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

AUG 24 2005

Dr. Marc Cornelis
Chief Veterinary Officer
Institute for Veterinary Inspection
Ministry of Social Affairs, Public Health and Environment
Blvd du Regent 27
1000 Brussels
Belgium

Dear Dr. Cornelis:

The Food Safety and Inspection Service (FSIS) recently conducted an on-site audit of Belgium's meat inspection system March 30 through April 6, 2005. Enclosed is a copy of the FSIS final audit report. Your comments regarding the information in this report are included as an addendum to the final audit report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White JD

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc.
Norval Francis Jr., Minister-Counselor, US Embassy, Brussels
Canice Nolan, Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the United States, Wash DC
Geert Criel, Minister-Counselor, Embassy of Belgium, Washington
Barbara Masters, Administrator, FSIS
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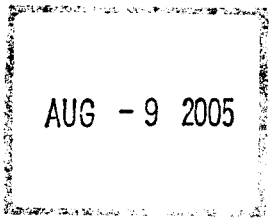
Mary Stanley, Director, IID, OIA
Amy Winton, State Department
Todd Furey, IES, OIA
Nancy Goodwin, IES, OIA
Belgium Country File

FINAL



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

MARCH 30 THROUGH APRIL 6, 2005

Food Safety and Inspection Service
United States Department of Agriculture

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14. CLOSING MEETING

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Federal Agency for the Safety of the Food Chain, or Food Safety Agency)
DG	Directorate General
FASFC	Federal Agency for the Safety of the Food Chain
FSA	Food Safety Agency
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
VIC	Veterinarian-In-Charge
PCU	Provincial Control Unit
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedure(s)
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species

1. INTRODUCTION

The audit took place in Belgium from March 30 through April 6, 2005.

An opening meeting was held on March 30, 2005, in Brussels with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of Belgium's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the Central Competent Authority (CCA), the Federal Agency for the Safety of the Food Chain, commonly called the Food Safety Agency (FSA), and/or representatives from the provincial and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective was to evaluate the performance of the CCA with respect to controls over the processing establishment certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one provincial office, one laboratory performing microbiological testing of U.S.-eligible product, and one meat processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	Brussels
	Provincial	1	Hasselt
Laboratories		1	Antwerp
Meat Processing Establishments		1	Hasselt

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 Belgium's inspection headquarters and provincial offices. The third part involved an on-site visit to the single meat processing establishment that was eligible to export to the United States. The fourth part involved a visit to one private laboratory. The Levetan Laboratory was conducting analyses of field samples for the presence of *Listeria monocytogenes*.

Program effectiveness determinations of Belgium's meat inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3)

slaughter/ processing controls, including the implementation and operation of Hazard Analysis/Critical Control Point (HACCP) programs, (4) residue controls, and (5) enforcement controls. Belgium's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the lead 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 Belgium 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.

In the opening meeting, the auditors explained to the CCA that its 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 auditors would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964. This directive has been declared equivalent under the VEA.

Second, in areas not covered by this directive, the auditors would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, the handling and disposal of inedible and condemned materials, species verification, and FSIS's requirements for HACCP and SSOP programs.

Third, FSIS auditors routinely audit against any equivalence determinations that have been made by FSIS. At this time, no equivalence agreements have been made for Belgium under the provisions of the Sanitary/Phytosanitary Agreement.

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 Community Directive was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat

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 two most recent FSIS audits of Belgium's meat inspection system were conducted in July 2003 (a routine audit) and January 2004 (an enforcement audit). One deficiency was identified during the FSIS audit of Belgium's meat inspection system that was conducted in July 2003:

- The FSA did not consistently provide inspection coverage on Saturdays when U.S. eligible production was conducted.

The establishment was delisted. As a result of the delistment of Belgium's only certified establishment, FSIS suspended the ability of Belgium's Central Authority to certify establishments for export to the United States.

No deficiencies were identified during the FSIS audit of Belgium's meat inspection system that was conducted in January 2004. FSIS reinstated Belgium's authority to certify establishments for export to the United States, effective February 12, 2004.

6. MAIN FINDINGS

6.1 Legislation

The auditors were informed that the relevant EC Directive, determined equivalent under the VEA, had been transposed into Belgium's legislation.

The following legal documents provide the legal basis for Belgium's meat inspection service authority:

- *Loi du 5 septembre 1952 relative à l'expertise et au commerce des viandes* [Law of September 5, 1952, concerning inspection of and trade in meat].

