



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

AUG 29 2003

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

Dear Dr. Cornelis:

The Food Safety and Inspection Service conducted an on-site audit of Belgium's meat inspection system from December 4 through December 17, 2002. The Government of Belgium did not provide any comments in response to the draft final audit report. Enclosed is a copy of the final audit report.

If you have any questions regarding the audit or need additional information, please feel free to contact me. My telephone number is 202-720-3781, my fax number is 202-690-4040, and my e-mail address is [sally.stratmoen@fsis.usda.gov](mailto:sally.stratmoen@fsis.usda.gov).

Sincerely,

for Sally Stratmoen  
Acting Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

Roger Wentzel, Counselor, US Embassy, Brussels  
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Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU/US Miss.  
Linda Swacina, Deputy Administrator, FSIS  
Norval Francis, Minister/Counselor for Agricultural Affairs, USEU/Brussels  
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Country File (Belgium FY 2003 Audit—December 02)

**FINAL**

**JUL 23 2003**

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

DECEMBER 4 THROUGH DECEMBER 17, 2002

Food Safety and Inspection Service  
United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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

## 1. INTRODUCTION

The audit took place in Belgium from December 4 through December 17, 2002.

An opening meeting was held on December 4, 2002 in Brussels with the Central Competent Authority (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*). 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 and representatives from the regional and local inspection offices.

## 2. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, the laboratory performing analytical testing on United States-destined product, one district office, and two meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	4	
	District	1	
Laboratories		1	
Meat Processing Establishments		2	

## 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 an audit of a selection of records in the Belgium's inspection headquarters or regional offices. The third part involved on-site visits to two processing establishments. The fourth part involved visits one laboratory, the Scientific Institute of Public Health – Louis Pasteur, which was conducting analyses of field samples for Belgium's national residue control program. Since no slaughter establishments were certified as eligible to export to the U.S. at the time of this audit, no microbiology laboratories were audited.

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 programs and the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls. Belgium's 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 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. Belgium's capability for testing for generic *E. coli* and *Salmonella* species would also be evaluated, although no slaughter establishments were currently certified for U.S. export.

No equivalence determinations have been made by FSIS for Belgium under 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 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/fofo/tsc](http://www.fsis.usda.gov/fofo/tsc).

Five establishments had been delisted during the 2001 audit for failure to meet FSIS requirements and one was evaluated as acceptable/re-review, and both the remaining certified establishments (the same two visited during the audit covered by this report) had received Notices of Intent to Delist 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 of the seven establishments certified for U.S. export in Belgium in August 2001, the following had been corrected by the February-March 2002 FSIS audit of the two establishments certified for U.S. export.

- ◆ *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's.*
- ◆ *Sanitizers were not maintained at the required temperature in some plants.*
- ◆ *Maintenance and cleaning of over-product equipment had been neglected in two plants.*
- ◆ *Pest control was inadequate in one plant.*

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

- ◆ *Implementation of HACCP programs had been deficient in six of the seven establishments.* During the last audit, the same deficiency was found in both establishments.
- ◆ *Implementation of SSOP's had been deficient in all seven establishments.* During the last 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 last audit, the same deficiency was found in one of the two establishments.

During the most recent 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.

## 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 was undergoing a major re-structuring of the organization of the entire meat inspection system, and was in a period of transition between the old and the new systems. This reorganization had been prompted in large part by the dioxin crisis in Belgium in 1999, and was expected to be completed during calendar year 2003.

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 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). Crisis management under this arrangement was very difficult.

Under the new system, with the foundation of 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, one for Laboratories, and one for General Services. The Directorate for Control carries the responsibility for inspection services, which 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. Within the Directorate for Control, there are 11 Control Units, one for each of the 10 Provinces and one for the capital city of Brussels. The details of the structure of the new Agency, the status of its personnel, etc. are still under development.

The Institute for Veterinary Inspection will “almost certainly” be integrated as a whole into FASFC. Regarding foodstuffs, only matters regarding food (including materials that come into contact with food) will be taken over by FASFC, and not other products (including cosmetics and tobacco). Human pharmaceuticals will not come under FASFC responsibility; as of the time of this audit, it is not yet clear to what extent the competencies regarding veterinary pharmaceuticals will be transferred.

