

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

FEB 17 2006

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 August 17, 2005 through August 31, 2005. Enclosed is the final audit report. We have attached to the report your letter of December 5, 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,

Pally White JD

Sally White Director International Equivalence Staff Office of International Affairs

Enclosure

cc:

Margaret Thursland, Counselor, American Embassy, Stockholm, Sweden Jörgen Halldin, Counselor, Embassy of Sweden, Wash DC Canice Nolan, 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 James Dever, FAS Area Director Amy Winton, State Department Mike Conlon, ITP, FAS Barbara Masters, Administrator, FSIS Karen Stuck, Assistant Administrator, OIA, FSIS William James, Deputy Assistant Administrator, OIA, FSIS Linda Swacina, Executive Director, FSIA, OIA Donald Smart, Director, Review Staff, OPEER, FSIS Sally White, Director, IES, OIA, FSIS Clark Danford, Director, IEPS, OIA, FSIS Mary Stanley, Director, IID, OIA, FSIS Barbara McNiff, FSIS Codex Programs Staff, OIA, FSIS Jack Mowbray, IES, OIA, FSIS Country File (FY 2005 Audit)

# JAN 2 4 2006

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

# AUGUST 17 THROUGH AUGUST 31, 2005

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
NFD	National Reference Laboratory
Overveterinar	Chief Veterinary Meat Inspector [Inspector in Charge]
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
Salmonella	Salmonella species
VEA	European Community/United States Veterinary Equivalence Agreement

#### 1. INTRODUCTION

The audit took place in Sweden from August 17 through August 31, 2005.

An opening meeting was held on August 17, 2005, 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.

#### 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 government offices at the establishment level, one private microbiology laboratory, two government residue testing laboratories performing analytical testing on United States-destined product, one swine slaughter/processing establishment, and one cold-storage facility.

Competent Authority Visits	Level		Comments
Competent Authority	Central	1	
	Local	2	Establishment level
Laboratories	3		
Meat Slaughter-Processing Es	1		
Cold Storage Facilities			

#### 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/processing (cutting) establishment and one cold-storage facility. The fourth part involved visits to two government laboratories and one private laboratory: the National Food Administration Laboratory and the National Veterinary Institute Laboratory were conducting analyses of field samples for Sweden's national residue control program. The ALcontrol Laboratories were conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and antibiotics.

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 both 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 and requirements for HACCP, SSOP, 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 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 September 2003 FSIS audit:

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

The following findings were reported from the September/October 2004 FSIS audit:

In the slaughter establishment:

- The establishment did not address chemical, physical, and biological hazards at each step of the hazard analysis.
- The establishment did not address the packaging materials either in the flow chart or in the hazard analysis.
- In the NFA 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.

In the ALcontrol Laboratory:

- The temperature in one freezer was not monitored between August 16 and August 22, 2004, as required per instructions.
- In the same freezer, a temperature deviation of -15°C occurred (the required temperature was no warmer than -19°C) between August 23 and August 29, 2004.
- The records did not contain corrective or preventive measures taken by the Laboratory Quality Assurance Manager.
- Calibration of the laboratory reference thermometer was not performed during 2004 as required per instructions.
- The laboratory was using a modified NMKL 147 method for the detection of generic *E. coli*; the method had 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 FSIS for equivalence determination prior to use.

All aforementioned deficiencies noted during the September/October 2004 FSIS audit had been addressed and corrected.

#### 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 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) Information and 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, there are five divisions: the Food Inspection Division, the Local Authority Support Division, the International Trade Division, the Control Program Division, and the Meat Inspection Division.

The Meat Inspection Division is responsible for meat inspection, direct control of meat establishments, and support and follow-up of meat establishment control. The Meat Inspection 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 of America. The Meat Inspection Division has a staff of approximately 300 personnel to carry out its meat inspection activities. 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.

