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

Dr. Tor Bergman
Chief Veterinary Officer
National Food Administration
Box 622
SE-75126 Uppsala
Sweden

Dear Dr. Bergman:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Sweden's meat inspection system August 13 through August 22, 2008. Comments from the government of Sweden have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

FOR

Manzoor Chaudry, DVM
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

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

AUGUST 13 THROUGH AUGUST 22, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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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
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
Salmonella	*Salmonella* species
VEA	European Community/United States Veterinary Equivalence Agreement

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Sweden from August 13 through 22, 2008. This was a routine audit. Sweden is eligible to export raw and processed pork meat to the United States. At the time of the audit, two establishments were eligible to export to the United States. During calendar year 2007 Sweden exported 1,299,530 pounds of raw pork meat to the United States; there were no rejections for food-safety concerns. Through July 31, 2008, Sweden exported 1,053,332 pounds of raw pork with 8075 pounds rejected non-food safety concerns. Activities of the current audit appear in the table below.

The findings of the previous audit conducted from April 23 through May 2, 2007, resulted in no restrictions of any Swedish establishment's ability to export raw and processed pork meat to the United States.

1.2 Comparison of the Current Audit and the Previous Audit

	CURRENT AUDIT DATES: August 13 through 22, 2008	PREVIOUS AUDIT DATES: April 23 through May 2, 2007
Levels of Government Oversight Audited		
Headquarters	1	1
Regional	1	0
Establishment Level	2	1
Laboratories Audited		
Microbiology	1	0
Residue	0	0
Establishments Audited		
Slaughter/processing	1	1
Cold Storage Facility	1	0
Enforcement Actions Initiated		
NOID	0	0
Delistment	1	0
Risk Area Findings		
Sanitation Controls (SSOP, SPS)	3	3
Animal Disease Controls	0	0
Slaughter/Processing (PR/HACCP)	0	1
Residue Controls	0	0
Microbiology Controls	1	0
Inspection/Enforcement Controls	1	0
Special Emphasis (HH, O157:H7)	0	0

1.3 Summary Comments for the Current Audit

The results of this audit include a delistment for Sanitation Controls and Inspection/Enforcement Controls.

2. INTRODUCTION

The audit took place in Sweden from August 13 through August 22, 2008.

An opening meeting was held on August 13, 2008, 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 (NFA), and/or representatives from local inspection offices.

3. OBJECTIVE OF THE AUDIT

This audit was a routine 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 office, two local government offices at the establishment level, one laboratory performing analytical testing on U.S.-destined product, one swine slaughter/processing establishment, and one cold storage facility.

4. 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, one regional office, and two local establishment-level offices. The third part involved on-site visits to one slaughter/processing establishment and one cold storage facility. The fourth part involved a visit to one private microbiology laboratory. "Alcontrol Laboratories" was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*).

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 (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis Critical Control Point Systems (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 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 that 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, and requirements for HACCP, SSOP, Sanitation Performance Standards (SPS), and testing programs 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 the use of an alternate laboratory testing method for *Salmonella* (NMKL 71).
- FSIS has granted Sweden an equivalence determination for the use of alternative lab method NMKL 147, which is a lab testing scheme used for the detection of generic *E. coli* in raw meat and poultry products.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. 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"

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS's website at the following address:

http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following deficiencies were reported from the January 2006 FSIS audit:

- The slaughter establishment did not conduct some of its operational procedures at the frequencies specified in its written SSOP program.
- In the slaughter establishment, maintenance and cleaning of the overhead structures had been neglected to varying degrees with loose and flaking paint, rust, molds, and holes in walls/ceiling into two carcass coolers.

All deficiencies noted during the January 2006 FSIS audit had been addressed and corrected.

The following findings were reported from the April/May 2007 FSIS audit:

- The anterior head portion of a swine carcass on a moving rail was dragging in the blood in the bleeding room.
- The preventive measures were not included as a part of corrective actions for SSOP deficiencies.
- The establishment neither included any written procedures in the SSOP nor recorded any corrective actions when meat pieces were picked off the floor for reconditioning in the boning room.
- The corrective actions records for tracing a product from the last acceptable check concerning the CCP were not initialed.