- *Arrêté Royal du 30 décembre 1992 relatif à l'agrément et aux conditions d'installation des abattoirs et d'autres établissements* [Royal Decree of December 30, 1992, concerning the approval of structural facilities of slaughter and other establishments].

- *Arrêté Royal du 4 juillet 1996 relatif aux conditions générales et spéciales d'exploitation des abattoirs et d'autres établissements* [Royal Decree of July 4, 1996, concerning general and specific daily functioning of slaughter and other establishments].

- *Arrêté Royal du 9 mars 1953 concernant le commerce des viandes de boucherie et règlement l'expertise des animaux abattus à l'interieur du pays* [Royal Decree of March 9, 1953, concerning trade of meat and control of inspection of slaughter animals within the country].

- *Arrêté Ministerial du 18 novembre 1991 relatif à l'examen visant à déceler la présence de trichines dans les viandes fraîches provenant l'animaux domestiques de l'espèce porcine, de chevaux et de sangliers ou d'autres espèces de gibier sensibles à la trichinose* [Ministerial Decree of November 18, 1991, concerning examination of fresh meat for the presence of trichinosis].

6.2 Government Oversight

The Federal Agency for the Safety of the Food Chain, commonly called the Food Safety Agency (FSA) has four Directorates General: one for Control Policy, one for Control, one for Laboratories, and one for Corporate Services. The Directorate for Control Policy (roughly equivalent to FSIS's Office of Program Development, Policy, and Equivalence) establishes process standards. The Directorate for Control (roughly equivalent to FSIS's Office of Field Operations) carries the responsibility for inspection/audit services and enforcement of process and product standards. This Directorate General (DG) for Control is divided into eleven Provincial Control Units (PCUs), one for each of the 10 Provinces and one for the capital city of Brussels. The DG for Control also has two Coordinators, one for the Flemish-speaking (northern) half of the country and one for the French-speaking (southern) half. These Coordinators supervise the Heads of the PCUs.

One modification has been made to the organizational structure of the FSA since the previous FSIS audit in January 2004: As of March 1, 2004, there are now three Sectors under each PCU, each of which a Sector Head. The three Sectors are:

1. Primary Production, responsible for live animals up to and including slaughter (areas of responsibility include animal welfare, animal disease, and controls of antibiotics and other veterinary pharmaceuticals) and vegetables before sale in the markets
2. Transformation (Processing), responsible for food (including meat processing), production of animal feed, and production of fertilizers and pesticides

3. Distribution, responsible for markets and restaurants

6.2.1 CCA Control Systems

When the management of an existing establishment wishes to become eligible to export to the United States, the manager makes an application to the PCU. A Provincial Official Inspector conducts an administrative and technical inquiry and submits a report of the results to the Chief of the PCU, who, in turn, makes a recommendation to the DG Control Headquarters on the basis of the report. The final approval for U.S.-export certification is the responsibility of DG Control. In order to qualify for eligibility to export to the United States, an establishment must first meet EC requirements and must be eligible to produce for inter-community trade. If there is any question regarding the full eligibility of the establishment, a headquarters official from DG Control - Transformation may visit the premises on-site before a final approval is granted.

Communications regarding FSIS requirements are transmitted directly and promptly, by the agricultural section of the American Embassy in The Hague, Netherlands, to the Head of FSA International Affairs [the Counselor General, DG Control Policy]. He transmits them, as well as other official guidelines and instructions that are issued by DG Control Policy, to the DG for Control (whose office is in the same facility). DG Control forwards them by e-mail and through the mail service promptly to the Head of the PCU. The latter, in turn, provides them immediately to the Veterinarian-In-Charge (VIC) and her alternate. The entire export manual is also available on FSA's Website. Hard copies of official U.S. requirements, including the U.S. Code of Federal Regulations, Directive 5000.1, and the new RTE Directive, were on hand in both the PCU and the establishment inspection office.

In order to maintain U.S. certification, an establishment must be in 100% compliance with a detailed checklist of FSIS requirements. The officials from the PCU ensure that these requirements continue to be met. If any of the requirements are not met, the PCU correlates with DG Control and U.S. eligibility is revoked by DG Control and the action is reported to International Affairs, DG Control Policy, with immediate notification of FSIS.

6.2.2 Ultimate Control and Supervision

The VIC of the establishment is a full-time FSA employee, who performs the inspection coverage of Est. B-156 on a circuit basis, in addition to coverage of other establishments. There is also a contract-FSA employee, also a qualified veterinarian, who alternates inspection coverage with the VIC and who has had the same inspection training, including numerous recent, documented, official courses in HACCP and SSOP, as the VIC.

