



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JAN 20 2004

Mr. Peter Weber
Chief Veterinary Officer
Veterinary Services
Budeskanzleramt
Radetzkystrasse 2
A-1031 Wien
Austria

Dear Mr. Weber:

The Food Safety and Inspection Service has completed an on-site audit of Austria's meat inspection program. The audit was conducted from June 30 through July 11, 2003. Enclosed is a copy of the final audit report. Comments from Austria have been included in the final report.

If you have questions regarding the audit or need additional information, please contact me at 202-720-3781, facsimile at 202-690-4040, and electronic mail at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Marcus Bertmann, Economic Counselor, Embassy of Austria, Washington, DC
Robert Curtis, Minister Counselor, FAS, US Embassy, Austria
Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the US
Norval Francis, Minister/Counselor for Agricultural Affairs, USEU/Brussels
Linda Swacina, Deputy Administrator, FSIS
James Dever, FAS Area Officer
Sally Stratmoen, Director, IES, OIA
Karen Stuck, Assistant Administrator, OIA
Donald Smart, Review Staff, PEER
Dave Young, ITP, FAS
Clark Danford, Director, IEPS, OIA
Amy Winton, State Department
Nancy Goodwin, IES, OIA
Todd Furey, IES, OIA
Austria Country File (Audit FY 2003—July 03)

FINAL

JAN 6 2004

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

June 30 through July 11, 2003

Food Safety and Inspection Service
United States Department of Agriculture

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14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority - Veterinary Services-Meat Hygiene/Residue Control/Poultry Hygiene/Raw Material of Animal Origin- Ministry of Health and Women
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species
<i>LM</i>	<i>Listeria monocytogenes</i>

1. INTRODUCTION

The audit took place in Austria from June 30 through July 11, 2003.

An opening meeting was held on June 30, 2003 in Vienna 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 relating to travel to various locations needed to complete the audit of Austria's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, Veterinary Services-Meat Hygiene/Residue control/Poultry Hygiene/Raw Material of Animal Origin-Ministry of Health and Women, and representatives from the Provincial and District Offices while visiting the establishment and the laboratories.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit with emphasis on the corrective actions taken in response to the last FSIS audit, which was conducted in March 2002. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the processing establishment previously certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: The headquarters of the CCA, one establishment and two laboratories. In addition, the auditor interviewed two officials, one from a Provincial Office and one from a District Office.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	*Provincial	1	Interview was held with head of the Office
	*District	1	Interview was held with head of the Office
	Local	1	Establishment level
Laboratories		2	
Meat Slaughter Establishments		N/A	
Meat Processing Establishments		1	
Cold Storage Facilities		N/A	

* Office was not visited

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 interviews with two inspection officials, one from the Provincial Office and one from the District Office. The third part involved an on-site visit to one processing establishment. The fourth part involved visits to two laboratories; one was a private laboratory and the other one was a government laboratory. The Institute for Bio-Analytic and Hygiene, the private laboratory, was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. The Federal Institute for Veterinary Medicine Examinations, the government laboratory, was conducting analyses of field samples for Austria's national residue control program.

Program effectiveness determinations of Austria'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*. Austria'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 Austria and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Austria under provisions of the Sanitary/Phytosanitary Agreement. The following equivalence determinations have been made for Austria.

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

Austria uses government laboratories to analyze samples for generic *E. coli*.

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

Austria uses establishment employees to select samples for *Salmonella* testing.

Austria uses private laboratories to analyze samples for *Salmonella*.

Austria collects 230 grams of raw ground product for analysis for *Salmonella*.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stock farming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' web site at www.fsis.usda.gov/ofotsc.

The following problems were noted during last two audits.

