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

OCT 29 2007

Dr. Peter W. de Leeuw
Chief Veterinary Officer
Ministry of Agriculture, Nature and Food Quality
PO Box 19506
2500 CM The Hague
Netherlands

Dear Dr. de Leeuw:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Netherlands' meat inspection system March 7 to March 27, 2007. Comments received from the government of the Netherlands have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

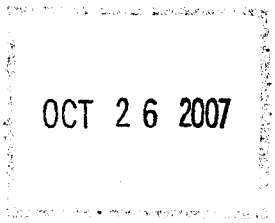
If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL



FINAL REPORT OF AN AUDIT CARRIED OUT IN THE NETHERLANDS COVERING THE NETHERLANDS' MEAT INSPECTION SYSTEM

MARCH 7 THROUGH MARCH 27, 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 [Food and Consumer Product Safety Authority (VWA)]
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
KvW	Inspectorate for Health Protection and Veterinary Public Health
LNV	Ministry of Agriculture, Nature and Food Quality
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RVV	National Inspection Service for Livestock and Meat or Rijksdienst voor de keuring van Vee en Vless (RVV)
Salmonella	*Salmonella* species
SSOP	Sanitation Standard Operating Procedures
USDA	United States Department of Agriculture
VEA	European Community (EC)/United States Veterinary Equivalence Agreement
VIC	Veterinarian-in-Charge
VWA	Food and Consumer Product Safety Authority or Voedsel-en Waren Autoriteit (CCA)
VWS	Ministry of Public Health, Welfare and Sport

1. INTRODUCTION

The audit took place in the Netherlands from March 7 through March 27, 2007.

An opening meeting was held on March 7, 2007, in The Hague 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 the Netherlands' meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Food and Consumer Product Safety Authority (VWA), and representatives from the east regional office.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit and included two objectives. The first and main 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 of the audit, the following sites were visited: the headquarters of the CCA, one regional inspection office, one team office, one laboratory performing microbiology testing on United States-destined product, three swine slaughter establishments and two meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central Headquarters	1	VWA The Hague
	North Regional Office	1	VWA Groningen
	Team Office	1	VWA Almelo
Microbiology Laboratory		1	LVWA Wageningen
Meat Slaughter Establishments		3	
Meat Processing Establishments		2	

The second objective was to conduct an on-site assessment of the Netherlands' proposed equivalence request to conduct visual post-mortem inspection (chain inspection system) for market hogs. The assessment of the chain inspection system was conducted in conjunction with a VWA senior systems auditor.

In pursuit of the objective of the assessment, the auditor conducted the following activities: an interview with the senior veterinarian-in-charge of the establishment audited, an on-site audit of the VWA's verification of chain inspection procedures and records documenting those procedures, an on-site audit of the establishment's chain inspection procedures and records documenting those procedures, an on-site audit of a swine production unit's records and practices, and an on-site audit of the central data management system.

The auditor was informed of the current status of validating the ELISA testing method used to detect *Mycobacterium avium* in market hogs and the practical application as it pertains to the chain inspection system.

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, regional offices and team offices. The third part involved on-site visits to five establishments: three slaughter establishments and two meat processing establishments. The fourth part involved a visit to one microbiology laboratory. The laboratory was conducting analyses of routine samples from certified slaughter establishments for the presence of *Salmonella* and antibiotic residue screening.

Program effectiveness determinations of the Netherlands' meat 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*. The Netherlands inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by the Netherlands 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, sanitation of facilities and equipment, residue testing, species verification testing, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for the Netherlands under provisions of the Sanitary/Phytosanitary Agreement. Accordingly, FSIS has made the following equivalence determinations for the Netherlands:

- Generic *E. coli* - same as FSIS with the following exceptions:
    - Using *Enterobacteriaceae* as an indicator organism in their testing program in-lieu-of of generic *E.coli.*
    - Using four sampling sites on the carcass (flank, brisket, rump, and back).
    - Using a destructive method (cork borer collection tool).
- *Salmonella* - same as FSIS with the following exceptions:
    - Using a continuous, ongoing sampling program to determine when to initiate additional *salmonella* testing.
    - Using ISO 6579: 2002 testing method for the detection of *Salmonella.*
    - Using VIDAS SLM screening method.
- Alternative Post-mortem inspection procedure for market hogs:
    - Observation but not palpation of the mesenteric lymph nodes.

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 Stock farming 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 deficiencies were identified during the FSIS audit of the Netherlands meat inspection system conducted in April/May 2004:

- Insanitary practice/procedure concerning handling contaminated hog carcasses as well as dripping condensation onto exposed hog carcasses were observed.
- Production line employees did not remove or change their working clothing before or after using restrooms and/or lunch/break room facilities.
- Submaxillary lymph nodes were not incised/examined by the responsible meat inspector(s) in one slaughter facility.

