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

OCT 1 2002

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

Dear Mr. Weber:

The Food Safety and Inspection Service (FSIS) has completed an on-site audit of Austria's meat inspection program. The audit was conducted from March 12 through March 21, 2002. Austria's comments on the draft final audit report have been included as Attachment G. We have made various editorial corrections to the report in accordance with your comments. Enclosed is a copy of the final audit report. I apologize for the delay in providing this report to you.

The audit report describes a number of serious deficiencies that are similar to those found during the previous three audits of Austria's meat inspection system (May 1998, November 1999, and March 2000). At each of the exit conferences for these audits, Austrian inspection officials assured the auditor that appropriate and effective corrective actions would be taken to rectify the observed deficiencies. However, the deficiencies found during this most recent audit were so serious that both of Austria's certified establishments were delisted for export to the United States. In accordance with FSIS policy regarding establishments that are delisted prior to or during an audit, these establishments may not be relisted for export to the United States until FSIS has (1) received and reviewed the corrective actions that were taken by the Government of Austria and the individual establishments, and (2) conducted an on-site audit of the establishment(s) proposed for relistment.

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 JD

Sally Stratmoen
Chief, Equivalence Section
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosure

cc:

Alejandro Checchi-Lang, European Commission, Brussels, Belgium
Robert Curtis, Minister-Counselor, U.S. Embassy, Vienna
Marcus Bertmann, Economic Counselor, Embassy of Austria, Washington, DC
Joerg Niederberger, Counselor (Agriculture), EU Mission to the US, Wash, DC
Norval Francis, Minister/Counselor for Agricultural Affairs, USEU/Brussels
Linda Swacina, Associate Administrator, FSIS
John Prucha, ADA, Program Coordination and Evaluation, OPPDE
Martiza Colon-Pullano, SAIFS, OPPDE
Sally Stratmoen, ES, IPS, OPPDE
Karen Stuck, IES, IPS, OPPDE
Donald Smart, Director, Review Staff, OFO
John Wilson, FAS
Amy Winton, State Department
Nancy Goodwin, ES, IPS
Country File-Austria (Audit FY 2002)

United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR AUSTRIA

March 12 through March 21, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Austria's meat inspection system from March 12 through March 21, 2002. Both establishments certified to export meat to the United States were audited (Ests. 02 and 08). One of these was a slaughter establishment and the other one was conducting processing operations.

The last audit of the Austrian meat inspection system was conducted in November 1999 and March 2000. Three establishments (02, 08, and 25-A) were audited. The auditor found serious deficiencies in two establishments (02 and 08) that were then designated as marginal/re-review at the next audit. One establishment (25-A) was found to be unacceptable.

The major concerns from the previous audit were the following:

1. The continuing problems with the implementation and maintenance of SSOP in certified establishments.
2. The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. The zero-tolerance policy for visible fecal material on carcasses was not enforced by either the establishments or Austrian inspection officials and no monitoring records were maintained to verify this activity.
5. No boneless meat re-inspection program was carried out either by the establishment or by Austrian inspection officials.
6. Condemned product was not denatured or slashed prior to leaving establishment Est. 25-A.
7. Testing for generic *E.coli* was required in two of the three establishments reviewed. Both establishments were using the sponge method to sample and excision criteria to evaluate the results (Ests. 02 and 25-A)

During calendar year 2001, Austrian establishments exported 122,770 pounds of cured pork, canned picnics, and sausages (trichina treated) to the U.S. Port-of-entry rejections were for processing defects (0.70% of the total) and contamination (0.07%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Austrian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second part was an on-site audit of Austria's two certified establishments. The third was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella* and *E. coli*. The fourth was a visit to a farm.

Austria's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the testing program for generic *E. coli*, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials. This was the case with two establishments 02 and 08.

RESULTS AND DISCUSSION

Summary

Both certified establishments were audited. The auditor found sanitation and other conditions to be so serious in both establishments (Ests. 02 and 08) that these establishments were delisted by the GOA. Details of the audit findings, including compliance with HACCP, SSOP, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

As stated above, numerous major concerns had been identified during the last audit of the Austrian meat inspection system conducted in November 1999 and March 2000.

During this new audit, the auditor determined that some of these concerns had been addressed and corrected by the Veterinary Services-Meat Hygiene/Residue Control. However, the following deficiencies identified in the November 1999 and March 2000 audits had not been addressed and corrected:

1. The continuing problems with the implementation and maintenance of SSOP in certified establishments. *Repeat deficiency from last audit.*

2. The continuing problems with implementation and maintenance of HACCP systems in certified establishments. *Repeat deficiency from last audit.*
3. Instances of actual product contamination and instances of the potential for direct product contamination. *Repeat deficiency from last audit.*
4. The zero-tolerance policy for visible fecal material on carcasses was not enforced by either establishment or GOA inspection officials, and no monitoring record was maintained to verify this activity. *Repeat deficiency from last audit*
5. No boneless meat re-inspection program was carried out either by the establishment or by Austrian inspection officials. *Corrected*
6. Generic *E.coli* testing that two of the three establishments were required to perform. Both establishments were using sponging method to sample and excision criteria to evaluate results (Est. 02 and 25-A*)* *Corrected*

During this new audit, implementation of the required HACCP programs was now found to be deficient in both establishments visited (Ests. 02 and 08). Details are provided in the Slaughter/ Processing Controls section later in this report.

