



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Don

APR 7 2005

Dr. Hans Wyss
Director,
Federal Veterinary Office
Bern-Liebefeld
Schwarzenburgstrasse 161
CH 3003
Bern, Switzerland

Dear Dr. Wyss:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Switzerland's meat inspection system July 14 through July 28, 2004. Enclosed is a copy of the final audit report. We understand that the government of Switzerland accepted the draft final report of the same audit without comments.

If you have any questions regarding the final audit report, please contact me at telephone number (202) 720-3781. You may also reach me at facsimile number (202) 690-4040, or at e-mail address sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc.

Mary E. Revelt, Minister-Counselor, Geneva, Switzerland

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Country File (FY 2004 Audit)

FINAL

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

JULY 14 THROUGH JULY 28, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

FVO	Federal Office for Veterinarians (Bundesamt für Veterinärwesen)
CCA	Central Competent Authority (Federal Veterinary Office)
BSE	Bovine Spongiform Encephalopathy
BVET	Willkommen im Bundesamt für Veterinärwesen
Canton	State
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>Salmonella</i>	<i>Salmonella</i> species

1. INTRODUCTION

The audit took place in Switzerland from July 14 through July 28, 2004.

An opening meeting was held on July 14, 2004, in Bern 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 Switzerland's meat inspection system. A discussion was held concerning Food Safety Inspection Service (FSIS) import requirements for Bovine Spongiform Encephalopathy (BSE), *E. coli* O157:H7 in raw beef and *Listeria monocytogenes* in ready-to-eat products.

The auditor was accompanied during the entire audit by a representative from the CCA, the veterinarian-in-charge of exports from the Division of Authorizations and Controls.

2. OBJECTIVE OF THE AUDIT

Switzerland declined to allow FSIS to perform an annual audit of Switzerland's Meat Inspection System in calendar year 2002; therefore FSIS suspended Switzerland's eligibility to export meat to the United States. In calendar year 2003, Switzerland again declined to allow FSIS to perform an annual audit and the suspension continued. The objective of this audit was to determine if the suspension of Switzerland's ability to export meat products to the United States would be lifted by evaluating 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, two state inspection offices, three laboratories performing analytical testing on United States-destined product and one meat processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	State	2	
	Local	1	Establishment level
Laboratories		3	
Meat Processing Establishments		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters and state offices. The third part involved an on-site visit to one processing establishment. The fourth part involved visits to two private laboratories, Interlabor Belp AG in Belp and UFAG Laboratorien AG in Sursee. One canton (state) laboratory for the canton of Basel-Landschaft, located in Liestal, was conducting analyses of field samples for Switzerland's national residue control program and microbiology samples.

Program effectiveness determinations of Switzerland'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 a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* and *Listeria monocytogenes*. Switzerland'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 Switzerland and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained that Switzerland's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Switzerland. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for Switzerland under provisions of the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement. Currently Switzerland's has the same requirement for generic *E. coli* testing as FSIS with the following exceptions:

- Government inspection officials take *E. coli* samples.
- Government laboratories analyze the samples.

Switzerland's has the same requirement as FSIS for *Salmonella* testing for pathogen reduction performance standards with the following exceptions:

- Private laboratories analyze *Salmonella* samples in lieu of government laboratories.
- Switzerland has requested the use of a different analytical method for testing United States-destined product for *Salmonella*. FSIS has determined that Switzerland's use of the ISO 6579 method is equivalent to FSIS' requirements.

Switzerland was exempt from conducting species verification testing. However, due to special BSE classification by the Animal Plant Health Inspection Service (APHIS), this exemption has been rescinded.

Switzerland had requested an alternative microbiological laboratory testing standard for *Salmonella* and *Listeria monocytogenes* in regard to ready-to-eat meat products. In a letter dated October 31, 2002, FSIS determined that Switzerland's alternative microbiological laboratory testing standards for *Salmonella* and *Listeria monocytogenes* in regard to ready-to-eat meat products were not equivalent. FSIS also advised Switzerland that they must implement the United States' standards.