- HACCP and SSOP record keeping deficiencies.

The following deficiencies were identified during the FSIS audit of the Netherlands meat inspection system conducted in May/June 2005:

- The dropped meat procedures, as written in establishment's SSOP plan, were not followed.
- Maintenance of overhead structures above exposed product/equipment (injecting and tumbling machines) in the curing room had been neglected and loose, flaking paint and numerous holes in ceiling were evident.
- HACCP records documenting the calibration of process-monitoring instruments did not include the time the specific event occurred.
- HACCP records did not document all four parts of corrective actions taken in response to a deviation from a critical limit.
- There were two stainless steel containers without proper identification in a production area.

During the current FSIS audit of the Netherlands' meat inspection system conducted March 7 through March 27, 2007, deficiencies identified during the May/June 2005 audit were found to be 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 the Netherlands' legislation.

6.2 Government Oversight

The former National Inspection Service for Livestock and Meat (RVV) and the former Inspectorate for Health Protection and Veterinary Public Health (KvW) was reorganized effective January 1, 2006 into the Food and Consumer Product Safety Authority (VWA).

The VWA is an independent agency organized under the reporting structure of the Ministry of Agriculture, Nature, and Food Quality (LNV) and the Ministry of Public Health, Welfare and Sport (VWS). The Chief Executive Officer is responsible for the administration of all programs within the VWA. The VWA is divided into four areas of responsibility: (1) Directorate for Inspection Strategy and Communication, (2) Directorate for Operations, (3) Office for Risk Assessment and (4) Directorate for Implementation, Enforcement, and Surveillance. The latter Directorate is responsible for administrative oversight of the VWA's five regional offices. Each regional office is structured to support team offices which have direct responsibility for supervision and inspection of slaughter and meat processing establishments.

The VWA is responsible for the inspection and supervision of food products of animal origin, live animal health and welfare, primary horticulture and agricultural products,

chemical and microbiological product safety, composite product consumers use or consume and non-food product testing.

The VWA 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. The VWA is responsible for directing, planning, and developing the meat inspection system in the Netherlands as well as oversight and enforcement of the FSIS regulatory requirements. The VWA ensures that the production and sale of animals and products of animal origin meet the standards required for public and animal health and animal welfare. These standards are laid down in European Union directives and Dutch law. The VWA also carries out tasks related to animal welfare and animal disease prevention and control through its operational staffs in the field.

The VWA has adequate personnel to carry out their meat inspection activities. All VWA inspection personnel assigned to establishments certified to export meat to the United States are either government employees or are contracted employees that are paid by the government and receive no remunerations from either industry groups or establishment personnel.

6.2.1 CCA Control Systems

The VWA regulatory oversight of its meat inspection program consists of three levels: central, regional and team. The VWA provides direct oversight of five regional offices, which provide oversight of team offices. Each team office provides oversight for several team leaders. The team leader has responsibility of two or more establishments. The team leader supervises two or more veterinarians-in-charge, other veterinarians assigned to an establishment, non-veterinary senior controllers (processing assignments), non-veterinary assistants (slaughter establishments), and part-time/contract veterinarians (practitioners). Post-mortem inspection is performed by non-VWA employees. Kwaliteitskeuring Dierlijke Sector (KDS) is the contracting company which provides post-mortem inspectors for slaughter establishments and is reimbursed by the VWA.

6.2.2 Ultimate Control and Supervision

The VWA has the legal authority to supervise and enforce the Netherlands' meat inspection activities through its linear government oversight, i.e., headquarters to regions, to team offices, to team leaders.

The in-plant inspection personnel (veterinarian-in-charge (VIC), senior controllers and/or assistants) are supervised by the team leader or the senior systems auditor, located at the team office. The VIC performs daily verification activities to ensure KDS post-mortem inspectors are conducting proper post-mortem inspection procedures, making proper inspection decisions and performing other standards set by the VWA. The VIC has the authority to suspend the establishment's production operation any time the wholesomeness and safety of the products are jeopardized. The VIC reports directly to the team leader. The team leader or the senior systems auditor is responsible for performing comprehensive monthly internal reviews of the establishments certified as eligible to produce products for export to the United States.

