



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

DEC 20 2007

Mag. Ulrich Herzog
Chief of Veterinary Officer
Director of Department
Section IV/B
Federal Ministry of Health, Family and Youth
Radetzkystrasse 2
1030 Wien, Austria

Dear Mag. Herzog:

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Austria's meat inspection system September 17 to September 27, 2007. Comments from Austria have been included in the final audit report. Enclosed is a copy of the final audit report.

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

Sincerely,

A handwritten signature in cursive script that reads "Sally White".

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

DEC 20 2007

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

September 17 through September 27, 2007

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority – Bundeministerium für Gesundheit, Familie, und Jugend (BMGFJ) - Ministry of Health, Family and Youth
DAA	District Administrative Authorities
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
LH	Landeshauptman (Provincial Governor)
<i>Lm</i>	<i>Listeria monocytogenes</i>
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
PVS	Provincial Veterinary Services
SSOP	Sanitation Standard Operating Procedures
<i>Salmonella</i>	<i>Salmonella</i> species
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Austria from September 17 through September 27, 2007.

An opening meeting was held on September 17, 2007, in Vienna with the Central Competent Authority (CCA). At this meeting, the audit team confirmed the objective and scope of the audit, the audit team's itinerary, and requested additional information needed to complete the audit of Austria's meat inspection system.

The audit team was accompanied during the entire audit by representatives from the CCA, Bundesministerium für Gesundheit, Familie, und Jugend (BMGFJ), and representatives from the provincial and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a special emphasis audit with the objective to determine whether Austria was operating a meat inspection system equivalent to the United States in order to reinstate Austria's eligibility to export meat products to the United States. This included an evaluation of the performance of the CCA with respect to government controls over the (a) two processing establishments that have requested to be certified by the CCA as eligible to export pork products to the United States, and (b) a German government laboratory selected by the CCA to perform microbiological analytical testing of meat products destined for the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, the provincial headquarters, the district office, and two processing establishments seeking approval to export product to the United States.

Competent Authority Visits			Comments
Competent Authority	Central	1	BMGFJ
	Province	1	Upper Austria Provincial Veterinary Services
	District Office	1	District Administrative Authorities
	Local	2	Establishment level
Laboratories		0	*Two meat processing establishments; one boning and cutting and one producing ready-to-eat products.
Meat Slaughter Establishments		0	
*Meat Processing Establishments		2	
Cold Storage Facilities		0	

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials, as well as provincial and district officials, regarding oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records and personal interviews in the country's inspection headquarters, regional offices, and local establishment level offices. The third part involved on-site visits to two processing establishments.

Program effectiveness determinations of Austria's inspection system focused on three areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) processing controls, including the implementation and operation of HACCP programs and (3) enforcement controls, including a testing program for *Salmonella* and *Listeria monocytogenes (Lm)*. Austria's inspection system was assessed by evaluating these three risk areas.

During the on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors 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.

In the opening meeting, the lead auditor explained that Austria's meat inspection system would be audited against three standards: (1) FSIS regulatory requirements (2) FSIS equivalence determinations made for Austria, and (3) the following three EC directives determined equivalent under the European Community/ United States Veterinary Equivalence Agreement (VEA): 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.

FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory visits to certified establishments, 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 *Salmonella* and *Lm*.

Equivalence determinations are those that have been made by FSIS for Austria under provisions of the Sanitary/Phytosanitary Agreement.

- Sample collection: Austria collects 230 grams of raw ground product for *Salmonella* analysis for PR-HACCP compliance related to slaughter.
- Private laboratories analyze samples for *Salmonella*.
- Establishment employee collects the samples for *Salmonella*.
- Government laboratories analyze samples for generic *E. coli*.

- The method for conducting *Salmonella* analysis in ready-to-eat food products is the same as the FSIS method.

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 Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of β -agonists.