There is a clear-cut chain of command from the headquarters of FSA down to the in-plant inspection personnel. The inspection office of the two veterinarians who share the oversight of the establishment is in the city of Hasselt, some six kilometers from the establishment. Both their immediate supervisor (the Head of the PCU) and the direct supervisor of the Head of the PCU (the Chief of the Province or Coordinator) also have their offices in the same facility, so there is almost daily face-to-face correlation between the veterinarians performing the inspection oversight and their supervisors. The Chief of the Province is supervised directly by the DG of Control in Brussels.

There is a full, written audit/review program with established system controls, including reporting documents and distribution of reports at all levels, as well as documented evidence of daily inspection in the establishment. This documentation was provided.

There are also detailed, written guidelines for supervision of veterinarians and other field FSA employees. Examples were provided. Written reports are required, produced, and distributed to the employees supervised as well as to the supervisors of the employee being evaluated.

Furthermore, there are written criteria for evaluation of the establishment's HACPP programs by the inspection staff. Detailed forms for this evaluation have been developed and are in daily use. Written reports are produced on a regular basis—some daily, some weekly, some monthly—and copies are maintained on record in the inspection files in the establishment. Copies are also routinely reviewed by the supervisors of the in-plant inspection staff. An on-going summary report of findings has been established, which refers back to specific findings, in order to facilitate the tracking of problems and the occurrence of trends.

6.2.3 Assignment of Competent, Qualified Inspectors

Applicants wishing employment in the FSA must take civil service examinations. Specific additional examinations are prepared and required for veterinarians. The responsibility for the hiring of veterinarians and other inspection employees lies with the Minister of Public Health. The hiring of independent veterinarians (such as the alternate veterinarian providing coverage in Est. B-156) is organized by the Provincial Control Unit. Both federally-recruited and independent veterinarians are required to spend one year in probationary status, during which they are given specific courses in the various aspects of meat inspection, in close coordination with university faculties for veterinary medicine and meat hygiene, and work together with an experienced official inspector. The FSA's Center for training and Education provides continuing training and education for official inspectors.

Both full-time and contract government employees are prohibited by law from performing any private, establishment-paid tasks at an establishment in which they perform official inspection duties. For the full-time government employees, this is regulated in the Law of July 13, 1981, "Creation of an Institute of Veterinary Expertise." A private-practice veterinarian may be hired as a part time or contract government employee, but may not perform any private, establishment-paid tasks in any establishment in which he/she has official duties, nor may he have any additional conflicts of interest. This is regulated by the Royal Decree of July 4, 1986.

There are no other conflict-of-interest concerns with the alternate veterinarian, because (1) no animals slaughtered in Belgium are eligible for use in U.S.-eligible product, (2) her practice does not include swine, and (3) she is even legally forbidden to treat the companion animals of establishment employees. Furthermore, her practice is not in the same community as the establishment.

If either of the veterinarians is unable perform inspection coverage, the other performs the service. They organize vacations in advance so that they are never absent at the same time. There have been no instances in which inspection coverage was not provided due to absence of both of these veterinarians.

There are no budgetary restrictions on the hours of inspection coverage at the establishment. The veterinarians are free to spend as much time on the premises as they feel is necessary.

6.2.4 Authority and Responsibility to Enforce the Laws

The VIC and her alternate, as well as all other authorities in the chain of command up to DG Control, have full regulatory authority from retention of product up to and including suspension of operations.

There are thorough written procedures for inspection controls, duties, and activities. Examples were provided. The correct implementation of these programs is ensured by both the Head of the PCU and DG Control Headquarters.

If the establishment management personnel note a microbiological problem involving any product, they are legally required to inform the VIC and to initiate a recall. If the VIC notes a public health concern as a result of export/import inspections, supervisory visits, in-plant inspections, or upper level audits/reviews, she immediately retains the affected product and notifies her supervisor in the PCU for further action. There is also a fully-implemented Rapid-Alert-System in Belgium, as mandated by the European Commission.

6.2.5. Adequate Administrative and Technical Support

FSA has the ability to support a third-party audit. Administrative and Technical Support appeared to be adequate at all levels.

6.3 Headquarters Audit

The auditors conducted a review of inspection system documents. This records review was conducted at the headquarters office of FSA in Brussels and in the provincial office in Hasselt, which provides supervisory oversight for the establishment. The records review focused primarily on food safety hazards and included the following.

