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

FEB 5 2004

Dr. Håkan Stenson
Chief Veterinary Officer for Public Health
Food Control Department
National Food Administration
Post Office Box 622
SE-751 26 Uppsala, Sweden

Dear Dr. Stenson:

Enclosed is the final report regarding the Food Safety and Inspection Service on-site audit of Sweden's meat inspection system. The audit was conducted September 15 through September 25, 2003. Comments received from the government of Sweden have been included as an attachment to the final report.

If you have questions regarding the audit or need additional information, please contact me at telephone number 202-720-3781, by facsimile at 202-690-4040, or by email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Lana Bennett, Minister Counselor, American Embassy, Stockholm
Klas Molin, Counselor, Embassy of Sweden, Washington, D.C.
Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to U.S. in Washington, D.C.
Norval Francis, Minister-Counselor, US Mission to the EU in Brussels
James Dever, FAS Area Director
Amy Winton, State Department
Dave Young, ITP, FAS
Linda Swacina, Deputy Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA, FSIS
Donald Smart, Director, Review Staff, OPEER, FSIS
Sally Stratmoen, Director, IES, OIA, FSIS
Steve McDermott, IES, OIA, FSIS
Clark Danford, Director, IEPS, OIA, FSIS
Shannon McMurtrey, IES, OIA, FSIS
Country File

FINAL

2004

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

SEPTEMBER 15 THROUGH SEPTEMBER 25, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [National Food Administration]
FSIS	Food Safety and Inspection Service
NFA	National Food Administration
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species

1. INTRODUCTION

The audit took place in Sweden from September 15 through September 25, 2003.

An opening meeting was held on September 15, 2003, in Uppsala with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the audit itinerary, and requested additional information needed to complete the audit of Sweden's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA, the National Food Administration, and/or representatives from the regional and local inspection offices.

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, one regional inspection office, one district inspection office, one private microbiology laboratory, one government (NFA) residue testing laboratory, one private (National Veterinary Institute) residue testing laboratory performing analytical testing on United States-destined product, one swine slaughter and pork processing establishment, one cold-storage facility, and one farm.

Competent Authority Visits			Comments
Competent Authority	Central	2	
	District veterinary Office	1	
	County Veterinary Office	1	
	Local	1	Establishment level
Laboratories		3	
Meat Slaughter-Processing Establishment		1	
Cold Storage Facilities		1	
Farm		1	

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 and local (establishment level) offices. The third part

involved on-site visits to two establishments: one slaughter and processing establishment and one cold storage facility, and one farm. The fourth part involved visits to two government laboratories and one private laboratory. The Alcontrol laboratory, a private laboratory, was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. The National Food Administration Laboratory, a government laboratory, and the National Veterinary Institute Laboratory, a private laboratory, were both conducting analyses of field samples for Sweden's national residue control program.

Program effectiveness determinations of Sweden'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*. Sweden's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors also assessed how inspection services are carried out by Sweden 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 auditors 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 auditors 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 auditors 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 auditors would audit against any equivalence determinations that have been made by FSIS for Sweden under provisions of the Sanitary/Phytosanitary Agreement. The following equivalence determinations have been made for Sweden:

- FSIS has granted Sweden an equivalence determination allowing them to use an alternate laboratory testing method for generic *E. coli* (NMKL147).
- FSIS has granted Sweden an equivalence determination allowing them to use alternate laboratory testing method for *Salmonella* (NMKL 71).

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

The following findings were reported from the August 2001 FSIS audit:

- Condemned materials were not denatured before being removed from the premises. This was a repeat deficiency.
- Documentation of corrective actions and preventive measures taken in response to sanitation problems was inadequate. This was a repeat deficiency.
- The HACCP program in the slaughter/processing establishment had still not been adequately developed and the documentation was deficient. (Some improvement was noted, but some areas were in need of further development.)
- The Pathogen Reduction program was deficient: generic *E. coli* samples were now being collected from the ham area as required and samples for testing for *Salmonella* species were not taken from the jowl area as required.
- The establishment had still not developed the required statistical process control program to evaluate the results of the *E. coli* testing. This was a repeat deficiency.
- Additional training for official (in-plant) inspection personnel regarding the FSIS requirements for PR/HACCP and SSOPs had been provided, but their knowledge of these requirements was still incomplete, and their documentation of their monitoring of establishment PR/HACCP activities and SSOPs was still deficient.
- Sweden had applied to FSIS for exemption from the testing requirement for mercury and arsenic and was waiting for a response; however, the 2001 national residue testing plan still called for these analyses. In the meantime, no testing for these heavy metals had resumed.
- Post-mortem inspection procedures were inadequate (incision and inspection of mandibular lymph nodes).