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.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following deficiencies were identified during the FSIS audit of Switzerland's meat inspection system conducted in January/February 2000:

- Inadequate control of condemned, inedible or dead-on-arrival (DOA) carcasses before off-premises shipment.
- Failure to identify hazards reasonably likely to occur.
- Failure to identify critical control points.
- Failure to document corrective actions taken.
- Failure to conduct pre-shipment verification review.
- Documentation in all establishments was inadequate.
- Variances were identified in microbiological standards for cured air-dried ready-to-eat (RTE) products for *Listeria monocytogenes* and *Salmonella* species testing.

All concerns and audit findings identified during the January/February 2000 audit were identified, addressed and corrected during the March/April 2001 audit.

The following deficiencies were identified during the FSIS audit of Switzerland's meat inspection system conducted in March/April 2001:

- In the HACCP plans of the six establishments audited, microbiological hazards had been identified as reasonably likely to occur at several process-control points. However, there was no supporting documentation that the microbiological hazards were being considered as Critical Control Points (CCP).

All concerns and audit findings identified during the March/April 2001 audit were found to be corrected during the July 2004 audit.

6. MAIN FINDINGS

6.1 Government Oversight

6.1.1 CCA Control Systems

The Central Competent Authority (CCA) in Switzerland for control of production of meat and meat products for export to the United States is the Federal Veterinary Office (FVO) of the Department Of Public Health. The FVO contains divisions which have responsibilities over Authorizations and Controls, Implementation and Support, Internal Services, Communications, Legislation and Monitoring. The Authorizations and Controls Section is responsible for control of Import and Export of live animals and animal products, Conservation of Species and Permits. The Veterinarian-in-Charge of the export section is directly responsible for the certification and decertification of United States export establishments and overseeing the supervision of export control veterinarians (contract veterinarian-in-charge of export establishments) and equal implementation of federal legislation as it pertains to the enforcement of export requirements.

The division of legal responsibilities between the Cantons (States) and the FVO is contained in the Swiss Food Law and further defined responsibilities are contained in Official Ordinances. Cantonal Veterinary Offices are responsible for the control of production of meat and meat products for the domestic market. There are 26 Cantons and 24 Canton Veterinary Offices. Two Cantons share Veterinary offices. Slaughter establishments are supervised by veterinarians and staffed by non-veterinary food inspectors. Processing establishments may be supervised by veterinary or non-veterinary food inspectors.

Each community (city) within a canton or the canton, depending on legally defined authority, is responsible for the hiring and payment for all veterinary inspectors and non-veterinary food inspectors and their assignment to establishments that produce meat and meat products for the domestic market. Slaughter establishments are assessed a fee by the canton or community for each animal slaughtered. No fee is assessed for the inspection of processing establishments that produce only for the domestic market. Export establishments are assessed an additional fee by the Cantonal Veterinary Office for supervisory reviews performed by the Cantonal Veterinarian.

Export control veterinarians assigned to export establishments are issued a separate contract for export duties by the FVO. The veterinarians under contract report hours worked per pay period to the FVO. The FVO is responsible for payment to the veterinarians and the FVO is reimbursed by the export establishment. Each contract veterinarian is required to submit a monthly supervisory report to the Authorizations and Controls division of the FVO.

6.1.2 Ultimate Control and Supervision

The FVO headquarters in Bern has ultimate control and supervision of Switzerland's meat inspection system. Although Switzerland's inspection system is supervised by the Cantonal Veterinary Offices, the FVO develops and distributes official legislation to the Cantonal Veterinary Offices. The FVO has the legal responsibility to ensure equal implementation of federal veterinary legislation. There appears to be adequate communication between the FVO and the Cantonal Veterinary Offices; and there appears to be adequate communication between Cantonal Veterinary Office and the FVO with the export control veterinarians regarding enforcement of FSIS requirements.

Legal ordinance drafted from the Swiss Food Law requires each establishment and inspection program be reviewed annually by the Cantonal Veterinary Office. The review report generated is maintained at the Cantonal Veterinary Office and also forwarded to the FVO.