6.2.3 Assignment of Competent, Qualified Inspectors

Veterinarians, senior controllers and assistants possess the required educational and or degree necessary to meet minimum qualifications set by VWA. These inspection personnel have participated in the introductory training courses: (1) a nine week course provided by the VWA, (2) eight weeks of on-the-job training and (3) one week of evaluation including receiving a passing test score. The regional offices maintain individual training records of inspection personnel. Based on these records, all official veterinarians, senior controllers and assistants assigned to the U.S. approved establishments are PR/HACCP trained. Team leaders and/or senior systems auditors carry the responsibility to evaluate and report on the performance of the in-plant inspection personnel.

6.2.4 Authority and Responsibility to Enforce the Laws

The VWA has the authority for carrying out the Netherlands' meat inspection program including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States. The VWA not only has the authority to certify establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not meet FSIS requirements. Through the legal process in the courts, the VWA, with the assistance of the Netherlands' Investigation and Prosecution Agency (AID), has the authority to prosecute meat establishments and withdraw official inspection.

Although the CCA has the legislative authority and the responsibility to enforce all FSIS requirements, not all FSIS requirements were enforced. For example:

- In five of the five establishments audited, FSIS requirements were not adequately enforced.

- In three of five establishments audited, the establishment did not monitor daily the implementation of the procedures in the SSOP.

- In five of five establishments audited, the establishment did not maintain daily SSOP records sufficient to document corrective actions taken.

- In one of five establishments audited, the establishment did not maintain adequate records documenting corrective actions for a deviation from a critical limit.

- In three of five establishments audited, the establishment did not maintain HACCP decisionmaking documents.

6.2.5 Adequate Administrative and Technical Support

The VWA has adequate administrative and technical support to operate the Netherlands' laboratory system. The Directorate of Operations, in The Hague, provides oversight for government and private laboratories. Laboratories are accredited by the Dutch Accreditation Council for ISO: 17025 accreditation. Major accreditation audits are conducted every four years and partial audits are conducted annually. Audit teams are

comprised of members of the Dutch Accreditation Council, Management, Internal Audit and Quality Assurance (KIC) and other subject-matter experts. Internal audits are conducted annually by KIC.

One time per year results from the Dutch Accreditation Council audits, the KIC audits, and the general report of activities from the laboratory director are presented to the regional director and the regional management team. These agenda items and other information are discussed and a strategic plan is developed for the next year.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at headquarters located in The Hague, one regional office located in Groningen, one team office located in Almelo, and all in-plant inspection offices located in the five establishments audited.

The records reviewed at government oversight offices focused primarily on food safety hazards and included the following records documenting:

- Government oversight documents, including organization, structure and staffing.
- Employment and payment records of VWA employees.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Internal and external audit programs.
- Supervision structure.
- Funding of the inspection program.
- Training programs and personnel records of training.
- Requirements for employment.
- Assignment of inspectors.
- Enforcement actions.
- The review and monitoring inspection results.
- Government oversight of U.S. establishments, other third country establishments and domestic establishments.
- Organization of the country's laboratory system.
- Equivalence determination for methods used to test product destine for the U.S.
- The certification process for government and private laboratories.
- Supervisory visits to establishments that were certified to export to the U.S.
- The food security system.
- Inspection coverage of U.S. certified establishments.
- Inspection records.
- Internal review reports.
- Export product inspection and control including export certificates.
- Records documenting the method of how laboratory testing request and laboratory results are obtained.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of five establishments. Three were slaughter establishments and two were meat processing establishments. None of the five establishments audited were delisted or received a Notice of Intent to Delist (NOID) from the VWA.

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. No residue laboratories were audited.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The Laboratory for the VWA (LVWA) located in Wageningen was audited. No concerns arose as a result of this audit.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, the Netherlands' 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, the Netherlands' inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

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

- In three of five of the establishments audited, the establishment did not monitor daily the implementation of the procedures in the SSOP. For example:
    - Livers, presented for post-mortem inspection on viscera hooks, were in contact with the edges of an inedible materials trough and a blood drip tray located below the viscera in the slaughter room.
    - All swine heads attached to carcasses, prior to post-mortem inspection, came in contact with a category-3 inedible materials container located below the carcasses on the slaughter line.
    - Viscera parts, during the evisceration process, contacted the flat horizontal surface of a work platform. The employee eviscerating the carcass picked up viscera from the platform surface and placed them into a post-mortem inspection viscera tray.
    - All viscera, during the evisceration process, were contacting a metal guard and blood drip tray prior to falling into post-mortem inspection viscera trays.
- In five of five of the establishments audited, the establishment did not maintain daily records sufficient to document corrective actions taken. For example:
    - Preventive measures for corrective actions were not adequately described in the establishment's daily records documenting regulatory noncompliances for product contact surfaces and/or product adulteration.

9.2 EC Directive 64/433

In the applicable establishments, the provisions of EC Directive 64/433 were effectively implemented regarding sanitary measures.