- Problems were noted regarding sanitary dressing procedures, control of condensation, pre-operational inspection, personal hygiene, pre-shipment review of HACCP records, maintenance and cleaning of over-product equipment, lighting at post-mortem inspection stations, and carcass selection for PR testing.
- No check samples had been run for chloramphenicol during the past several years.
- The FSIS method of testing for *Salmonella* species and generic *E. coli* was not used, and NFA had not submitted the alternate methods being employed to FSIS for equivalence determination.
- No species verification was being performed as required.

The following findings were reported from the August 2002 FSIS audit:

- Inadequate government enforcement in both establishments regarding SSOP.
- Species verification testing program was not implemented as required by FSIS.
- Insufficient SSOP documentation regarding corrective actions in one establishment and in another establishment daily documentation of sanitation records was inadequate.
- Minor problems with meat scraps on overhead product rails and other equipment in one establishment.
- Ingesta contamination on some carcasses contacting other carcasses in one establishment.
- Recoveries for sulfonamides in NFA laboratory ranged from 51-80%; FSIS expects recoveries of at least 70%.
- Turnaround time of laboratory results for diethylstilbestrol may take up to 8 weeks; FSIS expects turnaround time of up to 4 weeks.

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofo/tsc.

6. MAIN FINDINGS

6.1 Legislation

The auditors were informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Sweden legislation.

6.2 Government Oversight

The NFA is an agency of the Ministry of Agriculture. The Food Control Department, one of the five departments of NFA, is responsible for all activities involving the implementation of regulations and the exercise of public authority in the Administration's area of responsibility. Under the Food Control Department, the Meat Inspection Division carries out inspection and continuous control of slaughter facilities and other meat product establishments; together with the Inspection and Coordination Division, it is responsible, among other duties, for the implementation of regulations concerning export.

6.2.1 CCA Control Systems

NFA has the organizational structure and staffing to ensure uniform implementation of U.S. requirements and has strengthened the authority of the internal auditors to ensure adequate oversight of all inspection activities.

6.2.2 Ultimate Control and Supervision

NFA has ultimate control and supervision over official activities of all employees and certified establishments.

6.2.3 Assignment of Competent, Qualified Inspectors

NFA ensures the assignment of competent qualified inspectors. Supervision of inspectors at the local level in the certified establishment has improved and in-plant inspection personnel have received additional HACCP training.

6.2.4 Authority and Responsibility to Enforce the Laws

NFA has the authority and responsibility to ensure U.S. requirements. NFA has strengthened its ability to enforce U.S. requirements since the last FSIS audit.

6.2.5 Adequate Administrative and Technical Support

NFA has adequate administrative and technical support to operate the Swedish inspection system, and has the resources and ability to support a third-party audit.

6.3 Headquarters Audit

The auditors conducted a review of inspection system documents at the headquarters of the NFA in Uppsala. The records review focused primarily 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 and laboratory personnel.
- Label approval records such as generic labels and animal raising claims.
- 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.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

6.3.1 Audit of Regional and Local Inspection Sites

A County Office, a District Veterinary Office, and a private farm were visited. Details are included in Section 8.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of two establishments. One was a slaughter and processing establishment and the other was a cold storage facility. No establishments were delisted by the Swedish inspection officials. No establishments received a Notice of Intent to De-certify the establishment from the CCA.

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:

In the privately-owned Alcontrol Laboratory in Malmo, pork samples from Establishment 80 were analyzed for the presence of generic *E. coli*. No deficiencies were noted.

In the privately-owned National Veterinary Institute Laboratory in Uppsala, pork samples from Establishment 80 were analyzed for the presence of *Salmonella* species. This laboratory was also analyzing field samples for the Swedish national residue testing program.

The government-owned and managed National Food Administration laboratory in Uppsala was analyzing field samples for the Swedish national residue testing program. The findings in these two residue laboratories are discussed in Section 12 of this report (Residue Controls)

Visits to the County Office, District Veterinary Office and Private Farm

In the District Veterinary Office at Kristianstad, a database is maintained with a complete history of veterinary activities relating to animal treatment, and provides a means to track the movement of animals between farms, out of the country or to slaughter. If necessary, traceback to the farm of origin is possible.