Entrance Meeting

On March 12, 2002, an entrance meeting was held at the Veterinary Services offices of the Federal Ministry of Social Security and Generations in Vienna, and was attended by Dr. Peter Weber, Director of Veterinary Services; Dr. Peter Vitus Stangl, Head of Department 7 for Meat Hygiene/Food Control, Veterinary Services; Dr. Marina Mikula, Veterinary Medical Doctor, Department 3; Dr. Andrea Hoflechner, Veterinary Medical Doctor, Department 4; Ms. Michaela Leithner, and Dr. Faizur R. Choudry, International Audit Staff Officer, Technical Service Center (TSC), Food Safety and Inspection Service (FSIS).

Topics of discussion included the following:

1. Welcome by Dr. Peter Weber and explanation of the Austrian meat inspection system.
2. Training programs for GOA veterinary meat inspection officials for pathogen reduction and other food safety initiatives such as SSOPs and HACCP programs.
3. Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.
4. New laws and implementation documents such as regulations, notices, directives and guidelines.
5. The audit itinerary and travel arrangements.
6. The auditor provided a) FSIS Notice, Reassessment of Listeria Monocytogenes contamination of Ready-to-Eat Products (RTE). b) FSIS Notice-12-98, Notification to Establishments of Intended Enforcement Actions. c) FSIS Directive 6420.1, Livestock Post-mortem Inspection Activities-enforcing the zero tolerances for fecal material, ingesta, and milk.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last audit of Austria's meat inspection system in March 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

Government Oversight

All inspection veterinarians in establishments certified by Austria as eligible to export meat products to the United States were government employees. The veterinarians that actually perform the daily inspection activities are not hired or paid by the federal government but by the provincial government which receives its authority from Austria's federal government. The disciplining or firing of government veterinarians is not authorized for the federal government. This level of authority only recommends action against poor performing government employees.

The most relevant responsibilities of the federal government are to participate and negotiate during new or revised EC legislation, to implement EC legislation into Austrian law, to interpret and clarify EC Directives and federal laws and regulations, and to pass these documents on to the provincial government. These are then passed on to the districts and to the lower levels of inspection authority by the province. Although compliance is mandated by the federal government, there is no formal internal audit system to assure that the requirements of the laws, regulations, and circulars have been properly implemented.

Austria consists of nine provinces. Each province in Austria is further divided into districts. At the present time, there is only one province (Upper Austria) with establishments that are certified to export to the United States. The various levels of authority work together to implement Austria's meat inspection program.

Although direct and accountable supervision is different than what exists in the U.S., the experience, education, and examination of newly hired government veterinarians is used as a means of identifying performance weaknesses. The performance of responsibilities and duties of these veterinarians is, however, rarely questioned. Actual visits to determine competence by the federal level of authority may not be routinely performed or documented and are not part of any written supervisory plan. Although there are detailed instructions of what to do when visiting a provincial authority, including visits to an establishment, the federal and provincial governments rely heavily upon the results of EC and U.S. audits of their inspection system and appear to have a reactive system of maintaining compliance rather than a preventative system of maintaining compliance.

In addition, part of the responsibility of the province is to approve establishments for EC and U.S. markets and to withdraw federal approval from these establishments. The district office notifies the provincial office of each approval and withdrawal. The provincial office then

notifies the Veterinary Services offices of the Federal Ministry of Social Security and Generations in Vienna. The federal government does not visit these establishments as a result of the approval and does not supervise or question the validity of a provincial's decision to approve or withdraw an establishment. However, the provinces work closely with the district and local veterinarians to secure compliance for the approvals.

- Supervisory structure from the level of official veterinarian in the plant to district and to the province is weak.
- There is no formal internal audit system to assure that the requirements of the laws, regulations, and circulars have been properly implemented.
- There appears to be an inadequate understanding of U.S. requirements for SSOPs and PR/HACCP by both government veterinary meat inspectors and establishment personnel.

Establishment Audits

Two establishments were certified to export meat products to the United States at the time this audit was conducted. Both establishments were visited for on-site audits. Both establishments (Ests. 02 and 08) were found to be unacceptable because of critical sanitation problems, findings of direct product contamination, and noncompliance with FSIS regulatory requirements of HACCP program and were delisted by the government of Austria (GOA).

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; *intra*-laboratory quality assurance procedures, including sample handling; and methodology.

The Federal Institute for Veterinary Medicine in Moedling was audited on March 15, 2002. Except as noted below, effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analysis were acceptable. No compositing of samples was done.

Austria's microbiological testing for *E.coli* and *Salmonella* was being performed in both government and private laboratories. One of these private laboratories, the Institute for Bio-Analytic and Hygiene in Perg, Upper Austria, was audited on March 14, 2002. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS' Pathogen Reduction/HACCP rule.
These criteria are:

1. The laboratory was accredited by the Ministry of Economic Affairs Accreditation Department in 1997.
2. The laboratories had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Test results are provided directly to the government veterinarian.

The following concerns were noted:

1. Samples for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, antibiotics, and sulfonamides were not analyzed in a timely manner. For example 80% of samples were analyzed in 42 days. Timely analyses are critical for hormones, antibiotics, and sulfonamides.

2. Standards book for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, and sulfonamides was not properly maintained for quality assurance program such as: when solutions prepared by the analyst were not signed and verified by the supervisor before the solutions were used; pages were not serially numbered; sometimes the date of purchase and lot number was not recorded for standard solution/reagent/media ingredients.

3. The proficiency test (intra-laboratory and/or inter-laboratory check samples) for quality assurance program was not performed for sulfonamides, *E.coli,* and *Salmonella.*

Establishment Operations by Establishment Number

The following operations were being conducted in the two establishments:
Beef, veal, and pork slaughter, and boning - one establishment (Est. 02)
Beef, veal, and pork boning, curing, and cooking – one establishment (Est. 08)

SANITATION CONTROLS

Based on the on-site audits of establishments, Austria's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, hand washing facilities, separation of operations, pest control program, temperature control, operation work space, ventilation, outside premises, dry storage areas, welfare facilities, and product transportation.