Audit of March 2000

- Continuing problems with implementation of HACCP
- One instance of actual contamination of product
- Non-implementation of zero fecal tolerance by the establishment and non-enforcement of fecal zero tolerance by inspection officials
- Non-denaturization of condemned product
- Lack of boneless meat re-inspection program
- Improper interpretation of generic *E. coli* results

Audit of March 2002

- Continuing problems with implementation and maintenance of SSOP
- Continuing problems with implementation and maintenance of HACCP
- Instances of actual product contamination
- Non-implementation of zero fecal tolerance by the establishment and non-enforcement of fecal zero tolerance by inspection officials
- Lack of boneless meat re-inspection program
- Improper interpretation of generic *E. coli* results
- No check samples were provided to analysts in the laboratories to test their proficiency

All of the above deficiencies were repeat deficiencies.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

There has been a change in the organizational structure of the Austrian Veterinary Services since the March 2002 FSIS audit of Austria's meat inspection system. Veterinary Services is now part of the Federal Ministry of Health and Women.

6.2.1 CCA Control Systems

FSIS regulations require that foreign countries that wish to become eligible to export meat to the United States or to maintain their current eligibility be organized and administered by the national government. More specifically, there must be sufficient organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all establishments producing product for export to the United States. Second, the national government must have ultimate control and supervision over the official activities of all employees and licensees. Third, the national government must ensure the assignment of competent, qualified inspectors. Fourth, national inspection officials must have the authority and responsibility to enforce the laws and regulations governing meat inspection. Finally, the country must have adequate administrative and technical support to operate its inspection program.

Veterinary Services is managed indirectly by the federal administration. Federal administration is undertaken by the Provincial authorities who have the authority to issue directives relating to government oversight. All directives from the federal administration are sent to the Provincial offices, which are responsible for ensuring compliance by issuing their own instructions.

6.2.2 Ultimate Control And Supervision

As indicated above, Veterinary Services is indirectly managed by the federal administration through the Provincial and District Offices. Provincial Offices have the authority to supervise the activities of the District Offices, and the District Offices have the authority to supervise the activities of the in-plant veterinarians. Through a linear system, regulations and instructions are distributed by the CCA for implementation at the establishment level.

There appears to be no direct supervision from the CCA on activities of the field offices. Provincial Offices can develop instructions and checklists for use in the establishments, but they vary considerably in the detailing of specific information and in the level of personal contact with the individuals being supervised. To begin with, information is normally distributed via a CCA Intranet. This Intranet contains all of the applicable regulations and instructions, with new and updated instructions being identified as such. All applicable regulations are rendered or incorporated into instructions, as needed, by the CCA.

Checklists are normally developed from one or more instructions, either in part or in total, to ensure that inspection personnel account for all the provisions of the instructions.

There is very little direct field supervision by the CCA or the Provincial Office to verify the full implementation of legislation and regulatory instructions. Verification of the implementation of these regulations/instructions and the direct supervision of resident veterinarians and inspectors is the responsibility of the District Veterinarian. Consequently, the Provincial Head and the CCA were unaware of improper or inadequate interpretation and implementation of HACCP, SSOP and other FSIS requirements.

Correlation by the CCA Headquarters Office, with Provinces, Districts and field veterinarians is through the use of office meetings with management and supervisory personnel. However, no records of the attendance or the subject matter discussed are kept. There is very little supervision of the in-plant veterinary inspector.

6.2.3 Assignment of Competent, Qualified Inspectors

Private practitioners are hired on a part-time basis. These practitioners usually belong to a veterinary clinic or have a clinic of their own, and possess a veterinary degree. They are required to take the public health and/or animal health training after they are hired. They sign an employment contract and are advised to avoid any situations where a conflict-of-interest might occur.

6.2.4 Authority and Responsibility to Enforce the Laws

The CCA has indirect authority and responsibility to enforce the applicable laws relevant to U.S. certified establishments. Provincial Offices have the authority to approve establishments for export to the United States, and also the responsibility for withdrawing such approval when establishments do not have adequate and/or effective controls in place to prevent, detect, and eliminate product contamination/adulteration. Information

on status of the establishment(s) from the Provincial authorities is then communicated to the CCA. Establishments wishing to export product to the United States write a letter to the Provincial Office serving the Province where the establishment is located which assigns a District veterinarian the task of auditing the establishment and making a recommendation to the Provincial Office. If approved, the recommendation is forwarded to the CCA at Headquarters for confirmation and U.S. notification.