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 last two audits of Austria's inspection system have indicated repeated non-compliance with FSIS inspection requirements regarding HACCP and SSOP programs. The following findings were reported from these audits:

Audit of June/July 2003

Findings of this audit resulted in the continued delisting of both establishments. Findings included the lack of direct supervision by the CCA of field activities, the private laboratory was using methods to test for *Salmonella* that had not been found to be equivalent by FSIS, daily inspection of the second shift was not provided correctly, and inspection system controls were inadequate.

Audit of March 2002

At the time of this audit, Austria had two establishments that were certified to export meat to the United States. One was a slaughter establishment and the other was a processing establishment. Both establishments were delisted subsequent to this audit because of continuing problems with implementation and maintenance of SSOP and HACCP, and the lack of a boneless meat re-inspection program.

6. MAIN FINDINGS

6.1 Legislation

The CCA informed the lead auditor that Austria was operating under the EU Hygiene legislation that became effective January 2006 for EU countries. The lead auditor advised the CCA that the new legislation has not yet been determined equivalent by FSIS and that Council Directive 64/433/EEC of June 1964 is still applicable relative to meat exports to the United States.

6.2 Government Oversight

The CCA, for matters concerning food and veterinary matters, is the Ministry of Health, Family, and Youth's (BMGFJ) Division IV. The Subdivision B of Division IV consists of six departments as follows:

1. Department IV/B/4 – food safety in meat production, veterinary residues, and animal by-products.
2. Department IV/B/5 – animal health, trade of live animals and veterinary legislation.
3. Department IV/B/6 – animal welfare and control of animal diseases and zoonoses.
4. Department IV/B/7 – food safety and official foodstuff controls, and food legislation.
5. Department IV/B/8 – FAO/WHO – Codex Alimentarius, novel food and food additives.
6. Department IV/B/9 – Department for matters of gene technology

In January 2006, Article 51 of the Austrian Law on Food Safety and Consumer Protection was passed by the Austrian government. This new law increases the oversight that the BMGFJ has over establishments that export meat product from Austria. This law also gives the BMGFJ the responsibility to grant eligibility to those establishments that want to export product to other countries, as well as revoke that eligibility should the establishments not meet the standards of the receiving countries. Lack of direct oversight by the CCA has been a repetitive finding in previous FSIS audits.

6.2.1 CCA Control Systems

Department IV/B/4 of the BMGFJ is the competent authority for the inspection of meat and poultry products. For Austria's domestic market, controls over meat inspection are conducted through an indirect federal administration. Under this administration, the BMGFJ implements federal legislation through the use of the Provincial Governor (LH) and the provincial authorities, which act on the behalf of the BMGFJ. The provincial governors' carry out this responsibility through the veterinary officials in the provinces and districts. The controls that are provided by these officials in slaughter/processing establishments consist of ante-mortem and post-mortem inspection, as well as hygiene checks.

In response to a renewed interest in exporting product to the United States, and also from the results of previous FSIS audits in Austria, the BMGFJ has developed a new organizational structure to be utilized for product intended to be produced and shipped to the United States. This new structure provides the BMGFJ with a greater control over inspection activities at exporting establishments, and is intended to ensure uniform implementation of the U.S. requirements.

6.2.2 Ultimate Control and Supervision

The BMGFJ has the legal authority to supervise and enforce Austria's meat inspection activities. It does so through the use of front line inspectors and first line supervisors, which are employed by the Provincial Veterinary Services (PVS). However, regarding product to be shipped to the United States, the front line inspectors and first line supervisors are appointed by the Federal Minister and act by order on behalf of the Federal Minister. The front line inspectors have received training in FSIS inspection requirements from the first line supervisors. At this time, the CCA has contracts with three front line inspectors, which are veterinarians that serve part time in this capacity and also work as private practitioners. The CCA has legislation that prohibits such veterinarians from performing inspection duties that could result in a conflict of interest.

The first line supervisors received training at the FSIS seminars for international officials as well as other training provided by the CCA. They will conduct monthly audits of the establishments certified to ship to the United States. The CCA informed the audit team that they plan to certify only two establishments at this time, upon receiving export approval by FSIS. These two establishments, which are owned by the same company and located in the Province of Upper Austria, were never previously certified by Austria for exporting to the United States. The results of the monthly audits are compiled into reports that are sent to the BMGFJ. At this time, the CCA has contracts with four first line supervisors.

One of the four first line supervisors has been selected by the CCA as the senior first line supervisor, who is from the province of Styria, and will conduct annual audits of the two establishments on the behalf of the CCA. This supervisor is also given the responsibility from the CCA to assure that the two establishments and inspection personnel have current knowledge of the FSIS requirements and to convey changes to these requirements to the BMGFJ, provincial authorities, and the front line inspectors.

Daily inspection is provided in the two establishments audited by the front line inspectors.

6.2.3 Assignment of Competent, Qualified Inspectors

All inspectors are veterinarians who meet the qualifications set by the BMGFJ. The inspection personnel need to increase their knowledge of the FSIS HACCP and SSOP requirements.

6.2.4 Authority and Responsibility to Enforce the Laws

The BMGFJ has the ultimate legal control over, and supervision of, the official activities of the inspection personnel. The BMGFJ has an indirect authority over the Austrian meat inspection program. The provinces take a much larger role in the conduct of inspection activities for the Austrian domestic market. With regard to product intended to be exported to the United States, the BMGFJ has taken steps to increase their oversight of inspection activities. There will be provincial inspectors under contract to the BMGFJ auditing the establishments monthly (first line supervisors) and conducting daily inspection (front line inspectors). The BMGFJ has the authority to approve establishments for export to the United States. Should circumstances arise that the establishments no longer meet FSIS standards; the BMGFJ has the authority to immediately delist such establishments.

6.2.5 Adequate Administrative and Technical Support

The CCA has selected a German laboratory to perform official microbiological testing of meat samples destined for the United States. The CCA will provide indirect oversight of this laboratory and will provide the oversight protocols to FSIS.

6.3 Headquarters Audit

The FSIS lead auditor conducted a review of inspection system documents at the headquarters of the BMGFJ in Vienna and the provincial headquarters in Linz. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sanitation and processing inspection procedures and standards.
- Laboratory testing.

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

6.3.1 Audit of Regional and Local Inspection Sites

The FSIS lead auditor conducted interviews and reviewed records in three locations. The first was The Federal Ministry of Health, Family and Youth located in Vienna, Austria. The Head of Department IV/B/4 was interviewed in this office along with the Chief Veterinary Officer (Head of Subdivision B). The next office visited was The Provincial Government of Upper Austria, Department of Veterinary Services, in Linz, Austria. Here, the interviewees included the Director of the Department of Veterinary Services, a first line supervisor from the Department of Veterinary Services, and a front line

inspector. Finally, an interview of a second front line inspector was conducted in the establishment in Reichenthal, Austria.

The audits of these offices were conducted as a means of gathering information about the changes Austria has implemented since the last FSIS audit. As a result of these interviews, the lead auditor concluded that the Austrian inspection officials require further training in FSIS HACCP and SSOP programs. The CCA appears to have taken adequate measures to improve their degree of oversight of inspection activities.

7. ESTABLISHMENT AUDITS

The FSIS audit team visited two establishments, of which both were processing establishments; one cutting establishment and one ready-to eat (RTE) establishment. At the time of this audit, these two establishments were not eligible to export product to the United States. Currently, there are no slaughter establishments seeking eligibility. For the purpose of exporting to the United States, Austria will receive pork meat from establishments in Denmark or other establishments in other member states of the EU that are certified to export meat products to the United States.

Specific deficiencies are noted on the attached individual establishment reports.

8. LABORATORY AUDITS

There was no review of laboratories conducted for this audit. Austria does not plan to conduct slaughter activities for U.S. export; thus, FSIS residue requirements are not applicable at this time. Austria intends to produce RTE products for U.S. export, therefore, microbiological sampling and testing are required by Austria. The CCA had not approved any laboratories in Austria to conduct microbiological testing on product to be shipped to the United States. The CCA will send official samples to a laboratory in Germany, which is approved by Germany's CCA to carry out laboratory testing for the detection of *Salmonella* and *Lm* using methods that are consistent with the FSIS MLG methods.

