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
Slezska 7
120 56 Praha 2
Czech Republic

MAR 10 2009

Dear Dr. Malena:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Czech Republic's meat inspection system September 4 through September 11, 2009. Comments from the government of the Czech Republic have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

Manzoor H. Chaudry, DVM

Manzoor Chaudry, DVM
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

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

SEPTEMBER 4 THROUGH 11, 2008

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. SUMMARY
   1.1 Description/Eligibility
   1.2 Comparison of the Current Audit and the Previous Audit
   1.3 Summary Comments for the Current Audit
2. INTRODUCTION
3. OBJECTIVE OF THE AUDIT
4. PROTOCOL
5. LEGAL BASIS FOR THE AUDIT
6. SUMMARY OF PREVIOUS AUDITS
7. MAIN FINDINGS
   7.1 Legislation
   7.2 Government Oversight
   7.3 Headquarters, Regional, and District Offices Audit
8. ESTABLISHMENT AUDITS
9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS
10. SANITATION CONTROLS
   10.1 Sanitation Standard Operating Procedures
   10.2 EC Directive 64/433
11. ANIMAL DISEASE CONTROLS
12. SLAUGHTER/PROCESSING CONTROLS
   12.1 Humane Handling and Slaughter
   12.2 HACCP Implementation
   12.3 Testing for *Enterobacteriaceae*
   12.4 Microbiological Testing of Ready-to-Eat Products
   12.5 EC Directive 64/433
13. RESIDUE CONTROLS
   13.1 EC Directive 96/22
   13.2 EC Directive 96/23
14. ENFORCEMENT CONTROLS
   14.1 Daily Inspection
   14.2 Testing for *Salmonella* species
   14.3 Species Verification
   14.4 Periodic Supervisory Reviews
   14.5 Inspection System Controls

15. CLOSING MEETING

16. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (State Veterinary Administration)
DHVHD	District Head of Veterinary Hygiene Department
DRVA	Director of Regional Veterinary Administration
DVI	District Veterinary Inspectorate
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
Lm	*Listeria monocytogenes*
NRL	National Reference Laboratory
OVIC	Official Veterinarian-in-Charge
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Points
RVA	Regional Veterinary Administration
RVAD	Regional Veterinary Administration Director
Salmonella	*Salmonella* species
SSOP	Sanitation Standard Operating Procedures
SVA	State Veterinary Administration
SVI	State Veterinary Institute (Government Laboratories)
VEA	European Community/United States Veterinary Equivalence Agreement

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in The Czech Republic from September 4 through September 11, 2008. This was a routine audit. The Czech Republic is eligible to export porcine raw meat (not ground) products and processed products to the United States. At the time of the audit, one slaughter/processing establishment was eligible to export to the United States. Between January 1, 2008, and July 11, 2008, The Czech Republic has not exported any raw or processed pork product to the United States. Activities of the current audit appear in the table below.

The findings of the previous audit during May of 2007 resulted in no restrictions of any Czech Republic establishment's ability to export pork to the United States.

1.2 Comparison of the Current Audit and the Previous Audit

		09/4-09/11, 2008	05/2-05/17, 2007
Levels of Government Oversight Audited			
	Headquarters	1	1
	2nd Level	1	2
	Establishment Level	1	1
Laboratories Audited			
	Microbiology	1	1
	Residue	1	1
Establishments Audited			
	Slaughter/processing	1	1
	Processing	0	0
	Cold Storage	0	0
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	1	0
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	0	3
	Residue Controls	0	0
	Microbiology Controls	0	0
	Inspection/Enforcement Controls	0	0
	Special Emphasis (HH, O157:H7)	0	0

1.3 Summary Comments for the Current Audit

The results of this audit reflected a risk area finding in sanitation controls.
The deficiency reported was in pre-operational SSOP and inspection control.

2. INTRODUCTION

The audit took place in The Czech Republic from September 4 through September 12, 2008.

An opening meeting was held on September 4, 2008, in Prague with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of the Czech Republic's meat inspection system.

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

3. OBJECTIVE OF THE AUDIT

This 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.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA , one regional office, one local office at the establishment level, one swine slaughter and processing establishment, and two government laboratories: one performing analytical chemical analyses on US-destined product, and the other microbiological analyses.

