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

Dr. Milan Malena
Director General
State Veterinary Administration
of the Czech Republic
Tesnov 17
117 05 PRAHA 1
Czech Republic

DEC 16 2005

Dear Dr. Malena:

The Food Safety and Inspection Service completed an on-site audit of the Czech Republic's meat inspection system. The audit was conducted July 20 through July 29, 2005. The comments from the Czech Republic have been included in the final report. Enclosed is a copy of the final report.

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

Sincerely,

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

cc:

Quintin Gray, Minister Counselor, American Embassy, Vienna
Martin Dvorak, Economic Counselor, Embassy of The Czech Republic
Mr. Bernard Van Goethem, Acting Director, Directorate E, European Commission, Brussels
Canice Nolan, EU Mission to the US, Washington, DC
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
Bob Macke, Assistant Deputy Administrator, International Trade Policy, FAS
James Dever, FAS Area Officer
Amy Winton, State Department
Barbara Masters, Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA, FSIS
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Linda Swacina, Executive Director, FSIA, OIA
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Armia Tawadrous, Director, FSIS Codex Staff, OIA
Shannon McMurtrey, IES, OIA
Country File (Czech Republic, FY 2005 Annual Audit)

FINAL

DEC - 1 2005

FINAL REPORT OF AN AUDIT CARRIED OUT IN THE CZECH REPUBLIC COVERING THE CZECH REPUBLIC'S MEAT INSPECTION SYSTEM

JULY 20 THROUGH JULY 29, 2005

Food Safety and Inspection Service
United States Department of Agriculture

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14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (State Veterinary Administration)
SVA	State Veterinary Administration
SVI	State Veterinary Institute
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species
Lm	*Listeria monocytogenes*
DG	Director General
DVHPHE	Department of Veterinary Hygiene, Public Health and Ecology
DAHW	Department of Animal Health and Welfare
RVA	Regional Veterinary Administrations
DRVA	Director of Regional Veterinary Administrations
DVA	District Veterinary Administration
DDO	Director of District Office
VD	Veterinary Doctor
VA	Veterinary Assistant
VT	Veterinary Technician
VO	Veterinary Official

1. INTRODUCTION

The audit took place in The Czech Republic from July 20 through July 29, 2005.

An opening meeting was held on July 20, 2005, in Prague with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of the Czech Republic's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA, the State Veterinary Administration (SVA), and/or representatives from the regional and district inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishment certified by the CCA as eligible to export meat products to the United States. This was also an in-depth residue audit with an auditor from the Office of Public Health and Safety (OPHS) present.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA (SVA), one district office, one local office at the establishment level, one microbiological and residue laboratory performing analytical testing on United States-destined product, and one swine slaughter and processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	Headquarters (SVA)
	District	1	Tabor (DVA) office
	Local	1	Establishment level
Laboratories		1	
Meat Slaughter/Processing Establishments		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters and one district office. The third part involved an on-site visit to one slaughter and processing establishment. The fourth part involved two visits to one government laboratory. The government laboratory, the State Veterinary Institution (*Statni Veterinarni Ustav*, Jihlava) was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*), *Salmonella* species (*Salmonella*), and *Listeria monocytogenes*. This laboratory also was conducting analyses of field samples for the Czech Republic's national residue control program.

Program effectiveness determinations of the Czech Republic's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. The Czech Republic's inspection system was assessed by evaluating these five risk areas.

During all 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 the Czech Republic and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

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

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

Third, the auditors would audit against any equivalence determinations that have been made by FSIS for the Czech Republic under provisions of the Sanitary/Phytosanitary Agreement.

The Czech Republic has an equivalence determination from FSIS regarding the use of government laboratories to analyze samples under the generic *E. coli* sampling program (see section 11.3), and the use of a different testing strategy and a different analytical method (ISO 6579) for testing United States-destined product for *Salmonella* (see section 13.2).

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 B-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 following deficiencies were identified during the FSIS audit of the Czech Republic's meat inspection system conducted in April-May 2003. A Notice of Intent to Delist (NOID) for inadequate implementation of SSOP requirements was given to one of the two establishments audited.

- Condensation was observed over exposed product and exposed product traffic areas (product moving hall and cooler) in one establishment.
- Flaking paint was observed over carcasses on carcass rails in the hog carcass coolers in two establishments.
- In both establishments, daily records did not include all deficiencies observed during this audit.
- Condensate was dripping adjacent to product in the cooler in one establishment.
- Trimming of foreign particles from carcasses was not properly performed in one establishment.
- The HACCP plans did not include on-site verification of monitoring activities in both establishments.