Sanitation Standard Operating Procedures (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 data collection instrument used accompanies this report (Attachment A).

The SSOP in both establishments were found to meet the basic FSIS regulatory requirements with the following deficiencies.

- In one establishment, the written SSOP procedure did not address pre-operational sanitation.
- In one establishment, the written SSOP did not address operational sanitation.
- In both establishments, the daily pre-operational and operational sanitation deficiencies were not identified and any corrective action taken were not documented by the establishment personnel and monitoring records did not reflect the actual sanitary conditions observed in the establishment.

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in both establishments audited. Specific findings for each establishment audited on-site can be found in Attachment F.

Examples of findings of actual product contamination include:

- In both establishments, dripping condensate, from overhead refrigeration units, ducts, ceilings, and pipes that was not cleaned/sanitized daily, was falling onto hog carcasses and edible product in the carcass and offal coolers and brine injection room. Neither establishment nor GOA meat inspection officials took corrective actions. *Repeat deficiency in both establishments from last audit.*

- In one establishment, the sanitizing facility for knives was designed in such a way that it was not possible to sanitize knives completely and effectively in the slaughter room. Corrected immediately. *Repeat deficiency from last audit*

- In one establishment, automatic offal hook conveyor was observed with blood, and fat after washing/sanitizing in the slaughter room. *Establishment corrective action was inadequate.*

- In one establishment, beef carcasses were contacting employees' working platforms at the carcass evisceration, postmortem inspection, and trimming stations in the slaughter room. *Establishment officials ordered correction.*

- In both establishments, insanitary equipment was directly contacting edible product in the boning room, slaughter room, and brine injection room. For example, employees' knives and containers for edible product from previous days' operation were found with dried pieces of meat, fat, blood, and grease. *Neither establishment nor GOA meat inspection officials took corrective actions.*

- In one establishment, dirty water was dripping from the carcass splitting saw onto an exposed carcass during hog carcass splitting operation. *Neither establishment nor GOA meat inspection officials took corrective actions.*

- In both establishments, overhead supports, in the hog carcass cooler were observed with accumulation of rust. Flaking paint and numerous dirt spots were observed on the ceilings above the moving rail in the slaughter room and in the same establishment overhead refrigeration units, ducts, and ceilings in all coolers were observed with accumulations of dust, dirt, and black discoloration, and mold. *Repeat deficiency from last audit.*

- In one establishment, numerous automatic conveyor rollers and conveyor belts for transporting empty edible containers and containers with product were found with dried pieces of meat, fat, blood, dirt, and water droplets above the processed product and boning tables in the boning and processing rooms. Two containers of minced meat were found with rust and dirt particles under one of these automatic conveyor rollers in same establishment. Raw sausages and cooked sausages were contacting the wheels of the

portable smoking and cooking racks. Neither establishment nor GOA inspection officials took corrective action. *Repeat deficiency from last audit.*

Personal Hygiene and Practices: In the area of personal hygiene and practices, the following deficiencies were noted.

- In both establishments, employees were not observing good hygienic work habits to prevent direct product contamination such as: washing hands with dirty hose and handling edible product without washing unclean hands in sausage room; employees were not covering mesh gloves with rubber gloves to prevent cross contamination at the viscera and offal separation stations in the slaughter room. *Neither establishment nor GOA inspection officials took corrective action.*

Establishment Facilities: In the area of maintenance of establishment facilities, the following deficiencies were noted.

- In one establishment, light at the dropped meat reconditioning station in the boning room was inadequate. *Establishment officials ordered correction.*

ANIMAL DISEASE CONTROLS

Austria's inspection system had controls in place to ensure adequate animal identification, ante-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

The Federal Ministry of Social Security and Generations inspection officials indicated that first incidence of Bovine Sponigiform Encephalopathy (BSE) was found positive on December 7, 2001. In addition, Classical Swine Fever was found positive in November 2000, in a wild boar piglet in the National Park Donau-Auen. Plans for eradication and surveillance of classical swine fever were implemented and effectively controlled according to Council Directive 80/217/EEU.

RESIDUE CONTROLS

Austria's National Residue Testing Plan for 2002 was being followed and was on schedule. The Austrian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

The Federal Institute for Veterinary Medicine in Moedling was audited on March 15, 2002.

The following concerns were noted:

1. Samples for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, antibiotics, and sulfonamides were not analyzed in a timely manner. For example 80% of samples were analyzed in 42 days. Timely analyses is critical for hormones, antibiotics, and sulfonamides.

2. Standards book for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, and sulfonamides was not properly maintained for quality assurance program such as: when solutions prepared by the analyst were not signed and verified by the supervisor before the solutions were used; pages were not serially numbered; for some standard solution/reagent/media, date of purchase and lot number was not recorded.
3. The proficiency test (Intra-laboratory and/or inter-laboratory check samples) for quality assurance program was not performed for sulfonamides, *E.coli*, and *Salmonella.*

On Farm

The Riedberger farm, located in Ried/Riedmark, was visited on March 14, 2002. This farm is a small swine farm on approximately 100 acres of land with about 500 market hogs.

A private veterinarian visits this farm at least 78 times per year and if need arises the frequency of visits is increased. He makes the diagnosis, and prescribes and administers the drugs for treatment. Animals are identified by a single earmark, which identifies the farm, as well as a tattooing mark before leaving farm, the month of the birth of the animal and the code for the farm (premises). Medicated feeds are not given to market hogs in this farm.

The District Veterinarian is required to analyze one sample of feed and urine between two to three years to demonstrate that feed is not medicated and if there is any doubt then feed delivery company is required to take more samples.