- Internal review reports
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Sampling and laboratory analyses for microbiology
- Sanitation and processing inspection procedures and standards
- Control of inedible and condemned materials
- Export product inspection and control including export certificates
- Enforcement records, including examples of recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from an establishment that does not meet compliance standards

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

7. ESTABLISHMENT AUDITS

The FSIS lead auditor visited the single meat-processing establishment that was eligible to export to the United States. There was no delistment and no Notice of Intent to Delist was issued.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is 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.

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 auditors evaluate compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The private Levetan Laboratory for microbiology in Antwerp was audited. The following deficiencies were identified:

- The methods used in this laboratory for the analysis of ready-to-eat product for *Listeria monocytogenes* and *Salmonella* species were not the FSIS methods; the alternative methods being used had not been submitted in advance to FSIS for equivalence determination.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focus on five areas of risk to assess Belgium's meat inspection system. The first of these risk areas that the FSIS auditors review is Sanitation Controls.

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

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

9.1 SSOP

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP program in the establishment was found to meet the basic FSIS regulatory requirements.

9.2 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were effectively implemented.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors 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.

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, an assessment of Belgium's animal disease controls was not within the scope of this audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors 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 generic *Escherichia coli (E. coli)* testing program in slaughter establishments.

11.1 Humane Handling and Slaughter

No Belgian slaughter facilities are certified as eligible to export to the U.S. at this time.

11.2 HACCP Implementation

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

The HACCP program was reviewed during the on-site audit of the establishment. The establishment management had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, the establishment was not required to meet the basic FSIS regulatory requirements for generic *E. coli* testing.

11.4 Testing for *Listeria monocytogenes*

The establishment audited was producing ready-to-eat products (pork shoulder picnic hams) for export to the United States. Since this product is fully cooked in hermetically-sealed plastic pouches and there is no post-lethality exposure to the environment, the requirement to test the finished product for *Listeria monocytogenes* under FSIS Directive 10,240.4 does not apply.

However, this product is subject to non-risk-based testing for *Listeria monocytogenes,* as mandated by FSIS Directive 10,210.1 Amendment 6. During the audit of the establishment, the lead auditor determined that the U.S.-eligible product was being sampled for *Listeria monocytogenes* at least three times per year, as required (see also Section 8).

11.5 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. All meat for products eligible for export to the United States is imported from eligible establishments in the Netherlands.

12.1 EC Directive 96/22

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, evaluation of the residue testing program was not within the scope of this audit.

12.2 EC Directive 96/23

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, evaluation of the residue testing program was not within the scope of this audit.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the processing establishment on all days on which U.S.-eligible production was conducted, and this daily inspection coverage was routinely documented.

13.2 Testing for *Salmonella*

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, evaluation of a *Salmonella* testing program on slaughter animals was not within the scope of this audit.

However, the ready-to-eat product produced for export to the U.S. is subject to non-risk-based testing for *Salmonella* species as mandated by FSIS Directive 10,210.1 Amendment 6. During the audit of the establishment, the lead auditor identified the following deficiency:

- U.S.-eligible, ready-to-eat product was not being routinely subjected to non-risk-based testing at least three times per year for *Salmonella* species, as mandated by FSIS Directive 10,200.1 Amendment 6. It was noted that the product was sampled monthly and routinely tested for *Enterobacteriaceae*. In the event of positive results, the sample was subjected to further testing to determine the agent, including specific testing for *Salmonella* species. The method employed, however, was not the FSIS method (see also Section 8 of this report).

13.3 Species Verification

At the time of this audit, Belgium was required to test product for species verification. Species verification testing was being conducted as required.

13.4 Monthly Reviews

During this audit it was found that monthly supervisory reviews of the establishment were being performed and fully documented.

Monthly internal supervisory reviews of the in-plant inspection oversight are conducted by both the Head of the PCU in which the establishment is situated and another official, a HACCP specialist from the PCU of the city of Brussels, both of whom have had certified training in HACCP, SSOP, and other special export requirements. Each internal review report is delivered to the Chief of the Province, who reviews and signs it, and sends copies to the internal reviewer and the Veterinarian-In-Charge of the establishment. Copies of the monthly review reports for U.S.-eligible establishments are routinely provided to and reviewed by all levels of the chain of command, including the National Implementation Control Unit of DG-Control Headquarters in Brussels. The records are maintained on file for a minimum of three years. Internal reviews are not announced in advance to establishment management. The Veterinarian-In-Charge is informed approximately one day in advance of an internal supervisory review.