#### 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 his results to the Administration Directorate [for] Plants, which, in turn, makes a recommendation to the Minister 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 manager, who must describe corrective actions that have been taken within ten 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, 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 two U.S.-eligible establishments 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, although, in one of the regions, more decisive regulatory actions need to be taken when U.S. requirements are not adequately met.

### 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 at the headquarters of the inspection service. 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;
- 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 product in an establishment that is certified to export product to the United States.

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

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited the two establishments that were currently certified as eligible to export to the U.S. Both were processing establishments. One of the establishments was delisted by Belgium because of failure to meet U.S. requirements during its audit. None received a Notice of Intent to Delist from Belgium.

## 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. The findings in this laboratory are discussed in 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. Since testing for generic *E. coli* and *Salmonella* species was not required at the time of this audit (no slaughter establishments were currently certified as eligible to export to the United States), no microbiology laboratories were audited.

## 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 reviews is Sanitation Controls.

Based on the on-site audits of establishments, 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 both establishments, maintenance of over-product equipment had been neglected (to a minor extent in one establishment and grossly in the other).
- ◆ In one establishment, condensation was out of control in the tumbling room. The problem had been identified in the past by FASFC officials, who reported that it was a common occurrence in the area, and the problem had not been addressed by the establishment. An open container of exposed product was present in the room; no corrective actions were taken, either by establishment or FASFC officials, and the establishment had no provision or implements for removal of the condensation during production.
- ◆ In one establishment, several containers ready for use had not been adequately cleaned: meat residues were observed. The containers on which the meat scraps were readily visible were removed for re-cleaning, but the others in the stack were not removed for cleaning or reinspected for adequate cleaning.

In addition, 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

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP's were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP's in the two establishments were found to meet the basic FSIS regulatory requirements, with the following deficiency:

- ◆ In one establishment, documentation of pre-operational and operational findings, corrective actions, and preventive measures was inadequate, and did not reflect the actual conditions observed in the establishment during the audit. (For example, there was no establishment documentation of condensation problems and attempts at control, although condensation was clearly a common problem in this establishment.) This was a repeat finding from the last two FSIS audits. Furthermore, the in-plant FASFC officials reported that lack of adequate documentation of sanitation deficiencies by the establishment was a common occurrence.

### 9.2 EC Directive 64/433

In both establishments, problems with the implementation of the provisions of EC Directive 64/433 were found.

- In one of the establishments, a trend of noncompliance was noted. There were repeat deficiencies, and the inspection officials did not consistently take immediate corrective actions.

The specific deficiencies are noted in the attached individual establishment reports.

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviews is 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 include Bovine Spongiform Encephalopathy, bovine tuberculosis, toxoplasmosis, anthrax, trichinellosis, and trichomoniasis. Also, 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 reviews is 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 slaughter and processing establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the two establishments. Both establishments had adequately implemented the PR/HACCP requirements.

### 11.3 Testing for Generic *E. coli*

Belgium was not currently required to test for generic *E. coli*, since no slaughter establishments were certified for U.S. export at this time. 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).

#### 11.4 Testing for *Listeria monocytogenes*

Testing for *Listeria monocytogenes* was routinely conducted in both establishments.

#### 11.5 EC Directive 64/433

In one establishment, the provisions of EC Directive 64/433 relative to processing were effectively implemented with the following exception:

- ◆ In one establishment, in the preparation area for molds with plastic wrappings for cooked hams, an old, dirty, grossly deteriorated sheet of cardboard was routinely used as a spacer and was placed directly on open molds with the plastic wrappings in place, ready for filling. When the FSIS auditor pointed out the problem, no corrective actions were taken, either by establishment or FASFC officials.

## 12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviews is Residue Controls.

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

#### 12.1 EC Directive 96/22

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

#### 12.2 EC Directive 96/23

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

#### 12.3 Other FSIS Requirements

Although the majority of turnaround times (the amount of time elapsed between sample receipt in the laboratory and completion of analysis) were within the one-month period FSIS expects, some turnaround times ranged up to two months. It was noted that the turnaround times expected in the laboratory were within three weeks, and on several occasions, there had been documented internal "complaints" when this target period was exceeded. The FSIS auditor explained the FSIS expectation of turnaround times within one month, and the laboratory director gave assurances that an improved policy would be implemented, to improve the achievement of the target, before any Belgian slaughter establishments are certified as eligible to export meat to the U.S. Since no slaughter

establishments were currently certified for U.S. export, this finding was not viewed as a deficiency for the purposes of this audit.