The swine farm that was visited is not licensed to store animal drugs on site. Farms must be specifically approved to store animal drugs on the premises. On those farms which are not approved to store drugs, the veterinarian may only prescribe drugs in amounts that can be used immediately. Records are maintained on all animal drugs requiring prescription, which are written in duplicate so that copies can be maintained by the prescribing veterinarian and filed at the farm. The District Veterinarian cross check and verify all the prescriptions written or dispensed in the farm.

Certificates (affidavits) are issued for every group of animals moving off of the farm, whether to another farm or to slaughter. When drugs are used to treat animals to be slaughtered, the withdrawal period is recorded on the transportation documents, with a copy of the prescription attached. Animals may not be slaughtered during the withdrawal period.

The National Program for Residue Control is based on European Community legislation in force related to the ban of hormonal substances (Council Directive 96/22/EC April 1996) and the control of residues on live animals and animal products (Council Directive 96/23/EC of April 1996). These directives have been determined equivalent by FSIS.

Reporting Positive Results

Though no violations had occurred at the farm visited, the District Veterinarian stated that violations are followed up on a case-by-case approach, depending upon the substance in question. At the farm, the District Veterinarian will increase inspections but may not take a sample every time. On a first violation, District Veterinarian will take 10 % samples for

urine and feed and if less than half are positive, the positive animals are destroyed and that will lead to intensified sampling. Intensified sampling is statistically based, and if over half of the samples are positive, the entire herd will be destroyed. If the substance is prohibited, there are criminal sanctions resulting in arrest and possible fines/jail.

SLAUGHTER/PROCESSING CONTROLS

The Austrian inspection system had controls in place to ensure adequate animal identification, animal inspection procedures, ante-mortem disposition, humane slaughter, post-mortem dispositions, ingredients identification, control of restricted ingredients, formulations; packaging materials, label approvals, inspector monitoring, processing equipment, processing records, and post-processing handling.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of both establishments. The auditor found the following deviations from FSIS regulatory requirements:

1. In both establishments, the HACCP plan flow chart did not adequately describe the process steps and product flow.

2. In both establishments, the HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur.

3. In both establishments, the HACCP plan analysis did not include food safety hazards reasonably likely to occur. *Repeat deficiency in one establishment from last audit.*

4. In both establishments, the HACCP plan did not address the intended use of or the consumers of the finished product(s). *Repeat deficiency in one establishment from last audit.*

5. In both establishments, the HACCP plan did not specify critical limits, for each CCP and the frequency with which these procedures would be performed. *Repeat deficiency in one establishment from last audit.*

6. In both establishments, the HACCP plan did not address the corrective actions to be followed in response to a deviation from a critical limit. *Repeat deficiency in both establishments from last audit.*

7. In both establishments, the HACCP plan was not validated to determine that it was functioning as intended.

8. In both establishments, the HACCP plan did not state the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The on-going verification activities of the HACCP program were not performed by establishment personnel. *Repeat deficiency in both establishments from last audit.*

9. In both establishments, the HACCP plan's record-keeping system was not documenting the monitoring of CCPs. *Repeat deficiency in both establishments from last audit.*

10. In both establishments, the final review of all documentation associated with the production of the product prior to shipping was not done.

Testing for Generic *E. coli*

Austria has adopted the FSIS regulatory requirements for *E. coli* testing. One of the two establishments audited was required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and was audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing program was found to meet the basic FSIS regulatory requirements. The following variation was noted:

1. The carcass selection was not being done randomly

Additionally, both establishments had adequate controls in place to prevent meat products intended for Austrian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the Austrian inspection system controls [ante-inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for shipment security, and products entering the establishments from outside sources.

Inspection System Controls

1. Hog viscera was not synchronized and identity was not maintained with rest of the carcass and offal during postmortem inspection such as viscera from four carcasses were pooled together and then presented for postmortem inspection. This is a violation of EC Directive 64/433.
2. In one establishment, the zero-tolerances for visible fecal material/ ingesta contamination, and milk on carcasses were not enforced by the GOA meat inspection officials, and there was no monitoring record maintained to verify this activity. *Repeat deficiency from last audit.*
3. In both establishments, edible and inedible product containers were not identified to prevent possible cross-contamination/cross utilization in the boning room and processing rooms.
4. In both establishments, inedible product was not denatured/de-characterized or under security before shipping for rendering. *Repeat deficiency from last audit.*

Testing for *Salmonella* Species

One of the two establishments audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* testing program was audited and found to meet the basic FSIS regulatory requirements. Austria has adopted the FSIS regulatory requirements for *Salmonella* testing. The following variation was noted:

1. The carcass selection was not being done randomly

Species Verification Testing

The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Listeria monocytogenes Testing

Establishments producing ready-to-eat products are required to reassess their HACCP plans to determine if *Listeria monocytogenes* should be considered as a hazard reasonably likely to occur. These establishments must also implement a *Listeria monocytogenes* testing program for ready-to-eat products.

The following variation was noted.

- The control of *Listeria monocytogenes* in not included in the HACCP plans in one establishment producing ready-to-eat products. However, this establishment was testing for *Listeria monocytogenes* in ready-to-eat products.

Monthly Reviews

These reviews were being performed by Dr. Friedrich Mayr, District Veterinarian, Austria's equivalent of an Area Supervisor.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times, by individuals and at other times by a team of reviewers including a veterinarian from the State, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central office of the Veterinary Service in Vienna.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again be re-certified, an in-depth review is conducted and the results are reported to Dr. Werner Roitner, Deputy Chief Veterinary Officer, for the State of Oberosterreich; Dr. Peter Vitus Stangl, Head of Department of Veterinary Services, Meat Hygiene/Residue Control; and Dr. Marina Mikula, Veterinary Medical Doctor, for evaluation.