6.2.5 Adequate Administrative and Technical Support

The CCA consists of three veterinarians who have the responsibility to oversee activities of about 12,000 meat and poultry processing establishments and retail shops. It appears that CCA has only the bare minimum of resources to support third party audits.

6.3 Headquarters Audit

The auditor conducted interviews with two of the CCA veterinarians regarding government oversight functions and reviewed documents relating to supervisory visits to the certified establishment.

Documents reviewed included:

- Supervisory visits to establishments that were certified to export to the U.S.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Residue plans for 2003 and results from 2002.

The following concern arose as a result the examination of these documents.

It appears that the CCA lacks human and financial resources to provide direct oversight on activities of the certified establishment.

6.3.1 Audit of Regional and Local Inspection Sites

No on-site visits were made to the Provincial and District Offices responsible for oversight of the establishment. However, interviews were held with officials from both offices.

Control and supervision of the veterinary inspector in the establishment was inadequate. Little oversight is provided to the official inspector from provincial and higher levels. The inspector had no set hours of work and visits when time is available. Higher officials become aware of his visit only from reviewing a copy of the charges billed to the establishment.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited one processing establishment.

This establishment had been delisted by Austria as result of the March 2002 FSIS audit and it remained delisted following the current audit.

Specific deficiencies are noted on the attached individual establishment report.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the 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 evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following laboratories were reviewed:

1. Institute for Bio-Analytic and Hygiene, Perg, Upper Austria
2. Federal Institute for Veterinary Medicine Examinations, Modling

The first institute is a private accredited laboratory for microbiology and the second institute is the government institute and the reference laboratory for drugs and residue testing.

Our auditor found that the private accredited laboratory uses analytical methods to test samples for *Listeria monocytogenes* that have not been determined to be equivalent to FSIS methods.

A farm was also visited to verify proper control, storage and application of prescribed drugs for the treatment of animals. All drugs were properly secured and used. The owner and veterinarian kept a log of all drugs administered at the farm. The government veterinarian verifies proper drug use on a regular basis.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishment, inspection system had inadequate controls in place for SSOP programs, some aspects of facility and equipment sanitation and prevention of actual or potential instances of product cross-contamination. Inspection system had controls in place for good personal hygiene and practices, good product handling and storage practices water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

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

- Heavily beaded condensation was noted above exposed product in several areas of the establishment.
- Residues from previous days' operations were noted on ready-to-use tools and equipment.

These were repeat findings.

9.2 EC Directive 64/433

In the establishment audited, provisions of EC Directive 64/433 were not effectively implemented in the area of the pest control and lighting. Specific deficiencies are noted in the attached establishment report.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product.

Austria does not have any approved slaughter establishments at the present time. The auditor determined that Austria's inspection system had adequate controls in place for other areas.

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

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem

inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments. Austria does not have any approved slaughter establishments at the present time, therefore requirements concerning ante-mortem, post-mortem inspection procedures, dispositions, and generic *E. coli* testing do not apply.

11.1 Humane Handling and Humane Slaughter

Austria does not have any approved slaughter establishments at the present time.

11.2 HACCP Implementation

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

The HACCP program was reviewed during the on-site audit of the establishment. No deficiencies were noted.

11.3 Testing for Generic *E. coli*

Austria does not have any approved slaughter establishments at the present time; therefore, testing for generic *E. coli* is not required.