Each export establishment and inspection program is required by Swiss Food Law to be reviewed annually by the export section of the Authorizations and Control division. The report generated by this review serves to meet the annual certification requirement for establishments certified to export.

The veterinarian-in-charge of export activities at the FVO headquarters has ultimate control and supervision of export establishments. Establishments requesting export status, submit a written request to the Cantonal Veterinary Office. The Cantonal Veterinarian reviews the application and forwards the application to the export section of the FVO. The veterinarian-in-charge of the establishment will verify that export requirements are met and forward that information to the Cantonal Veterinary Office. When the Cantonal Veterinarian is assured export requirements are met, the veterinarian-in-charge of exports from the FVO will conduct an on-sight audit of the establishment. The Export Section of the Authorizations and Controls Division has legal authority to certify and decertify export establishments. This office also maintains the official list of establishments certified to export to the United States.

The Authorizations and Controls Section has the responsibility for designing of export certificates. The export certificates are distributed as models to export control veterinarians by e-mail and are distributed for use in a secured method by mail.

Official inspection instructions referred to as Technical Prescriptions, are issued by the FVO in Bern. Instructions are provided by e-mail, and hard copy to the Cantonal Veterinary Offices and, through them, to the field personnel and, if appropriate, also to the establishment and/or laboratory management officials. Under the current system, it is the responsibility of the Cantonal Veterinarians to delegate implementation instructions

to the appropriate officials under their supervision, and to ensure their implementation. The FVO at their discretion, will transmit export related Technical Prescriptions directly to the export control veterinarians as well as the Cantonal Veterinary Offices.

6.1.3 Assignment of Competent, Qualified Inspectors

The Cantonal Veterinary Offices are responsible for the initial and ongoing training of veterinarians and non-veterinary inspectors in the enforcement of Swiss legislation as it pertains to the Swiss Food Law.

Non-veterinary food inspectors are required to have special training, such as a cook, butcher or have served as an apprentice in a job specialty and have successfully completed a food inspection test. Quarterly training sessions are held each year. Non-veterinary food inspectors correlate every Monday prior to receiving their weekly assignment from their non-veterinary supervisor at the Cantonal Veterinary Office.

Each veterinarian receives six weeks of on-the-job training. After the initial on-the-job training is successfully completed, a written, oral and practical exam must be successfully completed by the veterinarian prior to their final assignment. The exam consists of a pathology section, an animal health section and meat inspection section. Veterinary and non-veterinary meat inspectors must complete a course in the theory of meat inspection. Continuing education is required by legislation to be conducted biannually for each veterinary meat inspector. The Organization of Veterinary Food Hygienist offers a one day continuing education course semiannually. Training records are maintained at the Cantonal Veterinary Offices. Veterinarians located at the Cantonal Veterinary Offices and veterinarians located at the FVO are trained at the FVO. The Cantonal Veterinary Office is responsible for placing newly hired veterinary and non-veterinary meat inspectors.

The Authorization and Controls Section of the FVO is responsible for the additional training of export control veterinarians assigned to certified export establishments. This is accomplished by official instructions contained in official ordinances and training courses designed by the export section. Training courses are conducted annually. Initial HACCP training was implemented in 1998 and has continued each year to date. The majority of HACCP training given to export veterinarians has been CODEX HACCP which differs from HACCP methodology implemented within the United States.

Export control veterinarians are normally part time and are contracted by the FVO for supervision of export establishments. Normally these veterinarians are engaged in a veterinary practice or other veterinary-related activities.

Specific instructions, originating from official legislative ordinances, for the export control veterinarians outline job requirements and how to implement export requirements. Specific export requirements for establishments certified for export to the United States are transmitted by means of Technical Prescriptions to Cantonal Veterinarians for distribution or directly to export control veterinarians.

