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

JAN 21 2004

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 has completed an on-site audit of Belgium's meat inspection system. The audit was conducted from July 15 through July 29, 2003. Enclosed is a copy of the final audit report. Comments from Belgium have been included as an attachment to the final 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 email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Steven McDermott for

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Roger Wentzel, Counselor, US Embassy, Brussels
Luc Devolder, Economic Counselor, Embassy of Belgium
Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the US
Norval Francis, Minister-Counselor, US Mission to the EU in Brussels
Linda Swacina, Deputy Administrator, FSIS
Dave Young, ITP, FAS
Scott Bleggi, FAS Area Officer
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Belgium—July03 Audit

FINAL

6 2004

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

JULY 15 THROUGH JULY 28, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. INTRODUCTION

2. OBJECTIVE OF THE AUDIT

3. PROTOCOL

4. LEGAL BASIS FOR THE AUDIT

5. SUMMARY OF PREVIOUS AUDITS

6. MAIN FINDINGS
   6.1 Legislation
   6.2 Government Oversight
   6.3 Headquarters Audit

7. ESTABLISHMENT AUDITS

8. LABORATORY AUDITS

9. SANITATION CONTROLS
   9.1 SSOP
   9.2 EC Directive 64/433

10. ANIMAL DISEASE CONTROLS

11. SLAUGHTER/PROCESSING CONTROLS
   11.1 Humane Handling and Slaughter
   11.2 HACCP Implementation
   11.3 Testing for Generic *Escherichia coli*
   11.4 Testing for *Listeria monocytogenes*
   11.5 EC Directive 64/433

12. RESIDUE CONTROLS
   12.1 FSIS Requirements
   12.2 EC Directive 96/22
   12.3 EC Directive 96/23

13. ENFORCEMENT CONTROLS
   13.1 Daily Inspection
   13.2 Testing for *Salmonella*
   13.3 Species Verification
   13.4 Monthly Reviews
   13.5 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Federal Agency for the Safety of the Food Chain, FASFC)
E. coli	*Escherichia coli*
FASFC	Federal Agency for the Safety of the Food Chain *(Federaal Agentschap voor de Veiligheid van de Voedselketen/ Agence Fédérale pour la Sécurité de la Chaîne Alimentaire*)
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction / Hazard Analysis and Critical Control Point Systems
Salmonella	*Salmonella* species
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Belgium from July 15 through July 28, 2003.

An opening meeting was held on July 15, 2003 in Brussels 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 Belgium's meat inspection system

The auditor was accompanied during the entire audit by representatives from the CCA, the Federal Agency for the Safety of the Food Chain, FASFC *(Federaal Agentschap voor de Veiligheid van de Voedselketen/Agence Fédérale pour la Sécurité de la Chaîne Alimentaire)* and representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a follow up audit with a special emphasis on the corrective actions taken in response to the FSIS audit of December 2002. The objective of the audit 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, three laboratories, one of which was performing analytical testing on United States-destined product, one district office, and one meat processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	District	1	Interview was held with the head of the District Office at the establishment
Laboratories		3	
Meat Processing Establishments		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with FASFC officials to discuss oversight programs and practices, including enforcement activities. The second part involved a review of documents in the country's inspection headquarters. The third part involved an on-site visit to one processing establishment. The fourth part involved visits to three laboratories; a) the Scientific Institute of Public Health – Louis Pasteur; which was conducting analyses of field samples for Belgium's national residue

control program; b) the National Reference Laboratory for Microbiology at Liege and c) the Quality Partner SA at Herstal - a private microbiology laboratory.
Program effectiveness determinations of Belgium's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP program., (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 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 also 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. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP programs and SSOP's.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Belgium under provisions of the Sanitary/Phytosanitary Agreement. Currently, no equivalence determinations have been made by FSIS for Belgium.

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 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists"
- Council Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS Website at www.fsis.usda.gov/ofo/tsc.

Five establishments had been delisted during the August 2001 audit for failure to meet FSIS requirements and one was evaluated as acceptable/re-review. Both of the remaining certified establishments had received Notices of Intent to Delist (NOID) as a result of the FSIS audit in February-March 2002 if HACCP and SSOP implementation deficiencies were not corrected within 30 days.

Of the problems identified during the FSIS audit in August 2001, the following had been corrected by the February-March 2002 FSIS audit.