The following concern was noted:

- Monthly supervisory audits were conducted by the District Veterinarian. A few deficiencies were noted in year 2001 and any corrective actions taken were not followed by either the veterinarian in charge or by the District Veterinarian.

Other Enforcement Activities

1. In one establishment, GOA meat inspection officials were not providing inspection coverage for second shift operations.
2. In one establishment, the GOA inspection officials were not monitoring pre-operational sanitation to verify the adequacy and effectiveness of the sanitation SSOP program and operational sanitation deficiencies were not identified and any corrective actions/preventive measures taken were not documented. In other establishment, the pre-operational and operational sanitation deficiencies were not identified and any corrective and preventive measures taken were not documented.
3. In both establishments, the on-going verification activities of the HACCP program were not performed by the GOA meat inspection officials.
4. In one establishment, inspection devices (brands) were not kept under inspection control. For example, brands were left in a locked inspection office and one key was given to establishment officials. Inspection officials indicated that it would be rectified immediately.

Exit Meeting – March 21, 2002

Two exit meetings were conducted. The first one was held on March 21, 2002, at the Veterinary Services offices of the Federal Ministry of Social Security and Generations in Vienna. The participants from the GOA were Dr. Peter Vitus Stangl, Head of Department 7

for Meat Hygiene/Food Control, Veterinary Services; Dr. Marina Mikula, Veterinary Medical Doctor, Department 3; Dr. Reinhard Kainz, Director of Food Trade, Department of Commerce; and Ms. Claudia Janecek, Deputy Director of Food Trade, Department of Commerce.

The U.S. participants were Mr. Robert Curtis, Agricultural Counselor, Foreign Agricultural Service (FAS), U.S. Embassy in Vienna; Mr. Paul Spencer, Agricultural Attache, FAS; Ms. Hildenbrandt, FAS, U.S. Embassy in Vienna; and Dr. Faizur R. Choudry, International Audit Staff Officer, FSIS.

Exit Meeting – March 22, 2002

A second exit meeting was conducted per telephone with the European Commission (EC) in Brussels, Belgium from Vienna, on March 22, 2002. The participants from the EC were Dr. Paolo M. Drostby, DG, SANCO, Unit E-3; and Dr. Willem Droppers.

The U. S. participants were Ms. Caroline Hommez, Agricultural Specialist, FAS, American Embassy in Brussels per telephone; and Dr. Faizur R. Choudry, International Audit Staff Officer, FSIS.

Dr. Peter Vitus Stangl opened the meeting. The following topics were discussed:

1. The continuing problems with the implementation and maintenance of SSOP in certified establishments.
2. The continuing problems with basic noncompliance of HACCP program requirements in certified establishments.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. In both establishments, the on-going verification activities of the HACCP program were not performed by the GOA meat inspection officials.
5. In both establishments, GOA meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP.
6. GOA meat inspection officials were not providing inspection coverage for second shift operation.
7. Edible and inedible product containers were not identified to prevent possible cross contamination/cross utilization in the boning room and processing rooms.
8. Inedible product was not denatured/decharacterized or under security before shipping for rendering.
9. Deficiencies in the approved private laboratories for the testing of *E.coli* and *Salmonella* concerning the laboratories' proficiency test (intra-laboratory and/or inter-laboratory check samples) for quality assurance program.
10. Deficiencies in the residue laboratory the Federal Institute for Veterinary Medicine Examinations in Moedling, concerning the laboratories' quality assurance programs.
11. Supervisory structure from the level of official veterinarian in the plant to district and to provincial veterinarian is weak.

The basis of the audit of GOA inspection system was in accordance with the European Union/United States Veterinary Equivalence Agreement. The auditor audited the meat inspection system using European Commission Directives, specifically 1) Council Directive 64/433/EEC of June 1964. Health problems affecting intra-Community trade in fresh meat. 2) Council Directives 96/23/EC of April 29, 1996: measures to monitor certain substances and residues thereof in live animals and animal products. 3) Council Directive 96/22/EC of April 29, 1996: prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and B-agonists. These three directives have been declared equivalent under the Agreement. In areas not covered by these directives, the auditor audited against FSIS requirements and equivalence determinations such as the requirements for SSOP, HACCP, and the testing programs for generic *E. coli* and *Salmonella*.

Dr. Peter Vitus Stangl stated that he would take the necessary steps to ensure that corrective actions and preventive measures, including HACCP, SSOP, and sanitation problems as promised during the audits and exit meetings in the individual establishments would be implemented.

CONCLUSION

The Austrian meat inspection system has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in this report. Two establishments were audited. The auditor found sanitation and other conditions to be so serious in both establishments that the establishments were delisted by the GOA.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed) *Dr. Faizur R. Choudry*

ATTACHMENTS

A. Data collection instrument for SSOP
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audit Form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for 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 data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.	2	3.	4.	5	6.	7.	8.
2	√	√	√	√	√	√	no	√
8	√	√	√	√	√	√	no	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11	12.
2	no	no	no	no	no	no	no	no	no	no	√	no
8	no	no	no	no	no	no	no	no	no	no	√	no

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.	2.	3.	4.	5..	6.	7.	8.	9.	10.
2	√	√	√	√	√	√	no	√	√	√
8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Attachment D

Data Collection Instrument for *Salmonella* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1	2.	3.	4.	5.	6.
2	√	√	N/A	no	√	√
8	N/A	N/A	N/A	N/A	N/A	N/A

Attachment E

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
03/15/02	Federal Institute for Veterinary Medicine Examinations

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Federal Ministry of Social Security and Gererations	Modling, Austria	Robert Kochgasse 17 2340 Modling, Austria

