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

FEB 10 2009

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 12 through April 10, 2008. Comments on the draft final report 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. We apologize for the delay in the submission of this report

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

Sincerely,

by Don Carlson, acting Director

For Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

U. S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL AUDIT STAFF
WASHINGTON, DC
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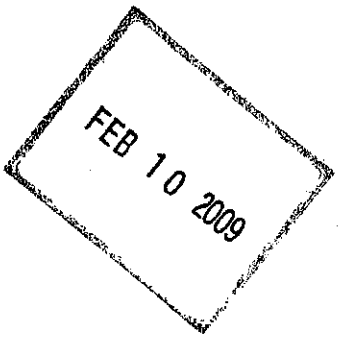

MEMORANDUM

TO: Steve Huete, Agricultural Attaché
American Embassy, Office of Agricultural Affairs
Lange Voorhout 102
2514 EJ The Hague
The Netherlands
PSC 71, Box 038
APO AE 09715

FROM: Manzoor Chaudry
Deputy Director
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR THE NETHERLANDS

Dear Mr. Huete,

Please deliver the attached final audit report to Dr. Peter W. de Leeuw, Chief Veterinary Officer, Ministry of Agriculture, Nature and Food Quality. Please contact me via email at manzoor.chaudry@fsis.usda.gov, if you have any further questions.

Best regards,

by Don Carlson, acting Director

for Manzoor Chaudry

cc list:

Stephen Huete, Agricultural Attaché, US Embassy, The Hague
Fritz Thissen, Agricultural Counselor, Netherlands Embassy
Canice Nolan, First Secretary, EU Mission to the US, Washington
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Francisco Gonzalez, IES, OIA
Netherlands Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3873:Netherlands
FINAL AUDIT LETTER February 9, 2009

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

MARCH 12 THROUGH APRIL 10, 2008

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

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
KDS	*Kwaliteitskeuring Dierlijke Sector*
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
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)

1. INTRODUCTION

The audit took place in the Netherlands from March 12 through April 10, 2008.

An opening meeting was held on March 12, 2008, 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 audit with a special emphasis on humane handling and humane slaughter of livestock 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. The second objective was to conduct an on-site assessment of the Netherlands' method of humane handling and humane slaughter of livestock in the three slaughter establishments audited.

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, two private laboratories, and one government contract laboratory performing tests on United States-destined product.

Competent Authority Visits			Comments
Competent Authority	Central Headquarters	1	VWA, The Hague
	East Regional Office	1	VWA, Zutphen
	Team Office	1	VWA, TLP, Zutphen
One Residue Laboratory		1	RIKILT, Wageningen
Two Private Laboratories		2	CCL Microbiology, Veghel TNO Species Testing, Zeist
Meat Slaughter Establishments		3	
Meat Processing Establishments		4	
Cold Storage Establishments		2	

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 office, team office and inspection offices located within individual establishments.

The third part involved on-site visits to nine establishments: Three slaughter establishments, four meat-processing establishments, and two cold-storage establishments. The fourth part involved visits to one private laboratory conducting testing for *Salmonella* and *Enterobacteriaceae* on swine carcasses, one private laboratory conducting species verification, and one government-contract residue laboratory conducting tests for the Netherlands' National Residue Testing Program. All were conducting tests on product destined for export to the United States.

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 Hazard Analysis Critical Control Points (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, species verification, 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 generic *E.coli*
    - Using four sampling sites on the carcass (flank, back, inside rump, and jowl).
    - 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

    - Samples are composited and the entire composite is analyzed.
    - Using the VIDAS SLM screening method
    - Using the ISO 6579:2002 testing method for the detection of *Salmonella*
- 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 May/June 2005:

- In three of ten establishments audited, FSIS requirements were not adequately enforced.
- In one of ten establishments audited, the dropped meat procedures, as written in establishment's SSOP plan, were not followed.
- In one of ten establishments audited, 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 the ceiling were evident.
- In two of ten establishments audited, HACCP records documenting the calibration of process-monitoring instruments did not include the times when the specific events occurred.
- In one of ten establishments audited, HACCP records did not document all four parts of corrective actions taken in response to a deviation from a critical limit.
- In one of ten establishments audited, there were two stainless steel containers without proper identification in a production area.