### 13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviews is 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 and documented daily in both processing establishments.

#### 13.2 Testing for *Salmonella* Species

Belgium was not currently required to test for *Salmonella* species, since no slaughter establishments were certified for U.S. export at this time. 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

At the time of this audit, Belgium was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

#### 13.4 Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system, not less frequent 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 two establishments certified for U.S. export. In the establishment in Hasselt, each of two internal reviewers conducted the supervisory reviews on alternate months. One internal reviewer was responsible for all monthly reviews in the establishment in Zele. All three 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. They 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, and noncompliance with the taking of corrective actions, are reported to the CVO and to the export department of the International Relations division.

During this audit it was found that, since the previous FSIS audit in February-March 2002, no monthly supervisory review had been performed as required, in one establishment for the months of July or August 2002, or in the other establishment for the month of March 2002.

The two internal reviewers who led the establishment audits demonstrated an adequate grasp of FSIS requirements; however, enforcement of those requirements varied considerably between the two. In the establishment that was determined to fail to meet FSIS requirements, when the establishment management failed to take corrective actions in response to several sanitation deficiencies observed during the audit, both the in-plant inspection staff and the internal reviewer leading the audit also failed to take corrective actions. Furthermore, at the end of the day's activities, the initial evaluation by the internal reviewer was that the establishment's compliance was acceptable and that its eligibility to export to the United States should be merely suspended for 30 days or so. When the FSIS auditor reviewed the findings, however, all the FASFC officials present agreed that the establishment failed to meet FSIS requirements and voluntarily delisted it. It is noteworthy that this establishment was evaluated as acceptable/re-review during the FSIS audit in 2001 and received a Notice of Intent to Delist, as a result of the previous FSIS audit in February-March 2002, if deficiencies identified during the audit were not corrected within 30 days.

### 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.

The following deficiencies in inspection system controls were identified:

- ◆ In one establishment, neither EC requirements nor FSIS requirements had been adequately enforced, either by the in-plant inspection personnel or by the internal supervisory reviewer, in spite of repeated failure by establishment management to take corrective actions and preventive measures in response to deficiencies identified and documented by the FASFC officials, and a repeated lack of adequate documentation of the sanitation problems.

#### 14. CLOSING MEETING

A closing meeting was held on December 17, 2002 in Brussels with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

 Gary D. Bolstad, DVM  
International Audit Staff Officer



## 15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Laboratory Form

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report (*no country response received*)

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

REVIEW DATE

NAME OF FOREIGN LABORATORY

*P. A. - ke*

Dec. 6, 2002

Scientific Institute of Public Health - Louis Pasteur

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 Federal Agency for the Safety of the Food  
 Chain (FAVV/AFSCA)

CITY & COUNTRY

Brussels, Belgium

ADDRESS OF LABORATORY

Rue Juliette Wytzman, 14

NAME OF REVIEWER

Dr. Gary D. Bolstad

NAME OF FOREIGN OFFICIAL

Dr. Jean-Marie Degroot

Residue Code/Name			chc	pcb	abc	cap	op	hm	hor	sul					
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A				
	Sampling Frequency	02		A	A	A	A	A	A	A	A				
	Timely Analyses	03		C	A	C	C	C	A	A	C				
	Compositing Procedure	04		O	O	O	O	O	O	O	O				
	Interpret Comp Data	05		O	O	O	O	O	O	O	O				
	Data Reporting	06													
ANALYTICAL PROCEDURES	Acceptable Method	07	GC-MS	GC-MS	A	A	A	A	A	GC-MS	A				
	Correct Tissue(s)	08	A	A	A	A	A	A	A	ur, fat feces	A				
	Equipment Operation	09	A	A	A	A	A	A	A	A	A				
	Instrument Printouts	10	A	A	A	A	A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	A				
	Recovery Frequency	12	A	A	A	A	A	A	A	A	A				
	Percent Recovery	13	A	A	A	A	A	A	A	A	A				
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A				
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A	A				
	Corrective Actions	16	A	A	A	A	A	A	A	A	A				
	International Check Samples	17	A	A	A	A	A	A	A	A	A				
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	0	0	0	0	0	0	0	0	0				
OTHER REVIEW		19													
		20													