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry	Dr. Marina Mikula, Dr. Sepp Flatscher, Deputy Director

	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	EVALUATION CODE	A	A	A	A	A	A						
	Correct Tissue(s)	08		A	A	A	A	A	A						
	Equipment Operation	09		C	A	C	C	C	C						
	Instrument Printouts	10		A	A	A	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	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 PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	A						
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER

DATE

Designed on FormFlow Softwar

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 03/15/02	NAME OF FOREIGN LABORATORY Federal Institute for Veterinary Medicine Examinations
FOREIGN GOV'T AGENCY Federal Ministry of Social Security and Gererations	CITY & COUNTRY Modling, Austria	ADDRESS OF LABORATORY Robert Kochgasse 17 2340 Modling, Austria
NAME OF REVIEWER Dr. Faizur R. Choudry	NAME OF FOREIGN OFFICIAL Dr. Marina Mikula, Dr. Sepp Flatscher, Deputy Director	

RESIDUE	ITEM	COMMENTS
100,200, 203,400, 500,800	3	Samples for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, antibiotics, and sufonamides were not analyzed in a timely manner such as 80% of samples were analyzed in 42 days. Timely analyses is critical for hormones, antibiotics, andsufonamides.
100,203, 400,500, 800	9	The standards book for chlorinated hydrocarbons, trace elements, hormones, chloramphenicol, and sulfonamides was not properly maintained for quality assurance program such as: when solutions prepared by the analyst were not signed and verified by the supervisor before the solutions were used; pages were not serially numbered; some standard solutions/reagents/media ingredients, date of purchase and lot number was not recorded.
800	14	The proficiency test (Intralaboratory and/or interlaboratory check samples) for quality assurance program was not performed for sulfonamides.

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
03/14/02	Institute for Bio-Analytic and Hygiene

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private accredited laboratory	Perg, Upper Austria	Perg, Upper Austria

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faiz R. Choudry	Dr. Marina Mikula

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

SIGNATURE OF REVIEWER

DATE

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 03/14/02	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. Faiz R. Choudry	NAME OF FOREIGN OFFICIAL Dr. Marina Mikula	

RESIDUE	ITEM	COMMENTS
	14	The proficiency test (Intralaboratory and/or interlaboratory check samples) for quality assurance program was not performed for *E.coli* and *Salmonella*. The Institute for Bio-Analytic and Hygiene was accredited by the Ministry of Ecnomic Affairs Accreditation Department in 1997.

ATTACHMENT F

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS **FOREIGN PLANT REVIEW FORM**	REVIEW DATE 03/18/02	ESTABLISHMENT NO. AND NAME Est. 2 Higelsberger GmbH & Company	CITY Schwertberg COUNTRY Austria
NAME OF REVIEWER Dr. Faiz R. Choudry	NAME OF FOREIGN OFFICIAL Dr.P.Stangl & Dr.W.Roitner, Deputy CVO	EVALUATION ☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable	

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 U	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 M	Effective maintenance program	33 U	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 U	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 U	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 A	Inspector verification	73 U
Over-product equipment	18 U	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 U
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 U
Personal hygiene practices	26 M	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	03/18/02	Est. 2 Higelsberger GmbH & Company	Schwertberg COUNTRY Austria

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr.P.Stangl & Dr.W.Roitner, Deputy CVO	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

COMMENTS:

05. The sanitizing facility for knives in slaughter room was designed in such a way that it was not possible to sanitize knife completely and effectively. Corrected immediately. *Repeat deficiency from last audit.*

17.a) Dripping condensate, from overhead refrigeration units, ceilings, pipes, and ducts that was not cleaned/sanitized daily, was falling onto offal and hog carcasses in the coolers. Neither establishment nor GOA inspection officials took corrective action. *Repeat deficiency from last audit.*

b) Flaking paint and numerous dirt spots were observed on the ceilings above the moving rail in the slaughter room. *Repeat deficiency from last audit.*

18. Overhead refrigeration units, ducts, and ceilings in all coolers were observed with accumulations of dust, dirt, and black discoloration, and mold. *Repeat deficiency from last audit.*

19. Dried pieces of fat and blood from previous day's operation were observed on containers for edible product in the slaughter rooms. Establishment officials took corrective action immediately..

26. Employees were not observing good hygienic work habits to prevent direct product contamination such as: employees were observed not covering mesh gloves with rubber gloves to prevent cross contamination at the viscera and offal separation stations in the slaughter room. Neither establishment nor GOA inspection officials took corrective action.

28. a) Beef carcasses were contacting employees' work platforms in the slaughter. b) Automatic offal hooks were observed with fat and blood after washing/sanitizing in the slaughter room. c) Dirty water was falling from carcass splitting saw onto hog carcass during carcass splitting in the slaughter room. Neither establishment nor GOA inspection officials took corrective action.

33. Establishment officials did not have effective maintenance program that prevents and corrects defects on a timely basis.

34, 35.a) The daily pre-operational and operational sanitation deficiencies were not identified and any corrective action taken were not documented by the establishment personnel and monitoring records did not reflect the actual sanitary conditions observed in the establishment. b) The daily pre-operational and operational sanitation deficiencies were not identified and any corrective and preventive measures taken were not documented by the GOA inspection officials.

41. Hog viscera was not synchronized and identity was not maintained with rest of the carcass and offal during postmortem inspection such as viscera from four carcasses were pooled together and then presented for postmortem inspection. This is a violation of Council Directive 64/433

43.a) Containers for edible and inedible product were not identified to prevent cross contamination/cross utilization in the boning.

b) Inedible product was not denatured/decharacterized or under security before shipping for rendering.