- Implementation of pre-shipment document reviews was inadequate.
- Monthly supervisory reviews were not performed in some certified establishments.
- A boneless meat inspection program had not been implemented as required.
- Dropped meat was not reconditioned in a sanitary manner.
- Dropped meat-reconditioning procedures were not part of the written SSOP.
- Sanitizers were not maintained at the required temperature in some establishments.
- Maintenance and cleaning of over-product equipment had been neglected in two establishments.
- Pest control was inadequate in one establishment.

The following issues from the FSIS audit in August 2001 had *not* been corrected by the February-March 2002 audit (repeat findings):

- Implementation of HACCP programs were deficient in six of the seven establishments. During the February-March 2002 audit, the same deficiency was found in both establishments.
- Implementation of SSOP's had been deficient in all seven establishments. During the February-March 2002 audit, the same deficiency was found in one of the two establishments.
- Actual and potential product contamination was found in six of the seven establishments audited. During the February-March 2002 audit, the same deficiency was found in one of the two establishments.

During the audit of Belgium, conducted by FSIS in February-March 2002, the following additional deficiencies were identified:

- Personal hygiene was deficient in one establishment.
- The knife-sanitizing equipment was inadequate in one establishment.

During the audit of Belgium conducted, by FSIS in December 2002, deficiencies were noted in daily SSOP records, establishment grounds and pest control, establishment construction/maintenance, equipment and utensils, sanitary operations and monthly reviews. One of the two establishments was delisted for failure to meet FSIS requirements.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Belgium's legislation.

6.2 Government Oversight

The CCA had undergone a major organizational re-structuring of the entire meat inspection system. This reorganization had been prompted in large part by the dioxin crisis in Belgium in 1999 and was completed a few weeks prior to the current audit.

In brief, under the old system, meat inspection services were the responsibility of the Institute for Veterinary Inspection, a division of the Ministry of Social Affairs, Public Health, and the Environment. There was a Chief Veterinary Officer for Public Health and, under him, two Directorates General: a Directorate [for] Plants and a Directorate [for] Veterinary Policy. The Directorate for Plants was responsible for slaughter animals; poultry, rabbits, and game; and fishery products. The Directorate for Veterinary Policy was responsible for international relations, microbiology, and physico-chemistry. The inspection department was divided into two national districts. The first of these was "Residue Controls and Fraud," and was responsible for the detection of residues, sampling for zoonoses, prosecution of fraud, and internal investigations. The second national district was "Quality and Prevention," and was responsible for the quality of food products, the development of quality systems, and the handling of complaints. The main shortcomings of the old system were:

- It was not responsible for all products of animal origin,
- It did not cover the entire production chain, and
- There were separate areas of responsibility, with a Ministry of Social Affairs, Public Health, and the Environment (the Institute for Veterinary Inspection, Inspection of General Foodstuffs, and Pharmaceutical Inspection) and a Ministry of Agriculture (management of animal health and animal products and management of raw materials and plant products). Under the new system, the Federal Agency for the Safety of the Food Chain was established in February 2000. Its authority covers:

- All products of animal origin;
- The entire production chain, "from stable to table," including vegetables for human consumption, ingredients for animal feed, animal feed production, live food-producing animals, slaughter and food production, and distribution and retail;
- Executive responsibility under a single Minister (of Public Health), to improve integrated controls across the system;
- A centralized crisis management department; and
- A more scientifically based system through risk-assessment.

6.2.1 CCA Control Systems

The new Agency (FASFC) has four Directorates General: one for Control Policy, one for Control of Central Services and Inspection, one for Laboratories, and one for Corporate Services. The Directorate for Control Policy establishes process standards and Directorate of Control of Central Services and Inspection carries the responsibility for inspection services and execution of Standards. This Directorate is divided into two national control groups, one for the Flemish-speaking (northern) half of the country and one for the French-speaking (southern) half. The Directorate has 11 Control Units, one for each of the 10 Provinces and one for the capital city of Brussels.

6.2.2 Ultimate Control and Supervision

When the management of an establishment wishes to become eligible to export to the United States, the manager makes an application to the Regional District. A Regional Administrative Officer conducts an administrative and technical inquiry and submits a report of the results to the Administration Directorate for Plants, which, in turn, makes a recommendation to the Minister of Public Health on the basis of the report. If the report is favorable, the Minister grants the approval. There is no additional on-site evaluation by headquarters personnel.