The District Veterinary Office is responsible for providing veterinary services at the farms. The office is provided with government vehicles, equipped with a laptop and a printer to record all needed information relating to identification, diagnosis and treatment of animals on the spot

Trolle Ljungy AB farm in Skane County was visited on September 18, 2003. It is a large farm that houses about 18,000 pigs, 193 cattle and a few horses. The farm owner is required to register and is responsible for identifying animals in accordance with requirements for the species. Swine are identified as a group with transportation documents that identify the origin and destination of the group. Individual records of animals diagnosed with disease conditions and treatment provided by the Official District Veterinarian are entered on the official laptop computer at the time of treatment and a copy is given to the owner. Any drugs dispensed by the veterinarian for later use by the owner are stored in a secured storage and the owner keeps treatment records in his log book. Sick animals are moved to a separate pen and are marked with an ink mark on the back for identification.

The County Veterinary Office of Skane County was visited on September 16, 2003. NFA sends a letter to the County Veterinarian on follow-up/ investigation of residue violators and the County Veterinarian reports back to the NFA the results of the investigation. The auditors reviewed reports of their activities concerning a recent violation of antibiotic residue from a pig farm. The reports were detailed and satisfied FSIS requirements for residues.

9. SANITATION CONTROLS

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

Based on the on-site audits of establishments, Sweden'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, Sweden's inspection system had controls in place for water potability records, 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 both establishments were found to meet the basic FSIS regulatory requirements with no deficiencies.

9.2 EC Directive 64/433

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

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditors determined that Sweden'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 auditors 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.

The HACCP program was reviewed during the on-site audit of the slaughter/processing establishment. The establishment had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

Sweden has adopted the FSIS regulatory requirements for testing for generic *E. coli* with the exception of the following equivalent measure(s).

- FSIS has granted Sweden an equivalence determination allowing them to use an alternative laboratory testing method for generic *E. coli* (NMKL 147).

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

Testing for generic *E. coli* was properly conducted as required in the one slaughter establishment.

11.4 Testing for *Listeria monocytogenes*

The slaughter/processing establishment was not producing ready-to-eat products for export to the United States. The HACCP plan in this establishment was not required to be reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to exist.

11.5 EC Directive 64/433

In all establishments, the provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors 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.

In the National Veterinary Institute Laboratory in Uppsala, screening tests were performed for sulfonamides, *Salmonella* species and quantitative confirmation was also conducted for heavy metals. The following deficiency was noted:

- The following information was missing in the official standards book for the preparation of stock solutions: Lot numbers, expiration dates, date solutions prepared, and the co-signature of the supervisor of the technician preparing the stock solutions for the trace elements.

In the National Reference Laboratory (NFA) in Uppsala, testing of field samples was done for antibiotics, chloramphenicol, hormones, sulfonamides and species verifications.

No deficiencies were noted.

Sweden's National Residue Control Program for the year 2003 was being followed and was on schedule.

12.1 EC Directive 96/22

In the National Reference Laboratory (NFA) and the National Veterinary Institute Laboratory, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Reference Laboratory (NFA) and the National Veterinary Institute Laboratory, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the slaughter and processing establishment.

13.2 Testing for *Salmonella*

Sweden has adopted the FSIS regulatory requirements for HACCP. *Salmonella* testing is the same with the exception of the following equivalent measure(s).

- FSIS has granted Sweden an equivalence determination allowing them to use an alternate laboratory testing method Salmonella (NMKL 71); *Salmonella* testing strategy; sampling tools; sampling techniques; and location and size of sample sites.

One of the two establishments audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

Salmonella testing was properly conducted in the establishment.

13.3 Species Verification

Species verification was being conducted in the establishment in which it was required.

13.4 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.

13.5 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.

No eligible livestock or meat was imported from other countries for export to the United States.

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 25, 2003 in Uppsala with the CCA and a second closing meeting was held by teleconference with representatives from the European Commission and FSIS. At these meetings, the primary findings and conclusions from the audit were presented by the auditors.

The CCA understood and accepted the findings.

Dr. Faiz R. Choudry
International Audit Staff Officer

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Individual Foreign Laboratory Forms
Foreign Country Response to Draft Final Audit Report

09 16 03 National Veterinary Institute

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
National Food Administration	Uppsala, Sweden	Box 7073 S-750 07 Uppsala, Sweden

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	Drs. Klas Svensson, Senior Veterinary Inspector and Ulf Bondesson

	Residue Code/Name ▶			400	800	Sal
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE			
	Sample Handling	01		A	A	A
	Sampling Frequency	02		A	A	A
	Timely Analyses	03		A	A	A
	Compositing Procedure	04		O	O	O
	Interpret Comp Data	05		O	O	O
	Data Reporting	06		A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A
	Correct Tissue(s)	08		A	A	A
	Equipment Operation	09		C	A	A
	Instrument Printouts	10		A	A	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	O
	Recovery Frequency	12		A	A	O
	Percent Recovery	13		A	A	O
	Check Sample Frequency	14		A	A	A
	All analyst w/Check Samples	15		A	A	A
	Corrective Actions	16		A	A	A
	International Check Samples	17		A	A	A
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A
OTHER REVIEW		19	EVAL. CODE			
		20				

