Donald Smart

3/24/03

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C 20250

MAR 14 2003

Dr. Christer Ohlsén
Senior Veterinary Officer
Food Control Department
National Food Administration
Post Office Box 622
SE-751 26 Uppsala
Sweden

Dear Dr. Ohlsén:

Enclosed is a copy of the final report of the Food Safety and Inspection Service (FSIS) August 21-30, 2002, audit of Sweden's meat inspection system. We have received Sweden's March 3, 2003 comments to the draft final report of the same audit and have included this document as an attachment to the final report.

As you know, the FSIS auditor reported deficiencies regarding his reviews of Establishment 80 and the National Food Administration's (NFA) residue laboratory. In regard to Establishment 80, we appreciate the assurances given by the Swedish Government that these deficiencies have been effectively addressed and corrected by the establishment and preventive measures implemented to ensure continuing compliance with U.S. import requirements. Accordingly, FSIS accepts your March 3, 2003 certification of Establishment 80 and has relisted this establishment in our records as being eligible to export pork products to the United States.

In regard to NFA residue laboratory findings, the FSIS auditor expressed concerns about insufficient recovery rate for sulfonamides and insufficient turnaround time of test results regarding diethylstilbestrol. In combination of our February 25, 2003 telephone conference call and your March 3, 2003 notification of corrective actions, we conclude that these two laboratory issues have been satisfactorily resolved.

In addition, as a follow-up to our February 25 telephone conference call, FSIS has completed its evaluation regarding Sweden laboratory methods NMKL 71 and 147 for testing the presence of *Salmonella* species and generic *Escherichia Coli*, respectively, and the FSIS judgement determinations of equivalence are forthcoming in the very near future.

If you have any questions regarding the FSIS audit or any matter discussed in this letter, please contact me at your earliest convenience at telephone number 202-720-3781, facsimile number

202-690-4040, or email address sally.stratmoen@fsis.usda.gov. At this time, I would like to convey my appreciation for our recent telephone conference as I feel this type of communication helps enhance the equivalence of our meat inspection systems.

Sincerely,

Sally Stratmoen, Acting Director
Equivalence Staff
Office of International Affairs

Enclosure

cc: Lana Bennett, Minister Counsellor, American Embassy, Stockholm
Klas Molin, Counsellor, Embassy of Sweden
Joerg Niederberger, Agric./Consumer Affairs, EU Mission to the U.S.
Norval Francis, Minister-Counsellor, US Mission to the EU in Brussels
James Dever, FAS Area Director
Amy Winton, State Department
Dave Young, FAS
Linda Swacina, Associate Administrator, FSIS
Donald Smart, Director, Review Staff, FSIS
Karen Stuck, Acting Deputy Assistant Administrator, OIA, FSIS
Sally Stratmoen, Acting Director, ES, OIA, FSIS
Clark Danford, Acting Director, IEPS, OIA, FSIS
Steve McDermott, ES, OIA, FSIS
Country File (FY 2002 Audits)

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

AUGUST 21 THROUGH 30, 2002

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 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 PR/HACCP Implementation
   - 11.3 Testing for Generic *Escherichia coli*
   - 11.4 Other FSIS Requirements
   - 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* Species
   - 13.3 Species Verification Testing
   - 13.4 Monthly Reviews
   - 13.5 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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

1. INTRODUCTION

The audit took place in Sweden from August 21 through August 30, 2002.

An opening meeting was held on August 21, 2002, in Uppsala with the Competent Central Authority (CCA), the National Food Administration (NFA). 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.

2. OBJECTIVE OF THE AUDIT

This 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, processing and other 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 swine slaughter and pork processing establishment, one cold-storage facility, one private microbiology laboratory, one government (NFA) residue-testing laboratory, and one private (National Veterinary Institute) residue-testing laboratory.