SIGNATURE OF REVIEWER

*Dr. Gary D. Bolstad*

DATE

*12/6/2002*

<b>FOREIGN COUNTRY LABORATORY REVIEW</b> <i>(Comment Sheet)</i>		REVIEW DATE Dec. 6, 2002	NAME OF FOREIGN LABORATORY Scientific Institute of Public Health - Louis Pasteur
FOREIGN GOV'T AGENCY Federal Agency for the Safety of the Food Chain (FAVV/AFSCA)	CITY & COUNTRY Brussels, Belgium		ADDRESS OF LABORATORY Rue Juliette Wytzman, 14
NAME OF REVIEWER Dr. Gary D. Bolstad		NAME OF FOREIGN OFFICIAL Dr. Jean-Marie Degroot	

RESIDUE	ITEM	COMMENTS
chc, abc, cap, op, sul	03	<p>Abbreviations: CHC = chlorinated hydrocarbons; PCB = polychlorinated biphenyls; ABC = antibiotics; CAP = chlormphenicol; OP = organophosphates; HM = hormones; SUL = sulfonamides</p> <p>Although the majority of turnaround times were within the one month period FSIS expects, some turnaround times ranged up to two months. It was noted that the turnaround times expected in the laboratory were within three weeks, and on several occasions, there had been documented internal "complaints" when this target period was exceeded. The FSIS auditor explained the FSIS expectation of turnaround times within one month, and he laboratory director gave assurances that an improved policy would be implemented, to improve the achievement of the target, before any Belgian slaughter establishments are certified as eligible to produce meat that will be eligible for U.S. export.</p>

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION N.V. Theo Bouwens  Zele	2. AUDIT DATE Dec. 10, 2002	3. ESTABLISHMENT NO. B-45	4. NAME OF COUNTRY Belgium
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP			33. Scheduled Sample	O
8. Records documenting implementation.			34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.			35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.			36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light	
14. Developed and implemented a written HACCP plan.			41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils	X
18. Monitoring of HACCP plan.			46. Sanitary Operations	X
19. Verification and validation of HACCP plan.			47. Employee Hygiene	X
20. Corrective action written in HACCP plan.			48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage	
23. Labeling - Product Standards			51. Enforcement	
24. Labeling - Net Weights			52. Humane Handling	O
25. General Labeling			53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection	O
27. Written Procedures		O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		O	56. European Community Directives	
29. Records		O	57. Monthly Review	X
Salmonella Performance Standards - Basic Requirements			58.	
30. Corrective Actions		O	59.	
31. Reassessment		O		
32. Written Assurance		O		