9. SANITATION CONTROLS

As stated earlier, the FSIS audit team focused on three areas of risk to assess Austria's meat inspection system. The first of these risk areas was Sanitation Controls.

Based on the on-site audits of the two establishments, and except as noted below, Austria's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

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 U.S. domestic inspection program. The SSOP in the two establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies.

- In both establishments, deficiencies identified on the daily pre-operational and operational sanitation SSOP reports were not adequately described.
- In both establishments, there was no documentation of the appropriate disposition of product(s) that may be contaminated and preventive measures for the recurrence of direct product contamination or adulteration in the pre-operational and operational sanitation monitoring records.

9.2 EC Directive 64/433

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

10. ANIMAL DISEASE CONTROLS

At the time of this audit, there were no animals from Austria's domestic stock being used for intended U.S. export. The animals used for this purpose originate, and are slaughtered, in Danish certified establishments. During the 2007 audit of Denmark, the auditor noted that there had been no outbreaks of animal diseases with public health significance.

11. SLAUGHTER/PROCESSING CONTROLS

The second risk area that the FSIS audit team reviewed was Processing Controls. The controls include the following areas: ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in both establishments.

11.1 Humane Handling and Humane Slaughter

Since there were no slaughter establishments audited, the FSIS audit team did not review this risk area.

11.2 HACCP Implementation

Both establishments reviewed were required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the U.S. domestic inspection program.

The deficiencies noted by the FSIS auditor were as follows:

- In both establishments, direct observations verification procedures were not being performed to ensure the effective implementation of the monitoring program.
- In both establishments, the BMGFJ inspection officials did not adequately describe the deficiencies identified and could provide no documentation to verify the appropriate disposition of the product involved (if any) and/or to verify the effectiveness of measures taken to prevent recurrence of direct product contamination or adulteration in the operational sanitation verification records.
- In both establishments, the BMGFJ inspection officials were not verifying the adequacy of the HACCP plan(s) to determine that the establishment HACCP plan met the FSIS requirements for reviewing the corrective actions, direct observation, or measurement at a CCP, and onsite observations. Records indicated that inspection officials had conducted only record reviews.
- In one establishment, the monitoring records for Critical Limits did not include the entries for the actual observations; e.g., the monitor was documenting one entry for the observation of five pH quantifiable values, whereas, according to the HACCP plan, entries were to be made for all of the quantifiable values monitored.

11.3 Testing for Generic *E. coli*

Since no slaughter establishments were reviewed during this audit, the FSIS audit team did not review this risk area. However, Austria has submitted a laboratory method for the testing of *E. coli* O157:H7 for an equivalence determination. Additional information has been requested from Austria, and they have replied that they are not interested in pursuing this determination at the present time.

11.4 Testing for *Listeria monocytogenes*

One of the establishments audited was producing a RTE product intended for indirect export to the United States. In accordance with FSIS requirements, the HACCP plan in this establishment had been reassessed to include *Lm* as a hazard reasonably likely to exist.

11.5 EC Directive 64/433

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

12. RESIDUE CONTROLS

This risk area does not apply to this audit because there are no approved slaughter establishments in Austria.

12.1 EC Directive 96/22

This directive does not apply to this audit because there are no approved slaughter establishments in Austria.

12.2 EC Directive 96/23

This directive does not apply to this audit because there are no approved slaughter establishments in Austria.

13. ENFORCEMENT CONTROLS

The third risk area that the FSIS audit team reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in both processing establishments.

13.2 Testing for *Salmonella*

Austria has adopted the FSIS regulatory requirements for testing of *Salmonella* in RTE products.

The CCA has selected an approved laboratory in Germany to perform analytical testing of official samples of meat products destined for the United States. The FSIS audit team did not audit the German laboratory. The scope of the audit was limited to CCA oversight of the German laboratory.