11.4 Testing for *Listeria monocytogenes*

The establishment audited was producing ready-to-eat products for export to the United States. In accordance with FSIS requirements, the HACCP plan in this establishment had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

11.5 EC Directive 64/433

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

12. RESIDUE CONTROLS

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

- Analysis for hormones, antibiotics and sulfonamides, although slightly improved, is not very timely.
- Proficiency testing for quality assurance program is not being done.
- No check sample program is conducted to test the efficiency of individual chemist for each compound he/she is responsible for analyzing. The Institute has recently started participating in an interlab check sample testing program.

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

12.1 EC Directive 96/22

In the Federal Institute for Veterinary Medicine Examination in Modling, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

Except as noted in Section 12 above regarding the proficiency testing program at the Federal Institute at Modling, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

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

In the establishment visited, there were deficiencies in the inspection controls involving monitoring of establishment compliance, pre-operational sanitation inspection and monitoring of the corrective actions. Inspectors lacked adequate knowledge of FSIS' HACCP and SSOP requirements as evidenced by the lack of HACCP and SSOP verification in the establishment. No records of time and actual values observed by the inspector had been documented.

13.1 Daily Inspection in Establishments

Daily inspection had not been provided as required by FSIS regulations. Therefore, the establishment remains delisted.

13.2 Testing for *Salmonella*

Austria does not have any approved slaughter establishments; therefore, testing for *Salmonella* is not required.

13.3 Species Verification

Species verification was being conducted as required in the establishment visited.

13.4 Monthly Reviews

During this audit it was found that in the establishment visited, monthly supervisory reviews were being performed.

13.5 Inspection System Controls

Inspection system controls were inadequate in the establishment visited. Inspectors had not enforced procedures to ensure that the establishment had taken permanent corrective actions for observed deficiencies. Repeat deficiencies were noted in SSOP and sanitation. Details are provided in the attached establishment report.

Controls were in place for the importation of meat only from approved establishments from eligible other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

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

14. CLOSING MEETING

A closing meeting was held on July 11, 2003 in Vienna 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. Ghias Mughal
Chief, International Audit Staff

A handwritten signature in cursive script, reading "Ghias Mughal", is written over a horizontal line.

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Audit Forms

Foreign Country Response to Draft Final Audit Report

6/3/2003

Institute for Bio-Analytic and Hygiene

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY Private accredited laboratory	CITY & COUNTRY Perg, Upper Austria	ADDRESS OF LABORATORY Perg, Upper Austria
NAME OF REVIEWER Dr. Ghias Mughal	NAME OF FOREIGN OFFICIAL Dr. Peter Stangl	

Residue Code/Name			E.co	Sal	List															
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE																	
	Sample Handling	01		A	A	A														
	Sampling Frequency	02		A	A	A														
	Timely Analyses	03		A	A	A														
	Compositing Procedure	04		O	O	O														
	Interpret Comp Data	05		O	O	O														
	Data Reporting	06	A	A	A															
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	C															
	Correct Tissue(s)	08	A	A	A															
	Equipment Operation	09	A	A	A															
	Instrument Printouts	10	O	O	O															
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O	O	O															
	Recovery Frequency	12	O	O	O															
	Percent Recovery	13	O	O	O															
	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	O	O	O															
REVIEW	Corrected Prior Deficiencies	18	O	O	A															
OTHER REVIEW		19	EVAL. CODE																	
		20	EVAL. CODE																	

SIGNATURE OF REVIEWER
 (for Ghias Mughal DVM)

DATE
 10/17/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

6/3/2003

NAME OF FOREIGN LABORATORY

Institute for Bio-Analytic and Hygiene

FOREIGN GOV'T AGENCY

Private accredited laboratory

CITY & COUNTRY

Perg, Upper Austria

ADDRESS OF LABORATORY

Perg, Upper Austria

NAME OF REVIEWER

Dr. Ghias Mughal

NAME OF FOREIGN OFFICIAL

Dr. Peter Stangl

RESIDUE

ITEM NO.

COMMENTS

07

This laboratory was using an analytical method not approved by FSIS.

