and private microbiology laboratories use an AOAC approved NMKL method or AOAC Petrifilm method to analyze samples for generic *E. coli*.

Carcass sampling for generic *E. coli* is performed by the establishment personnel and sent to the accredited private laboratory. Inspection personnel verify the written plan; that the written plan addresses the location of sampling, randomness, and sample integrity; that appropriate sampling methodology is used; that the lab uses an appropriate method for analysis; that the results are correctly evaluated; and that establishments take appropriate corrective action if and when a violation occurs. The FSIS auditor verified through document reviews and direct observation that the two audited slaughter and processing certified establishments had implemented generic *E. coli* testing requirements. The auditor reviewed the establishments' in-plant program and records and had no concerns as a result of this review.

The FSIS auditor reviewed Denmark's *Salmonella* sampling and testing program, the implementation of the program within the certified establishment by the in-plant personnel, and the results and records resulting from the program. Sampling and testing of carcasses for *Salmonella* occur in all certified establishments that slaughter livestock. Carcass sampling for *Salmonella* species (one carcass per 1000) is performed by the establishment under the supervision of the OV and verified by the CCA in all certified establishments. The FSIS auditor's review of 120 days of records at the two slaughter and processing establishments audited identified that no *Salmonella* set failures had occurred.

The establishments take samples according to the Order on Export of Foodstuffs (*Order no. 914 of September 10th 2012 Annex 6, Chapter 8*). The requirements that the establishments have to comply

with regarding *Salmonella* Performance Standards and appropriate actions to take if *Salmonella* performance standards are not met are listed in the Order on Export of Foodstuffs.

The DVFA inspection personnel routinely verify that the establishments follow all the requirements listed in the Order on Export of Foodstuffs. The planning of the verification (audit and inspection) is made using the Meat Inspection Plan – *Annex 29*, as described previously. The DVFA inspection personnel also take verification samples according to Guidance on Inspection of Export Establishments - *Annex 19* that requires that one carcass *Salmonella* verification sample per week is sent to the government laboratory in Ringsted. The CCA performs documented analyses of the results of microbiological testing programs (including baseline/prevalence/pathogen reduction studies) to demonstrate an ongoing effectiveness of the inspection system for *Salmonella* Performance Standards as outlined in *Annex 40* - Monitoring and Control of *Salmonella* in Pig Farms and Pork Production.

The FSIS auditor's verification review of the CCA's official *Salmonella* verification sampling program identified one concern. At one slaughter and processing establishment, inspection personnel failed to follow CCA requirements when a CCA official *Salmonella* verification sample result was found to be positive. Inspection personnel failed to follow protocol to evaluate and verify whether the establishment's *Salmonella* sampling program for the assessment of the company's sampling, sample storage, transportation, and processing are working correctly and according to directions. In case of discrepancy between the company and the Authority's results, the cause of the discrepancy must be resolved. When the company does not meet the *Salmonella* standard, Export of Foodstuffs (*Order no. 914 of September 10th 2012*) *Annex 6, Chapter 8*, states that the supervisory authority must take appropriate sanctions and ensure that the company performs corrective actions in accordance with the above export order.

During April and May 2014, FSIS received DVFA's response to FSIS' preliminary audit findings, contained in this audit report. DVFA's response provided implemented immediate corrective actions for the short-term and long-term prevention of recurrence of these findings. FSIS will verify these responses in follow-up audits.

Denmark has microbiological testing programs for *Salmonella* and for *Lm* in ready-to-eat (RTE) products. There is a regulatory definition for RTE products in the *EU Regulation 2073/2005 of November 15, 2005* that requires countries to fulfill the microbiological requirements of importing countries. FSIS' equivalence criteria for RTE products states that on an ongoing basis, the CCA should verify the implementation and effectiveness of zero tolerance control measures for *Lm* in each establishment certified for export to the United States by conducting verification sampling of post lethality exposed RTE products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective.

The FSIS auditor reviewed information provided by the CCA through the SRT and conducted interviews during the audit with the CCA and government laboratory's microbiological department in Ringsted. An analysis of all information obtained determined that the CCA's RTE *Lm* verification sampling of post lethality exposed RTE product used to verify the effectiveness of control measures of establishments certified for export to the United States is solely based on the official finished product sampling of the product destined to be exported to the United States. It does not include ongoing verification sampling of food contact surface and environmental (non-food contact) surface and is not

equivalent to FSIS' verification sampling program. Denmark does not export post lethality exposed RTE products to the United States.