73. The ongoing verification activities of the HACCP program were not performed by the GOA inspection officials

77. Inspection devices (brands) were not kept under inspectional control such as brands were left in a locked inspection office and one key was given to establishment officials. Inspection officiale indicated that it would be rectified immediately.

80. Because of gross product contamination, and lack of compliance of daily pre-operational and operational sanitation programs and procedures, inadequate inspectional controls, and noncompliance with basic regulatory requirements of HACCP program, the status of this establishment is not equivalent to that required in the U.S.programs. All the above deficiencies were discussed with Dr.Peter Stangl, Head Department 3, Veterinary Services and Dr.Werner Roitner, Deputy CVO and they agreed to remove Establishment 02 from the list of establishments eligible to export meat and meat products to the United States, effectiveMarch 18, 2002.

82. Establishment did not meet FSIS basic regulatory requirements of HACCP program.

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

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
03/19/02	Est. 8 Greisinger Fleisch-Wurst-und Selchwarenerzeugung GmbH	Munzbach
		COUNTRY: Austria

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Marina Mikula and Dr. Werner Roitner	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 U	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 U	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 U
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 U
Personal hygiene practices	26 M	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	03/19/02	Est. 8 Greisinger Fleisch-Wurst-und Selchwarenerzeugung GmbH	Munzbach
			COUNTRY Austria

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Marina Mikula and Dr. Werner Roitner	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

COMMENTS:

11. Light was inadequate at the dropped meat recoditioning stations in the boning room. Establishment ordered correction.

17. Dripping condensate, from overhead refrigeration units, ducts, and pipes that was not cleaned/sanitized daily, was falling onto hog carcasses and edible product in the cooler and brine injection room. Neither establishment nor GOA meat inspection officials took corrective actions. *Repeat deficiency from last audit.*

18. Overhead supports in the hog carcass cooler were observed with accumulation of rust. Establishment ordered correction.

19.a) Dried pieces of meat, fat, and grease from previous days' operation was observed on numerous containers for edible product in the boning room and brine injection room. b) Dried fat and grease from previous days' operation was observed on numerous working knives in the boning room. Neither establishment nor GOA meat inspection officials took corrective actions.

26. An employee was not observing good hygienic work habits to prevent direct product contamination such as: washing hands with dirty hose and, was also handling edible product. Establishment officials took corrective actions immediately.

28. a) Numerous automatic conveyor rollers and conveyor belts for transporting empty edible containers and containers with product were found with dried pieces of meat, fat, blood, dirt, and water droplets above the boning tables and processed product in the boning and other processing rooms. Two containers of minced meat were found with rust and dirt particles underneath of this area.
b) Raw sausages and cooked sausages were contacting the wheels of the portable smoking and cooking racks. *Repeat deficiency from last audit.* Neither establishment nor GOA inspection officials took corrective action.

33. Establishment officials did not have effective maintenance program that prevents and corrects defects on a timely basis.
34, 35.a) The daily pre-operational and operational sanitation deficiencies were not identified and any corrective action taken were not documented by the establishment personnel and monitoring records did not reflect the actual sanitary conditions observed in the establishment. b) The GOA inspection officials were not monitoring pre-operational sanitation to verify the adequacy and effectiveness of the sanitation SSOP program and operational sanitation deficiencies were not identified and any corrective actions/preventive measures taken were not documented.

43.a) Containers for edible and inedible product were not identified to prevent cross contamination/cross utilization in the boning and processing rooms.
b) Inedible product was not denatured/decharacterized or under security before shipping for rendering.

73.a) GOA meat inspection officials were not providing inspection coverage for second shift operation.
b) The ongoing verification activities of the HACCP program were not performed by the GOA inspection officials

76. Monthly supervisory audits were conducted but identified deficiencies were not followed by inspection officials.

80. Because of gross product contamination, and lack of compliance of daily pre-operational and operational sanitation programs and procedures, inadequate inspectional controls, and noncompliance with basic regulatory requirements of HACCP program, the status of this establishment is not equivalent to that required in the U.S.programs. All the above deficiencies were discussed with Dr.Marina Mikula Dr.Werner Roitner, Deputy CVO and they agreed to remove Establishment 08 from the list of establishments eligible to export meat and meat products to the United States, effectiveMarch 19, 2002.

82. Establishment did not meet FSIS basic regulatory requirements of HACCP program.

Attachment G

FEDERAL MINISTRY
OF SOCIAL SECURITY AND GENERATIONS

Sally Stratmoen, Chief
Equivalence Section,
International Policy Division,
OPPDE, FSIS,
Washington, DC
20250
USA

Our ref: 39.162/12-VII/B/7/02

Vienna, 5th July 2002

Dear Dr. Stratmoen:

The Austrian Veterinary Services of the Federal Ministry of Social Security and Generations thank you for the report of the audit that was conducted between March 12 and March 22, 2002.

As a consequence of the audit, the establishments Est. O2 and O8, which were audited by Dr. Faizur Choudry, were removed from the list of certified establishments.
Regarding this fact the Austrian Veterinary Services will not re-certify one of these establishments, before conducting a re-certification audit.
The Veterinary Services got information by the Provincial government of Upper Austria, that Establishment O 2 will not apply for US-certification for the time being.

/2

Organisation Unit VII/B/7, Information: Dr. Marina Mikula, EXT. 4352
A-1031 Wien, Radetzkystraße 2, Phone: (01) 711 00, Telefax: (01) 710 41 51, DVR:0017001

Establishment O 8 presented a catalogue of measures in order to show how and in which period of time they will take all the corrective actions. Among other things this catalogue of measures includes constructional measures, corrections relating to hygiene and development of HACCP.
After the implementation and realisation of this concept and if the establishment applies for a US re-certification, Austria will conduct a complete re-certification audit – as requested in the letter from April 30, 2002 – and will provide FSIS with documentation of the audit.