Legal ordinance drafted from the Swiss Food Law require each establishment and inspection program be reviewed annually by a veterinarian from the Cantonal Veterinary

Office. The report generated as a result of the annual review serves as the bases for a required oral supervisory performance review conducted for each veterinary inspector by the Cantonal Veterinarian. Guidelines for the performance review are taken from official legislative ordinances. The results of a satisfactory performance review are not documented. Unsatisfactory performance is documented. Supervisory inspections of export establishments and oral performance reviews for the export control veterinarian are performed annually by the Veterinarian-in-Charge of export inspections from the Office of Authorizations and Controls.

- Although the CCA offers continuing training to export control veterinarians, there was no evidence of training provided to export control veterinarians for current FSIS *Listeria monocytogenes* requirements for ready-to-eat meat products.

6.1.4 Authority and Responsibility to Enforce the Laws

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

- Verification testing programs that would meet FSIS testing requirements for *Salmonella* and *Listeria monocytogenes* in ready-to-eat meat products were not in place and ready for implementation.

6.1.5 Adequate Administrative and Technical Support

The CCA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate Switzerland's inspection system.

6.2 Audit of Headquarters, Cantons and Local Inspection Offices

The auditor conducted a review of inspection-related documents and interviewed inspection officials at the CCA headquarters located in Bern; two canton inspection offices, Bern Cantonal Veterinary Office, located in Bern and Grisons Cantonal Veterinary Office located in Chur; and one certified establishment, located in Frauenkirch. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to the establishment that were certified to export to the United States
- Training records for inspectors.
- Label approval records.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation and processing inspection procedures and standards.
- Control of products from livestock with conditions such as Tuberculosis, Cysticercosis, Bovine Spongiform Encephalopathy, and of inedible and condemned materials.

- Disease control measures relating to Brucellosis, Tuberculosis, Classical Swine Fever and Bovine Spongiform Encephalopathy (BSE).
- Export product inspection and control including export certificates.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited one certified processing establishment. If Switzerland was not suspended by FSIS and thus eligible to export meat products to the United States, the establishment audited would have received a Notice of Intent to Delist.

- The establishment audited failed to meet FSIS requirements for *Listeria monocytogenes* and had other HACCP and SSOP deficiencies.

Specific deficiencies are noted in the attached individual establishment review forms.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

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.

The following laboratories were reviewed:

Interlabor Laboratories Belp AG, located in Belp, and UFAG Laboratories AG, located in Sursee, were conducting analyses of field samples for Switzerland's National Residue Control Program. The State Laboratory for the state of Basel-Landschaft, located in Liestal, was conducting analysis of field samples for Switzerland's National Residue Control Program and Microbiological monitoring samples for food products.

Switzerland does not have any slaughter establishments certified to export to the United States; therefore laboratories are not testing for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella sp* for the pathogen reduction *Salmonella* performance standards.

The BVET National Reference and Research Laboratory located in Bern is no longer conducting analyses of field samples for Switzerland's National Residue Control Program.

No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess Switzerland'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 one establishment, and except as noted below, Switzerland's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices. The SSOP was not fully implemented in the establishment audited.

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

9.1 SSOP

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

- Unidentified white and black particles and product residue from the previous day's production were observed in a meat tumbler, three stainless steel product combos and two plastic product combos. The equipment was observed during pre-operational sanitation and was ready for the production of food products.
- Preventive measures for corrective actions were not included in the daily records documenting pre-operational sanitation noncompliances.

9.2 Sanitation Performance Standards

No deficiencies were noted.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate control over condemned and restricted product and procedures for sanitary handling of reconditioned product. The auditor determined that Switzerland's inspection system had adequate controls in place.

No deficiencies were noted

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

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

11.1 Humane Handling and Slaughter

There were no certified slaughter establishments eligible to export to the United States.

11.2 HACCP Implementation.

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

The HACCP programs were reviewed during the on-site audit of one establishment. The HACCP program was found to meet the basic FSIS regulatory requirements, with the following exceptions:

- Preventive measures for corrective actions for a deviation from a critical limit were not included in the written HACCP plan.
- Ongoing verification procedures were written in the HACCP plan and were performed, but ongoing verification activities were not documented.