Competent Authority Visits			**Comments**
Competent Authority	Central	1	
	Local	1	Establishment level
Laboratories		3	
Meat Slaughter-Processing Establishments		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 establishment and one cold-storage facility. The fourth part involved visits to one government laboratory and two private laboratories: the AlControl laboratory was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella,* and the NFA 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 the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species. 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. The auditor also 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 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 had been declared equivalent under the VEA.

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

Third, the auditor would audit against the following equivalence determinations that had been made by FSIS for Sweden under provisions of the Sanitary/Phytosanitary Agreement.

- An alternate method (NMKL 71) was being used for testing of raw United States-eligible product for *Salmonella* species and, as of the writing of this report, had been submitted to FSIS for equivalence determination and is in the process of being evaluated. FSIS had informed Sweden that this method may be used pending an equivalence decision by FSIS.

- FSIS had approved Sweden's request not to test field samples for mercury and arsenic. Sweden had deleted these compounds from its 2002 national residue-testing plan.

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 300 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," and
- 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 www.fsis.usda.gov/ofo/tsc.

The following findings were reported from the September 2000 FSIS audit:

- Condemned materials were not denatured before being removed from the premises.
- Documentation of corrective actions and preventive measures taken in response to sanitation problems was inadequate.
- The HACCP program in the slaughter-processing establishment had not been adequately developed, and the documentation was deficient.
- The Pathogen Reduction program was deficient: samples were not being collected from the ham area for testing for generic *E. coli* as required, and the establishment had not developed the required statistical process control program to evaluate the results of the *E. coli* testing.
- The official (in-plant) inspection personnel had not received adequate training in the requirements for PR/HACCP, nor were they routinely monitoring the establishment's compliance with the requirements of the PR/HACCP programs.
- Field meat samples were not being tested for mercury or arsenic residues as required in the 2000 national residue-testing plan.
- No improvements had been made to correct the deficiencies that had been identified, during the previous FSIS audit, regarding the timeliness of analysis of field samples for residues or the implementation of an effective intra-laboratory check sampling program.

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 from the September 2000 audit.
- 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; however, samples for testing for *Salmonella* species were now 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.

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 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 for the development of control activities. The International Trade Division 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 (and in the previously delisted 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 the responsibility to enforce 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. This 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.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- 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 of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments—one slaughter/processing establishment, that had been delisted by the Swedish officials one year ago and had not been relisted, and one cold storage facility.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

The microbiology laboratory audits focus on the analysts' 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 evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP 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.
The following laboratories were audited:

In the privately owned AlControl Laboratory in Malmö, pork samples from Est. 80 were analyzed for the presence of generic *E. coli*.

The following deficiency was noted:

- The method currently being used in this laboratory to culture samples from Est. 80 for generic *E. coli* used was AOAC-NMKL 147. This method had not been submitted to FSIS for an equivalence determination. (An alternate method—NMKL 125— which was also used at the laboratory, but for other customers, had been submitted to FSIS by mistake.) The details of the AOAC-NMKL 147 method were submitted to FSIS through channels on the day of the audit of this laboratory. NFA officials gave assurances that, once the slaughter establishment was re-certified, the FSIS method would be used pending an equivalence determination by FSIS of the alternate method.

In the government-owned and -managed National Veterinary Institute Laboratory in Uppsala, pork samples from Est. 80 were analyzed for the presence of *Salmonella* species.

- An alternate method (NMKL 71) was being used for the testing and, as of the writing of this report, has been submitted to FSIS for equivalence determination and is in the process of being evaluated. FSIS has informed Sweden that this method may be used, pending an equivalence decision by FSIS.

The two laboratories analyzing field samples for the Swedish national residue-testing program were the government-owned and -managed National Food Administration Laboratory and the National Veterinary Institute Laboratory, both in Uppsala. The findings in these two laboratories are 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 Sweden's meat inspection system. The first of these risk areas that the FSIS auditor reviews is Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below and in the attached individual establishment reports, 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 and in the attached individual establishment reports, Sweden's inspection system had controls in place for water records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

- In one establishment, the drying cabinet for gloves and boots was not clean and one glove was in contact with the sole of a boot. The NFA internal reviewer identified the problem and ordered immediate corrective actions and increased frequency of cleaning.