FOREIGN COUNTRY LABORATORY REVIEW

6/4/2003

Federal Institute for Veterinary Medicine
 Examinations

FOREIGN GOV'T AGENCY
 Federal Ministry of Social Security and
 Generations

CITY & COUNTRY
 Modling, Austria

ADDRESS OF LABORATORY
 Robert Kochgasse 17
 2340 Modling, Austria

NAME OF REVIEWER
 Dr. Ghias Mughal

NAME OF FOREIGN OFFICIAL
 Dr. Marina Mikula

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

Dr. Ghias Mughal

10/15/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

6/4/2003

NAME OF FOREIGN LABORATORY

Federal Institute for Veterinary Medicine
Examinations

FOREIGN GOV'T AGENCY

Federal Ministry of Social Security and
Generations

CITY & COUNTRY

Modling, Austria

ADDRESS OF LABORATORY

Robert Kochgasse 17
2340 Modling, Austria

NAME OF REVIEWER

Dr. Ghias Mughal

NAME OF FOREIGN OFFICIAL

Dr. Marina Mikula

RESIDUE	ITEM NO.	COMMENTS
100,200, 203,400, 500,800	3	Samples for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, antibiotics, and sulfonamides were not analyzed in a timely manner. Timely analyses is critical for hormones, antibiotics and sulfonamides.
800	14	This is a reference laboratory for all group A and some group B compounds. The proficiency test (intralaboratory and/or interlaboratory check samples) for quality assurance program is not performed for all compounds. The laboratory has recently started participating in "FAPAs" check sample program.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Greisinger Fleisch-, Wurst-und Selchwarenerzeugung GmbH Klamerstraße 10, A-4323 Munzbach, Austria	2. AUDIT DATE July 02, 2003	3. ESTABLISHMENT NO. Est. 08	4. NAME OF COUNTRY Austria
	5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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	
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.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
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.	X	47. Employee Hygiene	
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	X
23. Labeling - Product Standards		51. Enforcement	X
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	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Establishment: 08

Date of Audit: July 02, 2003

- 11 Residues from previous days' operations were observed on knives, knife box and some red colored plastic meat containers - all ready for use or in use. Some knife sharpening steels were touching employees' boots.
- 12 Heavily beaded condensation was observed above exposed product in several areas of the establishment.
- 19 Verification of CCPs was not timely - Verification is done on annual basis. Equipment calibration is done on a quarterly basis.
38. Lighting at the meat reconditioning table was less than adequate.
- 40 Cobwebs and spiders were observed in the large box storage room (dry storage room). Also, flies were observed in the hallway leading from the main entrance of the establishment.
- 50 Inspector visits establishment for one hour either on morning or on afternoon shift, inspection is never provided on both shifts.
- 51 Inspectors were not documenting FSIS's SSOP and HACCP monitoring and/or verification requirements.
- 56 No inspection coverage had been provided on the second shift.
58. Establishment remained delisted for failure to meet daily inspection requirements and for findings of several repeat deficiencies.

61. NAME OF AUDITOR

Dr. M. Ghias Muzhal

62. AUDITOR SIGNATURE AND DATE

for Manzoor H. Chaudry 10/15/03

BUNDESMINISTERIUM FÜR
GESUNDHEIT UND FRAUEN



Dr. Karen Stuck
Chief, Import and
Export Policy Section
Office of Policy, Program Development
and Evaluation

GZ 39.162/5-IV/B/7/03

Wien, 25. August 2003

**Subject: Comments to mission to Austria from June 30 through
July 11, 2003**

Dear Dr. Stuck:

The Austrian Veterinary Services of the Federal Ministry of Health and Women would like to give some advance information concerning the audit that was conducted between June 30 and July 11, 2003.

As a consequence of the audit in 2002, the establishment Est. 08 was removed from the list of certified establishments. Regarding this fact, the Austrian Veterinary Services asked for re-certification of this establishment and FSIS conducted a re-certification audit in July 2003.