On March 25, 2014, DVFA contacted FSIS' OPPD- IES to further engage in discussions concerning Denmark's RTE *Lm* verification sampling program and the equivalence criteria Denmark is required to meet for the export of RTE product to the United States.

In-plant inspection personnel and departmental supervisors are required to verify test results of official testing and establishment self-check testing and to institute enforcement actions if necessary. The DVFA inspection personnel are verifying that the establishment carries out intensified sampling in response to a positive result, according to Guidance on Inspection of Export Establishments (*Annex 19*), page 20, section: "Follow-up of microbiological tests." The DVFA official sampling program does not include provisions for intensified official sampling. However, inspectors can take unscheduled samples to verify that the establishments' procedures and products comply with requirements/legislation when deficiencies are identified during their verification task.

The FSIS auditor reviewed the ISO accreditation of DVFA's government Ringsted Laboratory for microbiological testing from the Danish Accreditation and Metrology Fund, DANAK accreditation body. This accreditation contains all microbiological analyses necessary to support the certified establishments. The FSIS auditor reviewed training materials and records along with the results of proficiency testing. Proficiency testing is proceeding as designed and all results reviewed were acceptable. The FSIS auditor review of the accreditation and third-party review and audit documents identified no concerns.

The methods for analyses are NMKL method No. 71 and iQ Check *Salmonella* Kit for *Salmonella* (both raw and RTE), and Rapid L. mono for the detection of *Lm* in Danish RTE meat products destined for the United States. These methods have been deemed equivalent by FSIS.

In summary, the audit found that Denmark's meat inspection system has a microbiological testing program, organized and administered by the national government, and that the CCA has implemented generic *E. coli*, *Salmonella* and *Lm* verification sampling and testing programs to verify its system. FSIS analysis of the CCA's control measures and on-site audit verification activities of Denmark's microbiological testing program as designed and implemented supported that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated by the FSIS import regulations (9 CFR 327.2). However, the on-site audit findings indicate a need for the CCA to improve its oversight activities concerning the above findings related to CCA *Salmonella* verification activities and *Lm* equivalence criteria. Therefore, FSIS determined that Denmark's microbiological testing program does support the finding that the CCA's meat inspection system continues to maintain equivalence and is operating at an "adequate" level for this component. It is therefore important that the CCA implement prompt corrective actions to address the above reported findings and provide to FSIS a report on the adequacy of their implementation within the next sixty days.

## **X. CONCLUSIONS AND NEXT STEPS**

The results of FSIS's 2014 verification audit results indicate that the Denmark's food safety inspection system is performing at an "adequate" level. The CCA meets most of the core criteria for all six equivalence components. FSIS identified CCA's government oversight weakness related to CCA sanitation verification activity including the verification of measures to prevent the reoccurrence of sanitation deficiencies, CCA inspection verification activity and recordkeeping, laboratory recordkeeping, and CCA's microbiological control verification program. These were discussed at the exit meeting on March 19, 2014, in Glostrup, Denmark. The CCA understood and accepted the nature of the finding. The audit findings are addressed in the respective sections of the report.

During the exit meeting on March 19, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions. FSIS will evaluate any information provided by the CCA including the submittal of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions. FSIS expects the CCA response within 60 days of the issuance of this report. Additionally, during April and May 2014, FSIS received DVFA's response to FSIS' preliminary audit findings, contained in this audit report. DVFA's response re-affirmed the implementation of corrective actions discussed at the exit meeting.

It is therefore important that the CCA provide any additional implemented corrective actions to address the reported findings in the audit and provide to FSIS a report on the adequacy of their implementation within the next sixty days.

## APPENDICES

**APPENDIX A: Individual Foreign Establishment Audit Checklist**

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Bragesvej 18 Ringsted	2. AUDIT DATE 03/12, 13/2014	3. ESTABLISHMENT NO. 25	4. NAME OF COUNTRY Denmark
	5. NAME OF AUDITOR(S) Kenneth E. Witek - SPA, CSO		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment Danish Crown - Ringsted, Est. 25, Slaughter/Processing, 03/12, 13/2014

10/51/ 56 During operations in the deboning area at break time, several employee stainless steel mesh gloves and finger attachments were observed hanging on their equipment rack at the employee's station in contact with either a non-product contact surface (metal platform) or hanging 1-2 inches above that surface. Although no actual product contamination was observed, this creates an insanitary condition and a potential source of product contamination. [9CFR 416.4, 9CFR 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II; and Order on export of foodstuffs, Annex 6 - Chapter 3]

The establishment had written procedures that address the operational monitoring and cleaning of food contact surfaces of facilities, equipment, and utensils. A review of daily records indicated that this non-compliance was not identified in the last 90 days. However, the establishment failed to identify the aforementioned non-compliances during its operational monitoring on March 12, 2014. The DVFA inspection rejected the affected utensils. The establishment's immediate corrective actions for this non-compliance were verified by inspection personnel with measures to prevent the reoccurrence to be provided by the establishment.

39/46/ 51 In production areas and coolers the following deficiencies were observed in the maintenance and cleaning of overhead product equipment and structures:

- 1) Overhead structures throughout the primal cutting department, processing coolers and slaughter floor were observed to have extensive and excessive rail grease on rails and switches
- 2) Broken and dislodged plastic covering around pipes and residue on these overhead structures in the clean equipment room area
- 3) Several areas of rust on overhead and wall structures on the slaughter floor and processing areas

Although no direct product contamination was observed, the nature and extent of the problems rendered it uncertain that direct product contamination would not occur in areas of the establishment. [9CFR 416.2(b), 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

The review of record indicated that the establishment has a monitoring program to address the maintenance and cleaning of rails. Additionally, the inspection personnel had identified the deficiency in the past during internal audit/periodic supervisory reviews. It appeared that the inspection enforcement actions were inadequate to correct the non-compliances. The inspection service ordered an improved maintenance and cleaning schedule by the establishment with increased monitoring activities by in-plant inspection during both pre-operational and operational inspection.

46/51 On the slaughter floor prior to evisceration station, longer carcass' heads was contacting non-product contact surfaces (employee platform) or the possibility of incidental contact with employee's boots. This could result in creation of insanitary condition and product adulteration. [9CFR 416.4 and 9CFR 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

DVFA stated that the establishment has initiated a plan of action to improve its operational procedures.

46/51 56 The following non-compliances were observed during pre-operational inspection verification. The area was released by the establishment for the day's production of food products. There was no product being processed at the time of the review.

- 1) Meat product residues and unidentified black color particles from the previous day's production were observed on several stainless steel conveyor pans that carry the intestines to the casing department. Additionally the hangers black metal hangers had residue build up from previous production days. [9CFR 416.4, 9CFR 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]
- 2) Several air knives on the slaughter floor were observed to have rust on the blades. These blades come in direct contact with the product creating an insanitary condition and the possibility of product adulteration. [9CFR 416.4, 9CFR 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

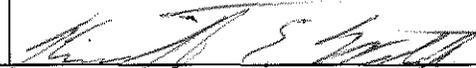
The establishment had written procedures that address the cleaning of food contact surfaces of facilities, equipment, and utensils. However, the establishment failed to identify the aforementioned non-compliances during its pre-operational monitoring on March 13, 2014. The DVFA inspection rejected all affected areas. The establishment did not start its operation until all non-compliances were corrected and verified by inspection personnel.

51 CCA carcass verification of zero-tolerance: On February 27, 2014, the establishment changed where DVFA inspection personnel conducted verification of zero-tolerance to an area further down the line prior to entering the cooler. The auditor was presented a demonstration twice of inspection personnel conducting DVFA verification of zero-tolerance and the auditor's observations indicated that:

61. NAME OF AUDITOR

Kenneth E. Witek -- SPA, CSO

62. AUDITOR SIGNATURE AND DATE



60. Observation of the Establishment Danish Crown - Ringsted, Est. 25, Slaughter/Processing, 03/12, 13/2014

- o Inspection personnel had little time to adequately conduct carcass verification of zero-tolerance for the area where relocated
- o Inspection personnel was not adequately prepared and/or trained, including how to take appropriate action when they are not able to adequately conduct carcass verification of zero-tolerance

\*Note: This observation was also identified by the CCA AU during the audit.

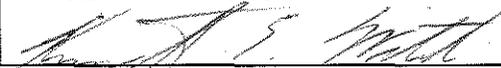
53/54/ 51 Ante-mortem suspect animal identification: Review of DVFA ante-mortem records for a 60-day period of suspect animals identified by the DVFA on ante-mortem identified that they did not correlate with the post-mortem final disposition records for those suspect animals on one occasion with the post-mortem disposition record for those animals. DVFA final disposition information was not recorded for two of seven swine that were identified as suspects during ante-mortem requiring final veterinary disposition according to *EU Regulation 854/2004*. [9CFR 309.2; EU Regulation 854/2004]

The animals were suspects for abnormalities. The IIP were able to identify those animals by the recorded gamble hook identification number associated with the animal through the electronic inspection system at post-mortem inspection stations, which records any associate pathology with the animal.

61. NAME OF AUDITOR

Kenneth E. Witek – SPA, CSO

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Tulip Food Company Tulipvej 10 DK-7100 Vejle	2. AUDIT DATE 03/06/2014	3. ESTABLISHMENT NO. 65	4. NAME OF COUNTRY Denmark
	5. NAME OF AUDITOR(S) Kenneth E. Witek – SPA, CSO		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment Tulip Food Company - Vejle, Est.65, Processing (Canning Operation), 03/06/2014

- 39/51 A number of small holes and loose mortar were observed along the wall in a room adjacent to the cooler of raw material storage and weighing area no exposed product passes along this area. [9CFR 416.2(b), 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

Records indicated that a number of construction/maintenance issues had been identified by the inspection personnel. The establishment will initiate a plan of action and review its building construction and maintenance.

- 41/46/ In the mixing room a cylinder shaped air exchange unit that runs almost the length of the room has vents along its  
51 length that is directed out in the vicinity, about 6 feet of the conveyor belt system product line that carries product creating a possibility for potential product contamination. Additionally one vent was located directly over where product passed through to another department. [9CFR 416.2(d), 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

DVFA establishment inspection officials nor internal audits/periodic supervisory review records did not identify the aforementioned non-compliance.

Immediate corrective action was taken by the establishment for the one vent located directly over where product passed by temporarily sealing the vent with plastic. The establishment provided supporting documents that the filter to the unit is changed regularly however the issue of the airflow over product remains to be addressed. DVFA stated that the establishment has initiated a plan of action to address these issues with a permanent solution.

- 44/46/ In the men's dressing room it was observed that some employees were storing clean establishment work clothes in  
51 their locker with their personnel belongings. [9CFR 416.5(a) and (b), 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

- 45/46/ The following deficiencies were observed in the maintenance and cleaning of equipment:  
51

1) In the cooler adjacent to the receiving area, a number of stainless steel combo bins that contained various types of raw pork meat within a plastic liner of the bin had cracked and jagged edges. Additionally, a substantial number of the edges around the bins were rolled under due to the physical damage. These issues create a situation that does not allow the bins to be properly cleans and a possibility for product contamination.

2) Through out the establishment a substantial number of plastic white product bins that carry exposed product along a conveyor belt system showed signs of frayed/jagged bits of plastic on the edges of the buckets creating a surface that was not smooth and a potential for product adulteration.

3) In the filling room large fans used between the end of clean up activities and the start of production had soap residue build up that poses a potential for the cross contamination of equipment with soap particles that could become dislodged when the fans are used in drying the area prior to the start of production.

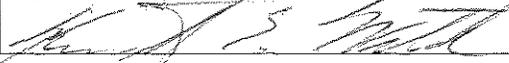
Although no direct product contamination was observed, the nature and extent of the problems rendered it uncertain that direct product contamination would not occur allowing for potential adulteration of product. [9CFR 416.3, 416.4, 416.17; Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

The establishment had written procedures that address the monitoring and maintenance of equipment. A review of establishment daily records indicates that these non-compliances were not identified in the last 90 days. DVFA establishment inspection officials nor internal audits/periodic supervisory review records did not identify the aforementioned non-compliance.

DVFA stated that the establishment has initiated a plan of action to address these issues and reassess their maintenance of equipment program.

61. NAME OF AUDITOR  
Kenneth E. Witek – SPA, CSO

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

<b>1. ESTABLISHMENT NAME AND LOCATION</b> Danish Crown Ostbirkvej 2 Horsens	<b>2. AUDIT DATE</b> 03/07/2014	<b>3. ESTABLISHMENT NO.</b> 320	<b>4. NAME OF COUNTRY</b> Denmark
<b>5. NAME OF AUDITOR(S)</b> Kenneth E. Witek – SPA, CSO		<b>6. TYPE OF AUDIT</b> <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment Danish Crown - Horsens, Est. 320, Slaughter/Processing, 03/07/2014

58/56 The auditor's identified deficiency while conducting the audit centered on DVFA's carcass *Salmonella* verification sampling by establishment inspection personnel undertaken by one (1) sample per week for analysis of *Salmonella*. The samples shall be taken and treated as indicated in the export notice, "Instructions about controls of businesses that export food to non-EU countries (export control instructions)" Appendix 6, Chapter 8, and be analyzed by the supervising authority's laboratory.

The supervisory authority's results are used in the evaluation of whether the business's sample taking, sample storage, shipment and analysis, etc. are done in a proper manner and according to regulations. In case of a lack of accord between the results obtained by the business and those obtained by the supervisory authority, an effort has to be made to determine the cause of the differences.

If the business exceeds the *Salmonella* standard (see export regulation, Appendix 6, chapter 8) the supervisory authority has to impose relevant sanctions and ensure that the business takes corrective measures in accordance with the export regulation (Appendix 6, chapter 8, no. 35-39).

Inspection personnel have failed to follow this guidance when the auditor's review of records indicated that DVFA's sample result was positive and that through further review of records and interviews with supervisory inspection personnel indicted that the establishment was only notified. A review of establishment records did indicate that all carcasses that are sampled for *Salmonella* verification testing are sent for heat treatment processing, following written establishment procedures.

The Head of Meat Inspection providing supervision for this establishment in the Meat Inspection Administration Office (regional) has address this issues and will be providing FSIS with changes to the procedures employed at this establishment by inspection personnel coupled with instruction (Notice) to all DVFA inspection staff at establishments that are certified to export to the U.S.

61. NAME OF AUDITOR  
Kenneth E. Witek – SPA, CSO

62. AUDITOR SIGNATURE AND DATE



**APPENDIX B: Denmark's Response to Draft Final Audit Report**

# Ministry of Food, Agriculture and Fisheries

Danish Veterinary and Food Administration



EXECUTIVE BOARD

Dr. Shaukat H. Syed,  
Director,  
International Audit Staff  
Office of Investigation, Enforcement and Audit

2014-30-1040-00003

**Comments on draft final report of an on-site-equivalence verification audit carried out in Denmark covering Denmark's food safety system governing the production of meat, March 4-19, 2014.**

Dear Dr Syed.

The Danish Veterinary and Food Administration (DVFA) acknowledges the receipt of the FSIS's draft final report of an audit carried out in Denmark covering Denmark's food safety system governing the production of meat, March 4-19, 2014.

By letter of October, 29th, 2014 FSIS has invited DVFA within 60 days of the receipt of the draft report to provide comments regarding the information in the report.

The DVFA would like to state the following comments:

Section IV. Component one: Government Oversight:

Page 5:

"The Audit Unit of International Trade Division is responsible for conducting periodic supervisory reviews of the inspection personnel in establishments certified as eligible to export to the United States based on the following minimum frequencies".

DVFA's comment: "Minimum frequencies" should be "standard frequencies".

"DVFA can increase the frequency of conducting periodic supervisory reviews of the inspection personnel in establishments certified as eligible to export to the United States based on results from the periodic supervisory reviews conducted by AU"

The DVFA's comment: "increase" should be "increase or decrease".

Page 5:

"The official veterinarians (OV) checks that the official auxiliaries ( i.e. in-plant inspection personnel) conduct inspection procedures on a daily basis as described in "Guidelines on Measuring..."

DVFA's comment:  
Should be:

"The official veterinarians (OV) checks that the official auxiliaries ( i.e. in-plant inspection personnel) conduct inspection procedures on a daily basis. "In addition the quality of the inspection is checked as described in "Guidelines on Measuring..."

Page 6:

"The review of CCA ante-mortem inspection records for a 60-day period of suspect animals at one establishment identified, that they did not correlate with the post-mortem final disposition records for those suspect animals"

DVFA's comment: The Meat Inspection Department has issued a notice of the importance of documenting the PM final disposition of the suspect animals, ensuring correlation between AM inspection records and PM final disposition records for the suspect animals. DVFA Audit Unit has verified the implementation of the procedures.

Page 7:

"At one slaughter and processing establishment, a recent slaughter floor design change had impacted the ability of inspection personnel to adequately conduct verification activities... It was observed, that the location provided for inspection personnel obstructed them from observing the carcass properly. This observation was also identified by the CCA AU during the audit".

DVFA's comment:

As stated in the draft final report, immediate actions were taken to address the issue. Furthermore the following actions have been taken:

- Export Inspection Guidance has been revised (1st of April 2014) with new guidelines for performing the verification of the establishment's procedures to ensure, that carcasses are not contaminated with fecal material, ingesta or milk.
- At all Inspection Units there has been, from the Meat Inspection Department, a quality supervision of the inspection personnel performing zero-tolerance-verification activities, covering both the actual performance of the verification task and the design of the location for the verification activities.
- DVFA Audit Unit has verified the implementation of the new guidelines.

Page 8:

"The supervisory reviews did not previously identify the following audit finding concerning the IIP suspect animal disposition documentation and IIP Salmonella verification activity."

DVFA's comment:

- On all swine slaughter establishments it has been verified, both by Meat Inspection Department and DVFA Audit Unit, that the procedures for IIP suspect animal disposition documentation are followed.
- The IIP Salmonella verification activity is covered by the Supervision performed by the Deputy Head of Meat inspection as well as the periodic supervisory reviews performed by the DVFA Audit Unit.
- Please also refer to DVFA's response to Section IX, page 19, IIP Salmonella verification activity

Page 9 and page 19-20:

"The CCA's RTE Lm verification sampling of post lethality exposed RTE product used to verify the effectiveness of control measures of establishments certified for export to the United States is solely based on the official finished product sampling of the product destined to be exported to the United States. It does not include ongoing verification sampling of food contact surface and environmental (non-food contact) surface and is not equivalent to FSIS RTE Lm verification sampling program".

DVFA will extend the focus on verification on Listeria samples in relation to contact surface and environmental surface. DVFA has planned a sample project in 2015 including 600 food contact surface and environmental surface samples for listeria in food producing establishments, including establishments certified for export to the United States.

Export Inspection Guidance states, that if CCA by verification sampling finds Listeria in RTE products, the CCA shall ensure, that the establishment's investigations of contact surface and environmental surface, processing areas and equipment are sufficient.

Page 9:

"Denmark does not export post lethality exposed RTE products to the United States, however".

DVFA's comment:

As already stated in the SRT for Tulip, Svenstrup, establishment No 211, Denmark does export post lethality exposed RTE products to the United States".

Page 10:

"The on-site audit findings indicate a need for the CCA to improve its oversight activities concerning the above findings related to the CCA government microbiological laboratory department".

DVFA's comment:

The DVFA laboratory is accredited by DANAK, which is the national accreditation body in Denmark. As the national accreditation body DANAK stands for accreditation in the technical field. By accreditation DANAK reviews the competence of the laboratory and participates to give DVFA an overview of the competence and need for improvement.

Section V. Component two: Statutory authority and food safety regulations:

Page 11:

"Visual inspection instead of palpation of mesenteric lymph nodes of slaughtered market hogs: This alternative inspection procedure was not observed. The CCA stated that at this time they are not ready to implement this alternative inspection procedure".

DVFA's comment:

Visual inspection instead of palpation of mesenteric lymph nodes is now implemented on two slaughter establishments in Denmark and is planned to be implemented on one more slaughter establishment January 2015.

Section VI. Component three: Sanitation.

Page 14:

"Additional emphasis is warranted for verifying that corrective measures adequately prevent the reoccurrence of these types of deficiencies":

DVFA's comment:

In Export Inspection Guidelines, section II, chapter 1, C it is stated that: "When inspection personnel by own observations during daily inspection finds noncompliances ... inspection personnel must ensure and document, that all parts of the corrective actions are taken, also actions to prevent reoccurrence. It is important, that the follow-up is documented, including disposition of products and actions to prevent reoccurrence. A noncompliance can not be closed, before inspection personnel has ensured, that the establishment has implemented the actions to prevent reoccurrence and that these are adequate"

Thus, the DVFA finds that the issue is adequately addressed in the guidelines for inspection personnel.

However, in addition to the above, the DVFA has instructed the DVFA inspection personnel to have focus on making critical evaluations of and to verify the establishments' corrective actions, emphasising an adequate prevention of reoccurrence of sanitary deficiencies, and to document the results.

Section IX. Component six: Microbiological testing programs.

Page 19:

"At one slaughter and processing establishment, inspection personnel failed to follow CCA requirements, when a CCA official Salmonella verification sample result was found to be positive".

DVFA's comment:

In the Export Inspection Guideline (April 1<sup>st</sup>, 2014), the guidelines for follow-up upon positive Salmonella verification samples were clarified.

Final DVFA comment:

DVFA Audit Unit has verified the implementation of all corrective actions stated in this report.

We hope these comments fulfil your requirements.

Please do not hesitate to contact the International Trade Division ([30@fvst.dk](mailto:30@fvst.dk)), if you have any questions regarding the above comments.

Yours sincerely



Annelise Fenger  
Deputy Director

Danish Veterinary and Food Administration