9.1 SSOP

Both establishments were evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the two establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- There was extensive documentation of both pre-operational and operational sanitation, but the documentation of corrective actions in one establishment was occasionally incomplete regarding preventive measures. The NFA officials discussed the requirement with the establishment officials, who agreed to implement improved documentation.

- In one establishment, the written SSOP called for daily cleaning of several areas of the establishment. There were no entries in the daily sanitation activities register indicating that cleaning had been done/checked in the main corridor (not a production or exposed-product area) for several days during the past month. The NFA internal reviewer noted this and ordered prompt corrective actions, as well as increased monitoring by NFA personnel.

9.2 EC Directive 64/433

The provisions of EC Directive 64/433 were applicable to one establishment. The 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 reviews is 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 have 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 reviews is 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, and equipment and records.

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 Slaughter

No deficiencies were noted.

11.2 PR/HACCP Implementation

All slaughter and processing 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 establishment in which it was required. The establishment had not adequately implemented the PR/HACCP requirements. The following deficiencies were noted:

- Implementation of the zero-tolerance policy for contamination with ingesta was in need of improvement. Two carcasses with ingesta contamination were not identified as required by the eviscerators, although other operators did identify them before they

reached the inspection station. The NFA officials identified the problem and enforced immediate corrective action through notification of the slaughter foreman.

- There was documentation of the monitoring of critical limits, but some of the descriptions of corrective actions taken when the critical limits (for product temperature at shipping) were exceeded were incomplete. The NFA officials discussed the requirement with the establishment officials, who promptly agreed to implement improved documentation.

11.3 Testing for Generic *E. coli*

Sweden has adopted the FSIS regulatory requirements for testing for generic *E. coli* testing. One of the two establishments audited was required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and was evaluated according to the criteria employed in the United States' domestic inspection program. Testing for generic *E. coli* was properly conducted in the slaughter establishment. Evaluation of the test results by the establishment management was in compliance with FSIS requirements, although the laboratory analyzing the samples was using an alternate method not yet approved by FSIS (see Section 8).

11.4 Other FSIS Requirements

No other deficiencies regarding FSIS requirements for slaughter/processing controls were noted.

11.5 EC Directive 64/433

In the establishment to which they were applicable, the provisions of EC Directive 64/433 regarding slaughter/processing controls were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviews is Residue Controls. As stated earlier, 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 two laboratories in which field samples for the Swedish national residue testing program were analyzed were audited; both were in Uppsala, and both were government-owned and -managed.

In the National Veterinary Institute Laboratory, screening tests were performed for heavy metals, sulfonamides, and trenbolone; quantitative confirmation was also done for heavy metals only.

No deficiencies were noted.

In The National Food Administration Laboratory, testing of field samples was done for antibiotics, chloramphenicol, tetracyclines, hormones, sulfonamides, and ivermectin.

The following findings were noted during the audit of this laboratory:

- Recoveries for sulfonamides in the NFA laboratory ranged from 51% to 80%. The laboratory director reported that an LC/MS-MS method is under development to raise the recovery for those sulfonamides whose results are in the lower range. (FSIS normally expects recoveries of at least 70% for sulfonamides).

- Turnaround times (the time from sample receipt in the laboratory until the analyses are complete) for diethylstilbestrol may range up to eight weeks. (FSIS expects turnaround times of four weeks.) NFA has applied to FSIS for approval of turnaround times of up to 8 weeks for DES.

- Intralaboratory check samples are performed at least monthly for all compounds except ivermectin. For this substance, check samples are run together with field samples, which are processed twice annually in runs that last 4-5 weeks. This was in compliance with the requirements of the European Commission and the Swedish Accreditation Board.