This audit was held by Dr. Ghias Mughal, chief of the International Audit Staff. This audit covered all aspects of the Austrian inspection system, as Pathogen Reduction program, HACCP and SSOP implementation, the implementation of EC Directives and the corrective actions which were taken.

In the exit meeting on July 11, 2003 Dr. Mughal addressed that there were only little indications that corrective actions were taken in response to the audit of March 2002. The fact is that Establishment 8 presented – after the last audit of March 2002 – a catalogue of measures in order to show how and in which period of time they will take all the corrective actions. This catalogue of measures included construction measures, corrections relating to hygiene and development of HACCP. The actual audit showed that most of the problems were solved.

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Due to the fact that deficiencies were observed during the audit of July 2003, the official veterinarians, responsible for this plant, took actions immediately. In the opinion of the Austrian Veterinary Services, it is not correct that in the establishment corrective actions were either lacking, inadequate or ineffective, because improvements were noticeable.

Deficiencies of the sanitation controls as spiders and cobb webs which had been observed in the box storage room, flies in the hall way leading from the entrance, lighting at the meat reconditioning station and residues from the previous day's operation in some ready to use tools and equipment were corrected. The technical equipment was improved and repaired or in some cases replaced (e.g. stainless steel buggies).

The problem of condensation which had been observed especially in one working area was solved. A second cooling aggregate was installed. During the controls by the official veterinarian, there was no condensation observed.

As attachment (A), you will find three reports by the official veterinarian of the district administrative authority (02.07.2003, 10.07.2003 and 07.08.2003) for your information.

As from now, the daily enforcement controls will be done by two official veterinarians according to a weekly plan which is presented to the supervising district administrative authority in advance. This plan includes both shifts and the minimum time of the control which should be one hour per shift. Two veterinarians are responsible for these daily controls of both shifts. The inspectors will direct their attention to the preoperational shift as well and they will document this preoperational sanitation inspection. Since calendar week 30 the inspection personnel assigned to this establishment enforced their controls with efficiency, covering the whole time of production and the documentation as required by the FSIS. It is ensured that all sectors of the establishment are regular part of the control and that HACCP, especially the CCPs and the SSOP are part of the daily controls (see attachment B).

In addition to the daily checking there will be a monthly supervision (at least once per month, but if necessary the inspections will be increased) by the official veterinarian of the district administrative authority of Perg. Beyond this, the Provincial Government of Upper Austria will conduct an audit of this establishment twice a year.

In general, the Austrian Veterinary Services would like to emphasize that the Veterinary Services are organized in **indirect federal administration**. In other words, the federal administration is undertaken by the provincial authorities under the authority of the federal ministers (Legal Basis: Federal Constitution Law, B-VG), who are authorized to issue orders.

Orders from federal ministers in indirect federal administration must always be directed to the federal provincial governor who **must** ensure that in indirect federal administration the federal regulations are complied with also by the provincial authorities under his responsibility (district administrative authorities, mayors).

In order to carry out these tasks in direct federal administration, meaning that employees of the Federal Ministry have the government supervision, it would be necessary to change the Federal Constitution of Austria. This is – to date – not possible.

But in future the Federal Minister will appoint inspection personnel for control and supervision of establishments which export to the US. For this purpose it was necessary to make legal adjustments by way of an amendment of the Meat Inspection Act.

The amendment of the Meat inspection Act implies that establishments have to be charged for this kind of service.

These appointed inspectors will be instructed and supervised by the Federal Minister and are to control all certified establishments.

The microbiological testing for Listeria is being performed in authorized laboratories! The legal basis for the approval of the laboratories can either be Article 27 of the Meat Inspection Act or Articles 42, 49 or 50 of the Food Act.

As attachment you will find results of Listeria testing. The samples were taken by an **official** of the Provincial government of Upper Austria and investigated by the Austrian Agency for Health and Food Safety (Attachment C). In future there will be a Listeria testing according to the FSIS requirements.

