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

APR 7 2005

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:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Sweden's meat inspection system September 22 through October 6, 2004. Enclosed is the final audit report. We have attached to the report, your letter of February 4, 2005, commenting on the draft final report of the same audit.

We appreciate the actions taken by Sweden 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

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Margaret Thursland, Counselor, American Embassy, Stockholm, Sweden
Klas Molin, Counselor, Embassy of Sweden, Wash DC
Tony Van der haegen, Agric. / Consumer Affairs, EU Mission to the U.S., Wash, DC
Norval Francis, Minister-Counselor, US Mission to the EU in Brussels
Robert Macke, Assistant Deputy Administrator, ITP, FAS
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Jack Mowbray, IES, OIA, FSIS
Steve McDermott, IES, OIA, FSIS
Country File (FY 2004 Audit)

FINAL

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

SEPTEMBER 22 THROUGH OCTOBER 6, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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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 22 through October 6, 2004.

An opening meeting was held on September 22, 2004, in Uppsala 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 Sweden's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the National Food Administration, and/or representatives from 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, two local (establishment level) offices, one private microbiology laboratory, one private residue testing laboratory, one government (NAF) residue testing laboratory, and one private (National Veterinary Institute) residue testing laboratory performing analytical testing on United States-destined product, one swine slaughter and pork processing establishment, and one cold-storage facility.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Local	2	Establishment level
Laboratories		4	
Meat Slaughter-Processing Establishment		1	
Cold Storage Facilities		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 and local (establishment level) offices. The third part involved on-site visits to two establishments: one slaughter and processing (cutting) establishment and one cold storage facility. The fourth part involved visits to two government laboratories and two private laboratories: the AnalyCen Nordic AB was conducting analyses of field samples for Sweden's national residue control program; the Alcontrol laboratory was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and antibiotics, and the National Food Administration Laboratory and the National Veterinary Institute Laboratory were 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 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 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 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 Sweden under provisions of the Sanitary/Phytosanitary Agreement.

- FSIS has granted Sweden an equivalence determination allowing them to use an alternate laboratory testing method for generic *E. coli* (NMKL 147).
- FSIS has granted Sweden an equivalence determination allowing them to use alternate laboratory testing method for Salmonella (NMKL 71).
- FSIS had approved Sweden's request not to test field samples for mercury and arsenic.

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 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.
- There was insufficient SSOP documentation regarding corrective actions in one establishment and in another establishment daily documentation of sanitation records were 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.

The following findings were reported from the September 2003 FSIS audit:

- 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.

6. MAIN FINDINGS

6.1 Legislation

The auditor was 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 the 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 Swedish inspection system, and has the resources and ability to support a third-party audit.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the National Food Administration 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.
- 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 Local Inspection Sites

The FSIS auditor reviewed Sweden's meat inspection records maintained at the local inspection sites certified to produce or export meat to the United States. In addition, the auditor interviewed the veterinarian-in-charge at each establishment.

The auditor concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters to the two local inspection sites. This was accomplished by both hard copy and e-mails.
- Inspection personnel demonstrated adequate knowledge of inspection requirements relative to the export and distribution of meat to the United States.
- The auditor found that the instructions had been received and implemented by the certified establishments visited.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments. One was a slaughter and processing establishment and the other was a cold storage facility. Neither establishment was delisted by Swedish inspection officials. Neither establishment received a Notice of Intent to Delist (NOID) the establishment from Swedish inspection officials.

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* and antibiotics.

- The privately owned AnalyCen Nordic AB laboratory was analyzing field samples for the Swedish national residue testing program.

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

- The government-owned and -managed National Food Administration Laboratory was analyzing field samples for the Swedish national residue testing program.

The findings at government and private laboratories will be discussed in Section 12 of this report (Residue Controls)

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, 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, and except as noted below, 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

In both establishments, the provisions of EC Directive 64/433 were effectively implemented. Specific deficiencies are noted in the attached individual establishment reports.

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, and procedures for sanitary handling of returned and reconditioned product. The auditor 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 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, and records and processing controls.

The controls also include the implementation of HACCP systems in both 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 programs were reviewed during the on-site audits of one establishment. One establishment was a cold storage facility. The only one establishment that was required to meet the HACCP programs requirements had adequately implemented the basic HACCP requirements.

The following deficiencies were noted by the auditor.

- The establishment did not address chemical, physical, and biological hazards at each step of their hazard analysis.

- The packaging materials were not addressed either in the flow chart or in their hazard analysis

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 were evaluated according to the criteria employed in the United States' domestic inspection program.

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

11.4 Testing for *Listeria monocytogenes*

Neither of the two establishments audited was required to meet the testing requirement for *Listeria monocytogenes* in Ready-To-Eat (RTE) products because they are not producing RTE products and Sweden is exporting only raw pork products to the U.S.

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 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.

In the National Veterinary Institute Laboratory in Uppsala, screening tests were performed for sulfonamides, *Salmonella* species and quantitative confirmation was also for heavy metals. No deficiencies were noted.

The National Reference Laboratory (NFD) in Uppsala, testing of field samples was done for antibiotics, chloramphenicol, hormones, sulfonamides and species verifications. No deficiencies were noted.

In the privately owned Alcontrol Laboratory in Malmo, pork samples from Establishment 80 were analyzed for the presence of generic *E. coli* and antibiotics.

The following deficiencies were noted:

- The temperature monitoring was not performed on one freezer between August 16 and August 22, 2004, as required per instructions.

- In the same freezer, temperature deviation occurred -15°C (required temperature was no less than -19°C) between August 23 and August 29, 2004.

- As the record indicated, there were no corrective and preventive actions taken by the Laboratory Quality Assurance Manager.

- The calibration of the laboratory reference thermometer was not performed this year as required per instructions and it was performed previously on January 31, 2003.

- ALcontrol Laboratories was using the modified NMKL 147 method for the detection of generic *E. coli*, which has been modified since June 5 2002, (48 hours incubation at 37°C was changed to 24 hours incubation at 44°C). This method was not submitted to the Office of International Affairs (OIA), Washington, DC, for equivalence determination prior to use.

The privately owned AnalyCen Nordic AB laboratory in Lidkoping was analyzing field samples for the Swedish national residue testing program.

The following deficiencies were noted.

- Turnaround time for chlorinated hydrocarbons, organophosphates and polychlorinated biphenyls was over four weeks when it is required within four weeks by the National Food Administration.

Sweden's National Residue Control Program for the year 2004 was being followed and was on schedule.

12.1 EC Directive 96/22

In the National Reference Laboratory (NFD) 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 (NFD) 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 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

Inspection was being conducted daily in all slaughter and processing establishments.

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; location and size of sample sites.

One of the two establishments audited 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 the establishments.

13.3 Species Verification

Species verification was being conducted in those establishments 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 livestock or meat was imported from third countries for product eligible 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.

The CCA, however, did not have all enforcement controls in place that are required by FSIS regulations. The following inadequacies were found:

- The establishment did not address chemical, physical, and biological hazards at each step of their hazard analysis.

- The packaging materials were not addressed either in the flow chart or in their hazard analysis.
- In the National Food Administration office in Uppsala, the verification documentation was not included in the record for corrective actions taken as a result of observations made during a monthly supervisory visit.
- ALcontrol Laboratories is using modified NMKL 147 method for the detection of gereric E.coli. which has been modified since June 5 2002, (48 hours incubation at 37°C was changed to 24 hours incubation at 44°C) and it was not submitted to OIA, Washington, D.C for equivalence determination prior to use.
- In the privately ownrd AnalyCen Nordic AB laboratory, turnaround time for chlorinated hydrocarbons, organophosphates and polychlorinated biphenyls was over four weeks when it is required within four weeks by the National Food Administration.

15. CLOSING MEETING

A closing meeting was held on October 6, 2004 in Uppsala with the CCA and a second closing meeting was held by teleconference with representatives from the European Commission and FSIS. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Faiz R. Choudry
International Audit Staff Officer

Manzoor H. Chaudry

15. ATTACHMENTS TO THE AUDIT REPORT

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

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 09/30/04

NAME OF FOREIGN 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	N/A

	Residue Code/Name ▶			200	Eco											
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVLUATION CODE													
	Sample Handling	01		C	C											
	Sample Frequency	02		A	A											
	Timely Analysis	03		A	A											
	Compositing Procedure	04		O	O											
	Interpret Comp Data	05		O	O											
	Data Reporting	06		A	A											
ANALYTICAL PROCEDURES	Acceptable Method	07	EVLUATION CODE	A	C											
	Correct Tissue(s)	08		A	A											
	Equipment Operation	09		A	A											
	Instrument Printouts	10		O	O											
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVLUATION 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	A	A											
OTHER REVIEW		19	EVAL. CODE													
		20														

Signature of reviewer: Faiz R Choudry

Date: 10/13/04

FSIS FORM 9520-4 (9/96)

Designed on Form Flow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 09/30/04	NAME OF FOREIGN LABORATORY ALcontrol Laboratories
FOREIGN GOV'T AGENCY Private Laboratory	CITY & COUNTRY Malmo, Sweden	ADDRESS OF LABORATORY Hojdrodergatan 32-34. 212 39 Malmo, Sweden
NAME OF REVIEWER Dr. Faizur R. Choudry, DVM	NAME OF FOREIGN OFFICIAL N/A	

RESIDUE	ITEM NO.	COMMENTS
A/B & E.coli	01	The following deficiencies were observed such as: 1. The temperature monitoring was not performed on one freezer between August 16 to 22, 2004, as required per instructions once per week. In the same freezer temperature deviation occurred -15 degree centigrade (required temperature was no less than -19 degree centigrade) between August 23 to 29. As record indicated there was no corrective and preventive actions taken by the Laboratory Quality Assurance Manager. 2. The caliberation of laboratory reference thermometer was not performed this year as required per instructions and it was performed previously on January 31, 2003.
E.coli	07	ALcontrol Laboratories is using NMKL 147 method for the detection of gereric E.coli. which has been modified since June 5 2002, (temperature for incubation was changed from 37C to 44C) and it was not submitted to OIA, Washington, D.C for equivalence determination prior to use.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 09/27/04

NAME OF FOREIGN LABORATORY: AnalyCen Nordic AB

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private Laboratory	Lidkoping, Sweden	P.O. Box 905, SE-531 19 Lidkoping

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	N/A

	Residue Code/Name ▶			100	111	300									
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVLUATION CODE												
	Sample Handling	01		A	A	A									
	Sample Frequency	02		A	A	A									
	Timely Analysis	03		C	C	C									
	Compositing Procedure	04		O	O	O									
	Interpret Comp Data	05		O	O	O									
	Data Reporting	06		A	A	A									
ANALYTICAL PROCEDURES	Acceptable Method	07	EVLUATION CODE	A	A	A									
	Correct Tissue(s)	08		A	A	A									
	Equipment Operation	09		A	A	A									
	Instrument Printouts	10		A	A	A									
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVLUATION CODE	A	A	A									
	Recovery Frequency	12		A	A	A									
	Percent Recovery	13		A	A	A									
	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: Faizur R Choudry

Date: 10/13/04

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 09/27/04	NAME OF FOREIGN LABORATORY
FOREIGN GOV'T AGENCY Private Laboratory	CITY & COUNTRY	ADDRESS OF LABORATORY
NAME OF REVIEWER Dr. Faizur R. Choudry, DVM	NAME OF FOREIGN OFFICIAL N/A	

RESIDUE	ITEM NO.	COMMENTS
100,111 ,300	3	Turnaround times for chlorinated hydrocarbons, organophosphates and polychlorinated biphenyls was over four weeks when it is required within four weeks by the National Food Administration.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 09/23/04

NAME OF FOREIGN LABORATORY: The National Reference Laboratory

FOREIGN GOVT 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	N/A

			Residue Code/Name ▶	200	203	500	800	S/V							
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVLUATION CODE													
	Sample Handling	01		A	A	A	A	A								
	Sample Frequency	02		A	A	A	A	A								
	Timely Analysis	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	EVLUATION CODE	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	EVLUATION CODE	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: Faizur R Choudry

Date: 10/13/04

FSIS FORM 9520-4 (9/96)

Designed on Form Flow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 09/23/04	NAME OF FOREIGN LABORATORY The National Reference Laboratory
FOREIGN GOVT AGENCY National Food Administration	CITY & COUNTRY Uppsala, Sweden	ADDRESS OF LABORATORY Box 622, SE-751, 26 Uppsala, Sweden
NAME OF REVIEWER Dr. Faizur R. Choudry, DVM	NAME OF FOREIGN OFFICIAL N/A	

RESIDUE	ITEM NO.	COMMENTS

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 09/24/04

NAME OF FOREIGN LABORATORY: National Veterinary Institute

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

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	N/A

	Residue Code/Name ►			400	500	800	Sal								
SAMPLING PROCEDURES	REVIEW ITEMS Sample Handling	ITEM # 01	EVLUATION CODE	A	A	A	A								
	Sample Frequency	02		A	A	A	A								
	Timely Analysis	03		A	A	A	A								
	Compositing Procedure	04		O	O	O	O								
	Interpret Comp Data	05		O	O	O	O								
	Data Reporting	06		A	A	A	A								
ANALYTICAL PROCEDURES	Acceptable Method	07	EVLUATION CODE	A	A	A	A								
	Correct Tissue(s)	08		A	A	A	A								
	Equipment Operation	09		A	A	A	A								
	Instrument Printouts	10		A	A	A	O								
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVLUATION CODE	A	A	A	O								
	Recovery Frequency	12		A	A	A	O								
	Percent Recovery	13		A	A	A	O								
	Check Sample Frequency	14		A	A	A	A								
	All Analyst W/Check Samples	15		A	A	A	A								
	Corrective Actions	16		A	A	A	A								
	International Check Samples	17		A	A	A	A								
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A	O	O	O								
OTHER REVIEW		19	EVAL. CODE												
		20													

Signature of reviewer: Faiz R Choudry

Date: 10/13/04

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 09/24/04	NAME OF FOREIGN LABORATORY National Veterinary Institute
FOREIGN GOV'T AGENCY National Food Administration	CITY & COUNTRY Uppsala, Sweden	ADDRESS OF LABORATORY Box 7073 S-750 Uppsala, Sweden
NAME OF REVIEWER Dr. Faizur R. Choudry, DVM	NAME OF FOREIGN OFFICIAL N/A	

RESIDUE	ITEM NO.	COMMENTS

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Swedish Quality Meats 29181 Kristianstad	09/28/04	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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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	X
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	X
58.	
59.	

60. Observation of the Establishment

Establishment # 80 Dated 09/28/04 Slaughter & Processing Operations

15, 51. The establishment did not address chemical, physical, and biological hazards at each step of their hazard analysis. The packaging materials were not addressed either in the flow chart or in their hazard analysis. 9 CFR 17.2(a)(1)(2)

57. In the National Food Administration office in Uppsala, the verification documentation was not included in the record for corrective actions taken as a result of observations made during a monthly supervisory visit. 9 CFR 416.17(c)

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
ColdSped AB Hedentorpsvagen 291 59 Kristianstad	09/29/04	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 09/29/04 ColdStorage

61. NAME OF AUDITOR
DR. Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

LIVSMEDELS VERKET
NATIONAL FOOD ADMINISTRATION

4 February 2005

Dnr ad 2106/04
Saknr 4119

Food Control Department
Meat Inspection Division
Christian Berking

Julia Sunesson
Assistant [redacted]
Foreign Agricultural Service
American Embassy
Dag Hammarskjölds Väg 31
115 89 Stockholm

Dear Julia Sunesson,

Please forward these comments to Dr. Sally White, Office of International Affairs, Food Safety and Inspection Service (FSIS) U.S. Department of Agriculture (USDA).

Comments on USDA-FSIS's draft final report covering Sweden's meat inspection system

Facts

In chapter *3 Protocol* are two establishments mentioned. One establishment (nr 80) is a slaughter- and cutting establishment. Establishment nr 80 is not processing.

Corrective actions

National Food Administration (NFA) has documented the deviations concerning HACCP in the monthly supervisory report addressed to establishment 80. The corrective actions taken by establishment 80 will be verified by NFA in February 2005.

The verification documentation is included in the monthly supervisory report.

ALcontrol Laboratories is using the original method NMKL 147 for the detection of generic E.coli.

The turnaround time for chlorinated hydrocarbons, organophosphates and polychlorinated biphenyls are now less than four weeks.

Equivalence determination

NFA apply for equivalence determination for the method ISO 4832, 1991. The method is identical with NMKL 147. The description of method ISO 4832, 1991 is enclosed.

Peter Brådenmark
Head of the Food Control Department

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NATIONAL FOOD ADMINISTRATION
Food Control Department
Meat Inspection Division
Christian Berking

4 February 2005

Dnr ad 2106/04
Saknr 4119

For your information
Sally White, USDA-FSIS (e-mail)
Lorenzo Terzi, European Commission (e-mail)
CVO Håkan Stenson, R
Ingrid Nordlander, T/KP
Klas Svensson, T/KT