All deficiencies noted during the April/May 2007 FSIS audit had been addressed and corrected.

7. MAIN FINDINGS

7.1 Legislation

The relevant EC Directives, determined equivalent under the VEA, were used in auditing U. S. certified establishments.

7.2 Government Oversight

The National Food Administration (NFA), an autonomous government agency under the Ministry of Agriculture, Food and Fisheries, is the central administrative authority for matters concerning food. The NFA consists of five departments, as follows:

1) Research and Development Department.
2) Food Standards Department.
3) Food Control Department.
4) Nutrition Department.
5) Administration Department.

The Food Control Department is responsible for all activities involving the implementation of regulations and the exercise of public authority in the administration's area of responsibility. Within the Food Control Department are five divisions: The Food Inspection Division, the Local Authority Support Division, the International Trade Division, the Control Program Division, and the Meat Control Division.

The Meat Control Division is responsible for meat inspection, direct control of meat establishments, and support and follow-up of meat establishment control. The Meat Control Division has the organizational structure and staffing to ensure uniform implementation of U.S. requirements in those establishments certified to export meat to the United States. All inspection personnel assigned to establishments certified to export meat to the United States are government employees receiving no remunerations from either industry groups or establishment personnel.

7.2.1 CCA Control Systems

The Meat Control Division's regulatory oversight of its meat inspection program consists of three levels: a central level located in the Uppsala, regional level (there are six regions in Sweden), and an establishment level.

At the North Skane Regional level, a senior veterinary inspector supervises government oversight of the U. S. certified establishments. The senior veterinary inspector also supervises two or more veterinary meat inspectors (*officiell veterinär*) and a number of non-veterinary meat inspectors at the U. S. certified establishments.

7.2.2 Ultimate Control and Supervision

The Meat Control Division has the legal authority to supervise and enforce Sweden's meat inspection activities. The in-plant inspection personnel are supervised by a senior veterinary inspector. The senior veterinary inspector reports directly to the head of the region. The head of the region has the authority to suspend the establishment's production operation any time the wholesomeness and safety of the product are jeopardized.

A senior veterinary inspector, from the North Skane region, performs the monthly internal reviews of the establishments certified as eligible to produce products for export to the United States.

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

7.2.3 Assignment of Competent, Qualified Inspectors

Veterinarians and non-veterinary meat inspectors possess the required educational degrees necessary to meet minimum qualifications set by NFA.

7.2.4 Authority and Responsibility to Enforce the Laws

NFA has the authority for carrying out Sweden's meat inspection program, including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States. NFA not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements.

7.2.5 Adequate Administrative and Technical Support

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

7.3 Headquarters Audit

The auditor 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 United States.
- Training records for inspectors.
- 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, and control of noncompliant product.

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

7.3.1 Audit of Regional and Local Inspection Sites

The FSIS auditor reviewed Sweden's meat inspection records maintained in the regional office, and establishments certified to produce meat for and/or export meat to the United States. In addition, the auditor interviewed the veterinary meat inspectors at the establishments.

The auditor found that:

- All relevant regulations, notices, and inspection documents were adequately disseminated from headquarters to the certified establishment.

- Inspection personnel demonstrated adequate knowledge of the US inspection requirements relative to the export of meat to the United States.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments. One was a slaughter/processing establishment and one was a cold storage facility. One establishment was delisted due to government inspectors not observing and palpating the mesenteric lymph nodes at the post-mortem stations. The inspection of small intestines is a significant component in determining the overall health status of the swine and their suitability for human consumption. No establishment received a Notice of Intent to Delist (NOID) from Swedish inspection officials.

Specific deficiencies are noted on the attached establishment report.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

While an actual residue laboratory visit was not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, Regional, and local inspection offices.

During these interviews, emphasis was placed on ensuring that the application of procedures and standards are equivalent to U.S. requirements. Assessment of the residue laboratory focused on timely analysis, analytical methodologies, and recording and reporting of results.