The following deficiencies were identified during the FSIS audit of the Netherlands' meat inspection system conducted in March 2007:

- In five of five establishments audited, FSIS requirements were not adequately enforced.
- In three of five establishments audited, the establishments did not monitor daily the implementation of the procedures in the SSOP.
- In five of five establishments audited, the establishments 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 establishments did not maintain HACCP decision-making documents.

During the current FSIS audit of the Netherlands' meat inspection system conducted March 12 through April 10, 2008, deficiencies identified during the March 2007 audit were found to have been 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 auditor was informed by the CCA that there had been no significant changes in the organization and structure of the VWA since the March 2007 audit.

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 products that consumers use or consume, and non-food-product testing.

The VWA has the organizational structure and staffing to ensure uniform implementation of the United States' 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 its meat inspection activities. All VWA inspection personnel assigned to establishments certified to export meat to the United States are either government employees or are contract employees who 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. There is one team leader who is in-charge of each team office. The team leader has responsibility over two or more establishments. The team leader supervises two or more Veterinarians-in-Charge, other veterinarians assigned to an establishment, non-veterinary senior controllers (on processing assignments), non-veterinary assistants (in 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, regions to team leaders within team offices, and team leaders to the VICs of individual establishments.

The in-plant inspection personnel, VICs, senior controllers and/or assistants, are supervised by the team leader or the senior systems auditor, located with-in the team office. The VIC performs daily verification activities to ensure that KDS post-mortem inspectors are conducting proper post-mortem inspection procedures, making proper inspection decisions and performing to 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 periodic 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 education and or degree necessary to meet minimum qualifications set by VWA. These inspection personnel have participated in the introductory training courses: a nine week course provided by the VWA, eight weeks of on-the-job training, and 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 establishment certified for U.S export, have received PR/HACCP training. Team leaders and/or senior systems auditors have 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 administer penalties, prosecute meat-producing establishments, and withdraw official inspection.

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

- The CCA did not provide official government oversight for one private species testing laboratory (TNO) and one contract residue laboratory (RIKILT).

- The CCA had not requested an equivalence determination for the use of private laboratories that conduct testing that is the responsibility of the CCA.

- In four of nine establishments audited, some FSIS requirements were not adequately enforced.

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

- In four of nine establishments audited, the establishments did not maintain adequate records documenting corrective actions for deviations from critical limits.

- In two of nine establishments audited, preshipment review records were initialed but not signed.

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 the government laboratory system. Government and private 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 and other technical experts. Audits of government laboratories are conducted annually by the Staff of the Department of External Audits and Good Laboratory Practices (EA/GLP).

Once per year, results from the Dutch Accreditation Council audits, the (EA/GLP) 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.

Although the VWA has adequate administrative and technical support to operate the Netherlands' laboratory system, the following deficiencies were identified:

- The CCA had not requested an equivalence determination for the use of private laboratories that conduct testing that is the responsibility of the CCA.

- The CCA did not provide official government oversight for one private species testing laboratory (TNO) and one contract residue laboratory (RIKILT).
    - The CCA had not conducted any official audits or other government oversight activities at these two laboratories.

6.3 Headquarters Audit

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

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

- Government oversight documents, including organization, structure, and staffing
- 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 records of personnel training
- Assignment of inspectors
- Enforcement actions
- The review and monitoring inspection results
- Government oversight of United States establishments, other third country establishments and domestic establishments
- Organization of the country's laboratory system
- The certification process for government and private laboratories
- Supervisory visits to establishments that were certified to export to the United States
- Inspection coverage of establishment certified for U.S export
- Inspection records

- Internal review reports
- Export product inspection and control including export certificates
- Records documenting laboratory testing request and results
- 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 nine establishments. Three were slaughter establishments, four were meat processing establishments, and two were cold storage establishments. None of the nine establishments audited was delisted or received a Notice of Intent to Delist (NOID) from the VWA.

Specific deficiencies are noted on the attached individual establishment reports.

8. LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to the 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. The following government laboratory was audited:

- The Research Institute of Food Safety (RIKILT), located in Wageningen, is a contract residue-testing laboratory that conducts analysis of 20 per cent of test samples taken for the Netherlands National Residue Testing Program.