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 the Netherlands' 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, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

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

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

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

The HACCP programs were reviewed during the on-site audits of the five establishments. Five establishments had adequately implemented the HACCP requirements while three establishments did not fully meet HACCP implementation requirements. For example:

- In three of five establishments audited, the establishment did not maintain decisionmaking documents associated with the selection and development of critical control points and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

- In one of five establishments audited, corrective actions, including all actions taken in response to a deviation from a critical limit and the verification of corrective actions, were not adequately described.

11.3 Testing for Generic *E. coli*

The Netherlands has adopted the FSIS requirements for testing for *E. coli* with the exception of the following equivalent measures:

- Using *Enterobacteriaceae* as an indicator organism in their testing program in-lieu-of of generic *E.coli.*
- Using four sampling sites on the carcass (flank, brisket, rump, and back).
- Using a destructive method, (cork borer collection tool).

Three of the five establishments audited were required to meet the equivalent of the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program and the alternative procedures submitted by the CCA and determined equivalent by FSIS.

Equivalent generic *E. coli* testing (i.e., *Enterobacteriaceae*) was properly conducted in the three slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

One of the five establishments audited was producing ready-to-eat products for export to the United States. The one certified establishment was a canning establishment and was producing commercially sterile pork products (i.e., canned hams, canned luncheon meat, and canned cocktail sausages). *Listeria* testing is not required by FSIS for these types of ready-to-eat products.

11.5 EC Directive 64/433

In the applicable establishments, the provisions of EC Directive 64/433 were effectively implemented regarding slaughter/processing controls.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. Based on the document review in regional, district, and applicable inspection offices, the Netherlands' National Residue Control Program was being followed and was on schedule. For this audit, FSIS did not review any laboratory conducting residue testing.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella.*

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all establishments audited.

13.2 Testing for *Salmonella*

The Netherlands has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

- The Netherlands uses a continuous, on-going sampling program to determine when to initiate additional *Salmonella* testing.
- The Netherlands uses a swab protocol for sampling. Samples are composited and the entire composite is analyzed.
- The Netherlands uses the ISO 6579: 2002 testing method for the detection of *Salmonella.*

- The Netherlands uses the VIDAS SLM screening method for *Salmonella*.

Three of the five establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Salmonella testing was properly conducted in the three certified slaughter establishments audited.

13.3 Species Verification

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

13.4 Periodic Reviews

During this audit it was found that in all establishments visited, periodic 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.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

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

14. CLOSING MEETING

A closing meeting was held on March 27, 2007, in The Hague 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.

Don Carlson 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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Scherpenzeel B.V. 't Zwarte Land 13 Scherpenzeel (Gld.) 3925 Ck	3/15/2007	NL82EEG	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, 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.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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	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	O
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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment | Processing | Date: 3/15/2007 Est: NL82EEG [] (Scherpenzeel (Gld.), Netherlands)

13/51 The establishment did not maintain daily records sufficient to document corrective actions taken. Preventive measures for corrective actions were not adequately described in the establishment's daily records documenting regulatory noncompliances for product contact surfaces and product adulteration. [Regulatory references: 9CFR §416.16 (a) and 416.17]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson DVM 03/15/07

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
Zwanenberg Food Group Almelo Sluisweg 7 Almelo 7602 PR	3/13/2007	NL129EEG	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, 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.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment | Processing | Date: 3/13/2007 Est: NL129EEG [] (Almelo, Netherlands)

13/51 The establishment did not maintain daily records sufficient to document corrective actions taken. Preventive measures for corrective actions were not adequately described in the establishment's daily records documenting regulatory noncompliances for product contact surfaces. [Regulatory references: 9CFR §416.16 (a) and 416.17]

22/51 The establishment did not maintain decisionmaking documents associated with the selection and development of critical control points and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures. [9CFR §417.5 (a) (2) and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/13/07

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
Vion Meppel B.V. Galgenkampsweg 10A Meppel 7942 HD	3/14/07	NL193EEG	Netherlands
	5. NAME OF AUDITOR(S) Don Carlson, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment | Slaughter/Processing | Date: 3/14/07 Est: NL193EEG [] (Meppel, Netherlands)

10/51 The establishment did not monitor daily the implementation of the procedures in the SSOP. Livers, presented for post-mortem inspection on viscera hooks, were in contact with the edges of an inedible materials trough and a blood drip tray located below the viscera in the slaughter room. Corrective actions were implemented by the establishment after the finding was discussed with the VWA veterinarian-in-charge. [Regulatory references: 9CFR §416.13 (b) and 416.17]