#### 6.2.1 CCA Control Systems

The Meat Inspection Division's regulatory oversight of its meat inspection program consists of two levels: a central level located in Uppsala and an establishment (local) level. At the local level, a Chief Veterinary Meat Inspector, *Overveterinär* or Inspector in Charge (IIC), supervises government oversight of the only certified slaughter establishment. The IIC supervises two or more veterinary meat inspectors (*Besiktningsveterinar*) and a number of non-veterinary meat inspectors.

NFA has the organizational structure and staffing to ensure uniform implementation of U.S. requirements.

6.2.2 Ultimate Control and Supervision

The Meat Inspection Division has the legal authority to supervise and enforce Sweden's meat inspection activities. The in-plant inspection personnel are supervised by a Chief Veterinary Meat Inspector who has the authority to suspend the establishment's production operation any time the wholesomeness and safety of the product are jeopardized. The Chief Veterinary Meat Inspector reports directly to the head of the Meat Inspection Division in Uppsala.

A senior veterinary inspector from the NFA headquarters 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.

6.2.3 Assignment of Competent, Qualified Inspectors

Veterinarians and non-veterinary meat inspectors possess the required educational degrees necessary to meet minimum qualifications set by NFA. Continuing education is provided for all inspection personnel as needed.

6.2.4 Authority and Responsibility to Enforce the Laws

NFA has the authority for carrying out Sweden's meat inspection program, including oversight and enforcement of 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.

6.2.5 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.

#### 6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of NFA in Uppsala. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors

- 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.

#### 6.3.1 Audit of Local Inspection Sites

The FSIS auditor reviewed the meat inspection records maintained in the establishments certified to produce and/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 inspection documents were adequately disseminated from headquarters to the two certified establishments.
- Inspection personnel demonstrated adequate knowledge of U.S. inspection requirements relative to the export of meat to the United States.

#### 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments. One was a slaughter/processing establishment and the other was a cold storage facility. Neither of the two establishments was delisted nor received a Notice of Intent to Delist (NOID) 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 evaluates 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 Laboratories in Malmö, pork samples from certified slaughter establishment were analyzed for the presence of generic *E. coli* and antibiotics.
- In the government-owned and managed National Veterinary Institute Laboratory in Uppsala, pork samples from certified slaughter establishment were analyzed for the presence of *Salmonella* species. The laboratory was also analyzing field samples for the Swedish national residue testing program.
- The government-owned and managed National Food Administration Laboratory in Uppsala, the reference laboratory for residue testing in Sweden, was analyzing field samples for the Swedish national residue testing program.

#### 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 the establishments, Sweden's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

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

Specific deficiencies are noted on the attached individual establishment reports.

#### 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 both establishments were found to meet the basic FSIS regulatory requirements, with the following exception:

• In the slaughter establishment, beaded condensation from the overhead structures was observed dripping onto exposed swine carcasses in one carcass cooler.

#### 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, records, and processing controls.

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

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

#### 11.2 HACCP Implementation

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

The HACCP program was reviewed during the on-site audit of the slaughter establishment. This establishment met the HACCP programs requirements and had adequately implemented the basic HACCP requirements. The other establishment was a cold storage facility, which did not require a HACCP program.

The following deficiency was noted in the slaughter establishment:

• HACCP verification records did not document the review of records or the results of on-going verification.

11.3 Testing for Generic E. coli

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

11.4 Testing for *Listeria monocytogenes* 

The requirements for testing for *Listeria monocytogenes* in ready-to-eat products did not apply to Sweden's two certified establishments. Neither of the two establishments audited was producing any ready-to-eat (RTE) products for export to the United States.

11.5 EC Directive 64/433

In both 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.

Sweden's National Residue Control Program for 2005 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 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 the certified establishments.

13.2 Testing for Salmonella

Sweden has adopted the FSIS regulatory requirements for *Salmonella* 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 alternate *Salmonella* testing strategy, sampling tools, sampling techniques, and 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 was evaluated according to the criteria employed in the United States' domestic inspection program.

Salmonella testing was properly conducted in the slaughter establishment.

13.3 Species Verification

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

13.4 Monthly Reviews

During this audit it was found that, in both establishments, 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.