The following concerns were identified as a result of this audit:

- This government contract laboratory was not under the direct oversight of the CCA. The CCA had not conducted routine audits or other oversight activities.

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 private laboratories were audited:

- The CCL Research laboratory located in Veghel was conducting PR/HACCP testing for *Salmonella* sp and *Enterobacteriaceae* from porcine carcasses for establishment certified for U.S export.
- The Netherlands Organization for Applied Scientific Research (TNO), located in Zeist, was conducting species verification on finished processed product for the CCA species

verification program.

The following concerns were identified as a result of the audit of TNO:

- The laboratory could not provide adequate information contained in their quality management system necessary for the audit.
- The laboratory could not provide the scheduled frequency of calibration of equipment.
- Calibration records for the ELISA microplate reader indicated that it was not calibrated on a routine schedule, but as stated above, the calibration frequency schedule was not available for review.

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 nine establishments audited were found to meet the basic FSIS regulatory requirements with the following exception:

- In one of nine of establishments audited, 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/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

Three of the nine establishments audited were slaughter establishments and were required to meet FSIS regulatory requirements for humane handling and Humane slaughter. These three establishments were evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiencies were noted.

11.2 HACCP Implementation

All establishments certified to export meat products to the United States are required to have developed and adequately implemented HACCP programs. 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 nine establishments. All nine establishments had adequately implemented the HACCP requirements, but four establishments did not fully meet HACCP record-keeping requirements:

- In two of the nine establishments audited, preshipment review records were initialed but not signed.

- In four of the nine establishments audited, corrective actions, including all actions taken in response to deviations from critical limits 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 the testing for *E. coli* with the exception of the following equivalent measures:

- Using *Enterobacteriaceae* as an indicator organism in lieu of generic *E.coli*
- Using four sampling sites on the carcass (medial ham, back, belly and jowl)
- Using a destructive method, (cork-borer collection tool)

Three of the nine establishments audited were required to meet the equivalent of the basic FSIS regulatory requirements for testing for generic *E. coli.* These establishments 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 testing for generic *E. coli* (i.e., *Enterobacteriaceae*) was properly conducted in the three slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

Two of the nine establishments audited were producing ready-to-eat products for export to the United States. These two were canning establishments and were producing commercially-sterile pork products (i.e., 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, the Research Institute of Food Safety (RIKILT), located in Wageningen, was audited. RIKILT is a government contract laboratory conducting tests for the Netherlands' National Residue Testing Program.

No concerns arose as a result of 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 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 VIDAS SLM screening method for *Salmonella*.
- The Netherlands uses the ISO 6579:2002 testing method for the detection of *Salmonella*.

Three of the nine 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

Two of nine establishments audited were required to meet FSIS regulatory requirements for species verification. Species verification was conducted in the two establishments in which it was required.

13.4 Periodic Reviews

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 April 10, 2008 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

Don Carlson, DVM

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
VION Boxtel, BV Boseind 10 Boxtel 5281 RM Region South,	04/03/2008	NL6IEEG	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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
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	O
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

Deboning, Date: 04/03/2008 Est #: NL6IEEG (VION Boxtel, BV) (Boxtel, Netherlands)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 04/03/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zwanenberg Food Group Almelo Sluisweg 7 Almelo 7602 PR Region North, Groningen	3/27/2008	NL129EEG	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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
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 Thermal Processing Date: 3/27/2008 Est: NL129EEG [] (Almelo, Netherlands)

22/51 1. 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]
2. Preshipment review records were initialed, but were not signed. [9CFR 417.5 (c) and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/27/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zwanenberg Food Group B.V. Westdorplaan 225, Raalte Region East, Zutphen	03/25/2008	NL153EEG	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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
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 Thermal Processing, Date: 03/25/2008 Est #: NL153EEG (Zwanenberg Food Group B.V. [P]) (Raalte, Netherlands)

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 03/25/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Meppel B.V. Galgenkampsweg 10A,7942 HD, Meppel, Region, North Groningen	3/21/08	NL193EEG	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 SSOPs have failed to prevent direct *product contamination or adulteration.*	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	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	
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 and Cutting, Date: 3/20/08 Est #: NL193EEG (Vion Meppel B.V. [J) (Meppel, Netherlands)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/21/08