All of the above findings had been corrected by the time of the 2004 FSIS audit.

The following deficiencies were identified during the FSIS audit of the Czech Republic's meat inspection system conducted in May-June 2004.

- In one establishment, there was a build-up of rust and pieces of fat and meat observed at various places over the hog carcass rail in the hallway leading to the carcass cooler.
- In one establishment, the sponging method was used for hog carcass sampling but statistical process control was not used for evaluation of the test results.
- In one establishment, the establishment employee only signed the records once per day, but the frequency of monitoring the CCP was every two hours.
- At the laboratory it was noted that the temperature of incoming samples was not recorded on the form in the sample receival room as specified in their plan.

All of the above findings had been corrected by the time of the 2005 FSIS audit.

6. MAIN FINDINGS

6.1 Legislation

The auditors were informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into the Czech Republic's legislation.

6.2 Government Oversight

The State Veterinary Administration (SVA) of the Czech Republic is the Competent Central Authority (CCA), and the Director General is appointed by the Minister of Agriculture. This is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced. The Czech Republic's meat inspection system is organized in three levels: central, regional, and district.

The first level is the State Veterinary Administration (SVA), which includes the Department of Veterinary Hygiene, Public Health and Ecology (DVHPHE), the Department of Animal Health and Welfare (DAHW), the Department of Veterinary Protection of State Territory and Foreign Relations (DVPSTFR), the Institute of State Control of Veterinary Biological and Medicaments (ISCVBM), seven State Veterinary Institutes (SVI), 13 Regional Veterinary Administrations (RVA), and one Municipal Veterinary Administration (MVA) in Prague. The SVA, with regard to meat inspection, is staffed with approximately 1,300 personnel. These personnel are scattered throughout the 14 Regions of the Czech Republic.

The second level is the 13 RVA offices and one MVA office, within which there are 74 District Veterinary Administration (DVA) offices. The RVA in each region consists of between 2 to 12 DVAs. These RVA and MVA offices are directly under the SVA office in Prague.

The third level is the District Veterinary Administration (DVA), which provides the inspectors for inspection activities.

6.2.1 CCA Control Systems

An official of the RVA staff, the district director, and the in-plant supervisor oversee the maintenance of eligibility to export to United States. These supervisors have the authority, under the Czech Republic's regulations, to enforce the necessary requirements to export to another country. Their duties also include initiating investigations into failure on the part of an establishment to meet the standards of the importing country and to delist those establishments that fail in this requirement.

All inspection personnel assigned to establishments certified to export meat to the United States are full-time government employees receiving no remuneration from either industry or establishment personnel. Inspection personnel cannot obtain outside employment.

6.2.2 Ultimate Control And Supervision

The Veterinary Official (VO) has the authority to cease the establishment's production operations any time the wholesomeness and safety of the product is jeopardized. He/she reports directly to the district director and consults with him/her regarding all decisions involving enforcement activities. The decision as to whether the establishment is failing to meet U.S. import requirements and the recommendation that it should be delisted is a combined effort of the veterinary inspector, district director, and regional director, and may also include headquarters officials. The Regional State Veterinary Administration Director (RSVAD) will make the ultimate decision and will advise SVA authorities.

The VO has direct supervision over all other inspection personnel assigned to certified establishments. This includes supervision over veterinary officers, the senior veterinary assistant, and meat inspectors (technicians). In the establishment certified to export meat to the United States, the district office has placed a sufficient number of official inspection personnel to adequately carry out the U.S. import requirements.

Control in both slaughter and processing establishments is accomplished by the official veterinarian-in-charge. These official veterinarians-in-charge are supervised by officials from the respective DVA. Overall control and supervision is the responsibility of the RVA office in Ceske Budejovice. Permits to export to other countries are granted or withdrawn by the headquarters office.

6.2.3 Assignment of Competent, Qualified Inspectors

All inspection personnel assigned to certified establishments undergo formal introductory training as well as participate in on-the-job practical training under the supervision of experienced veterinarians. Additional training is provided for all inspection personnel as needed.

The Veterinary Technicians (VTs) have passed a specialized professional training organized by the SVA in the relevant field and Veterinary Assistants (VAs) have acquired their qualifications in a study program for a bachelor's degree in veterinary medicine and hygiene. All official veterinarians are qualified veterinarians who have obtained their professional university veterinary degrees.

Ensuring adequate training of inspectors before assignment to a position is the responsibility of the regional veterinary administration staff. It is also the responsibility of the district director to see that all establishments are adequately staffed with trained and competent inspectors.

6.2.4 Authority and Responsibility to Enforce the Laws

The official veterinarian (veterinarian-in-charge) and meat inspectors are authorized to enforce European Community (EC) legislation and U.S. import requirements, including animal health and welfare, control of animal disease, veterinary medicines, and the production of safe foods of animal origin. The RVA (with assistance of SVA) has the legal power to suspend and delist certified establishments to prevent the export of unsafe meat to the United States.

6.2.5 Adequate Administrative and Technical Support

During this audit, the FSIS auditors determined that the CCA has adequate administrative and technical support in the central, regional, and district offices and in the field to operate the Czech Republic's meat inspection system and has the resources and the capability to support a third-party audit. The SVA demonstrated an adequate amount of supervisory oversight to ensure compliance with U.S. import requirements

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters, district, and local (establishment level) offices. Some of the following records were reviewed at the laboratory level also. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Supervisory visits to the establishment that was certified to export to the United States
- Training records for inspectors
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Sampling and laboratory analyses for residues
- Sanitation, slaughter and processing inspection procedures and standards
- Control of products from livestock with conditions such as tuberculosis, etc., and of inedible and condemned materials
- Export product inspection and control, including export certificates
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, or withdrawing inspection services from or delisting an establishment that is certified to export product to the United States
- Label approval records, such as generic labels and animal raising claims

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

6.3.1 Audit of the District Inspection Site

The District Office at Tabor was audited. The Regional Veterinary Officer, the Head of the Public Health Department and the District Veterinary Officer were present. The only documents available at this level were the monthly supervisory reviews. The purpose of the interviews was to determine the level of government oversight and control provided by the DVA offices relative to the certified establishment.

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

7. ESTABLISHMENT AUDITS

The FSIS lead auditor visited one slaughter and processing establishment. This establishment received a Notice of Intent to De-list (NOID) from the Czech Republic. This

NOID was given for deficiencies in SSOP and HACCP programs, and in the requirements of EC Directive 64/433. This establishment may retain its certification for export to the United States provided that all deficiencies noted during the audit are corrected within 30 days of the date the establishment was audited.

Specific deficiencies are noted on the attached individual establishment report.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples.

The following laboratory was reviewed:

The SVA State Veterinary Institute laboratory located in Jihlava is a state laboratory, which conducts analyses of field samples for the Czech Republic's national residue program and analyses of field samples for the presence of *Salmonella* and the generic *E. coli* sampling program. This laboratory has received ISO Standard 17025 accreditation.

The findings at the SVA State Veterinary Institute laboratory are discussed in Section 12 (Residue Controls).

9. SANITATION CONTROLS

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

Based on the on-site audit of establishment, and except as noted below, the Czech Republic'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.

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

9.1 SSOP

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

- Actual and potential cross contamination of product with boots and foot stands was observed in the slaughter area at viscera removal and in the deboning area at the removal of the neck. The veterinary service ordered immediate correction of the procedures and condemned the affected product.

9.2 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were not effectively implemented. See Section 11.5 for the specific findings.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that the Czech Republic's inspection system had adequate controls in place. No deficiencies were noted.

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

11. SLAUGHTER/PROCESSING CONTROLS

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

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

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented HACCP programs. Each of these programs is

evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP program was reviewed during the on-site audit of the establishment. This establishment had adequately implemented the HACCP requirements except as noted below:

- The written thermometer calibration program stated that actual calibration was to be performed every 24 months. There was no supporting documentation provided for calibration at that frequency.

11.3 Testing for Generic *E. coli*

The Czech Republic has adopted the FSIS regulatory requirements for testing for generic *E. coli* with the exception of the following equivalent measure: The Czech Republic has an equivalence determination from FSIS regarding the use of government laboratories to analyze samples under the generic *E. coli* sampling program

The one establishment audited was required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and was evaluated according to the criteria employed in the United States' domestic inspection program.

- Testing for generic *E. coli* was not properly conducted in the slaughter establishment: Generic *Escherichia coli (E. coli)* samples were not taken at the frequency stated in the HACCP plan. The plan stated that the samples would be taken at one per thousand swine and if thirteen samples were negative, then the sampling frequency would be one per three thousand swine. The actual sampling frequency varied, with an approximate average of once per week, but this did not follow the frequency specified in the written plan (the weekly slaughter volume was 4,000-4,500 swine). Also, the samples were taken with a swab rather than a sponge.

11.4 Testing for *Listeria monocytogenes*

The establishment audited was not producing ready-to-eat products for export to the United States. Therefore, the HACCP plans in these establishments had not been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to exist.

11.5 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were not effectively implemented and the following deficiencies were noted:

- The pest control program did not include any interior control of rodents, only a comment about visual sightings.
- In the shipping area for cooked product, several brown, oblong objects (apparently insect cocoons or pupa cases) were found under a pallet. This will be investigated for identification of the pest and how it came to be in the shipping area.

- There was heavy beaded condensation over the doorway leading from the cooler to the deboning area. The veterinary service ordered immediate correction.
- Inedible containers were in contact with edible containers in both a storage area and in the pork skin sorting area during operations. The veterinary service ordered immediate correction.
- Most of the stainless steel carts in use in the processing area had unsmooth welds and cracks which could lead to the formation of biofilms. This area had completed production for the day. The veterinary service discussed the finding with the establishment management and found that new carts had been ordered. Management officials assured the veterinary service that a program would be developed to control the welding process, the condition of the carts, and the potential exposure of product to insanitary conditions.

12. RESIDUE CONTROLS

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

The laboratory audited was the SVA State Veterinary Institute (SVI) laboratory located in Jihlava. This is a government laboratory in which field samples are analyzed for the Czech Republic's national residue program.

The following deficiencies were noted:

- One set of samples for tetracycline analysis received at the residue laboratory at Jihlava had not been sealed before shipping. This was contrary to the laboratory SOP. The laboratory immediately contacted the IIC of the establishment. The samples were scheduled for analysis.
- FSIS was not notified of the correct information for residue laboratories analyzing U.S.-eligible product for the certified establishment. The ISCVBM Brno (Institute for State Control of Veterinary Biologicals and Medicaments in Brno) was also testing samples from this establishment.

The Czech Republic's national residue testing program for 2005 was being followed and was on schedule.

12.1 EC Directive 96/22

In the SVA State Veterinary Institute laboratory located in Jihlava, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the SVA State Veterinary Institute laboratory located in Jihlava, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the slaughter and processing establishment.

13.2 Testing for *Salmonella*

The Czech Republic has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s): An equivalence determination has been made to allow the use of a different testing strategy and a different analytical method (ISO 6579) for testing United States-destined product for *Salmonella*

The establishment audited was required to meet the basic FSIS regulatory requirements for *Salmonella* testing and was evaluated according to the criteria employed in the United States' domestic inspection program.

- *Salmonella* testing was not properly conducted in the establishment. *Salmonella* species samples were not taken at the frequency agreed to as equivalent (twice per week continuously until a violation occurred). The actual sampling averaged once per week. Also, the samples were taken with a swab rather than a sponge.

13.3 Species Verification

Species verification was being conducted in the establishment in which it was required.

13.4 Monthly Reviews

During this audit, it was found that monthly supervisory reviews of the certified establishment were being performed and documented as required.

13.5 Inspection System Controls

Inspection system controls would not have adequately controlled the production of product for US export if such product had been produced.

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 counties for further processing.

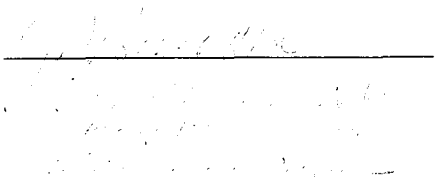
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishment from outside sources.

14. CLOSING MEETING

A closing meeting was held on July 29, 2005 in Prague with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.

Rori K. Craver, DVM
Senior Program Auditor



15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Form
Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Maso Planá a.s. Prümyslová 499 39111 Planá nad Lužnici 92	25 July	CZ 15	The Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Rori K. Craver, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	X
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58. Notice of Intent to Delist	X
59.	

60. Observation of the Establishment

25 July 2005
The Czech Republic
Est. CZ 15
Maso Planá a.s.
Planá nad Lužnici

10. Actual and potential cross contamination of product with boots and foot stands was observed in the slaughter area at viscera removal and in the deboning area at the removal of the neck. The veterinary service ordered immediate correction of the procedures and condemned the affected product. Regulatory reference: 9 CFR § 416.13(b)

22/51. The written thermometer calibration program stated that actual calibration was to be performed every 24 months. There was no supporting documentation provided for calibration at that frequency. 9 CFR § 417.5(a)(1,2), 9 CFR § 417.8

28/51. Generic *Escherichia coli (E. coli)* samples were not taken at the frequency stated in the HACCP plan. The plan stated that the samples would be taken at one per thousand swine and if thirteen samples were negative, then the sampling frequency would be one per three thousand swine. The actual sampling frequency varied, with an approximate average of once per week, but this did not follow the frequency specified in the written plan (the weekly slaughter volume was 4,000-4,500 swine). Also, the samples were taken with a swab rather than a sponge. 9 CFR § 310.25

31/51. *Salmonella* species samples were not taken at the frequency agreed to as equivalent (twice per week continuously until a violation occurred). The actual sampling averaged once per week. Also, the samples were taken with a swab rather than a sponge. 9 CFR § 310.25

38. (A) The pest control program did not include any interior control of rodents, only a comment about visual sightings. The veterinary service ordered immediate correction. (B) In the shipping area for cooked product, several brown, oblong objects (apparently insect cocoons or pupa cases) were found under a pallet. This will be investigated for identification of the pest and how it came to be in the shipping area. EEC 64/433 Annex I, Chapter I (v)

41. There was heavy beaded condensation over the doorway leading from the cooler to the deboning area. The veterinary service ordered immediate correction. EEC 64/433 Annex I, Chapter I (n)

45. Inedible containers were in contact with edible containers in both a storage area and in the pork skin sorting area during operations. The veterinary service ordered immediate correction. 9 CFR § 416.3(c) and EEC/ 64/433 Annex I, Chapter V

45/51. Most of the stainless steel carts in use in the processing area had unsmooth welds and cracks which could lead to the formation of biofilms. Production for the day had been completed in this area. The veterinary service discussed the finding with the establishment management and found that new carts had been ordered. Management officials assured the veterinary service that a program would be developed to control the welding process, the condition of the carts, and the potential exposure of product to insanitary conditions. EEC 64/433 Annex I, Chapter II (n)

58. Upon a consensus agreement of the combined SVA/FSIS audit team for this establishment, a Notice of Intent to Delist (NOID) was issued, based on the audit findings above.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Rori K. Craver, DVM	Rori K Craver DVM 25 July 05

STATE VETERINARY ADMINISTRATION
Czech Republic

Slezská 7, 120 56 PRAHA 2 Tel.: (+420) 227010186 Fax.: (+420) 227010600

Your letter d/d	:		Attachement	:
Your reference	:		File handled by	: Dr. Brychta
Our reference	:	2005 / 513 / INT	Department	: of External Affairs and Import and Export Control
		RED/2097/05	Phone	: (+ 420) 227 010 185
			Fax	: (+ 420) 227 010 600

Dr. Sally White, Director
International Equivalence Staff
Office of International Affairs
USDA - FSIS
1400 Independence Ave.
20250 Washington D.C
USA

Prague: 23.11.2005

Re: FSIS audit in the Czech plant (CZ 15) exporting to USA

Dear Sally White,

On the basis of preliminary findings of the USDA-FSIS audit carried out in the Czech Republic from 19 July to 29 July 2005 by inspectors Mrs. Rori K. Craver, DVM and Mrs. Penny Zervos and covering the Czech meat inspection system, we are sending you comments of the State Veterinary Administration of Czech Republic to the Draft final report of the audit.

We would like the following to be corrected:

1) IN THE DRAFT, COMMENTS ARE NOT INCLUDED THAT WE SENT ON 19 August 2005 BY LETTER No. 2005/863/HYG TO USDA-FSIS (in enclosure)

2) Page No. 5: Used abbreviation "OPHS" is used without further explanation of its meaning

3) Page No. 9: We suggest to replace the word "Commission" with the word "Community" (EC legislation means European Community legislation)

4) Page No. 10: The sentence "*Through legal process in the courts, the RVA, with the assistance of the SVA, has the authority to suspend and delist certified establishments to prevent the export of unsafe meat to the United States*" should be replaced with

"The RVA (with assistance of SVA) has the legal power to suspend and delist certified establishments to prevent the export of unsafe meat to the United States"

5) Page No. 11, point 8 and following text: "Government laboratory" replace with "State laboratory"

6) Page No. 14, point 12: "The SVI laboratory at Brno" should be replaced with "The ISCVBM Brno" (Institute for State Control of Veterinary Biologicals and Medicaments in Brno).

We hope that you will find the suggested corrections appropriate and acceptable.

For any additional information please do not hesitate to contact Dr. Lenka Peklova, tel.: +420 22 70 10 159, l.peklova@svscr.cz.

Kindest regards,

MVDr. Milan Malena
Director General (CVO).

C. c.:
Ing. P. Chotěborská, Foreign Agricultural Service, Embassy of the USA, Prague
Ing. J. Ivánek, Ministry of Agriculture of the Czech Republic
RVA for South-bohemian region
SVI Jihlava

Enclosure