The Laboratory in Perg, which is testing for Listeria as well, is a private lab, but approved officially under § 50 of the Food Act.

Beside the official samples, the establishment is testing their products for Listeria as part of the self control program in authorized laboratories.

Referring to the concern that timely analyses are critical for hormones, antibiotics and sulfonamides:

With regard to the available staff and equipment the analyses are performed as quickly as possible to ensure an effective residue control system. Nevertheless, there is no EC -Regulation or Decision where it is required to perform and finalize the analyses of official samples for monitoring of residues in a certain time period.

It is the aim of the Agency to improve this and to fulfil all criteria in order to ensure the quality and comparability of the analytical results in the official residue control.

Referring to the concern that proficiency tests for quality assurance programs were not performed for sulfonamides:

As pointed out during the audits, in each batch at least one spiked control sample and if necessary a negative control sample or samples with different internal standards are analysed in order to control the whole procedure of analyses. According to relevant EC-regulations and the accreditation standard ISO 17025 additional control samples are not obligatory.

The Agency - Veterinary Med. Examinations Mödling, takes part in different ringtests – as shown during the audit – which are organized by FAPAS-United Kingdom, or the Community Reference Laboratories in Bilthoven, Fougères and Rome.

Due to the fact that Est. 8 is not approved for US-export it was not possible to present a preshipment control. In order to show how they will do preshipment control in future you will find a draft of the report as an attachment (Attachment D).

The Veterinary Services hope that by this information it will become obvious to you that corrective actions in the sanitation area have been taken, that veterinary inspection is newly organised and that governmental supervision has been improved.

For the Federal Minister:
Dr. DAMOSER



Dr. Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs
e-Mail: sally.stratmoen@usda.gov

GZ: 39.162/13-IV/B/7/03

Wien, am 17.12.2003

Subject: Comments from Austria to Draft Final Audit Report of the mission to Austria from June 30 through July 11, 2003

Dear Dr. Stratmoen:

The Austrian Federal Ministry of Health and Women thank you for the Draft Final Audit Report concerning the audit that was conducted between June 30 and July 11, 2003.

At the beginning, the Veterinary Services would like to refer to the statements of Austria to this mission sent to FSIS on August 25, 2003 (GZ 39.162/5-IV/B/7/03).

In addition to this, there are some general and technical comments to the Draft Final Audit Report:

2. OBJECTIVE OF THE AUDIT:

It is not correct that the processing establishment – at that time - was certified by the CCA, because in 2002 the plant was removed from the list of certified establishments.

3. PROTOCOL

Paragraph 4: In general the correct standards for auditing meat products establishments are those laid down by Directive 77/99/EC and not Directive 64/433/EEC plus the special conditions laid down in Annex V of the EC/US Veterinary Agreement. See also page 7 (4. LEGAL BASIS FOR AUDIT), page 12 (9.2 EC Directive 64/433) and page 13 (11.5 EC Directive 64/433)

On page 7: Austria collects 250 (and not 230) grams of raw ground product for analysis for Salmonella.

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6. MAIN FINDINGS

6.2.5 Adequate Administrative and Technical support

It is correct that the CCA consists of three veterinarians. The responsibility of these three persons is to oversee the meat and poultry processing establishments (not the retail shops, they are under the responsibility of another department) and residue control and animal by-products.

6.3 last paragraph:

As already mentioned in the letter from August 25, 2003 the Federal Ministry of Health and Women nearly finalized the legal adjustments by way of an amendment to the Meat Inspection Act in order to appoint personnel for control and supervision of exporting establishments. Consequently in 2004, there will be a reorganization (increase of staff) in order to provide direct supervision of activities of certified establishments.

Pending the fact that the lack of human resources is solved, the inspectors will be trained in order to get better knowledge of FSIS requirements for Sanitation Standard Operating Procedures and Hazard Analysis and Critical Control Point systems.