4. 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 visits to two laboratories. The State Veterinary Institute Jihlava was conducting microbiological analyses of field samples for the presence of *Enterobacteriaceae* and *Salmonella* species (*Salmonella)*, as well as chemical analyses in conjunction with 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 of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation of Hazard Analysis and Critical Control Points (HACCP) programs and a testing program for *Enterobacteriaceae*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species. The Czech Republic's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by 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 auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964, European Commission Directive 96/22/EC of April 1996, and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

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

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

FSIS has now determined the analysis of *Enterobacteriaceae* and Total Viable Count in lieu of generic *Escherichia coli (E. coli)* is acceptable for all EU exporting countries. In addition, The Czech Republic has equivalence determinations in place allowing analysis for *Enterobacteriaceae* to be conducted in government laboratories (see section 12.3), as well as the use of a different testing strategy and a different analytical method (ISO 6579) for analyzing US-destined product for *Salmonella* (see section 14.2).

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. 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 ß-agonists."

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the 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 July 2005. Consequently, the establishment was given a Notice of Intent to Delist (NOID) by the SVA officials.

- 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 neck removal station.

- The thermometer calibration program required actual calibration only every 24 months. There was no supporting documentation provided for calibration at that frequency.

- Testing for generic *E. coli* was not properly conducted in the slaughter establishment: Generic *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 13 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.

- 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.

- There was heavily beaded condensate over the doorway leading from the cooler to the deboning area.

- Inedible containers were in contact with edible containers in both a storage area and in the pork skin sorting area during operations.

- 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.

- *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.

Laboratory Audit:

- 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 Standard Operating Procedure. (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 US-eligible product for the certified establishment. The SVI laboratory at Brno was also testing samples from this establishment.

All of the above findings had been corrected by the time of the 2007 FSIS audit.

The following deficiencies were identified during the FSIS audit of The Czech Republic's meat inspection system conducted in May 2007:

- The written HACCP plan did not contain a description of the verification procedures (calibration of process-monitoring instruments and review of records generated and maintained under HACCP plan) or the frequency with which those procedures were to be performed.

- Verification records for CCP seven (zero tolerance for feces, ingesta, and milk) and CCP eight (product temperature) did not properly document the type of verification procedures performed or the results of the verification.

- Verification records for CCPs seven and eight did not document the times when the specific events occurred.

All of the above findings had been corrected by the time of the 2008 FSIS audit.

7. MAIN FINDINGS

7.1 Legislation

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

7.2 Government Oversight

The State Veterinary Administration (SVA) in The Czech Republic, a public administration body under the Ministry of Agriculture, is the CCA and its Director General (Chief Veterinary Officer) is appointed by the Minister of Agriculture. Administration, development, coordination, and the formation of rules and regulations take place in the headquarters of the SVA in Prague. This is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced. The addition of a department dealing with EU issues has been established since the last audit.

The Czech Republic's meat inspection system is organized in three levels: central, regional, and district.

The first level is the SVA headquarters in Prague, which consists of the following eight departments:

1) Personnel Department
2) Economy Department
3) Legislative and Juridical Department
4) Information and Communication Technologies Department
5) Internal Audit and Control Department
6) External Relations, Export, and Import Department
7) Animal Health and Welfare Department
8) Public Health, Veterinary Hygiene, and Ecology Department

The Institute of State Control of Veterinary Biological and Medicaments (ISCVBM), six State Veterinary Institutes (SVI), 13 Regional Veterinary Administrations (RVA), and one Municipal Veterinary Administration (MVA) in Prague are under the direct supervision of the Director General.

The second level encompasses 13 RVA offices and one MVA office. Within each RVA is the Regional Veterinary Administration Director (RVAD), in charge of implementation of inspection activities, who has overall control and supervision in his/her region.

The District Veterinary Inspectorate (DVI) forms the third level. There are a total of 65 DVI offices. Within each DVI is the District Head of the Veterinary Hygiene Department (DHVHD, in-charge of all supervision activities), who serves as the field supervisor over the Official Veterinarian-in-Charge (OVIC) located at the establishment level.

7.2.1 CCA Control Systems

The DHVHD and the in-plant OVIC oversee the maintenance of eligibility to export to the 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 the establishment certified to export meat and meat products to the United States are full-time government employees receiving no remuneration from either industry groups or establishment personnel.

7.2.2 Ultimate Control And Supervision

The OVIC has the authority to stop the establishment's production operations any time the wholesomeness and/or safety of the product is jeopardized. He/she reports directly to the DHVHD and consults with him/her regarding all decisions involving enforcement activities. The decision as to whether the establishment is failing to meet US import requirements, and the recommendation that it should be delisted, is a combined effort of the

OVIC, DHVHD, and RVAD, and may also include headquarters officials. The RVAD will make the ultimate decision and will advise SVA authorities.

The OVIC has direct supervision over all other inspection personnel assigned to the certified establishment, including associate veterinary officers and non-veterinary inspection personnel (veterinary assistants and veterinary 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 US import requirements.

Overall control and supervision is the responsibility of the RVA office in Ceske Budejovice. The OVIC is responsible for certification of products to be exported.

7.2.3 Assignment of Competent and Qualified Inspectors

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.

All inspection personnel assigned to the certified establishment 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 have passed a specialized post-mortem inspection training organized by the SVA in the relevant fields. The veterinary assistants have acquired their qualifications in a study program for a two-year degree in veterinary hygiene.
All veterinarians possess a professional university veterinary degree.

Ensuring adequate training of inspectors before assignment to a position is the responsibility of the regional veterinary administration office. It is also the responsibility of the DHVHD to ensure that all establishments are adequately staffed with trained and competent inspection personnel.

7.2.4 Authority and Responsibility to Enforce the Laws

The SVA has the legal authority and the responsibility to enforce all FSIS requirements. The OVIC and other qualified in-plant inspection personnel are authorized to enforce European Commission legislation and US import requirements. The RVA, with the assistance of SVA, has the legal authority to suspend and/or delist the only US-certified establishment to prevent the export of unwholesome products to the United States.

7.2.5 Adequate Administrative and Technical Support

The SVA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate The Czech Republic's meat inspection system.

Administration, development, coordination, and the formation of rules and regulations take place in the headquarters of the SVA in Prague.

7.3 Headquarters and District Office Audit

The auditor conducted a review of inspection system documents at the headquarters of the SVA located in Prague. The auditor also interviewed inspection officials at the DVI office located in Tabor for the purpose of determining the supervisory structure and to review records pertinent to the US-certified establishment. The records review focused primarily on food safety hazards and included the following:

- Government oversight documents, including organizational structure and staffing.
- Periodic supervisory visits to the establishment that was certified to export to the United States.
- Training programs and personnel records of training.
- Requirements for employment and payment records of SVA employees.
- New laws and implementation documents such as regulations, notices, directives, and guidelines.
- Assignment of inspectors and inspection coverage of the US-certified establishment.
- Inspection records and enforcement actions such as withholding, suspending, or withdrawing inspection services from or delisting an establishment certified to export product to the United States.
- Organization of the country's laboratory system.
- Microbiology and residue sampling and laboratory analyses.
- Export product inspection and control, including export certificates.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Funding of The Czech Republic's inspection program.
- The food security/defense system.

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

8. ESTABLISHMENT AUDITS

The FSIS auditor visited one swine slaughter and processing establishment. The establishment was not delisted and did not receive a Notice of Intent to Delist (NOID).

Specific deficiencies are reported on the attached individual establishment checklist.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

The following National Reference Laboratory (NRL) was reviewed:

The State Veterinary Institute Jihlava, a government NRL located in Jihlava, which conducts analyses of field samples for the presence of *Enterobacteriaceae*, *Salmonella*, and residues of veterinary drugs.

This laboratory was ISO 17025 certified by the Czech Accreditation Institute. No deficiencies were reported.

10. 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 the establishment, 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, 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.

10.1 Sanitation Standard Operating Procedures

The establishment was evaluated to determine if the basic FSIS regulatory requirements for Sanitation Standard Operating Procedures (SSOP) were met, according to the criteria employed in the US domestic inspection program. The SSOP in the establishment was found to meet the basic FSIS regulatory requirements except:

- During the pre-operational sanitation of the boning room, several meat scraps and fat particles were observed on several product contact areas such as boning tables, conveyor belts, and rail support.

10.2 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were effectively implemented regarding sanitary measures except as noted above.

11. 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 reported.

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

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

The controls also include the implementation of a HACCP system in the establishment, and implementation of a testing program for *Enterobacteriaceae* in the slaughter establishment.

12.1 Humane Handling and Humane Slaughter

No deficiencies were reported.

12.2 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 US domestic inspection program.

The HACCP program was reviewed during the on-site audit of the establishment. This establishment had adequately implemented the HACCP requirements.

12.3 Testing for *Enterobacteriaceae*

The Czech Republic has adopted the FSIS regulatory requirements for testing for *Enterobacteriaceae* 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 *Enterobacteriaceae* sampling program.

The establishment was required to meet the basic FSIS regulatory requirements for testing for *Enterobacteriaceae* and was evaluated according to the criteria employed in the U.S. domestic inspection program.

Testing for *Enterobacteriaceae* was properly conducted in this establishment.

12.4 Microbiological Testing of Ready-to-Eat Products

The establishment audited was not exporting any ready-to-eat products to the United States so analysis for *Listeria monocytogenes* was not required.

12.5 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were effectively implemented regarding slaughter/processing controls.

13. RESIDUE CONTROLS

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

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

The Czech Republic's national residue testing program for 2008 was being followed and was on schedule.

13.1 EC Directive 96/22

In the SVI laboratory located in Jihlava, the provisions of EC Directive 96/22 were effectively implemented.

13.2 EC Directive 96/23

In the SVI laboratory located in Jihlava, the provisions of EC Directive 96/23 were effectively implemented.

14. 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*. No deficiencies were reported.

14.1 Daily Inspection

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

14.2 Testing for *Salmonella* species

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

The establishment 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 properly conducted in the establishment.

14.3 Species Verification

Species verification was being conducted as required.

14.4 Periodic Supervisory Reviews

Periodic supervisory reviews of the certified establishment were being performed monthly and documented as required.

14.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

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

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

15. CLOSING MEETING

A closing meeting was held on September 11, 2008, in Prague with the CCA. At this meeting, the preliminary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Oto Urban, DVM
Senior Program Auditor

M. Manzoor A. Chaudry, DVM

16. ATTACHMENTS TO THE AUDIT REPORT

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

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 Plana & Luznici	09/10/2008	CZ15	The Czech Republic
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT [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 SSOPs 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.	
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	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
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	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 09/10/2008 Est #: CZ15 (Maso Planá a.s. [S/P/CS]) (Plana & Luznici, The Czech Republic)

10/51/56 During pre-operational sanitation inspection in the boning room, meat scraps and fat particles were observed on several product-contact surfaces, including boning tables, conveyor belts and rail supports. This deficiency was corrected immediately by the establishment officials. [Regulatory references: 9 CFR §416.13(c), 416.16; EC Directive 64/433, Chapter III, 3(c)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban, DVM	Manjoor H. Chaudry, 9/10/08

STATE VETERINARY ADMINISTRATION
Czech Republic

Slezská 7, 120 56 PRAGUE 2 Phone: +420 227 010 142 Fax.: +420 227 010 191

Your letter:
d/d: DEC 30 2008
Our reference: 2009 / 714 / SVS
Department: of Veterinary Hygiene, Public Health and Ecology
Phone: +420 227 010 160
Prague: 06. 03. 2009

Dr. Donald Smart
Director
USDA, FSIS, OIA, IAS
1299 Farnam Street
Suite 300, Landmark Center
Omaha, NE 68 102
United States of America

Re: COMMENTS TO THE FINAL REPORT OF AN AUDIT CARRIED OUT IN THE CZECH REPUBLIC ON 4 - 11 SEPTEMBER 2008 COVERING THE CZECH REPUBLIC'S MEAT INSPECTION SYSTEM

Dear Dr. Smart,

Many thanks for sending us the final report on the audit carried out in the Czech Republic on 4 – 11 September 2008.

The Czech Republic has no comments on the final report. All shortcomings found during the audit were rectified immediately.

Kind regards.

Assoc. prof. Milan Malena, DVM, Ph.D.
Director General (CVO)