12.1 FSIS Requirements

Apart from the findings mentioned above, no deficiencies were noted.

12.2 EC Directive 96/22

In the National Veterinary Institute Laboratory and the National Food Administration Laboratory, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Veterinary Institute Laboratory and the National Food Administration 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 reviews is 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/processing establishment.

13.2 Testing for *Salmonella* Species

Sweden had adopted the FSIS regulatory requirements for testing for *Salmonella* species.

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.

Testing for *Salmonella* species was properly conducted in the establishment.

13.3 Species Verification

At the time of this audit, Sweden was not required to test product for species verification. Species verification had not been conducted since the single slaughter/processing establishment certified as eligible for export to the United States had been delisted one year ago. NFA officials gave assurances that, once the decertified establishment was re-certified for export to the United States, a species verification program would be implemented. On the day of the exit meeting in Uppsala, a draft proposal for a species verification program was submitted to FSIS.

13.4 Monthly Reviews

During this audit it was found that in both establishments, monthly supervisory reviews 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 U.S. 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.

Following the audit of the slaughter/processing establishment, the attending NFA internal reviewers and the Veterinarian-In-Charge agreed to recommend that the establishment *should not* be re-certified as eligible to produce product for the United States until the establishment demonstrates that the deficiencies identified have been addressed and corrected, and preventive measures implemented to ensure continuing compliance.

14. CLOSING MEETING

A closing meeting was held on August 30, 2002, 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, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

15. ATTACHMENTS

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

Dr. Gary D. Bolstad
International Audit Staff Officer

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 Hedentorpsvägen 291 59 Kristianstad	Aug. 23, 2002	455	Sweden
	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT [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.	X
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	X
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	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

SWEDEN – Est. 455

13 – The written SSOPs called for daily cleaning of several areas of the establishmen . There were no entries in the daily sanitation activities register indicating that cleaning had been done/checked in the ma n corridor for several days during the past month. The NFA internal reviewer noted this and ordered prompt corrective actions, s well as increased monitoring by NFA personnel.

44 – The drying cabinet for gloves and boots was not clean, and one glove was in cor tact with the sole of a boot. The NFA internal reviewer identified the problem and ordered immediate corrective actions an increased frequency of cleaning.

51 – Adequate monitoring of the establishment's SSOPs was not being conducted/mc nitored by the assigned inspection officials.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Garv D. Bolstad	

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 Meats ek. för. 29181 Kristianstad	Aug. 26, 2002	80	Sweden
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Gary D. Bolstad		[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.	X
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.	
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.	X
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	X
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	O
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygien	
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

SWEDEN – Est. 80

13 – There was extensive documentation of both pre-operational and operational san: ation, but the documentation of corrective actions was occasionally incomplete regarding preventive measures. The NFA offici ils discussed the requirement with the establishment officials; the latter agreed to implement improved cleaning and monitc ing procedures.

22 – There was documentation of the monitoring of critical limits, but some of the de scriptions of corrective actions taken when the CLs were exceeded were incomplete. NFA officials discussed the requirement w th the establishment officials; the latter agreed to implement improvement.

34 – No species verification was being performed. NFA had applied to FSIS for an e xemption from the requirement, but the exemption had not yet, as of the time of this audit, been granted. NFA officials gave assurances that, once the slaughter-processing establishment again becomes eligible for export to the United States, if th : exemption still has not been granted at that time, a program of species verification would commence.

39 – Maintenance of over-product equipment had been significantly improved since he previous FSIS audit in August 2001, but cleaning of some structures still was in need of improvement: several meat scrap: were found adhered to over-product rails and other equipment in a few production areas. In all cases, the NFA officials ensure d that immediate corrective actions were appropriate and complete; the actions were initiated by the establishment officials.

46/56 – An unmanageable number of carcasses had been diverted onto the side rail, s ome for trimming of bristles and some for contamination with ingesta; these had been allowed to gather in contact with each otl er in the small, congested area available, in violation of EC Directive 64/433. The veterinarian in charge of the establishment stopped the line to allow the trimmers time to perform their trimming and, after consulting with the attending NFA upper-level o fficials, proposed requiring the establishment management to develop alternate facilities and/or procedures to relieve the congestion and prevent the resulting cross-contamination, or other measures would be taken, such as more frequent line st oppage or reduction of the line speed.

46/56 – The side rail trimmers were not consistently sterilizing their knives after usir g their sharpening steels, which were suspended from their belts by long chains, so that the steels were not clean. This was in violation of EC Directive 64/433. NFA officials took immediate corrective actions.

51 – Adequate monitoring of the establishment's SSOPs and HACCP program was r ot being conducted/documented by the assigned inspection officials.

NOTE: This establishment had been delisted by the Swedish officials as a result of n oncompliance with FSIS requirements in many areas during the previous FSIS audit in August 2001. This was a special audit of the establishment to determine whether adequate corrective actions had been taken and improved procedures developed and implemented to warrant its restoration to eligibility to produce product eligible for export to the United States. The FSIS audi or determined that the great majority of deficiencies noted during the previous FSIS audit had indeed been corrected and/or . ignificantly reduced in severity. Following this audit, the attending NFA officials proposed reinstatement of the estab ishment's U.S.-export eligibility only after NFA is able to notify FSIS that the deficiencies noted during this special follow-up a dit have been effectively addressed and corrected, and effective preventive measures have been implemented.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Garv D. Bolstad	

March 3, 2003 Dnr 976/02
Saknr 4119

Food Control Department
Klas Svensson

Dr. Sally Stratn oen
Acting Directoı
United States D epartment of Agriculture
Food Safety an Inspection Service
Office of Intern ational Affairs
1400 Independe nce Avenue, SW
Washington, D 20250
USA

Dear Dr. Stratmoen,

Comments on draft final audit repor from Sweden, August 2002

Below you will find the comments of the National Food Administration on the draft final audit report FYI 2002.

8. ***Microbiology d ficiency***

The alternate method (NMKL 147) for E.C oli is now approved by USDA.

9. ***Sanitation Con rols, Other Requirements***
(Dressing Roon s/Lavatories)

The non compliance was promptly correct d by the establishment. NFA has required increased frequency of cleaning a id improved routines.

9.1 ***SSOP, Daily re ords documentation***

The records have been improved in both e tablishments and are now considered sufficient by the NFA.

11.2 ***PR/HACCP***

Zero-tolerance for contamination with in esta

Immediate corrective actions were taken. S ince then, extensive actions has been taken by the establishment in questio ı to ensure continuing compliance. The NFA inspectors and the NFA in-plant personnel have followed up the zero-tolerance policy for FIM and the estal lishment is now in compliance with the requirements.

Food Control Department
Klas Svensson

March 3, 2003

976/02
Saknr 4119

Documentation of corrective actions whe ı critical limits were exceeded

The HACCP-plan has been modified by th ɜ establishment. Improved documentation (of corrective actions) has ı een implemented.

12. Residue contro. s

Recoveries for sulfonamides

The method ensures recoveries over 70% ı or sulfonamides that are in our residue plan for FY 2003.

Turnaround-time for DES

Turn-around-times for DES-analysis in pi ɛ s was less than four weeks in the autumn 2002 (sampling made after the US inspection).

The NFA now consider all deficiencies eff ctively addressed and corrected by establishment 80, and preventive measure: to be implemented in order to ensure continuing compliance. NFA has n tified FSIS concerning recertification of the establishment for exp ɔrt to the United States.

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

Yours sincerely,

Peter Brådenmark
Deputy Head Food Control Department

For your information

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Sally Stratmoen, USDA, fax +1 202 720 7 ɔ90