15. CLOSING MEETING

A closing meeting was held on August 31, 2005 in Uppsala with the CCA. At this meeting, the primary findings and conclusions were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Nader Memarian Senior Program Auditor

Mangrer Hickoulty

#### 15. ATTACHMENTS TO THE AUDIT REPORT

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

United	States	Depa	artment	of A	Agriculture	
Food	i Safety	and	Inspect	ion	Service	

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT D	DATE	3. ESTABLISHMENT NO.	4. N	AME OF COUNTRY		
Swedish Meats	08/23/05		80		Sweden		
29181 Kristianstad	5. NAME OF AUDIT		FOR(S)		6. TYPEOF AUDIT		
Sweden	Dr. Nader Me		arian	$\mathbf{x}$			
					·	DOUMENT AUDIT	
Place an X in the Audit Results block to in Part A - Sanitation Standard Operating Procedures		· · · · · · · · · · · · · · · · · · ·			Continued		
Basic Requirements	(330P)	Audit Results	Eco	Audit Results			
7. Written SSOP	······································		33. Scheduled Sample				
8. Records documenting implementation.		†	34. Species Testing				
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue				
Sanitation Standard Operating Procedures (SSO Ongoing Requirements	P)		Part E -	Othe	er Requirements		
10. Implementation of SSOP's, including monitoring of imple	mentation.	X	36. Export				
11. Maintenance and evaluation of the effectiveness of SSOF	"s.		37. Import				
<ol> <li>Corrective action when the SSOP's have failed to prevent product contamination or adulteration.</li> </ol>	direct		38. Establishment Grounds	and P	est Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construc	tion/M	iaintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light				
14. Developed and implemented a written HACCP plan.			41. Ventilation				
<ol> <li>Contents of the HACCP list the food safety hazards, crit points, critical limits, procedures, corrective actions.</li> </ol>	ical control		42. Plumbing and Sewage				
<ol> <li>Records documenting implementation and monitoring of t HACCP plan.</li> </ol>	he		43. Water Supply				
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavato 45. Equipment and Utensils				
Hazard Analysis and Critical Control Point							
(HACCP) Systems - Ongoing Requirements 18. Monitoring of HACCP plan.		<u> </u>	46. Sanitary Operations				
<ol> <li>Monitoling of PACCP plan.</li> <li>19. Verification and validation of HACCP plan.</li> </ol>			47. Employee Hygiene				
·		 	48. Condemned Product Co	ontrol			
20. Corrective action written in HACCP plan.			Part F - Ir	Ispec	tion Requirements		
21. Reassessed adequacy of the HACCP plan.           22. Records documenting: the written HACCP plan, monitori	ng of the						
critical control points, dates and times of specific event	occurrences.	X	49. Government Staffing				
Part C - Economic / Wholesomeness 23. Labeling - Product Standards			50. Daily Inspection Covera	ge			
23. Labeling - Hobbel Standards 24. Labeling - Net Weights			51. Enforcement			Х	
25. General Labeling			52. Humane Handling				
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/M	Moisture)		53, Animal Identification				
Part D - Sampling							
Generic E. coli Testing			54. Ante Mortem Inspection				
27. Written Procedures			55. Post Mortem hspection				
28. Sample Collection/Analysis							
29. Records			Part G - Other Regu	ilatoņ	y Oversight Requiremen	nts	
Salmonella Performance Standards - Basic Requirements			56. European Community Dir	rective	S		
30. Corrective Actions	/		57. Monthly Review			]	
31, Reassessment			58.				
32. Written Assurance			59,			1	

FISIS- 5000-6 (04/04/2002)

FSIS 5000-6- (04/04/2002)

Establishment # 80

_				 	
60,	Observation	of the	Establishment		

Dated 08/23/05

Slaughter & Processing Operations

- 10/51 Beaded condensation from overhead structures was observed dripping onto exposed swine carcasses in one cooler [9 CFR 416.13].
- 22/51 The HACCP verification records did not document the review of records and the results of ongoing verification as required in 9 CFR part 417.5(a)(3).