The procedure for withdrawing the approval of an establishment, for such reasons as structural deficiencies, involves a written notification to the owner/operator, who must describe corrective actions that have been taken within 10 days of receipt of the notification and provide the description to the Regional Officer of the District. The latter, in turn, forwards the report to the Minister of Public Health, who will make a decision, based on the report from the Regional Officer of the District, within 30 days. In cases that involve fraud or production of products that are dangerous to human health, the Minister may withdraw approval immediately.

6.2.3 Assignment of Competent, Qualified Inspectors

All inspection officials in positions of authority in the U.S.-eligible establishment were veterinarians and full-time employees of FASFC.

The performance of the field veterinarians was evaluated by their supervisors, who, in establishments eligible to export to the U.S., were the internal reviewers. The results of

these evaluations were discussed orally with the field veterinarians. All field veterinarians and all three internal reviewers provided documentation of HACCP training courses.

6.2.4 Authority and Responsibility to Enforce the Laws

FASFC has the authority and the responsibility to enforce U.S. requirements.

6.2.5 Adequate Administrative and Technical Support

FASFC has the administrative and technical support necessary to operate Belgium's inspection system and has the resources and ability to support a third-party audit.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents and held discussions with the of inspection officials at the headquarters of the inspection service. This review and these discussions 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;
- The current status of animal diseases;
- Controls on movement of animals within and into the country;
- Label approval records;
- New laws and implementation documents such as regulations, notices, directives and guidelines;
- Belgium's Contaminants Surveillance System (CONSUM) and Transmissible Spongiform Encephalopathy (TSE) databases;
- Sampling and laboratory analyses for residues;
- Sanitation, slaughter and processing inspection procedures and standards;
- Export product inspection and control, including export certificates;
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant products.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited the one establishment that was currently certified as eligible to export to the United States. The establishment was closed for repairs during the time of the FSIS visit. However, the auditor was able to review establishment and inspection documents and found that all deficiencies noted during previous audits had been corrected.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

The government laboratory in the Scientific Institute of Public Health – Louis Pasteur, in which field samples are analyzed for the national residue-testing program, was audited. No problems were noted. See Also, Section 12 (Residue Controls) of this report.

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 FSIS Pathogen Reduction/HACCP requirements. A private laboratory (Quality Partner) at Herstal was visited. This laboratory does not routinely test any samples from U.S.-destined product. Since testing for generic *E. coli* and *Salmonella* species is not required, these programs were not evaluated. This laboratory, however, is also approved for testing of ready-to-eat products for *Listeria monocytogenes*. The sample size and test methods employed are different than the one used by FSIS. These methods had not been submitted to FSIS for equivalence determination.

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 audit of establishment, and except as noted below, Belgium's meat inspection system had controls in place for SSOP programs, facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

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

9.1 SSOP's

Establishment records were evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the United States

domestic inspection program. The SSOP were found to meet the basic FSIS regulatory requirements with no deficiencies.

9.2 EC Directive 64/433

The records review did not indicate any problems with the implementation of the provisions of EC Directive 64/433.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These include control over condemned and restricted products and procedures for sanitary handling of returned and reconditioned products. The auditor determined that Belgium's inspection system had adequate controls in place. No deficiencies were noted.

Animal diseases in Belgium with public health significance include Bovine Spongiform Encephalopathy, bovine tuberculosis, toxoplasmosis, anthrax, trichinellosis, and trichinosis. On November 8, 2002, one case of hog cholera/classical swine fever was confirmed in a wild boar.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. Since no slaughter establishments were currently certified for U.S. export, slaughter controls did not apply. The processing controls include the following areas: 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.

11.1 Humane Handling and Humane Slaughter

No slaughter establishments were certified for U.S. export at the time of this audit.

11.2 HACCP Implementation

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

The HACCP program was reviewed during the on-site record review. This review indicated that establishment had adequately implemented the PR/HACCP requirements.

11.3 Testing for Generic *E. coli*

Belgium is not currently required to test for generic *E. coli*. Belgium obtains meat for U.S. export from hogs slaughtered in countries eligible to export slaughtered hogs to the United States (Denmark and the Netherlands).

11.4 Testing for *Listeria monocytogenes*

Testing for *Listeria monocytogenes* is regularly conducted by the establishment.

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11.5 EC Directive 64/433

In the establishment visited, the provisions of EC Directive 64/433 relative to processing were effectively implemented.

12. RESIDUE CONTROLS

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

The government laboratory of the Scientific Institute of Public Health – Louis Pasteur was audited.

Belgium's National Residue Control Program for 2003 was being followed and was on schedule.