13/51 The establishment did not maintain daily records sufficient to document corrective actions taken. Preventive measures for corrective actions were not adequately described in the establishment's daily records documenting regulatory noncompliances for product contact surfaces and product adulteration.
[Regulatory references: 9CFR §416.16 (a) and 416.17]

22/51 Corrective actions, including all actions taken in response to a deviation from a critical limit and the verification of corrective actions, were not adequately described.
[9CFR §417.5 (a) (3) and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/14/07

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
Vion Druten B.V. Kerkstraat 40 Druten 6651 KG	3/16/2007	NL236EEG	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, 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.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment | Slaughter/Processing | Date: 3/16/2007 Est: NL236EEG [] (Druten, Netherlands)

10/51 The establishment did not monitor daily the implementation of the procedures in the SSOP. All swine heads attached to carcasses, prior to post-mortem inspection, came in contact with a category-3 inedible materials container located below the carcasses on the slaughter line. Corrective actions were implemented by the establishment after the finding was discussed with the VWA veterinarian-in-charge. [Regulatory references: 9CFR §416.13 (b) and 416.17]

13/51 The establishment did not maintain daily records sufficient to document corrective actions taken. Preventive measures for corrective actions were not adequately described in the establishment's daily records documenting regulatory noncompliances for product contact surfaces and product adulteration. [9CFR §416.16 (a) and 416.17]

22/51 The establishment did not maintain decisionmaking documents associated with the selection and development of critical control points and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures. [9CFR §417.5 (a) (2) and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/16/07

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
Vion Helmond B.V. Graandijk 5 Helmond 5704 RB	3/19/2007	NL378EEG	Netherlands
	5. NAME OF AUDITOR(S) Don Carlson, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. *Written Procedures*	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. *Post Mortem Inspection*	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment | Slaughter/Processing | Date: 3/19/2007 Est: NL378EEG [] (Helmond, Netherlands)

10/51 The establishment did not monitor daily the implementation of the procedures in the SSOP.

1. Viscera parts, during the evisceration process, contacted the flat horizontal surface of a work platform. The employee eviscerating the carcass picked up viscera from the platform surface and placed them into a post-mortem inspection viscera tray. The work platform surface and the employee's work boots were not cleaned and/or sanitized as part of the evisceration process. Corrective actions were implemented by the establishment after the finding was discussed with the VWA veterinarian-in-charge. [Regulatory references: 9CFR §416.13 (b) and 416.17]
2. All viscera, during the evisceration process, were contacting a metal guard and blood drip tray prior to falling into post-mortem inspection viscera trays. The metal guard and the blood trip tray were not cleaned and/or sanitized between each set of viscera. Corrective actions were implemented by the establishment after the finding was discussed with the VWA veterinarian-in-charge. [9CFR §416.13 (b) and 416.17]

13/51 The establishment did not maintain daily records sufficient to document corrective actions taken. Preventive measures for corrective actions were not adequately described in the establishment's daily records documenting regulatory noncompliances for product contact surfaces. [9CFR §416.16 (a) and 416.17]

22/51 The establishment did not maintain decisionmaking documents associated with the selection and development of critical control points and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures. [9CFR §417.5 (a) (2) and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/19/07

Ministerie van
Landbouw, Natuur en Voedselkwaliteit

Ministry of Agriculture, Nature and Food Quality

U.S. Department of Agriculture
Food Safety and Inspection Service
Office of International Affairs
Mr. Donald Smart
Director, International Audit Staff
Washington, D.C. 20250

landbouw, natuur en voedselkwaliteit

Your letter of	your reference	our reference	date
August 1, 2007		VD 07.2496/IH	October 16 2007
re:		extension no.	enclosures
Draft Final Audit Report 2007		+31(0)70-3785435	

Dear Mr. Smart,

Thank you for providing us with the opportunity to review the draft Final Audit Report of the on-site audit of The Netherlands meat inspection system, which took place from March 7 through March 27, 2007.

The audit was a routine annual audit and I was pleased to note that in general the findings of the auditor were positive. The Food and Consumer Product Safety Authority (VWA) took all required corrective actions and I submitted an overview of these actions to you on May 21, 2007.

This year's audit included an on-site assessment of our visual post-mortem inspection system for market hogs in regard to our request for an equivalence determination. I understand that a separate report has been made covering this assessment. I would very much appreciate receiving a copy of that report as well.

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Nature and Food Quality
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Quality and Animal Health
International Affairs
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Sincerely yours,

CHIEF VETERINARY OFFICER,

Dr. P.W. de Leeuw

CC.: VWA, Mrs. Sally White, USDA/FSIS, Agricultural Counsellor at Washington D.C.