13.3 Species Verification

Species verification was discussed with the BMGFJ officials, and they informed the FSIS audit team that species verification testing would be performed quarterly within the first year of shipping product to the United States, and then the frequency would be re-evaluated. The CCA will submit its species verification testing program to FSIS for review.

13.4 Periodic Reviews

During this audit it was found that in both establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for restricted product and inspection samples; shipment security, including shipment between establishments; and prevention of commingling of

product intended for export to the United States with product intended for the domestic market.

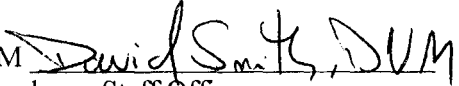
In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

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 September 27, 2007, in Vienna, Austria with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the audit team.

The CCA understood and accepted the findings.

David Smith, DVM 
International Equivalence Staff Officer

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report (when it becomes available)



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BMGFJ-74440/0235-IV/B/4/2007

26.11.2007

Comments on the Draft Final Report of an Audit carried out in Austria covering Austria's Meat Inspection System, sent by e-mail on November 1, 2007

Dear Dr. White,

The Federal Ministry for Health, Family and Youth thanks you for sending the above mentioned draft and would like to suggest the following changes:

Notes regarding Corrections:

- Pg. 5, Nr. 1., Paragraph 3. Sentence 2:

Clerical error: Bundesministerium

- Pg. 5, Nr. 2, Table:

Involved are not (2) Meat Processing Establishments but rather (**one**) Meat Processing Establishment and (**one**) Cutting Plant.

- Pg. 8, Nr. 6.2, Sentence 2, one should add:

The Subdivision B of Division IV consists of **six** departments as follows:

1 – 5 correct as written. Therefore, the following should be added:

6. Department IV/B/9 Department for Matters of Gene Technology

- Pg. 9, Nr. 6.2.2, Sentence 3 should read:

However, regarding production of goods to be shipped to the United States, the front line inspectors and first line supervisors **are appointed by the Federal Minister and act by order on behalf of the Federal Minister.**

- Pg. 10, Nr. 6.3.1, Sentence 3 should read:

The Head of Department IV/B/4 was interviewed in this office, along **with the Chief Veterinary Officer (Head of Subdivision B).**

- Pg. 11, Nr. 7 in the last sentence, should read:

For the purpose of exporting to the United States, Austria will receive pork meat from establishments in Denmark **or other establishments in other member states of the EU** that are certified to export meat products to the United States.

Comments:

- 6.2.3

Please note that remarks by the Federal Ministry of Health, Family and Youth regarding information in the audit report are contained in Point 4 of the File GZ BMGFJ-74440/0227-IV/B/4/2007 and have already been sent to FSIS on October 15, 2007 (see Att. E.).

- 6.2.5

Please note that remarks by the Federal Ministry of Health, Family and Youth regarding information in the audit report are contained in Point 1 of the File GZ BMGFJ-74440/0227-IV/B/4/2007 and have already been sent to FSIS on October 15, 2007 (see Att E.).

- 9.1. and 11.2

Please note that by the Federal Ministry of Health, Family and Youth regarding information in the audit report contained in Point 3 of the File GZ BMGFJ-74440/0226-IV/B/4/2007 and have already been sent to FSIS on October 15, 2007 (see Att. D.)

Enclosures:

E-mail from the head of the laboratory, Dr. Schleuter, approving the information (Att. A)

Excerpt - regarding the laboratory audit of LAVES
Veterinarinstitut - from the Draft Final Report of an audit carried out in Germany covering Germany's Meat Inspection System
(Att. B.)

Confirmation of accreditation from the State Accreditation Body in
Hannover
(Att. C.)

File GZ BMGFJ-74440/0226-IV/B/4/2007 to FSIS, October 15,
2007
(Att. D.)

File GZ BMGFJ-74440/0227-IV/B/4/2007 to FSIS, October 15, 2007
(Att. E.)

For the Federal Minister:
Ulrich Herzog

Attachements A-E:

Transmitted electronically