12.1 FSIS Requirements

There were no negative findings.

12.2 EC Directive 96/22

In the laboratory of the Scientific Institute of Public Health – Louis Pasteur, the provisions of EC Directive 96/22 were effectively implemented.

12.3 EC Directive 96/23

In the laboratory of the Scientific Institute of Public Health – Louis Pasteur, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements for SSOP, HACCP/PR and other inspection activities.

The establishment regularly works six days a week (Monday through Saturday). Inspection records showed inspection presence during Monday through Friday only. The establishment had apparently been working without any inspection coverage on Saturday. The establishment was delisted because of failure to meet U.S. requirements for daily inspection coverage.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily for Monday through Friday operations. No inspector was assigned for Saturday work. The establishment was delisted for non-compliance with FSIS requirements for daily inspection coverage.

13.2 Testing for *Salmonella* Species

Belgium is not currently required to test for *Salmonella* species. Belgium obtained meat for U.S. export from hogs slaughtered in countries eligible to export slaughtered hogs to the United States (Denmark and the Netherlands).

13.3 Species Verification

Species verification was being conducted in the one establishment visited.

13.4 Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system, no less frequently than one such visit per month to each establishment certified, during periods when the establishment is engaged in producing products for exportation to the United States.

There were three internal reviewers ("lead assessors") performing the internal supervisory reviews of the establishment certified for U.S. export. Two internal reviewers conducted the supervisory reviews on alternate months. Both were veterinarians. The internal reviewers were supervised by the Chiefs of the Districts who, in turn, reported to the Chief Veterinary Officer.

Internal reviews are not announced in advance to establishment management. The Veterinarian-In-Charge is informed approximately one day in advance.

Each internal review report is delivered to the Chief of the District, who reviews and signs it, and sends copies to the internal reviewer and the Veterinarian-In-Charge of the establishment. The records are maintained on file for a minimum of three years. According to information provided in the meat inspection headquarters offices, in the event of relatively minor problems identified during internal reviews, the establishment is given up to 30 days to correct them. More serious problems, including noncompliance with the taking of corrective actions, are reported to the CVO and to the export department of the International Relations Division.

13.5 Inspection System Controls

The CCA had controls in place for restricted product and inspection samples; 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 products from other countries for further processing.

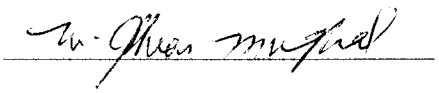
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on July 28, 2003 in Brussels 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.

M. Ghias Mughal, DVM
Chief, International Audit Staff



15. ATTACHMENTS TO THE AUDIT REPORT

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

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
July 22, 2003	Quality Partners SA

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Ministry of Social Affairs, Public Health and Environment	Brussels, Belgium	rue Hayeneux 62 4040 Herstal

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. M. Ghias Mughal	Dr. Marc Cornelis

	Residue Code/Name ▶		100	111	300	400	500	200	203	800	E.co	Sal	List
	REVIEW ITEMS	ITEM #											
SAMPLING PROCEDURES	Sample Handling	01	A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03	A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A	A	C
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A	A	A
	Equipment Operation	09	A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10	A	A	A	A	A	A	A	A	O	O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	O	O	O
	Recovery Frequency	12	A	A	A	A	A	A	A	A	O	O	O
	Percent Recovery	13	A	A	A	A	A	A	A	A	O	O	O
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A	A	A
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16	A	A	A	A	A	A	A	A	A	A	A
	International Check Samples	17	A	A	A	A	A	A	A	A	A	A	A
REVIEW	Corrected Prior Deficiencies	18	O	O	O	O	O	O	O	O	O	O	O
OTHER REVIEW		19											
		20											

EVALUATION CODE / EVAL. CODE

SIGNATURE OF REVIEWER

for Ghias Mughal DVM

DATE

10/23/2003

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE	NAME OF FOREIGN LABORATORY
July 22, 2003	Quality Partners SA

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Ministry of Social Affairs, Public Health and Environment	Brussels, Belgium	rue Hayeneux 62 4040 Herstal

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. M. Ghias Mughal	Dr. Marc Cornelis

RESIDUE	ITEM NO.	COMMENTS
	07	Test sample size and analytical methods used by this private laboratory are different from FSIS sample size and method. These methods have not been submitted to FSIS for equivalence determination.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: July 22, 2003

NAME OF FOREIGN LABORATORY: ULG-Laboratory Microbiology
National Reference Laboratory for Microbiology

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Ministry of Social Affairs, Public Health and Environment	Brussels, Belgium	Boulevarde de Colonster Batiment B43 bis Liege

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. M. Ghias Mughal	Dr. Marc Cornelis

	REVIEW ITEMS	ITEM #	EVALUATION CODE	100	111	300	400	500	200	203	800	E.co	Sal	List
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06		A	A	A	A	A	A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A	A	A	A	A	A	A
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	O	O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	A	A	A	A	O	O	O
	Recovery Frequency	12		A	A	A	A	A	A	A	A	O	O	O
	Percent Recovery	13		A	A	A	A	A	A	A	A	O	O	O
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	A
	International Check Samples	17		A	A	A	A	A	A	A	A	A	A	A
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O	O	A
OTHER REVIEW		19	EVAL. CODE											
		20	EVAL. CODE											

SIGNATURE OF REVIEWER: M Ghias Mughal

DATE: 9/30/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE	NAME OF FOREIGN LABORATORY
July 22, 2003	ULG-Laboratory Microbiology National Reference Laboratory for Microbiology

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Ministry of Social Affairs, Public Health and Environment	Brussels, Belgium	Boulevarde de Colonster Batiment B43 bis Liege

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. M. Ghias Mughal	Dr. Marc Cornelis

RESIDUE	ITEM NO.	COMMENTS

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: July 18, 2003

NAME OF FOREIGN LABORATORY: Scientific Institute of Public Health - Louis Pasteur

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Ministry of Social Affairs, Public Health and Environment	Brussels, Belgium	Juliette Wytsmanstraat 14 1050 Brussels, Belgium

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. M. Ghias Mughal	J.M. Degroodt and Dr. Sofie Huyberechts

	REVIEW ITEMS	ITEM #	EVALUATION CODE	100	111	300	400	500	200	203	800	E.co	Sal	List
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06		A	A	A	A	A	A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A	A	A	A	A	A	A
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	O	O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	A	A	A	A	O	O	O
	Recovery Frequency	12		A	A	A	A	A	A	A	A	O	O	O
	Percent Recovery	13		A	A	A	A	A	A	A	A	O	O	O
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	A
	International Check Samples	17		A	A	A	A	A	A	A	A	A	A	A
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O	O	A
OTHER REVIEW		19	EVAL. CODE											
		20	EVAL. CODE											

SIGNATURE OF REVIEWER: - M Ghias Mughal

DATE: 9/30/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE	NAME OF FOREIGN LABORATORY
July 18, 2003	Scientific Institute of Public Health - Louis Pasteur

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Ministry of Social Affairs, Public Health and Environment	Brussels, Belgium	Juliette Wytsmanstraat 14 1050 Brussels, Belgium

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. M. Ghias Mughal	J.M. Degroodt and Dr. Sofie Huyberechts

RESIDUE	ITEM NO.	COMMENTS

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
Deko Hasselt	July 17, 2003	156	Belgium
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[ ] ON-SITE AUDIT [X] 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	
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	O
41. Ventilation	O
42. Plumbing and Sewage	O
43. Water Supply	O
44. Dressing Rooms/Lavatories	O
45. Equipment and Utensils	O
46. Sanitary Operations	O
47. Employee Hygiene	O
48. Condemned Product Control	O
Part F - Inspection Requirements	
49. Government Staffing	X
50. Daily Inspection Coverage	X
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

BELGIUM - Est. 156 Date of visit: July 17, 2006

The establishment was not in operation on day of the visit.

49, 50 and 51 – The establishment regularly operates one shift on Saturday. Document review showed that no inspection coverage had been provided on Saturdays. Since no government inspector was required to work on Saturday, there was no enforcement of FSIS regulations on these days.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

Agence Fédérale pour la Sécurité de la Chaîne Alimentaire · A.F.S.C.A. · Federaal Agentschap voor de Veiligheid van de Voedselketen · F.A.V.V.

DG CONTROL POLICY

INTERNATIONAL AFFAIRS

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USDA – FSIS
Office of International Affairs
International Equivalence Staff
Mrs. Sally Stratmoen, director
140 Independence Avenue, SW
Washington DC 20250
United States of America

Your letter	Your references	Our references	Annexes	date
October 16, 2003		PCCB/S4/MCS/ 40931		

Concern: **USDA-FSIS July 2003 audit – Belgian meat inspection system: draft final audit report.**

Dear Mrs. Sally Stratmoen,

The Food Safety and Inspection Service (FSIS) completed an on-site audit of Belgium's meat inspection system from July 15 trough July 29, 2003. In this letter we submit comments regarding the information in the draft final report of this audit and the attached letter, that we received on October 24, 2003.