11.3 Testing for Generic *E. coli*

Switzerland has adopted the FSIS requirements for generic *E. coli* testing with the exception of the following equivalent measures.

- Government inspection officials take *E. coli* samples.
- Government laboratories analyze *E. coli* samples.

The establishment audited was not required to meet the basic FSIS regulatory requirements for generic *E. coli* testing.

11.4 Testing for *Listeria monocytogenes*

In the establishment audited, ready-to-eat products were produced for potential export to the United States. In accordance with United States requirements, the HACCP plan in this establishment had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur, but was not reassessed to meet current FSIS requirements for control of *Listeria monocytogenes*.

- The establishment did not specifically address *Listeria monocytogenes* in their HACCP plan, Sanitation SOP, or other prerequisite programs for products exposed to the environment after they have undergone a lethality treatment.

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 operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

Interlabor Laboratories Belp AG, located in Belp, UFAG Laboratories AG, located in Sursee, and the State Laboratory for the states of Basel and Landschaft, located in Listal, were conducting analyses of field samples for Switzerland's National Residue Control Program.

No deficiencies were noted.

Switzerland's National Residue Testing Plan for 2004 was being followed and was on schedule.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

The establishment audited was not producing products for export to the United States, but provisions were in place to provide daily inspection for future United States export production.

13.2 Testing for *Salmonella*

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

- Private laboratories analyze *Salmonella* samples.
- Laboratory testing method: ISO 6579

The establishment audited was not required to meet the basic FSIS regulatory requirements for *Salmonella* testing to meet FSIS pathogen reduction *Salmonella* performance standards.

13.3 Verification Testing Program for Ready-to-Eat Product

Switzerland did not have a verification testing program in place that met United States' import requirements for the testing of ready-to-eat product for the presents of *Salmonella* and *Listeria monocytogenes*.

The United States has a zero tolerance for *Salmonella* in all RTE meat products, and the United States requires a sample size of 325 grams being analyzed by a qualitative enrichment method.

- Switzerland's verification testing program for *Salmonella* had results reported as acceptable if there are zero CFU/25 gram sample.

The United States has a zero tolerance for *Listeria monocytogenes* in all RTE meat products, and the United States requires a sample size of 25 grams being analyzed by a qualitative enrichment method.

- Switzerland's verification testing program for *Listeria monocytogenes* had results reported as acceptable if there are <100 CFU/25 gram sample.

13.4 Species Verification

Switzerland was exempted from conducting species verification testing. However, due to special BSE classification by APHIS, this exemption has been rescinded.

13.5 Monthly Reviews

The establishment audited was not producing product for export to the United State. Supervisory reviews were conducted quarterly.

13.6 Inspection System Controls

The CCA had controls in place for restricted product and inspection samples; shipment security; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible meat products from other counties for further processing.

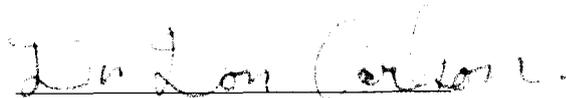
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on July 28, 2004 in Bern 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.

Dr. Don Carlson
International Audit Staff Officer

A handwritten signature in black ink that reads "Don Carlson". The signature is written in a cursive style and is positioned to the right of the typed name.

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Reports

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: July 15, 2004
 LABORATORY: Interlaboratory Belp AG (Private Laboratory)

FOREIGN GOVT AGENCY FVO	CITY & COUNTRY Belp, Switzerland	ADDRESS OF LABORATORY Birkenweg 6, Postfach CH-3123
NAME OF REVIEWER Dr. Don Carlson	NAME OF FOREIGN OFFICIAL Ruedi Camenzind Director Dr. Silke Holznagel FVO, National Representative)	