Independent from this, the deficiencies according to the Austrian Meat and Hygiene Law, in connection with the implementation of EC Directive 64/433 noted in the audit are in the process of correction and improvement (e.g. constructional problems).

Nevertheless the Veterinary Services would like to provide some written comments and corrections (written in italics and in bold types) regarding information in the draft report:

Entrance Meeting (page 3)

- The name of the Head of Department 7 of the Veterinary Services for Meat **Hygiene*/Residue Control/Poultry Hygiene/Raw Material of Animal Origin is Dr. Peter-Vitus Stangl.***
- Dr. Andrea Höflechner, Veterinary Medical Doctor, Department **4** (since July 1, Department 8)

Please indicate the correct name of Dr. Peter-Vitus Stangl (see also page 19 and 20 of the report).

Government oversight (page 4)

The veterinarians that actually perform the daily inspection are paid by the provincial government, because they are provincial employees (it is correct that they are not hired and paid by the federal government).

Veterinary services are organized in indirect federal administration (**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 is 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).

Second paragraph:

Besides participation in development and negotiation of EC legislation, interpretation and clarification of international and national law, one of the most relevant responsibilities of the federal government is – and this is a very important scope of duties of the Federal Ministries – to implement EC Legislation into Austrian Law.

Third paragraph:

- **Austria** consists of ~~the~~ nine provinces.

Laboratory Audits

Second paragraph, page 5 and Attachment D:

The name of the laboratory, which was audited on March 15, 2002, was the **Federal Institute for Veterinary Medicine in Mödling** (or Moedling).

First paragraph, page 6:

It is not correct that Austria's microbiological testing for E.coli and Salmonella is being performed exclusively in private laboratories! Each laboratory, analysing microbiological samples, has been approved officially, this applies to private laboratories as well. The legal basis for the approval of the laboratories can either be Article 27 of the Meat Inspection Act or Article 42, 49 or 50 of the Food Act.

Microbiological testing for E.coli and Salmonella is also done in State laboratories. Since June 1, 2002 it is done by the Agency –Austrian Agency for Health and Nutrition -, where all State laboratories (veterinary labs, human labs and food labs) are included.

The Laboratory in Perg, which is testing E.coli and Salmonella for US-certified establishments, is a private one, but approved officially under § 50 of the Food Act.

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 quick 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.

Also from the technical point of view no problems occur for the stability of the substances mentioned in the draft report.

The laboratory tries hard to improve this, although problems regarding staff resources and technical equipment make this difficult. It is the aim of the lab 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 the standards book was not properly maintained:
The system of record keeping is in accordance with the accreditation standard ISO/IEC 17052, which has been approved by the EC. As a result of a control by the Community Reference laboratory Fougères in June 2002, the standards book presented was fully accepted.
The way of keeping this book is in line with the ISO 17025. When the technical staff prepare the standard solutions it is not necessary to supervise or verify and sign this in the standards book before use, on condition that the level of education of the technical staff in the lab is high.
The registration of the lot-number of the standards and the date of purchase will be done in the future. For the registration of the pages of the standards book, which were already archived, a new system will be developed.

Referring to the concern that proficiency tests for quality assurance programs were not performed for sulfonamides:
First of all some clarification: E. coli and Salmonella are not investigated in the laboratory approved for official residue control; these two terms should be deleted.

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 last ring test for sulfonamides where the lab participated was organised by FAPAS, United Kingdom, in autumn 1999. Since this time neither the Community Reference Laboratory Fougères nor FAPAS organised ring tests for this group of substances.

Sanitation Controls (page 6 to 8)

In both establishments the written SSOP and the identification in the daily pre-operational and operational sanitation deficiencies will be revised and improved.

Animal Disease Controls (page 8/9)

It is not correct that Austria shares a border with a country or countries that are not free from Foot and Mouth Disease (FMD):

Although FMD occurred in some countries of the European Union, there was no out-break of FMD in Germany, a neighbouring country. The third countries, which have a border to Austria, are free from FMD as well! **The conclusion of these facts is that Austria is not a substantial risk for FMD!**

Residue Controls (page 9/10)

See the comments to the chapter "Laboratory Audits", page 5/6.

On farm (page 9/10)

Page 10: additional information to paragraph 2:

The Austrian Veterinary Services would like to emphasize that it is forbidden to slaughter animals during the withdrawal period, the only thing possible is to kill them for animal welfare reasons.

Conclusions (page 16)

As a result of this audit the Department 3 (since July 1: Department 7) of the Veterinary Services organized a meeting (May 14, 2002) with governmental experts on meat hygiene of all provinces of Austria in order to discuss the lack of oversight in the meat inspection system.

According to the problems of HACCP implementation in the establishments a workshop is scheduled at the beginning of autumn. The participants will be experts sent by the governmental officials of the Provinces.

Foreign Country Laboratory Review (Review date 03/15/02)

The City&Country is **Mödling (or Moedling)**

Name of foreign officials: ....Dr. **Josef** Flatscher, Deputy Director

Statements to the comments see chapter "Laboratory Audits"

Foreign Country Laboratory Review (Review date 03/14/02)

Name of foreign officials: **Dr. Peter-Vitus Stangl** (and not Dr. Mikula)

Referring to the concern that the proficiency test for quality assurance program were not performed for E.coli and Salmonella:

The proficiency tests for quality assurance program will be implemented for E.coli and Salmonella at the moment one of the establishments ask for a US-recertification. In the same way it is scheduled that the carcass selection will be done randomly.

For the Federal Minister:
Dr. DAMOSER

For the rightness
of the copy: