



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
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Dr. Birgitte Povlsen
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Dear Dr. Povlsen:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Denmark's meat inspection system September 1 through September 28, 2004. Enclosed is the final audit report. We have attached to the report, your letter of March 1, 2005, commenting on the draft final report of the same audit.

We appreciate the actions taken by Denmark to correct the deficiencies identified during the audit. If you have any questions regarding the FSIS audit, please contact me at my telephone number (202) 720-3781. You may also reach me at my facsimile number (202) 690-4040 or e-mail address sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

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Country File (FY 2004 Audit)

FINAL

MAR 22 2005

FINAL REPORT OF AN AUDIT CARRIED OUT IN DENMARK
COVERING DENMARK'S MEAT INSPECTION SYSTEM

SEPTEMBER 1 THROUGH SEPTEMBER 28, 2004

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
 - 6.1 Legislation
 - 6.2 Government Oversight
 - 6.3 Headquarters and Regional Offices Audit
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
 - 9.1 SSOP
 - 9.2 EC Directive 64/433
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
 - 11.1 Humane Handling and Slaughter
 - 11.2 HACCP Implementation
 - 11.3 Testing for Generic *Escherichia coli*
 - 11.4 Testing for *Listeria monocytogenes*
 - 11.5 EC Directive 64/433
12. RESIDUE CONTROLS
 - 12.1 FSIS Requirements
 - 12.2 EC Directive 96/22
 - 12.3 EC Directive 96/23
13. ENFORCEMENT CONTROLS
 - 13.1 Daily Inspection
 - 13.2 Testing for *Salmonella*
 - 13.3 Verification Testing
 - 13.4 Species Verification
 - 13.5 Monthly Reviews
 - 13.6 Enforcement
 - 13.7 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Danish Veterinary and Food Administration)
DVFA	Danish Veterinary and Food Administration
RVFCA	Regional Veterinary and Food Control Authority
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

1. INTRODUCTION

The audit took place in Denmark from September 1 through September 28, 2004.

An opening meeting was held on September 1, 2004, in Mørkhøj (Copenhagen) with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Denmark's meat inspection system.

The auditor was accompanied during the entire audit by one of three representatives from the Audit Unit, a division within the Danish Veterinary and Food Administration (DVFA).

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: The headquarters of the CCA, three regional inspection offices, two laboratories performing analytical testing on United States-destined product, four swine slaughter establishments, seven meat processing establishments and two cold storage facilities.

Competent Authority Visit			Comments
	Central	1	
	Regional	3	
	Local	13	Establishment level
Laboratories		2	
Meat Slaughter Establishments		4	
Meat Processing Establishments		7	
Cold Storage Facilities		2	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to thirteen establishments: four slaughter establishments, seven processing establishments and two cold storage facilities. The fourth part involved visits to two government laboratories. The Regional Microbiology Laboratory, located in Esbjerg was conducting analyses of field verification samples for the presence *Salmonella* and the National Residue Reference Laboratory, located in Copenhagen was conducting verification analyses of field samples for Denmark's national residue control program.

Program effectiveness determinations of Denmark's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Denmark's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Denmark and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any Equivalence determinations that have been made by FSIS for Denmark under provisions of the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement. Currently, Denmark has the same requirement for generic *E. coli* testing as FSIS with the following exceptions:

- A gauze pad sampling tool is used
- NMKL method is used to analysis samples.

Denmark has the same requirement as FSIS for *Salmonella* testing for pathogen reduction performance standards with the following exceptions:

- The establishments take the samples.
- Private laboratories analyze the samples.
- Continuous, on-going sampling program is used.
- A gauze pad sampling tool is used.

- NMKL method is used to analysis samples.

4. LEGAL BASIS FOR THE AUDIT

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat.
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products.
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following deficiencies were identified during the FSIS audit of Denmark's meat inspection system conducted in January/February 2002:

Government Oversight

- Organizational Structure: National and regional directors appeared to be somewhat reactive, rather than proactive.
- Control and Supervision: Supervision of field employees seemed to concentrate more on the paperwork produced than on the effectiveness or accuracy of the tasks assigned.
- Enforcement of U.S. Requirements: Two establishments were delisted.

Sanitation

- Four establishments had not adequately implemented SSOP procedures.
- Two establishments had not adequately documented deficiencies or corrective actions.

- EC Directive 64/433 was not enforced in all the establishments audited.
- Other sanitation deficiencies were documented in five establishments.

Slaughter/Processing

- Four establishments had not adequately implemented their HACCP plans.
- Three establishments had not completely developed and implemented a written HACCP plan.
- In one establishment, statistical process control to evaluate the results of testing for generic *E. coli* had not been properly implemented and documented.
- Postmortem incision and observation procedures were not performed adequately in one establishment.
- EC Directive 64/433: Postmortem incision and observation procedures were not performed adequately in one establishment.

Enforcement

- Monthly supervisory reviews were not consistently conducted.

All findings from the previous audit conducted in January/February 2002 were found to have been corrected during the January/February 2003 audit except for the following:

- Statistical process control to evaluate the results of testing for generic *E. coli* had not been properly implemented and documented in one establishment.
- Beef carcasses were contacting the boot guard of the eviscerator platform in one establishment.
- Fecal contamination was identified on a carcass and tails that had passed final inspection in one establishment.

These audit findings were found to have been corrected during the September 2004 audit.

The following deficiencies were identified during the FSIS audit of Denmark's meat inspection system conducted in January/February 2003:

Government Oversight

- Assignment of Inspectors: Deficiencies in inspection controls were identified in three establishments.
- Enforcement of U.S. Requirements: One establishment was delisted and two received a Notice of Intent to Delist.

Sanitation

- Four establishments had not adequately implemented their SSOP.
- Five establishments had not adequately documented deficiencies or corrective actions.
- Seven establishments had not met the requirements of EC Directive 64/433.
- Other sanitation deficiencies were documented in five establishments.

Slaughter/Processing

- Three establishments had not fully implemented their HACCP plans.
- Testing for Generic *E coli*: In one establishment statistical process control to evaluate the results of testing for generic *E. coli* had not been properly implemented and documented.
- Ante-mortem and post-mortem inspection: Unified synchronization of inspected carcasses needs improvement in one establishment.

All audit findings identified during the January/February 2003 audit were found to have been corrected during the September 2004 audit except for the following:

- Preventive measures for corrective actions were not included in the daily records documenting pre-operational sanitation noncompliances for product contact equipment.
- Non-compliances were not sufficiently documented to demonstrate the monitoring of the SSOP in the daily pre-operational sanitation records.
- On-going verification activities for the direct observation of the monitoring of critical control points and corrective actions were not performed.
- On-going verification activities for the review of records generated and maintained accordance with 9CFR 417.5 (a) (3) was not performed.
- The establishment had not included in their HACCP plan corrective actions identifying the cause and elimination of a deviation and had not established measures to prevent recurrence when a deviation from a critical limit was identified.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Denmark's legislation.

The auditor was informed that relevant FSIS regulations were in the process of being transposed into Denmark's legislation.

6.2 Government Oversight

6.2.1 CCA Control Systems

The Danish Veterinary and Food Administration (DVFA) prior to August 1, 2004 was a part of the Ministry of Food, Agriculture and Fisheries. The reporting structure remains the same, but after August 1, 2004 the ministry name was changed to the Ministry of Family and Consumer Affairs.

The DVFA is considered the CCA and is comparable to the Food Safety Inspection Service (FSIS) in the United States. Administration, development, coordination and the formation of rules and regulation take place in the headquarters of the DVFA in Copenhagen and are organized in three units: The Food Department, the Veterinary Service Department and the Administrative Department.

The Food Department is divided into five divisions: The Division of Control Coordination, Division of Food Safety, Division of Nutrition, Division of Organic Food, Marketing and Food Technology and Division of Internal Control, Import, Export and the Audit Unit. The Division of Internal Control, Import, Export and Audit Unit is responsible for rules on internal control, rules concerning national and international inspection procedures, rules on authorization, approval and registration of food enterprises, management of the control of food imports and exports, management of the control of food stuffs trade, planning and organizing inspection visits and international inspection procedures, civil contingency capabilities, serving as a contact point for the Rapid Alert System and the Audit Unit.

The Audit Unit was established January 1, 2004 and conducts regular audits of Denmark's meat inspection system and FSIS requirements in United States certified establishments. The intent of the Audit Unit is to perform a total and complete annual audit of the entire inspection system in each establishment certified to export to the United States. The Audit Unit has not totally implemented their plan and in many establishments partial audits have been completed, but complete audits in all United States certified establishments have not yet been performed.

Food control and veterinary inspection responsibilities are managed from 10 Regional Veterinary and Food Control Authorities (RVFCA). Each RVFCA contains a Food Department, a Veterinary Department and an Administration Department. Six of the 10 RVFCA contain laboratories for the testing of food products.

Within each RVFCA was the Head of the Regional Food Department, in-charge of all supervision activities and the Chief Veterinarians, who served as field supervisors over the official veterinarians located at the establishment level. Non-veterinary technicians assigned to either slaughter or processing establishments are supervised by either the chief veterinarian or the official veterinarian.

6.2.2 Ultimate Control and Supervision

The DVFA headquarters in Copenhagen has ultimate control and supervision of Denmark's meat inspection system. Although Denmark's inspection system is supervised by individual RVFCA, the DVFA develops and distributes official legislation to the RVFCA. The DVFA coordinates the implementation of inspection activities at each RVFCA and carries out training programs for the regional staff, organizes country-wide campaigns and assesses the performance of the regional units with regard to food and veterinary control by visiting each unit. The DVFA transposes EC legislation into Danish legislation with related guidelines.

The RVFCA is responsible for recommending the certification or decertification of establishments eligible to export to the United States to the DVFA headquarters in Copenhagen. The head of the Import and Export division of the Food Department is responsible for the official certification or decertification of U.S. establishments and is responsible for maintaining the official list of establishments eligible to export to the United States.

6.2.3 Assignment of Competent, Qualified Inspectors

The RVFCA is responsible for the initial hiring, training and payment of veterinarians and non-veterinary technicians. Veterinarians receive class room training in public health and food inspection as part of their normal veterinary degree course of study. Veterinarians receive on-the-job training at the establishment level. Non-veterinary technicians often have experience as a slaughterhouse worker. They are educated at the Danish Meat Trade College. The course consists of 14 weeks of theoretical training and seven weeks of practical training. On-going training needs are determined and scheduled by the official veterinarian or the chief veterinarian through consultation with the RVFCA. Special emphasizes is placed on HACCP, SSOP and Supervision training.

A yearly performance conference for each DVFA employee is required by Danish law. There are written guidelines describing how the performances conferences should be conducted. The performance conferences are documented and retained by the supervisor of the employee in a confidential personnel file.

Quality supervision consisting of an administrative component and a program component is conducted for Veterinarians and non-veterinary technicians at least once every two years. The quality supervision report is maintained at the RVFCA. This is required by an official contract between the RVFCA and the DVFA.

The RVFCA coordinators and Chief Veterinary Officers develop a yearly supervision plan to be conducted monthly for each U.S.-certified establishment. The plan includes evaluation of the supervision in the last month with recommendations, audit reports, special subjects, legislation and checklists.

6.2.4 Authority and Responsibility to Enforce the Laws

The DVFA has the legislative authority and the responsibility to enforce all FSIS requirements. The Audit Unit had identified problems in the enforcement of FSIS requirements in establishments where partial audits of Denmark's meat inspection system had been performed, but complete audits in all United States certified establishments had not been completed; therefore not all FSIS requirements were enforced. For example:

- FSIS requirements were not completely enforced in nine establishments.
- The FSIS auditor recommended a Notice of Intent to Delist be issued to two establishments.
- Some general audit findings identified during the January/February audit of 2003 were also identified during the current September 2004 audit. Examples of general repeat audit findings:
 - Preventive measures for corrective actions were not included in the daily records documenting pre-operational sanitation non-compliances for product contact equipment.
 - Non-compliances were not sufficiently documented to demonstrate the monitoring of the SSOP in the daily pre-operational sanitation records.
 - On-going verification activities for the direct observation of the monitoring of critical control points and corrective actions were not performed.
 - On-going verification activities for the review of records generated and maintained in accordance with 9CFR 417.5 (a) (3) were not performed.
 - The establishment did not include in their HACCP plan corrective actions identifying the cause and elimination of a deviation and did not establish measures to prevent recurrence when a deviation from a critical limit was identified.

6.2.5 Adequate Administrative and Technical Support

The DVFA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate Denmark's inspection system.

6.3 Headquarters and Regional Offices Audit

The auditor conducted a review of inspection system documents at the headquarters of the DVFA located in Copenhagen. The auditor also conducted a review of records at the RVFCA located in Aalborg, Esbjerg and Viborg for the purpose of determining the supervisory structure of the region and to review records pertinent to establishments included in the audit of Denmark's meat inspection system. Other records reviewed focused on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- Training programs for inspection personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with disease conditions and of inedible and condemned materials.
- Export product inspection and control.

No concerns arose as a result the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 13 establishments. Four were slaughter establishments, seven were processing establishments and two were cold storage facilities. No establishments were delisted by Denmark. Two establishments received a Notice of Intent to Delist (NOID) from the Office of International Affairs. One establishment was issued a NOID because the HACCP system was determined to be inadequate and another establishment received a NOID for failure to meet FSIS requirements for HACCP, SSOP and *Listeria*. These establishments may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following laboratories were reviewed:

One Regional Microbiology Laboratory, located in Esbjerg and the National Residue Reference Laboratory, located in Copenhagen. No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Denmark's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

In addition, and except as noted below, Denmark's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in the establishments audited were found to meet the basic FSIS regulatory requirements, with the following exceptions:

- One establishment did not monitor daily the implementation of the procedures in the SSOP. For example:
 - The kidneys and livers at evisceration stations and the front feet of swine carcasses at two work stands were allowed to come into contact with the same surface of the platforms that establishment employees stand on.
- Six establishments were not maintaining daily records sufficient to document the implementation and monitoring of the establishment's SSOP. For example:
 - Preventive measures for corrective actions were not included in the daily records documenting pre-operational sanitation noncompliances for product contact equipment.
 - Non-compliances were not sufficiently documented to demonstrate the monitoring of the SSOP in the daily pre-operational sanitation records.

9.2 EC Directive 64/433

In six establishments, the provisions of EC Directive 64/433 were effectively implemented. In the seven establishments with deficiencies, the specific deficiencies are noted in this section and other applicable sections and sub-sections of this report and in the attached individual establishment reports.

- Seven establishments did not meet the requirements of EC Directive 64/433 and were not operating and maintained in a manner sufficient to prevent creation of insanitary conditions and to ensure that product is not adulterated. For example:
 - Four wheel product tub transportation carts were stacked with the wheels in contact with the top surface of the cart. The surface of the four wheel carts contained a black residue. Plastic product tubs used for edible product were stacked with the top lip of the product contact surface of the tub in direct contact with the top surface of the four wheel cart. The carts were not maintained in sanitary condition so as not to adulterate product.
 - Work stations for establishment slaughter employees were not provided with soap to prevent the creation of insanitary conditions and the adulteration of product.
 - Protective gloves and wire mesh gloves worn by establishment slaughter employees were not cleaned or sanitized in a manner that would protect product from adulteration.
 - Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms.
 - Establishment employees working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms that were not clean and free of visible contamination at the start of each working day.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, procedures for sanitary handling of returned, reconditioned product and the implementation of the requirements for the control of Bovine Spongiform Encephalopathy. The auditor determined that Denmark's inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

Two establishments audited were cold storage facilities that conducted freezing and storage of boxed pork products for export to the United States and were not required to have developed a HACCP program.

The HACCP programs were reviewed during the on-site audit of eleven establishments. Although the HACCP plans in the 11 establishments were found to meet the basic FSIS regulatory requirements, it was found that nine of the 11 establishments had not adequately implemented their HACCP plans. Examples of these deficiencies include:

- In nine establishments the HACCP plan did not include all required components.
 - The establishment had not listed the food safety hazards that are reasonably likely to occur and did not consider biological, chemical and physical hazards for each processing step in the flow chart.
 - The direct observation component of on-going verification for monitoring procedures was not listed in the HACCP plan.
 - The records verification component for on-going verification of monitoring records was not listed in the HACCP plan.
 - The establishment had not identified the intended use or the consumers of the finished product in their written HACCP plan.

- The procedure for determining the number of samples that will be used to monitor each of the critical control points to ensure compliance with critical limits was not listed in the HACCP plan.
- Monitoring of zero-tolerance for fecal contamination was performed, but the monitoring procedures were not listed in the HACCP plan as they were actually performed in the establishment.
- Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis.
- One establishment did not verify that the HACCP plan was being effectively implemented. For example:
 - On-going verification activities for the direct observation of the monitoring of critical control points and corrective actions were not performed.
 - On-going verification activities for the review of records generated and maintained accordance with 9CFR 417.5 (a) (3) were not performed.
- Four establishments did not identify the corrective action to be followed in response to a deviation from a critical limit. For example:
 - The establishment did not include in their HACCP plan corrective actions identifying the cause and elimination of a deviation and did not establish measures to prevent recurrence when a deviation from a critical limit was identified.
- Three establishments did not maintain records that document their HACCP plan. For example:
 - The establishment did not maintain records of corrective action measures to prevent recurrence when a deviation from a critical limit was identified.
 - Each entry recording the measurement of critical limits was not initialed by the employee monitoring critical control points.
 - The establishment conducted a pre-shipment review of all records associated with the production of that product including corrective actions, but the records were initialed and not signed by the responsible establishment employee.

11.3 Testing for Generic *E. coli*

Denmark has adopted the FSIS regulatory requirements for testing for generic *E. coli* with the exception of the following equivalent measures:

1. Denmark establishments use a gauze swab sampling tool.

2. Private microbiology laboratories use an AOAC approved NMKL method to analyze samples for generic *E. coli*.

Denmark has submitted the use of an AOAC approved NMKL method as the equivalent method to be used to analyze samples for generic *E. coli*, but sample result reports from private laboratories reported that a different method was used to analyze samples for generic *E. coli*.

- Private microbiology laboratories reporting results for generic *E. coli* testing were using the U.S. AOAC 991.14 Petrifilm method for the analysis of generic *E. coli* samples.

Four establishments were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in all four of the slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

One establishment that was producing ready-to-eat products for export to the United States did not meet FSIS *Listeria* requirements.

- The establishment had not reassessed their HACCP program for the control of *Listeria monocytogenes* for ready-to-eat products that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

11.5 EC Directive 64/433

The provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The National Residue Reference Laboratory, located in Copenhagen was audited. No deficiencies were noted.

Denmark's National Residue Control Program for 2004 was being followed and was on schedule.

12.1 EC Directive 96/22

In the National Reference Residue Laboratory, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Reference Residue Laboratory, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

Daily inspection was provided as required for all establishments audited, but inspection was not provided as required for each shift preparing product for export to the United States.

- In one establishment the DVFA did not provide direct and continuous official supervision of preparation of product by the assignment of inspectors to the second and third shifts to assure that adulterated or misbranded product is not prepared for export to the United States.

13.2 Testing for *Salmonella*, *Salmonella* Performance Standards

Denmark has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

1. Establishments take the official *Salmonella* Performance Standards samples.
 - The DVFA provides a clearly written sampling plan with instruction for sample collection and processing.
 - Sample verification testing is performed by an official DVFA veterinarian once every week and the sample is analyzed in one of the six Regional Government Microbiology Laboratories.
2. Private laboratories located in selected establishments analyze *Salmonella* Performance Standards samples.
 - Test results are provided directly to the government veterinarian.
 - NMKL method is used to analysis samples.

3. *Salmonella* testing strategy

- The DVFA uses a continuous, ongoing sampling program. Denmark collects one sample per production day, grouped in sample sets of 55 samples and uses FSIS Performance Standards and enforcement procedures.
 - The DVFA testing program has statistical criteria for evaluating test results.
4. A gauze pad sampling tool is used.

Four establishments were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Salmonella testing was properly conducted in four of the four slaughter establishments.

13.3 Verification Testing Program for Ready-to-Eat Product

Denmark did not have a verification testing program in place that met United States' import requirements for the testing of ready-to-eat product for the presence of *Listeria monocytogenes* and *Salmonella*. The United States has a zero tolerance for *Salmonella* in all RTE meat products, and the United States requires a sample size of 325 grams being analyzed by a qualitative enrichment method. The United States also has a zero tolerance for *Listeria monocytogenes* in all RTE meat products, and the United States requires a sample size of 25 grams being analyzed by a qualitative enrichment method.

Denmark has started to implement procedures to meet United States' import requirements by:

- The central office of the DVFA has issued a Circular dated August 31, 2004 that instructs Regional Veterinary Food Control Authorities to perform monthly verification testing that meet US import requirements for *Salmonella* and *Listeria* and the methods to be used in the analysis of *Salmonella* and *Listeria* in RTE products. The methods are in the process of being submitted to International Equivalence Staff for an equivalence determination.

13.4 Species Verification

Three of 13 establishments audited were required to meet FSIS requirements for species verification testing. Species verification testing was being conducted in the three establishments

13.5 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.6 Enforcement of FSIS Requirements

FSIS requirements were not enforced in nine establishments. For example:

- The FSIS auditor recommended to the Office of International Affairs that Notices of Intent to Delist be issued to two establishments.
- Preventive measures for corrective actions were not included in the daily records documenting pre-operational sanitation non-compliances for product contact equipment.
- Non-compliances were not sufficiently documented to demonstrate adequate monitoring of the SSOP in the daily pre-operational sanitation records.
- The direct observation component of on-going verification for monitoring procedures was not listed in the HACCP plan.
- The records verification component for on-going verification of monitoring records was not listed in the HACCP plan.
- The establishment had not identified the intended use or the consumers of the finished product in their written HACCP plan.
- The establishment had not listed the food safety hazards that are reasonably likely to occur and had not considered biological, chemical and physical hazards for each processing step in the flow chart.
- The procedure for determining the number of samples that will be used to monitor each of the critical control points to ensure compliance with critical limits was not listed in the HACCP plan.
- On-going verification activities for the direct observation of the monitoring of critical control points and corrective actions were not performed.
- On-going verification activities for the review of records generated and maintained accordance with 9CFR 417.5 (a) (3) were not performed.
- The establishment had not included in their HACCP plan corrective actions identifying the cause and elimination of a deviation and had not established measures to prevent recurrence when a deviation from a critical limit was identified.
- The establishment did not maintain records of corrective action measures to prevent recurrence when a deviation from a critical limit was identified.
- Each entry recording the measurement of critical limits was not initialed by the employee monitoring critical control points.
- Establishment employees and inspection personnel working in contact with product,

food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms.

- Establishment employees working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms that were not clean and free of visible contamination at the start of each working day.

13.7 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on September 28, 2004, in Copenhagen with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Don Carlson, DVM
International Audit Staff Officer

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Audit Forms

Foreign Country Response to Draft Final Audit Report

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 09/24/2004

NAME OF FOREIGN LABORATORY
 Danish Institute for Food and Veterinary Research
 Department of Food Chemistry (Residue Reference Laboratory)

FOREIGN GOVT AGENCY
 Danish Veterinary and Food
 Administration

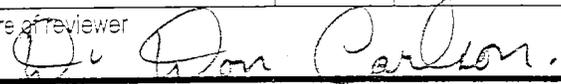
CITY & COUNTRY
 Mørkhøj (Copenhagen), Denmark

ADDRESS OF LABORATORY
 Mørkhøj Bygade 19
 DK-2860 Søborg

NAME OF REVIEWER
 Dr. Don Carlson

NAME OF FOREIGN OFFICIAL
 Anne Dragsbaek Rasmussen, Head of Section
 Mette Hjulmand-Lassen, Deputy Director Import/Export Section DVFA

Residue Code/Name			203																
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE	A															
	Sample Handling	01		A															
	Sample Frequency	02		A															
	Timely Analysis	03		A															
	Compositing Procedure	04		O															
	Interpret Comp Data	05		O															
Data Reporting	06	A																	
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A															
	Correct Tissue(s)	08		A															
	Equipment Operation	09		A															
	Instrument Printouts	10		A															
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A															
	Recovery Frequency	12		A															
	Percent Recovery	13		A															
	Check Sample Frequency	14		A															
	All Analyst W/Check Samples	15		A															
	Corrective Actions	16		A															
International Check Samples	17	A																	
REVIEW	Corrected Prior Deficiencies	18	Eval. Code	O															
OTHER REVIEW		19	Eval. Code	O															
		20		O															

Signature of reviewer


Date
 09/24/2004

REVIEW DATE
 09/06/2004

NAME OF FOREIGN LABORATORY
 Esbjerg Region Microbiology Laboratory, Government

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY
 Danish Veterinary and Food
 Administration

CITY & COUNTRY
 Esbjerg, Denmark

ADDRESS OF LABORATORY
 Høgevej 25
 6736 Esbjerg p

NAME OF REVIEWER
 Dr. Don Carlson

NAME OF FOREIGN OFFICIAL
 Marie Thisgaard Laboratory Chief
 Annette Petersen, Official Veterinary Auditor, Audit Unit Division for Own-check, Import/Export (Official Auditor)

Residue Code/Name			Sal																	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE																	
	Sample Handling	01		A																
	Sample Frequency	02		A																
	Timely Analysis	03		A																
	Compositing Procedure	04		O																
	Interpret Comp Data	05		O																
	Data Reporting	06	A																	
ANALYTICAL PROCEDURES	Acceptable Method	07	A																	
	Correct Tissue(s)	08	A																	
	Equipment Operation	09	A																	
	Instrument Printouts	10	O																	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O																	
	Recovery Frequency	12	O																	
	Percent Recovery	13	O																	
	Check Sample Frequency	14	A																	
	All Analyst W/Check Samples	15	A																	
	Corrective Actions	16	A																	
	International Check Samples	17	A																	
REVIEW	Corrected Prior Deficiencies	18	O																	
OTHER REVIEW		19	O																	
		20	O																	

Signature of reviewer *Dr. Don Carlson*

Date *09/06/2004*

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 09/06/2004	NAME OF FOREIGN LABORATORY Esbjerg Region Microbiology Laboratory, Government
FOREIGN GOVT AGENCY Danish Veterinary and Food Administration	CITY & COUNTRY Esbjerg, Denmark	ADDRESS OF LABORATORY Hogevej 25 6705 Esbjerg Ø	
NAME OF REVIEWER Dr. Don Carlson	NAME OF FOREIGN OFFICIAL Marie Thisgard Laboratory Chief Annette Petersen, Official Veterinary Auditor, Audit Unit Division for Own-check, Import/Export (Official Auditor)		

RESIDUE	ITEM NO.	COMMENTS
		ISO 17025 Accredited Method: Nordic Methodic Committee for Foodstuffs (NMKL) nr. 71.5 1999 FDIR version 22/03/2003

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Hjorring afdeling Wenbovej 11-9800 Hjorring, Denmark	2. AUDIT DATE 09/16/2004	3. ESTABLISHMENT NO. 13	4. NAME OF COUNTRY Denmark
		5. NAME OF AUDITOR(S) Dr. Don Carlson	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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

September 16, 2004: Est. 13, Danish Crown, Hjerring, Denmark

- 15/51
1. Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis . [9CFR 417.2 (a) (2) and (c) (1)] [9CFR 417.8]
 2. The processing steps for the production of pumped hams were not included in the flow chart, but food safety hazards for this process were identified in the hazard analysis . [9CFR 417.2 (a) (2)] [9CFR 417.8]
 3. The direct observation component of ongoing verification for monitoring procedures was performed and documented but was not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
 4. The records verification component for ongoing verification of monitoring records was performed and documented but was not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
- 47/56 Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. [9CFR 416.5] [EC Directive 64/433]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 16, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Steff-Houlsberg or Tulip Food Company Ringsted, Denmark	2. AUDIT DATE 09/23/2004	3. ESTABLISHMENT NO. 25	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
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.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	X	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

September 23, 2004: Est. 25, Danish Crown, Ringsted, Denmark

- 10 The establishment did not monitor daily the implementation of the procedures in the SSOP. The kidneys and livers at the evisceration stations and the front feet of swine carcasses at two work stands were allowed to come into contact with the same surface of the platforms that establishment employees stand on. The establishment and DVFA auditor took appropriate corrective actions. [9CFR 416.13 (c)]
- 13/51 Preventive measures for corrective actions were not included in the daily records documenting operational sanitation noncompliances for product contact equipment. [9CFR 416.16 (a) and 416.17]
- 15/51
1. Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. [9CFR 417.2 (a) (2) and (c) (1)] [9CFR 417.8]
 2. The establishment did not identify the intended use or the consumers of the finished product in their written HACCP plan. [9CFR 417.2 (a) (2) and 417.8]
 3. Monitoring of room temperature was performed, but the monitoring procedures were not listed in the HACCP plan as they were actually performed in the establishment. [9CFR 417.2 (c) (4) and 417.8]
- 20/51 Each entry on the record maintained for the monitoring of critical limits for room temperature was not signed or initialed. [9CFR 417.5 (3) (b) and 417.8]
- 21/51) The establishment was testing for *Listeria monocytogenes* in finished Ready-to-Eat products and product contact surfaces, but the establishment did not reassess their HACCP program for the control of *Listeria monocytogenes* for Ready-to-Eat product that comes into direct contact with a food contact surfaces after the lethality treatment in a post-lethality processing environment. [9CFR 417.4 (a) (3), 9CFR 417.8 and 430.4]
- 46/56 Non-food contact surfaces of the chain positioned over the hanging viscera and viscera pan was identified with an excessive amount of grease, rust and beading water. [9CFR 416.4 (b)] [EC Directive 64/433]
- 47/56 Establishment employees working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms that were not clean and free of visible contamination at the start of each working day. The establishment issued clean work uniforms two to three times per week. [9CFR 416.5] [EC Directive 64/433]
- 58 The FSIS auditor recommended that a Notice of Intent to Delist be issued to this establishment because of HACCP deficiencies, SSOP implementation deficiencies and the failure to reassess the HACCP program for the control of *Listeria monocytogenes* in Ready-to-Eat product in a post-lethality processing environment.

61. NAME OF AUDITOR
Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 23, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Herning, Herning, Denmark	2. AUDIT DATE 09/09/2004	3. ESTABLISHMENT NO. 31	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs 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.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

September 09, 2004: Est. 31, Herning, Herning, Denmark

- 13/51 Preventive measures for corrective actions were not included in the daily records documenting operational sanitation noncompliances for product contact equipment. [9CFR 416.16 (a) and 416.17]
- 15/51 Monitoring of zero-tolerance for fecal contamination was performed, but the monitoring procedures were not listed in the HACCP plan as they were actually performed in the establishment. [9CFR 417.2 (c) (4) and 417.8]
- 45/56 Four wheel product tub transportation carts were stacked with the wheels in contact with the top surface of the cart. The surface of the four wheel carts contained a black residue. Plastic product tubs used for edible product were stacked with the top lip of the product contact surface of the tub in direct contact with the top surface of the four wheel cart. The carts were not maintained in sanitary condition so as not to adulterate product. [9CFR 416.3 (a)] [EC Directive 64/433]
- 46/56 1. Work stations for establishment slaughter employees were not provided with soap to prevent the creation of insanitary conditions and the adulteration of product. [9CFR 416.4 (a)] [EC Directive 64/433]
2. Protective gloves and wire mesh gloves worn by establishment slaughter employees were not cleaned or sanitized in a manner that would protect product from adulteration. [9CFR 416.4 (c)] [EC Directive 64/433]
- 47/56 Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. [9CFR 416.5] [EC Directive 64/433]

61. NAME OF AUDITOR

Dr. Don Carlos

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 09, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Faaborg, Faaborg, Denmark	2. AUDIT DATE 09/22/2004	3. ESTABLISHMENT NO. 45	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 22, 2004: Est. 45, Danish Crown, Faaborg, Faaborg, Denmark

- 13/51 Preventive measures for corrective actions were not included in the daily records documenting operational sanitation noncompliances for product contact equipment. [9CFR 416.16 (a) and 416.17]
- 15/51 The records verification component for ongoing verification of monitoring records was not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
- 20/51 The establishment did not include in their HACCP plan corrective actions to establish measures to prevent recurrence when a deviation from a critical limit was identified. [9CFR 4.17 (a) (1) (3) and 417.8]
- 47/56
1. Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. [9CFR 416.5] [EC Directive 64/433]
 2. Establishment employees working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms that were not clean and free of visible contamination at the start of each working day. The establishment issued clean work uniforms two to three times per week. [9CFR 416.5] [EC Directive 64/433]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 22, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tulip Food Company Vejle Nord Vejle, Vejle	2. AUDIT DATE 09/02/2004	3. ESTABLISHMENT NO. 65	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Stancards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 02, 2004: Est. 65 Tulip Food Company, Vejle, Vejle, Denmark

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

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 16, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Saeby, Denmark	2. AUDIT DATE 09/17/2004	3. ESTABLISHMENT NO. 71	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

September 17, 2004: Est. 71, Saeby, Denmark

- 13/51 Preventive measures for corrective actions were not included in the daily records documenting operational sanitation noncompliances for product contact equipment. [9CFR 416.16 (a) and 416.17]
- 15/51 1. Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. [9CFR 417.2 (a) (2) and (c) (1)] [9CFR 417.8]
2. The establishment did not list the food safety hazards that might be expected to arise and did not consider biological, chemical and physical hazards for each processing step in the flow chart. [9CFR 417.2 (a) and (c) and 417.8]
- 20/51 The establishment did not include in their HACCP plan corrective actions to establish measures to prevent recurrence when a deviation from a critical limit was identified. [9CFR 4.17 (a) (1) (3) and 417.8]
- 22/51 The establishment conducted a pre-shipment review of all records associated with the production of that product including corrective actions, but the record was initialed and not signed by the responsible establishment employee. [9CFR 417.5 9 (c) and 417.8]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 17, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Danish Crown Viborg, Viborg, Denmark	2. AUDIT DATE 09/14/2004	3. ESTABLISHMENT NO. 78	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 14, 2004: Est. 78, Danish Crown, Viborg, Viborg, Denmark

- 13/51 Preventive measures for corrective actions were not included in the daily records documenting operational sanitation noncompliances for product contact equipment. [9CFR 416.16 (a) and 416.17]
- 15/51 1. Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. [9CFR 417.2 (a) (2) and (c) (1)] [9CFR 417.8]
2. The records verification component for ongoing verification of monitoring records was not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
- 47/56 Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. [9CFR 416.5] [EC Directive 64/433].

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 14, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Esbjerg Frysehus, I/S Esbjerg, Denmark	2. AUDIT DATE 09/08/2004	3. ESTABLISHMENT NO. 160	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O	33. Scheduled Sample	O
8. Records documenting implementation.	O	34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	O	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.	O	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	O	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 08, 2004: Est. 160, Esbjerg Frysehus, I/S, Esbjerg, Denmark

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

61. NAME OF AUDITOR

Dr Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 08, 2004

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigoscandia A/S Odense, Odense, Denmark	2. AUDIT DATE 09/21/2004	3. ESTABLISHMENT NO. 198	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O	33. Scheduled Sample	O
8. Records documenting implementation.	O	34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.	O	35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	O	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	O	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	O	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	O	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.	O	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	O	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	O	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	O	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	O	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	O	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	O	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 21, 2004: Est. 198, Frigoscandia A/S, Odense, Odense, Denmark

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

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 21, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Scanflavour A/S Møldrup Denmark	2. AUDIT DATE 09/13/2004	3. ESTABLISHMENT NO. 215	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic <i>E. coli</i> Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Notice of Intent to Delist	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 13, 2004: Est. 215, Scanflavour A/S, Møldrup Denmark

- 15/51
1. The direct observation component of ongoing verification for monitoring procedures was not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
 2. The records verification component for ongoing verification of monitoring records was not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
 3. The establishment did not identify the intended use or the consumers of the finished product in their written HACCP plan. [9CFR 417.2 (a) (2) and 417.8]
 4. The establishment did not list the food safety hazards that are reasonably likely to occur and did not consider biological, chemical and physical hazards for each processing step in the flow chart. [9CFR 417.2 (a) and (c) and 417.8]
 5. The procedure for determining the number of samples that will be used to monitor each of the critical control points to ensure compliance with critical limits was not listed in the HACCP plan. [9CFR 417.2 (c) (4) and 417.8]
- 19/51
1. Ongoing verification activities for the direct observation of the monitoring of critical control points and corrective actions were not performed. [9CFR 417.4 (a) (2) (ii) and 417.8]
 2. Ongoing verification activities for the review of records generated and maintained accordance with 9CFR 417.5 (a) (3) was not performed. [9CFR 417.4 (a) (2) (iii) and 417.8]
- 20/51
- The establishment did not include in their HACCP plan corrective actions identifying the cause and elimination of a deviation and did not establish measures to prevent recurrence when a deviation from a critical limit was identified. [9CFR 4.17 (a) (1) (3) and 417.8]
- 22/51
1. The establishment did not maintain in their records for corrective action measures to prevent recurrence when a deviation from a critical limit was identified. [9CFR 4.17.5 (a) (3) and 417.8]
 2. Each entry made on the record maintained to document recording of the measurement of critical limits was not initialed by the employee monitoring critical limits. [9CFR 417.5 (b)]
- 58
- The FSIS auditor determined the HACCP system was inadequate and recommended to the Office of International Affairs that a Notice of Intent to Delist be issued to this establishment.

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 13, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tulip Food Company, Brabrand, Braband, Denmark	2. AUDIT DATE 09/03/2004	3. ESTABLISHMENT NO. 220	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 15, 2004: Est. 220, Tulip Food Company, Brabrand, Denmark

- 15/51 1. Preventive measures for corrective actions were not included in the daily records documenting operational sanitation noncompliances for product contact equipment. [9CFR 416.16 (a) and 416.17]
2. Noncompliances were not sufficiently documented to demonstrate the monitoring of the SSOP in the daily pre-operational sanitation records. [9CFR 416.16 (a) and 416.17]
- 15/51 Ongoing verification procedures were performed, but verification procedures were not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
- 47/56 Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. [9CFR 416.5] [EC Directive 64/433]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 03, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Dat-Schaub, A. m. r. A. Esbjerg, Denmark	2. AUDIT DATE 09/07/2004	3. ESTABLISHMENT NO. 417	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 07, 2004: Est. 417, Dat-Schaub, A. m. r. A., Esbjerg, Denmark

- 15/51
1. The direct observation component of ongoing verification procedures was performed, but the verification procedures were not listed in the HACCP plan. [9CFR 417.2 (c) (7) and 417.8]
 2. The establishment did not identify the intended use or the consumers of the finished product in their written HACCP plan. [9CFR 417.2 (a) (2) and 417.8]
 3. The establishment did not list the food safety hazards that is reasonable likely to occur and did not consider biological, chemical and physical hazards for each processing step in the flow chart. [9CFR 417.2 (a) and (c) and 417.8]
- 22/51
1. The establishment did not maintain records documenting preventive measures for corrective actions when a deviation of the critical limit for the zero defects CCP was recorded. [9CFR 4.17 (3) and 417.8]
 2. The results of direct observation of monitoring procedures were not recorded in the daily records documenting ongoing verification activities. [9CFR 417.3 and 417.8]
- 47/56
- Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms. [9CFR 416.5] [EC Directive 64/433]

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 07, 2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION JK Ventures A/S Sendersø, Denmark	2. AUDIT DATE 09/26/2004	3. ESTABLISHMENT NO. 4627	4. NAME OF COUNTRY Denmark
5. NAME OF AUDITOR(S) Dr. Don Carlson		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

September 20, 2004: Est. 4627, JK Ventures A/S, Søndergå, Denmark

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

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ September 20, 2004



MINISTERIET FOR FAMILIE-
OG FORBRUGERANLIGGENDER

Fødevarestyrelsen

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C.
20250
USA

att.: Sally White, Director
International Equivalence Staff
Office of International Affairs

Date: 1 March 2005

Our ref.: HP

File: 2004-20-7515-00056

Please note when replying

Sent by fax
202-690-4040
4 pages incl. this page.

Re.: Comments on draft audit report.

This is in response to letter of December 16 2004, received January 3, 2005 from FSIS, enclosed the draft audit report for the on-site audit of Denmark's meat inspection system, conducted by FSIS from September 1, 2004 through September 28, 2005.

By the letter Denmark was invited to provide comments regarding the information in the report within 60 days of the receipt of the letter. The Danish Veterinary and Food Administration (DVFA) hereby wish to forward the following comments:

1. Re: page 10 – 6.2.1 CCA Control Systems:

Comment: Although the DVFA is the CCA, it would probably be more accurate to say that the DVFA is comparable to FSIS rather than the Department of Agriculture, which is comparable to the Danish Ministry of Family and Consumer Affairs.

2. Re: page 10, 6.2.1, last paragraph:

Comment: *Head Veterinarian* should be *Head of the Regional Food Department*.

3. Re: page 11, 6.2.3. Non-veterinary technicians:

Comment: *Non- veterinary technicians must have experience as a slaughterhouse worker to be considered for employment.*

Should be:

Non- veterinary technicians often have experience as a slaughterhouse worker.

4. Re: page 11, 6.2.3, quality supervision:

A spelling error in the line:

... at least once very two years.

Should be

... at least once every two years.

5. Re: page 11, 6.2.3, quality supervision:

Comment: *This is required by an official contract between regional employees and the RVFCA.*

Should be

This is required by an official contract between the RVFCA and DVFA.

6. Re: page 11, 6.2.3, last paragraph:

The RVFCA coordinators and Chief Veterinary Officers develop a yearly supervision plan to be conducted monthly for each export establishment.

Comment: The second line should be:

...to be conducted monthly for each US certified establishment.

7. Re: page 15 – 9.2 EC Directive 64/433:

Comment: The EC Directive has been transposed into Danish legislation and all establishments must meet all provisions of the Directive. Steps are therefore being taken to ensure compliance by the establishments in question as well as all other establishments in the country.

However, with regard to the issue of employees and inspection personnel wearing work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms, DVFA have the following comments: There is no specific provision in the Directive against this practice, since the Directive merely specifies that staff “*must wear clean working clothes at the commencement of each working day and must renew such clothing during the day as necessary*”, cf. Annex I, Chapter V, No. 18 (a). Therefore, it is the view of the DVFA that this practice need not be discontinued, provided workers and inspection personnel remain within the premises of the establishments and establishments have measures in place to change any work uniforms, which may become dirty or contaminated outside the establishment.

8. Re: pages 17 – 18. 11.3 Use by private laboratories of the U.S. AOAC 991.14 Petrifilm method for the analysis of generic *E. coli* samples:

Comment: This issue is slightly more complicated. The fact of the matter is that in our letter of 14 January 1998 on equivalence of *E. coli* testing requirements in Denmark, the

DVFA informed FSIS that most of the slaughterhouses carry out generic *E. coli* testing using the AOAC approved petrifilm *E. coli* plate count method and as such fulfil FSIS requirements. However, the DVFA made a case for the use of the NMKL method as this was and still is the nationally approved method.

Although the FSIS gave tentative approval for the use of the NMKL method in a letter of 22 February 1999, the DVFA has not specifically required all establishment and private laboratories to revert to the NMKL method. This is why the petrifilm method is still in use in some laboratories. The DVFA has not previously considered this a problem. Following the remarks on this issue in the current audit report and as a matter of procedure, the DVFA hereby wish to notify FSIS that both the petrifilm and the NMKL methods are in use in Denmark.

9. Re: page 19. 13.1 Daily inspections in Establishments:

In one establishment the DVFA did not provide direct and continuous official supervision of preparation of product by the assignment of inspectors to the second and third shifts to assure that adulterated or misbranded product is not prepared for export to the United States.

Comment: With regard to the interpretation of the requirement *direct and continuous official supervision* the DVFA have forwarded certain questions in letter of December 23, 2004 to FSIS.

10. Re: page 20. 13.3 Verification Testing Program for Ready to Eat Product, laboratory methods:

The methods are in the process of being submitted to International Equivalence Staff for an equivalence determination.

Comment: The DVFA have forwarded laboratory methods for equivalence determination in letter to FSIS of November 2, 2004.

11. Re: page 21. 13.6 last bullet:

Establishment employees and inspection personnel working in contact with product, food-contact surfaces, and product-packaging materials did not adhere to hygienic practices by the wearing of work uniforms outside the establishment and then returning to production areas inside the establishment without changing work uniforms.

Comments: Please see the above comments on item 9.2.

12. Re: page 22. 13.7, 2nd paragraph:

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Comments: These controls are only applicable for products, which are eligible for export to USA.

Yours Sincerely

A handwritten signature in black ink, appearing to read 'B. Povlsen', with a long horizontal stroke extending to the left.

Dr. Birgitte Povlsen
Senior Veterinary Officer
Head of Import-Export Division
Food Department