



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Håkan Stenson
Chief Veterinary Officer
National Food Administration
Box 622
S-751 26 Uppsala, Sweden

SEP 18 2007

Dear Dr. Stenson:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Sweden's meat inspection system May 22 to June 1, 2007. Comments from Sweden have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL

SEP 13 2007

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

April 23 through May 2, 2007

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

1. INTRODUCTION

The audit took place in Sweden from April 23 through May 2, 2007.

An opening meeting was held on April 23, 2007, 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 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 local government offices at the establishment level, and one swine slaughter/cutting establishment.

| Competent Authority Visits | Level | | Comments |
|------------------------------|---------|---|---------------------|
| Competent Authority | Central | 1 | Headquarters |
| | Local | 1 | Establishment level |
| Laboratories | | 0 | |
| Meat Slaughter Establishment | | 1 | |
| Cold Storage Facilities | | 0 | |

3. PROTOCOL

This on-site audit was conducted in three 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 office. The third part involved on-site visits to one slaughter/cutting establishment.

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 the on-site establishment visit, 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 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.
- 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 August 2005 FSIS audit:

In the slaughter establishment:

- Condensation from the over head structures was observed dripping onto swine carcasses in one carcass cooler.
- HACCP verification records did not document the review of records or the results of ongoing verification.

All deficiencies noted during the August 2005 FSIS audit had been addressed and corrected.

The following findings 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 Sanitation Standard Operating Procedures program.
- In the slaughter establishment, maintenance and cleaning of the overhead structures had been neglected to varying degrees with evidence of flaking paint, rust, molds, and holes in walls/ceiling in two carcass coolers.

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

6. MAIN FINDINGS

6.1 Legislation

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

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 follow:

- 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. 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 three levels: a central level located in Uppsala, regional level (there are six regions in Sweden which are newly developed since January 2007), and an establishment level.

At the region of North Skane 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 (*Besiktningveterinär*) and a number of non veterinary meat inspectors at the U. S. certified establishments.

In January 2007, NFA established a new 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 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.

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.

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 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.

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 the NFA in Uppsala. The records review focused primarily on food safety hazards and included the following:

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

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

The auditor concluded that:

- All relevant regulations, notices, and inspection documents were adequately disseminated from headquarters to the certified establishment.
- 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 one U.S. certified slaughter/cutting establishment. This establishment was not delisted and did not receive a Notice of Intent to Delist (NOID) from Swedish inspection officials.

Specific deficiencies are noted on the attached establishment report.

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.

No laboratory was audited during this audit.

9. SANITATION CONTROLS

As stated earlier, 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, workspace, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

Specific deficiencies are noted on the attached establishment report.

9.1 SSOP

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the establishment was found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- The head of a swine carcass on a moving rail was dragging into the blood on the slaughter floor in the bleeding room.
- 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.

9.2 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were implemented. Specific deficiencies are noted in the attached establishment report.

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 system and implementation of a testing program for generic *E. coli* in the slaughter establishment.

11.1 Humane Handling and Humane Slaughter

No deficiencies were observed.

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/cutting establishment. This establishment met the HACCP programs requirements and had adequately implemented the basic HACCP requirements, with the following deficiency:

- The monitoring records for tracing product to the last acceptable check concerning the CCP were not initialed.

11.3 Testing for Generic *E. coli*

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

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

The 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 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. The establishment audited was not producing any ready-to-eat (RTE) products for export to the United States.

11.5 EC Directive 64/433

In the establishment audited, 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 was being followed and was on schedule.

12.1 EC Directive 96/22

No residues laboratory was audited during this audit.

12.2 EC Directive 96/23

No residues laboratory was audited during this audit.

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

Salmonella testing was properly conducted in the slaughter establishment.

13.3 Species Verification

Species verification was being conducted in the establishment.

13.4 Periodic Supervisory Reviews

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

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between

establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

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

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.


In the establishment audited, deficiencies observed concerning the SSOP and HACCP were as follows:

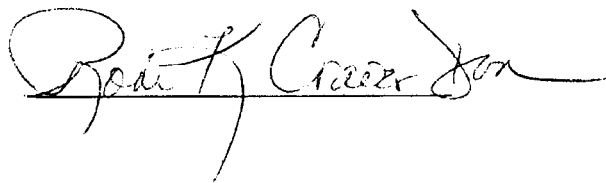
- The head portion of a swine carcass on a moving rail was dragging into the blood on the slaughter floor in the bleeding room.
- The preventive measures were not included as a part of corrective actions for SSOP deficiencies.
- The establishment neither included any written procedures in the SSOP nor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

14. CLOSING MEETING

A closing meeting was held on May 2, 2007 in Uppsala with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the 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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION SCAN AB SE-291 81 Kristianstad 0 | 2. AUDIT DATE 4/25-26/2007 | 3. ESTABLISHMENT NO. 80 | 4. NAME OF COUNTRY Sweden |
| | 5. NAME OF AUDITOR(S) Farooq Ahmad, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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 | Part D - Continued Economic Sampling | 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 (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | X | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | X | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | X | 39. Establishment Construction/Maintenance | X |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan . | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | X | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod Standards/Boneless (Defects/AQL/Park Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | X |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 4/25-26/2007 Est #: 80 (SCAN AB [S]) (Kristianstad, Sweden)

10/39/51/56 The anterior head portion of swine carcass on a moving rail was dragging into the blood in the bleeding room. Immediate corrective actions were taken. [Regulatory references: 9CFR 416.2(b)(1), 416.13(c), 416.15(a), EC Directive 64/433 Annex 1 Chapter 1(b), and Chapter 111]


12 The preventive measures were not included as a part of corrective actions for SSOP deficiencies. Inspection officials assured that immediate corrective actions will be taken. [9CFR 416.15]

13/51 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 inspection officials assured that reconditioning procedures will be included in the SSOP. [9CFR 416.16(a)]

22 The monitoring records for tracing a product for the last acceptable check, concerning the CCP were not initialed. Immediate corrective actions were taken. [9CFR 417.5(3)]

61. NAME OF AUDITOR
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 5/30/2007



**LIVSMEDELS
VERKET**

NATIONAL FOOD
ADMINISTRATION

Food Control Department
Meat Inspection Division
Markus Ollikainen

1 (1)

September 10, 2007

Dnr ad 265/07
Saknr 410

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

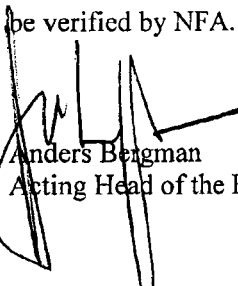
Dear Åsa Lexmon,

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

Corrective actions

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



Anders Bergman
Acting Head of the Food Control Department

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