SIGNATURE OF REVIEWER

S. Bondesson MV (for F.R. Choudry DVM)

DATE 10/17/03

SIS FORM 9520-4 (9/96)

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW

Comment Sheet

	09 15 03	National Veterinary Institute

FOREIGN GOVT AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
National Food Administration	Uppsala, Sweden	Box 7073 S-750 07 Uppsala, Sweden

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	Drs. Klas Svensson, Senior Veterinary Inspector and Ulf Bondesson

RESIDUE	ITEM NO.	COMMENTS
400	09	The following information was missing in the official standards book for the preparation of stock solutions; lot numbers, expiration dates, date solutions preparesd, and the co-signature of the supervisor of the technician preparing the stock solutions for the trace elements.

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

09 22 03 The National Reference Laboratory

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
National Food Administration	Uppsala, Sweden	Box 622, SE-751, 26 Uppsala, Sweden

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	Dr. Klas Svensson, Senior Veterinary Inspector & Ms. Ingrid Nordlander

	REVIEW ITEMS	ITEM #	EVALUATION CODE	200	203	501	800	S/V
	Residue Code/Name ▶			200	203	501	800	S/V
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O
	Data Reporting	06		A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A
	Correct Tissue(s)	08		A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	O
	Recovery Frequency	12		A	A	A	A	O
	Percent Recovery	13		A	A	A	A	O
	Check Sample Frequency	14		A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A
	International Check Samples	17		A	A	A	A	A
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A	A	A
OTHER REVIEW		19	EVAL. CODE					
		20						

SIGNATURE OF REVIEWER

JD Bolster MV (for F.R. Choudry DVM)

DATE

10/17/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE	NAME OF FOREIGN LABORATORY
09 22 03	The National Reference Laboratory

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
National Food Administration	Uppsala, Sweden	Box 622, SE-751, 26 Uppsala, Sweden

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	Dr. Klas Svensson, Senior Veterinary Inspector & Ms. Ingrid Nordlander

RESIDUE	ITEM NO.	COMMENTS
		No comments

FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

REVIEW DATE: 09 19 03

NAME OF ROUTE OBJECTIVE: ALcontrol Laboratories

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private Laboratory	Malmo, Sweden	Hojdrodergatan 32-34. 212 39 Malmo, Sweden

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	Dr. Klas Svensson

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

SIGNATURE OF REVIEWER: [signature] (for F.R. Choudry DVM)

DATE: 10/17/03

FSIS FORM 9520-4 (9/96)

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE: 09-19-06

NAME OF LABORATORY: ALcontrol Laboratories

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private Laboratory	Malmo, Sweden	Hojdrodergatan 32-34, 212 39 Malmo, Sweden

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	Dr. Klas Svensson

RESIDUE	ITEM NO.	COMMENTS
		No comments

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
ColdSped AB Hedentorpsvagen 291 59 Kristianstad	09/17/03	455	Sweden
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60 Observation of the Establishment

Establishment # 455 Dated 09.17.03

No comments.

61. NAME OF AUDITOR

DR. Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

10/17/03 (for F.R. Choudry DVM)

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Swedish Quality Meats 29181 Kristianstad	09/18/03	80	Sweden
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment:

Establishment = 80 Dated 09/18/03

No comments.

61. NAME OF AUDITOR

Dr. Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

10/17/03 (for F.R. Choudry DVM)

December 10, 2003 Dnr 1844/03
Saknr 4119

Food Control Department
Klas Svensson

Dr. Sally Stratmoen
United States Department of Agriculture
Food Safety and Inspection Service
Office of International Affairs
1400 Independence Avenue, SW
Washington, DC 20250
USA

Dear Dr. Stratmoen,

Comments on the draft final audit report from Sweden, September 2003

Below you will find the comments of the National Food Administration on the draft final audit report FYI 2003.

12. Residue controls

Quantitative confirmation for heavy metals

The National Veterinary Institute Laboratory has now implemented a system for documentation in the official standard books for the preparation of stock solutions for trace elements that include:

- Lot numbers.
- Expiration dates.
- Dates solutions prepared.
- Co-signature of the technician preparing the stock solution.
- Co-signature of the supervisor of the technician preparing the stock solution.

These comments will be sent by post, fax and by e-mail.

Yours sincerely,

Peter Brådenmark
Deputy Head Food Control Department

For your information
CVO Håkan Stenson, R
Sally Stratmoen, USDA, facsimile +1 202 699 4040