A. **General remarks**

During the audit carried out in July 2003 the only plant listed for US export, a meat product plant (Deko), was visited.

At the opening meeting on July 16, 2003 we highlighted to the auditor an imprecision in the audit standards that FSIS intended to use for the audit that is: Directive 64/433/EEC (fresh meat); the correct standard being: Directive 77/99/EEC (meat products), plus the special conditions laid down in Annex V of the EC/US Veterinary Agreement.

However we, as central competent authority, didn't object to the continuation of the audit.

The plant was visited on July 17, 2003 while it was not operational; only the documentation was reviewed and the auditor found that all deficiencies noted during previous audits had been corrected.

Although the overall result was satisfactory, the plant was immediately delisted due to a shortcoming highlighted by the auditor concerning the absence of an inspector on Saturday's shifts. Already on July 17, 2003 during the audit the director of the Provincial Control Unit took immediate corrective action and appointed a veterinarian to provide inspection coverage on Saturday. On July 23, 2003 (before the closing meeting) we informed you by letter that corrective action had been taken and that a veterinarian would be present on Saturday's shifts at the start of the production activities on August 4, 2003.

At the closing meeting on July 28, 2003 we confirmed our position that the audit standard, Directive 64/433/EEC, that FSIS used as a basis for the audit was incorrect, the correct standard being Directive 77/99/EEC (meat products).

B. Specific remarks

1. page 6: 3. Protocol –3rd paragraph

To be added: *"The Belgian central competent authority stated that, in accordance with the EC/US Veterinary Agreement, the establishment couldn't be audited against the European Council Directive 64/433/EEC (fresh meat), but against European Council Directive 77/99/EEC (meat products).".*

2. page 7, 1st bullet point: Legal basis for the audit

To be changed: *"Council Directive 77/99/EEC of December 21, 1976 on health problems affecting intra-Community trade in meat products".*

3. page 9: 6.2.1 CCA Control Systems

To be changed: *"The new Agency (FASFC) has Four Directorates General: one for Control policy, one for Control, one for Laboratories, and one for Corporate Services. The directorate for Control Policy establishes process standards and the Directorate for Control carries the responsibility for inspection/audit services and enforcement of process and product standards. The Directorate General for Control is divided into 11 Provincial Control Units, one for each of the 10 Provinces and one for the capital city of Brussels. This Directorate has also 2 coordinators one for the Flemish-speaking (northern) half of the country and one for the French/German speaking (southern) half."*

4. **page 12: 9.2. EC Directive 64/433**

   The reference to this Directive is incorrect and should be deleted and replaced, because the establishment is approved and working under Directive 77/99/EEC.

5. **page 13: 11.5. EC Directive 64/433**

   The reference to this Directive is incorrect and should be deleted and replaced, because the establishment is approved and working under Directive 77/99/EEC.

6. **page 14: 13.1. Daily inspection in establishments**

   See under A. General remarks and C. Final remarks.

7. **page 15: 14. Closing Meeting**

   See under A. General remaks.
   To be added: *"At this meeting the CCA reaffirmed his position that the audit standard, Directive 64/433/EEC, that FSIS used as a basis for the audit was incorrect, the correct standard being Directive 77/99/EEC (meat products).".*

C. Final remarks

In spite of the guarantees given by the director of the Provincial Control Unit during the audit on July 17, 2003 and the official letter sent on July 23, 2003 the establishment has not been relisted.

In light of the fact that we have immediately taken the corrective action requested by FSIS, we consider that on the basis of Directive 77/99/EEC (meat products), the correct standard for auditing a meat products establishment, plus the special conditions laid down in Annex V of the EC/US Veterinary Agreement, the daily presence of an official inspector in a meat products plant is not an obligatory requirement.

Sincerely,

Ir. G. Houins

Director-general

cc. A. Checchi-Lang, European Commission, DG SANCO – Directorate E, Belliardstraat, 1049 Brussel
F. Swartenbroux, Permanent Representation of Belgium to the EC, Schumannplein 6, 1040 Brussel
P. Vanthemsche, CEO, FASFC
J.-M. Dochy, director-general Control, FASFC
V. Merken, director-general Laboratories, FASFC