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 Region East, Zutphen	3/26/2008	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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling **Generic *E. coli* Testing**	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. *Corrective Actions*	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	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	
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, Cutting, Deboning, Date: 3/26/2008 Est #: NL236EEG (Vion Druten B.V. [P/CS]) (Druten, Netherlands)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/26/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
VION Apeldoorn B.V. *Laan van Malkenschoten 77, 7333 NP* Apeldoorn, East/Zutphen 0	3/18/2008	NL312EEG	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.	
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 and Cutting, Date: 3/18/2008 . Est #: NL312EEG (VION Apeldoorn B.V. [S/P]) (Apeldoorn, 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. [9CFR 416.16 (a) and 416.17]

22/51 1. Preventive measures and the verification of the corrective actions were not described in the corrective actions documented for a deviation from the critical limit for zero tolerance for feces, ingesta and milk. [9CFR 417.5 (a) (3) and 417.8]
2. Preshipment review records were initialed, but were not signed. [9CFR 417.5 (c) and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 3/18/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
VION Doetinchem B.V. Voltastraat 21 Doetinchem, Region East, Zutphen	04/01/2008	NL404EEG	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.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
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	
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/Deboning Date: 04/01/2008 Est #: NL404EEG (VION Doetinchem) B.V. [P]) (Doetinchem, Netherlands)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 04/01/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Lau Van Haren Coldstores B.V. Metaalweg 15 Weurt, Region East, Zutphen	03/31/08	NL584EEG	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.	
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	O
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

Cold Storage & Re-boxing, Date: 03/31/08 Est #: NL584EEG (Lau Van Haren Coldstores B.V. []) (Weurt,

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 03/31/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Bussink Vrieshuis Van Weerden Poelmanweg 5, 7802 PC Almelo. Region North Groningen	03/19/08	NL589EEG	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.	
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	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	O
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 Cold Storage with Plate Freezing and Defrosting/Tempering, Date: 03/19/08 Est #: NL589EEG (Bussink []) (Almelo,

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 03/19/2008

Ministerie van Landbouw, Natuur en Voedselkwaliteit

Ministry of Agriculture, Nature and Food Quality

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

landbouw, natuur en voedselkwaliteit

your letter of	your reference	our reference	date
May 7, 2008		VD 08.1711/IH	August 20, 2008
re:		extension no.	enclosures
Audit Netherlands Meat Inspection System, March 12-April 10, 2008		+31(0)70 3785435	

Dear Mr. Smart,

With reference to your letter of May 7, 2008, which was received by me on June 18, 2008, I would like to provide the following response to your findings in the Draft Report of the Audit carried out in The Netherlands, covering The Netherlands' Meat Inspection System, from March 12 through April 10, 2008.

First of all, I would like to address your concerns resulting from the laboratory audits, in particular the official government oversight of private and contracted laboratories, and your observation that the CCA had not requested an equivalence determination for the use of private laboratories that conduct testing that is the responsibility of the CCA.

We were not familiar with the requirement for an equivalence determination for the use of private laboratories. In response to a request from you, we informed you about all laboratories that are used for the export of meat and meat products to the USA as recent as February 2, 2007 (our reference VD 07.240). We were under the assumption that this information would be sufficient.

Meanwhile, all establishments eligible for export to the USA have been informed that the private laboratories they use should not only be accredited, but should also be under official government oversight.

However, in the specific case of the RIKILT laboratory, I would like to point out that it is accredited by the Council on Accreditation; part of the laboratory is an official government laboratory (http://www.rikilt.wur.nl/UK/about/). It would be contrary to the basic structure of the accreditation system as it is applied in The Netherlands to bring all the activities of the laboratory entirely under official government oversight.

Secondly, your concerns resulting from the establishment audits concerning the enforcement of certain FSIS requirements, the maintenance of daily SSOP records and records documenting corrective actions for deviations from critical limits, and the signing of pre-shipment review records, have been addressed. The shortcomings and corrective

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actions were documented and will be discussed on CCA central and regional levels in order to prevent their reoccurrence.

Thank you for providing the opportunity to submit these comments.

Sincerely yours,

THE DEPUTY CHIEF VETERINARY OFFICER,

Dr. C.J.M. Bruschke

Cc: VWA: Bettine Murlat, VIP, Agricultural Counselor at Washington, D.C.