62. , AUDI

OR SIGNATURE AND DATE

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09-06-05

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

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	08/24/05		455		Sweden			
Hedentorpsvagen	5. NAME OF AUDITO		DR(S)		6. TYPE OF AUDIT			
291 59 Kristianstad	Dr. Nad	er Mem	aria	n	x	ON-SITE AUDIT	Босиме	NE ALIDIE
Place an X in the Audit Results block to inc	l dicate non	compli	anc	e with requireme		1	L	
Part A - Sanitation Standard Operating Procedures (		Audit	1			Continued		Audit
Basic Requirements	. ,	Results						Results
7. Written SSOP			33.	Scheduled Sample				0
8. Records documenting implementation.			34.	Species Testing			_	0
9. Signed and dated SSOP, by on-site or overall authority.			35.	Residue				0
Sanitation Standard Operating Procedures (SSOP Ongoing Requirements	)			Part E -	Othe	r Requirements		
10. Implementation of SSOP's, including monitoring of implem	entation.		36.	Export				
11. Maintenance and evaluation of the effectiveness of SSOP's			37.	import				
<ol> <li>Corrective action when the SSOPs have failed to prevent or product contamination or adulteration.</li> </ol>	lirect		38.	Establishment Grounds	and Pe	est Control		
13. Daily records document item 10, 11 and 12 above.			39.	Establishment Construc	tion/M	aintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements				Light				
14. Developed and implemented a written HACCP plan .		0	41.	Ventilation				_
<ol> <li>Contents of the HACCP list the food safety hazards, critic points, critical limits, procedures, corrective actions.</li> </ol>	al control	0	42.	Plumbing and Sewage				
<ol> <li>Records documenting implementation and monitoring of th HACCP plan.</li> </ol>	e	0		Water Supply				
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>		0	<u> </u>	Dressing Rooms/Lavato				
Hazard Analysis and Critical Control Point				Sanitary Operations				
(HACCP) Systems - Ongoing Requirements 18. Monitoring of HACCP plan.								
19. Verification and validation of HACCP plan.		0	47.	Employee Hygiene				
· · · · · · · · · · · · · · · · · · ·			48.	Condemned Product Co	ntrol			
20. Corrective action written in HACCP plan.		0		Part F - In	spec	tion Requirement	ts	
21. Reassessed adequacy of the HACCP plan.     22. Records documenting: the written HACCP plan, monitorin	g of the	0	49.	Government Staffing				
critical control points, dates and times of specific event or Part C - Economic / Wholesomeness	currences.			Daily Inspection Coverag				
23. Labeling - Product Standards					je 			1
24. Labeling - Net Weights		0	51.	Enforcement				
25. General Labeling		0	52.	Humane Handling				0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	pisture)	Õ	53.	Animal Identification				0
Part D - Sampling Generic <i>E. coli</i> Testing			54.	Ante Mortem hspection				0
27. Written Procedures		0	55.	Post Mortem Inspection				0
28. Sample Collection/Analysis		0						
29. Records		0		Part G - Other Regu	laton	y Oversight Requ	irements	
Salmonella Performance Standards - Basic Requirements			56.	European CommunityDir	ective	s		 
30. Corrective Actions		0	57,	Monthly Review				İ
31. Reássessment		0	58.					
32. Written Assurance		0	59.					

FSIS- 5000-6 (04/04/2002)

FSIS 5000-6 (04/04/2002)

60. Observation of the EstablishmentColdStorage FacilityEstablishment # 455Dated 08/24/05

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

61. NAME OF AUDITOR	52. AUDITOR SIGNATURE AND DATE
Dr. Nader Memarian	Nader/Mar 09-06-05



NATIONAL FOOD ADMINISTRATION

Food Control Department Meat Inspection Division Christian Berking 5 December 2005

Dnr ad 2106/04 Saknr 4119

Julia Suneson Foreign Agricultural Service American Embassy Dag Hammarskjölds Väg 31 115 89 Stockholm

Dear Julia Suneson,

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

#### Corrective actions

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

Peter Brådenmark Head of the Food Control Department

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PlusGirc 476 59 00-8 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 Eva Eriksson T/KT/BVO