No concerns arose as a result of these interviews.

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 U. S. samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following laboratory was audited:

"Alcontrol Laboratories" is a private microbiology laboratory, located in Malmo, Sweden.

The following deficiency was reported:

- The calibration of two incubators used for testing of generic *E. coli* was not being conducted.

Sweden has not requested nor received an equivalence determination allowing the use of private laboratories.

10. 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 the establishments, and except as noted below, 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.

Specific deficiencies are noted on the attached establishment report.

10.1 SSOP

The slaughter/processing establishment was 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 establishment was found to meet the basic FSIS regulatory requirements.

10.2 SPS

The enforcement of some aspects of FSIS Sanitation Performance Standards (SPS) requirements were not implemented by government inspectors in the slaughter/processing establishment audited.

The following deficiencies were reported:

- Blood and residue build-up on the plastic curtains were observed at the entrance door of chilling room #201.
- Flaking paint and rust on the overhead rails, at the door panels, and torn plastic curtains were observed at the entrance door of chilling room #123.
- Heavily beaded condensate on the overhead structure was observed at the entrance door of chilling room #201.

10.3 EC Directive 64/433

In the slaughter/processing establishment audited, the provisions of EC Directive 64/433 were not effectively implemented. Specific deficiencies are noted in the attached establishment report.

11. 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 reported.

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

12. 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, records, and processing controls.

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

The following deficiency was reported:

- Government inspectors were not observing and palpating the mesenteric lymph nodes at the post-mortem stations. The inspection of small intestines is a significant component in determining the overall health status of the swine and their suitability for human consumption.

12.1 Humane Handling and Humane Slaughter

No deficiencies were reported.

12.2. 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 U.S. domestic inspection program.

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

No deficiencies were reported.

12.3. 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):

- An alternate laboratory testing method (NMKL 147) for the detection of generic *E. coli.*

The slaughter/processing establishment 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 U.S. domestic inspection program.

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

12.4. Testing for *Listeria monocytogenes*

The requirements for testing for *Listeria monocytogenes* in ready-to-eat (RTE) products did not apply to Sweden's certified establishment. The establishment audited was not producing any RTE products for export to the United States.

12.5 EC Directive 64/433

The provisions of EC Directive 64/433 were not effectively implemented in the establishment audited. Specific deficiencies are noted in the attached establishment report.

13. 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 print-outs, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

Sweden's National Residue Control Program for 2008 was being followed and was on schedule.

No residue laboratory was audited during this audit.

13.1 EC Directive 96/22

No residue laboratory was audited during this audit.

13.2 EC Directive 96/23

No residue laboratory was audited during this audit.

14. 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*.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily in the certified establishments audited.

14.2 Testing for *Salmonella*

Sweden has adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measure.

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

The slaughter/processing establishment audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the U.S. domestic inspection program.

Salmonella testing was properly conducted in the slaughter establishment.

14.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

14.4 Periodic Supervisory Reviews

During this audit, it was found that in the establishments visited, periodic supervisory reviews were being performed and documented as required.

14.5 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.

In the slaughter/processing establishment audited, the deficiency observed concerning the post-mortem inspection was as follows:

- Government inspectors were not observing and palpating the mesenteric lymph nodes at the post-mortem stations. The inspection of small intestines is a significant component in determining the overall health status of the swine and their suitability for human consumption.

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.

15. CLOSING MEETING

A closing meeting was held on August 22, 2008, in Uppsala with the CCA. At this meeting, the preliminary audit findings were presented by the FSIS auditor.

The CCA understood and accepted the findings.

Farooq Ahmad, DVM
Senior Program Auditor

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report (when it becomes available)

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
SCAN AB SE-291 81 Kristianstad 0	8/18/2008	80	Sweden
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Farooq Ahmad, 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, 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.	
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	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58. Delistment	X
59.	

60. Observation of the Establishment

Date: 8/18/2008 Est #: 80 (SCAN AB [S]) (Kristianstad, Sweden)

39/46/51/56 Blood and residues build-up on the plastic curtains were observed at the entrance door of chilling room # 201. This was a potential source of carcass contamination during carcass transit. The Government officials took immediate corrective actions. [Regulatory references: 9 CFR 416.2(b), 416.4(b) and EC Directive 64/433, ANNEX 1, CHAPTER 111, 3]

39/51/56 Flaking paint and rust on the overhead rails, at the door panels and torn plastic curtains were observed at the entrance door of chilling room # 123. This was a potential source of carcass contamination during carcass transit. The government official assured immediate corrective actions.
[9 CFR 416.2(b) and EC Directive 64/433, ANNEX 1, CHAPTER 111, 3]

41/51/56 Heavily beaded condensate on the overhead structure was observed at the entrance door of chilling room # 201. This was a potential source of carcass contamination during carcass transit. The Government officials took immediate corrective actions. [9 CFR 416.2(d) and EC Directive 64/433, ANNEX 1, CHAPTER 1(n)]

51/55/56 Government inspectors were not observing and palpating the mesenteric lymph nodes at the post mortem stations. The inspection of small intestines is a significant component in determining the overall health status of the swine, and their suitability for human consumption. [9 CFR 310.1 and EC Directive 64/433, ANNES 1, CHAPTER VI, 25(g)]

58. After considering the extent of the findings, inspection officials of Sweden later removed this establishment from the list of establishments certified as eligible to export to the United States, effective 08/21/08.

61. NAME OF AUDITOR
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE
9/15/2008

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
Schenker AB, Cold Sped Lager Hedentorpsvagen 291 59 Kristianstad 0	8/19/08	455	Sweden
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Farooq Ahmad, 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	
24. Labeling - Net Weights	
25. General Labeling	
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

Date: 8/19/08 Est #: 455 (Schenker AB, Cold Sped Lager [CS]) (Kristianstad, Sweden)

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

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

Farooq Ahmad 9/15/2008

LIVSMEDELS VERKET
NATIONAL FOOD ADMINISTRATION
Food Control Department
Meat Control Division
G Gålne

13th February, 2009

Dnr 2710/2008
Saknr 6120

Åsa Lexmon
Agricultural Specialist
Foreign Agricultural Service
U.S. Embassy
Dag Hammarskölds väg 31
115 89 STOCKHOLM

Dear Åsa Lexmon,

Please forward these comments to Mr. Donald Smart, 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, August 2008

8. Establishment audits

The delistment of one establishment was due to government inspectors not *palpating* the mesenteric lymph nodes at the post-mortem stations. The observing of mesenteric lymph nodes was in place. National Food Administration (NFA) immediately took corrective action due to EEC Directive 64/433 and stopped all export to the USA from the establishment as of the 19th of August 2008.

During the exit conference of the FSIS inspection mission in Sweden, 22nd of August 2008, NFA was informed that the establishment (est. 80) could be relisted once the post mortem inspection includes palpation of the mesenteric lymph nodes. The matter has been dealt with in mail correspondence between Rauni Niskanen, Head of Meat Control Division, NFA, and Manzoor Chaudry, DVM, Deputy Director, International Audit Staff, FSIS, USDA, between 22nd of August and 25th of August 2008. According to this correspondence the establishment was eligible to export again on the 25th of August 2008, as NFA had taken the proper corrective action.

9. Residue and microbiology laboratory audits

Alcontrol Laboratory, located in Malmö, has reported to NFA that the procedure for calibration of two incubators used for testing of generic *E. coli* now is in place.

According to correspondence between FSIS and NFA between 19th of December 2008 and 6th of February 2009 (at first Dr. Sally White and later

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Dr. Francisco Gonzalez) the issue of equivalence determination allowing the use of private laboratories is not applicable in the case of the Alcontrol Laboratory. This laboratory uses a quantitative method for the analysis of generic *E. coli* that is approved as an AOAC Official Method of the AOAC International. The analysis of generic *E. coli* is the only analysis that this laboratory is engaged for.

Peter Brådenmark
Head of the Food Control Department

For your information
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