6.3.1. Audit of Regional and Local Inspection Sites

Second paragraph:

Austria does not agree that the control and supervision of the veterinary inspector in the establishment is incorrect. The veterinary inspector visits the establishment daily. The time of control is different from day to day and not exactly determined in order to get a better overview and control of the production. The official veterinarian is responsible for the supervision of the veterinary inspector periodically (e.g. control of audit documents, establishment control, ..), a daily presence of an official veterinarian in a meat processing plant is not an obligatory requirement.

8. RESIDUE AND MICROBIOLOGICAL LABORATORY

Comments see letter from August 25, 2003 (GZ 39.162/5-IV/B/7/03).

Concerning the methods to test for *Listeria monocytogenes*: The laboratory in Perg is accredited (EN/ISO IEC 17025). The procedure A W06601/11/1 for analysing *Listeria monocytogenes* is in our opinion a method which is equivalent to FSIS methods.

9. SANITATION CONTROLS

Comments to 9.1 and 9.2 see letter from August 25, 2003 (GZ 39.162/5-IV/B/7/03).

12. RESIDUE CONTROL

Comments see letter from August 25, 2003 (GZ 39.162/5-IV/B/7/03).

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13. ENFORCMENT CONTROLS

As already mentioned (see point 6) Austria is reorganizing the inspection system, but nevertheless the Competent Authorities have immediately taken the corrective actions requested by FSIS (see the report of August 25, 2003; GZ 39.162/5-IV/B/7/03).

13.1 Daily Inspection in Establishment

It is not correct that the daily inspection had not been provided, only the daily inspection of the second shift was not performed correctly. Now it is organized in a way that both shifts are inspected by a veterinary inspector. As already mentioned, the daily presence of an official veterinarian in a meat processing plant is not obligatory.

13.5 Inspection System Control

Deficiencies of the sanitation controls see comments from August 25, 2003 (GZ 39.162/5-IV/B/7/03).

Foreign establishment Audit Checklist:

Item 11: Residues from previous days

In order to control the washing machine for plastic meat containers the officials of the plant installed an additional control point in order to set actions immediately if a plastic meat container will not be clean. The washing machine for plastic meat containers is element of the daily audits (§ 17 of the Meat Inspection Act).

Item 12: Condensation

The problem of the condensation has been solved in the way of the installation of a second cooling unit.

Item 19: Verification

The officials of the establishment were enforced to verify and register the CCPs in time.

Item 38: Lighting

The lamps at the meat reconditioning table were defective and were replaced.

Item 40: Cobwebs and flies

The cobwebs were removed immediately. The dry storage room is now part of the self control system and part of the daily audits (§ 17 of the Meat Inspection Act). The door closer mechanism of the main entrance has been reinforced.

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Item 50: Inspections

As already explained under point 13.1 now the inspection is provided on both shifts, as long as it is necessary.

Item 51: Documentation

The SSOP and HACCP monitoring are integral part of the daily audits including the documentation according to § 17 of the Meat Inspection Act.

Item 56: Second shift

Now the inspection (audits according to § 17 of the Meat Inspection Act) covers the second shift too.

In general it has to be stated that regarding all deficiencies which were observed during the audit of July 2003, the official veterinarians, responsible for this plant, took actions when it was possible immediately or in an acceptable period of time.

It is correct that the result of the audit was not satisfactory. However Austria cannot accept that FSIS declares the whole Austrian meat inspection system as inadequate. With no doubt the lack of personnel and financial resources were or are obvious, but as it was written in our information of August 25, 2003 (GZ 39.162/5-IV/B/7/03) and in this letter, Austria is on the way to solve this problem.

In the light of this information and the measures which were taken by the Federal Ministry of Health and Women, Austria respectfully hopes that FSIS is reconsidering its cancelling of the suspension as certification authority.

With best regards

On behalf of the Federal Minister:
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