13.5 Inspection System Controls

The CCA had controls in place for restricted product, shipment security, including shipment between establishments, and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible meat from other counties for further processing, security items, shipment security, and products entering the establishments from outside sources.

The following deficiencies were identified:

- The FSA had not enforced the FSIS requirement for routine, non-risk-based testing, at least three times per year, of U.S.-eligible product for *Salmonella* species.

- The FSA had not enforced the FSIS requirement that the methods used for required microbiological testing of U.S.-eligible product, if different from the methods employed by FSIS, are to be submitted in advance to FSIS for equivalence determination.

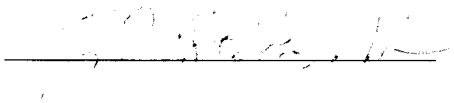
Note: During the exit meeting, the FSA officials gave assurances that they would immediately initiate routine testing, at least three times per year, of U.S.-eligible product specifically for *Salmonella* species and that they would promptly submit the alternative methods being used to test for *Listeria monocytogenes* and *Salmonella* species to FSIS for equivalence determination, and also that they were willing to employ the FSIS methods for the testing, if required, pending the equivalence determination.

14. CLOSING MEETING

A closing meeting was held on April 6, 2005, in Brussels with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditors.

The CCA understood and accepted the findings.

Gary D. Bolstad, DVM
Senior Program Auditor



15. ATTACHMENTS

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

United States Department of Agriculture
Food Safety and Inspection Service

Attachment A-1

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
N.V. Vleeswarenfabriek Deko	Mar. 31, 2005	B-156	Belgium
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Gary D. Bolstad	[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	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	X
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

A-2

March 31, 2005, Est. B-156, N.V. Vleeswarenfabriek Deko, Hasselt, Belgium.

33/51 Microbiological testing of finished product is performed monthly and includes specific testing for *Listeria monocytogenes* and for *Enterobacteriaceae*. Specific testing for *Salmonella* species is not routinely performed; however, if there are any positive results from the testing for *Enterobacteriaceae*, further testing, including specific testing for *Salmonella* species, is performed to identify the agent(s). The FASFC officials gave assurances that testing of 325-gram samples of U.S.-eligible, ready-to-eat product specifically for *Salmonella* species (at least three times per year) would commence during the week immediately following this exit conference. The first sample would be taken by FASFC and subsequent sampling would be performed by the establishment, under FASFC supervision. [Regulatory reference: FSIS Directive 10,210, Amendment 6]

Note: A review of the documentation showed that there have been no positive results for any *Enterobacteriaceae* since this establishment was re-listed as eligible to export to the United States on March 15, 2004.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

March 31, 2005

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Your letter from	Your reference	Our reference	Enclosures	Date
May 16 2005		PCCB/S4/SHS/ 38461		27.06.05

Subject : **FSIS on-site Audit of Belgium's meat inspection system/ comments report**

Dear colleague,

Concerning the Food Safety and Inspection Service (FSIS) conducted on-site audit of Belgium's meat inspection system from March 30 through April 6, 2005 , you will find below the comments of the Belgian authority regarding the information in the audit report:

1) Page 1, title: " annual routine" instead of "enforcement" (in line with the objective of the audit: page 5, point 2)

2) Page 9, point 6.2.2 Ultimate Control and Supervision (2e paragraph): 4th and 5th line: "sector manager transformation " instead of "Head of the PCU"
5th line: "Head of the PCU" instead of "the Chief of the Province or Coordinator"

3) Page 16, point 13.4 Monthly Reviews: "Monthly internal supervisory reviews of the in-plant oversight are conducted by both the Head of the PCU in which the establishment is situated and another official, a HACCP specialist....".
This should be adapted by "... by the official veterinarian and the sector manager transformation of the PCU in which the establishment is situated and/or a HACCP auditor"

4) Page 5: point 3 Protocol,
Page 6, point 4 Legal basis for the audit,
Page 13: point 9.2 EC Directive 64/433,
Page 14: point 11.5 EC Directive 64/433:

In these points, there is always a reference to Directive 64/433/EEC (fresh meat) while the company "Deko" has an approval according to Directive 77/99/EEC (meat products). This reference should be changed accordingly.

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The remark has already been made in our previous comments on the "Final Report of an audit carried out in Belgium covering Belgium's meat inspection system" in 2003 and in 2004.

If there are any questions, please feel free to contact the office of International affairs.

Yours sincerely,

Ir. G. HOUINS
Director general

Cc: Dr. J.M. DOCHY, Director general, DG Control