## 60. Observation of the Establishment

B-10

Dec. 10, 2002, Est. B-45: N.V. Theo Bouwens, Zele, Belgium

- 13 Establishment documentation of pre-operational and operational sanitation findings did not reflect actual conditions observed in the plant on the day of the audit. In-plant FASFC officials reported that this was a common occurrence. There was no establishment documentation of condensation problems or attempts at control (see items 41 and 46, below). Inadequate documentation of sanitation findings and corrective actions had been identified as a deficiency during the previous two FSIS audits (this was again a repeat finding).
- 38 Old cobwebs were found in the dry-storage area for non-meat ingredients. FASFC officials ordered prompt correction.
- 39 Maintenance of over-product equipment and ceilings had been neglected to varying degrees in several areas. Gross neglect was evident on all ten motor housings for the mixers in the brine room, which were severely corroded and rusty, with large patches of flaking paint. Flaking paint was also seen on ceilings in several rooms and on rail supports in the receiving area. The majority of wheeled stainless combo bins and large plastic in use had cracked and broken edges and a number of these had old product residues caked in the damaged areas. No immediate corrective actions were taken, either by establishment or FASFC officials.
- 41/46 Condensation was out of control in the tumbling room; an open container of exposed product was present in the room. This had been identified in the past by FASFC officials, who reported that it was a common occurrence in the area, and the problem had not been addressed by the establishment. No corrective actions were taken, and the establishment had no provision or implements for removal of the condensation during production. (See also item 13, above.)
- 45 Several containers ready for use had not been adequately cleaned: meat residues were observed. This was in violation of EC Directive 64/433. The containers on which the meat scraps were readily visible were removed for re-cleaning, but the others in the stack were not removed for cleaning or reinspected for adequate cleaning.
- 46a There was inadequate separation of edible-product contact surfaces and inedible containers. Plastic sheets for product-contact purposes were routinely stored in an inedible container that was clearly marked "INEDIBLE." This was in violation of EC Directive 64/433. FASFC officials ordered immediate correction. Also, an inedible container was observed to be in contact with the liner of a container holding meat. This was another violation of EC Directive 64/433. The inedible container was moved, but the contaminated portion of the liner was not removed until the FSIS auditor pointed out the need.
- 46b In the preparation area for molds with plastic wrappings for cooked hams, an old, dirty, grossly deteriorated sheet of cardboard was routinely used as a spacer and was placed directly on open molds with the plastic wrappings in place, ready for filling. When the FSIS auditor pointed out the problem, no corrective actions were taken, either by establishment or FASFC officials.
- 47 On two occasions, employees did not wash their hands after handling unclean materials before continuing to work with edible product. This was in violation of EC Directive 64/433. FASFC officials ordered corrective actions.
- 57 There were no monthly supervisory reviews in July, or August 2002.

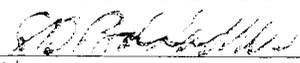
Following the audit of the premises and the documentation, the proposal of the FASFC officials was to *suspend* the establishment's eligibility to export to the United States for 30 days, but when the FSIS auditor reviewed the deficiencies from the FSIS point of view, including the fact that the establishment had been evaluated as acceptable/re-review during the FSIS audit in 2001 and had received a Notice of Intent to Delist as a result of deficiencies identified during the FSIS audit in February-March 2002, the Belgian officials agreed that the establishment did not meet FSIS requirements and agreed to voluntarily revoke its eligibility to export to the U.S. as of the start of operations on the day of the audit.

FASFC officials: Dr. Sofie Huyberechts, International Relations; Dr. lic. Johan Colle, Director, District of Gent; Dr. lic. Noël Van der Stede, internal reviewer; Dr. lic. Marc Riebbels, Veterinarian-In-Charge; Dr. Christian Props, Assistant Veterinarian. (Inspection coverage: two veterinarians.) Product exported to the U.S.: Canned shoulder picnic ham and cooked, smoked bacon

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE


 12/10/2002

B. Lee

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION N.V. Vleeswarenfabriek Deko	2. AUDIT DATE Dec. 9, 2002	3. ESTABLISHMENT NO. B-156	4. NAME OF COUNTRY Belgium
5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	X
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

B-26

60. Observation of the Establishment

Dec. 9, 2002, Est. B-156, N.V. Vleeswarenfabriek Deko, Hasselt, Belgium. FASFC officials: Dr. Sofie Huyberechts, International Relations; Dr. Jacques De Lathouwers (internal reviewer); Dr. Edith Vanhese, Veterinarian-In-Charge

39 Maintenance of some over-product equipment had been neglected: rust, dust, and flaking paint were present on motor housings and support structures above the brine stirring vats; a number of openings in ceilings, and one opening in an outside wall, where wiring and/or pipes entered production rooms were inadequately sealed. The FASFC officials ordered prompt sealing of the openings.

47 An employee was observed operating a power fork lift with unclean handles and continuing to work emptying containers of exposed pork onto a table, handling the insides of the containers in the process (the meat also contacted the insides of the containers as it was emptied onto the table). The Veterinarian-In-Charge instructed the worker to wash his hands, and the latter subsequently continued to do so each time he used the controls of the fork lift.

57 Monthly supervisory reviews were complete with one exception: there was none in March 2002.

NOTE: All previously identified deficiencies had been adequately addressed and corrected.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

*G. D. Bolstad* 12/13/2002

**Country Response Not Received**