Residue Code/Name			203	501	510	800	910	923	950					
SAMPLING PROCEDURES	REVIEW ITEMS Sample Handling	ITEM # 01	EVALUATION CODE	A	A	A	A	A	A	A				
	Sample Frequency	02		A	A	A	A	A	A	A				
	Timely Analysis	03		A	A	A	A	A	A	A				
	Compositing Procedure	04		O	O	O	O	O	O	O				
	Interpret Comp Data	05		O	O	O	O	O	O	O				
	Data Reporting	06		A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A				
	Correct Tissue(s)	08		A	A	A	A	A	A	A				
	Equipment Operation	09		A	A	A	A	A	A	A				
	Instrument Printouts	10		A	A	A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A				
	Recovery Frequency	12		A	A	A	A	A	A	A				
	Percent Recovery	13		A	A	A	A	A	A	A				
	Check Sample Frequency	14		A	A	A	A	A	A	A				
	All Analyst W/Check Samples	15		A	A	A	A	A	A	A				
	Corrective Actions	16		A	A	A	A	A	A	A	A			
International Check Samples	17	A	A	A	A	A	A	A	A					
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	0	0	0	0	0	0	0				
OTHER REVIEW		19	EVAL. CODE											
		20												

Signature of reviewer Dr. Don Carlson /s/	Date July 15, 2004
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FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE July 15 2004	NAME OF FOREIGN LABORATORY Interlabor Belp AG (Private Laboratory)
FOREIGN GOVT AGENCY FVO	CITY & COUNTRY Belp, Switzerland		ADDRESS OF LABORATORY Birkenweg 6, Postfach CH-3123
NAME OF REVIEWER Dr. Don Carlson		NAME OF FOREIGN OFFICIAL Ruedi Camenzind Director Dr. Silke Holznagel (FVO), National Representative)	

RESIDUE	ITEM NO.	COMMENTS
		No comments made concerning any notable deficiencies.

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY FVO	CITY & COUNTRY Sursee, Switzerland	ADDRESS OF LABORATORY Kornfeldstrasse 4 Postfach, CH-6210
NAME OF REVIEWER Dr. Don Carlson	NAME OF FOREIGN OFFICIAL Dr. Thomas Bischofberber, Laboratory Director Dr. Silke Holznagel (FVO, National Representative)	

Residue Code/Name			100	404	406									
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		A	A	A								
	Sample Frequency	02		A	A	A								
	Timely Analysis	03		A	A	A								
	Compositing Procedure	04		0	0	0								
	Interpret Comp Data	05		0	0	0								
	Data Reporting	06	A	A	A									
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A									
	Correct Tissue(s)	08	A	A	A									
	Equipment Operation	09	A	A	A									
	Instrument Printouts	10	A	A	A									
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A									
	Recovery Frequency	12	A	A	A									
	Percent Recovery	13	A	A	A									
	Check Sample Frequency	14	A	A	A									
	All Analyst W/Check Samples	15	A	A	A									
	Corrective Actions	16	A	A	A									
	International Check Samples	17	A	A	A									
REVIEW	Corrected Prior Deficiencies	18	0	0	0									
OTHER REVIEW		19												
		20												

Signature of reviewer	Dr. Don Carlson /s/	Date	July 16, 2004
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FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE July 16 2004	NAME OF FOREIGN LABORATORY UFAG laboratorien (Laboratory) AG (Private Laboratory)
FOREIGN GOV'T AGENCY FVO	CITY & COUNTRY Sursee, Switzerland	ADDRESS OF LABORATORY Kornfeldstrasse 4 Postfach, CH-6210	
NAME OF REVIEWER Dr. Don Carlson	NAME OF FOREIGN OFFICIAL Dr. Thomas Bischofberber, Laboratory Director Dr. Silke Holznagel (FVO, National Representative)		

RESIDUE	ITEM NO.	COMMENTS
		No comments made concerning any notable deficiencies.

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
July 19, 2004

LABORATORY NAME
Kantonales Laboratorium / Cantonal Laboratory
Basel-Landschaft

FOREIGN GOVT AGENCY FVO	CITY & COUNTRY Liestal, Switzerland CH-4410	ADDRESS OF LABORATORY Hammerstr. 25
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NAME OF REVIEWER Dr. Don Carlson	NAME OF FOREIGN OFFICIAL Dr. Niklaus Jaggi, Laboratory Director Dr. Silke Holznagel (FVO), National Representative)
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Residue Code/Name			200	500	<i>E. coli</i>	<i>Sal. sp</i>	<i>List. m</i>							
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		A	A	A	A	A						
	Sample Frequency	02		A	A	A	A	A						
	Timely Analysis	03		A	A	A	A	A						
	Compositing Procedure	04		O	O	O	O	O						
	Interpret Comp Data	05		O	O	O	O	O						
	Data Reporting	06	A	A	A	A	A							
ANALYTICAL PROCEDURES			EVALUATION CODE	A	A	A	A	A						
	Acceptable Method	07		A	A	A	A	A						
	Correct Tissue(s)	08		A	A	A	A	A						
	Equipment Operation	09		A	A	A	A	A						
	Instrument Printouts	10	A	A	A	A	A							
QUALITY ASSURANCE PROCEDURES			EVALUATION CODE	A	A	A	A	A						
	Minimum Detection Levels	11		A	A	A	A	A						
	Recovery Frequency	12		A	A	O	O	O						
	Percent Recovery	13		A	A	O	O	O						
	Check Sample Frequency	14		A	A	A	A	A						
	All Analyst W/Check Samples	15		A	A	A	A	A						
	Corrective Actions	16		A	A	A	A	A						
	International Check Samples	17	A	A	A	A	A							
REVIEW	Corrected Prior Deficiencies	18	Eval. Code	O	O	O	O	O						
OTHER REVIEW		19	EVAL. CODE											
		20												

Signature of reviewer: Dr. Don Carlson /s/ Date: July 19, 2004

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE July 19, 2004	NAME OF FOREIGN LABORATORY Kantonaes Laboratorium (Cantonal Laboratory) Basel-Landschaft
FOREIGN GOV'T AGENCY FVO	CITY & COUNTRY Liestal, Switzerland CH-4410	ADDRESS OF LABORATORY Hammerstr. 25	
NAME OF REVIEWER Dr. Don Carlson	NAME OF FOREIGN OFFICIAL Dr. Niklaus Jaggi, Laboratory Director Dr. Silke Holznagel (FVO), National Representative)		
RESIDUE	ITEM NO.	COMMENTS	
		No comments made concerning any notable deficiencies.	

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Albert Spiess AG Fleischtrocknerei CH-7275 Davos Frauenkirch, Switzerland	2. AUDIT DATE 07/21/2004	3. ESTABLISHMENT NO. 205	4. NAME OF COUNTRY Switzerland
		5. NAME OF AUDITOR(S) Dr. Don Carlson	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.	X	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.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	X	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights	O	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	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Notice of Intent to Delist (NOID)	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Switzerland. Est.205. July 21, 2004. Albert Spiess AG. Davos, Frauenkirch, Switzerland

10. Unidentified white and black particles and product residue from the previous day's production were observed in a meat tumbler, three stainless steel product combos and two plastic product combos. The equipment was observed during pre-operational sanitation and was ready for the production of food products. Appropriate corrective actions were initiated by the establishment and the official BVET inspector. [Regulatory references: 9CFR § 416.13]
- 13/51. Preventive measures for corrective actions were not included in the daily records documenting pre-operational sanitation noncompliances. [9CFR §§ 416.16 (a) and 416.17]
- 20/51. Preventive measures for corrective actions for a deviation from a critical limit were not included in the written HACCP plan. [9CFR §§ 417.3 (a) and 417.8]
- 21/51. The establishment had implemented a testing procedure for the presences *Listeria monocytogenes* in ready-to-eat dried meat products, but the establishment did not specifically address *Listeria monocytogenes* in their HACCP plan, Sanitation SOP, or other prerequisite programs for products exposed to the environment after they have undergone a lethality treatment. [9CFR §§ 430.4, 417.4 (a) (3) and 416.17]
- 22/51. Ongoing verification procedures were written in the HACCP plan and were performed, but ongoing verification activities were not documented. [9CFR §§ 417.5 (a)(3) and 417.8]
51. The CCA did not have a verification testing program in place that met FSIS requirements for *Listeria monocytogenes*. *Listeria monocytogenes* is monitored and is a part of a state monitoring program for ready-to-eat products. The results are reported as acceptable if the results are <100 CFU/25 gram sample which does not meet FSIS requirements of zero CFU/25 gram sample. [9CFR §§ 327.3 and 417.8]
58. If Switzerland was not suspended by FSIS and thus eligible to export meat products to the United States, this establishment would have received a Notice of Intent to Delist and been required to adequately address and correct the deficiencies within 30 days.

61. NAME OF AUDITOR

Dr. Don Carlson

62. AUDITOR SIGNATURE AND DATE

Dr. Don Carlson /s/ July 21, 2004

Foreign Establishment Profile

Part A - General Information

1. ESTABLISHMENT NAME AND LOCATION Albert Spiess AG Fleischtrocknerei CH-7275 Davos Frauenkirch, Switzerland	2. DATE July 21, 2004	3. ESTABLISHMENT NO. 205
	4. NAME OF COUNTRY Switzerland	

Part B - Establishment Operation

5. TYPE OF OPERATION (check all that apply)	6. SIZE OF ESTABLISHMENT (per HACCP criteria)	7. NUMBER OF ESTABLISHMENT EMPLOYEES
<input type="checkbox"/> SLAUGHTER <input type="checkbox"/> FREEZER/COLD STORE	<input type="checkbox"/> LARGE <input type="checkbox"/> VERY SMALL	
<input checked="" type="checkbox"/> PROCESSING	<input checked="" type="checkbox"/> SMALL	27

Part C - Processes/Products

8. SLAUGHTER

<input type="checkbox"/> YOUNG CHICKENS	<input type="checkbox"/> PORCINE	<input type="checkbox"/> OVINE	<input type="checkbox"/> CAPRINE	<input checked="" type="checkbox"/> DUCKS	<input type="checkbox"/> GEESE	<input type="checkbox"/> GUINEA
<input type="checkbox"/> MATURE CHICKENS	<input type="checkbox"/> EQUINE	<input type="checkbox"/> CALVES	<input type="checkbox"/> TURKEYS	<input type="checkbox"/> BOVINE	<input type="checkbox"/> RATITES	<input type="checkbox"/> OTHER

9. OTHER PRODUCT CATEGORIES

<input type="checkbox"/> RAW MEAT (GROUND)	<input type="checkbox"/> RAW MEAT (NOT GROUND)	<input type="checkbox"/> THERMALLY PROCESSED/COMMERCIALY STERILE
<input checked="" type="checkbox"/> NOT HEAT-TREATED (SHELF STABLE)	<input type="checkbox"/> HEAT-TREATED (SHELF STABLE)	<input type="checkbox"/> PRODUCT WITH SECONDARY INHIBITORS (NOT SHELF STABLE)
<input type="checkbox"/> FULLY COOKED (NOT SHELF STABLE)	<input type="checkbox"/> EGG PRODUCT	<input type="checkbox"/> HEAT-TREATED (NOT FULLY COOKED/NOT SHELF STABLE)

10. SOURCE OF MEAT, POULTRY OR EGG PRODUCTS

SPECIES	COUNTRY OF ORIGIN	ESTABLISHMENT NUMBER
Swine	Domestic (Swiss)	
Bovine	Brazil, Domestic (Swiss)	

For US production Brazil, Uruguay & Argentina Last export to US 2001 therefore potential sources

Part D - Remarks (Use additional sheets of paper if necessary)

Willi Schoch Quality Manager.
Aldo Scaruffi Production Manager
Company established in 1906
There are two processing establishments in Switzerland.
There is one establishment in Australia.

11. NAME OF AUDITOR Dr. Don Carlson	12. AUDITOR SIGNATURE AND DATE Dr. Don Carlson /s/ 07/21/2004
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Country Response Not Received