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

Dr. Milan Malena
Director General (CVO)
State Veterinary Administration
of the Czech Republic
Slezska 7
120 56 Praha 2
Czech Republic

OCT 0 5 2007

Dear Dr. Malena:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Czech Republic's meat inspection system May 2 to May 17, 2007. Comments from the Czech Republic have been included in the final audit report. Enclosed is a copy of the final audit report.

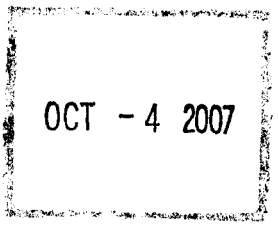
If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL



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

MAY 2 THROUGH MAY 17, 2007

Food Safety and Inspection Service
United States Department of Agriculture

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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. INTRODUCTION

The audit took place in the Czech Republic from May 2 through May 17, 2007.

An opening meeting was held on May 2, 2007, 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.

2. 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 district office, one local office at the establishment level, two government laboratories performing analytical testing on United States-destined product, and one swine slaughter and processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central Headquarters	1	Prague
	Regional	1	Ceske Budejovice Inspection Office
	District	1	Tabor Inspection Office
	Local	1	Establishment level
Laboratories		2	
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, one regional, and one district offices. 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 analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* species (*Salmonella).* The State Veterinary Institute Prague 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* species. The Czech Republic's inspection system was assessed by evaluating these five risk areas.

During 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 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* species.

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.

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 May/June 2004.

- In one establishment, a build-up of rust and pieces of meat products were observed in various places above the hog carcass rail in the hallway leading to the carcass cooler.

- In one establishment, the sponging method was used for hog carcass sampling for generic *Escherichia coli* (*E. coli*) but statistical process control was not used for evaluation of the test results.

- In one establishment, the establishment employee only signed the monitoring records once per day, but the frequency of monitoring the CCP was every two hours.

Laboratory Audit:

- The temperature of incoming samples was not recorded on the form in the sample receiving room as specified in the laboratory plan.

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 condensation 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 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 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.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

The State Veterinary Administration (SVA) in the Czech Republic, a public administration body under the Ministry of Agriculture, is the Central Competent Authority (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 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 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 Veterinary Hygiene Department (DHVHD), in-charge of all supervision activities, who serves as field supervisors over the Official Veterinarian-in-Charge (OVIC) located at the establishment level.

6.2.1 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.

6.2.2 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 District Head of Veterinary Hygiene Department 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 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 U.S. 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.

6.2.3 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.

6.2.4 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 (EC) legislation and U.S. import requirements. The RVA, with the assistance of SVA, has the legal authority to suspend and/or delist the only U.S. certified establishment to prevent the export of unwholesome products to the United States.

6.2.5 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.

6.3 Headquarters, Regional, and District Offices 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 RVA office located in Ceske Budejovice and DVI office located in Tabor for the purpose of determining the supervisory structure and to review records pertinent to the U.S. 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 U.S. certified establishment
- Inspection records and enforcement actions such as withholding, suspending, or withdrawing inspection services from or delisting an establishment that is 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.

7. 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 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 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.

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 National Reference Laboratories (NRL) were reviewed:

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

The State Veterinary Institute Prague, a government NRL located in Prague, which conducts analyses of field samples for the Czech Republic's national residue program.

Both laboratories were ISO 17025 certified by the Czech Accreditation Institute. No deficiencies were noted.

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 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.

9.1 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 United States' domestic inspection program. The SSOP in the establishment was found to meet the basic FSIS regulatory requirements.

9.2 EC Directive 64/433

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

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 for cured, dried, and cooked products.

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

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 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 the 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.

11.3 Testing for Generic *Escherichia 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 establishment 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 properly conducted in this establishment.

11.4 Testing for *Listeria monocytogenes*

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

11.5 EC Directive 64/433

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

12. RESIDUE CONTROLS

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

The State Veterinary Institute (SVI) Prague 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 2007 was being followed and was on schedule.

12.1 EC Directive 96/22

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

12.2 EC Directive 96/23

In the SVI laboratory located in Prague, 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* species. No deficiencies were observed.

13.1 Daily Inspection

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

13.2 Testing for *Salmonella* species

The Czech Republic has adopted the FSIS requirements for testing for *Salmonella* species 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* species.

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

Salmonella species testing was properly conducted in the establishment.

13.3 Species Verification

Species verification was being conducted as required.

13.4 Periodic Supervisory Reviews

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

13.5 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 counties for further processing.

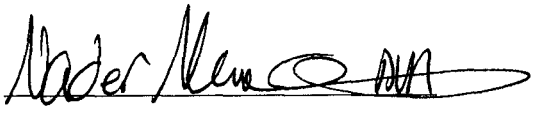
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on May 17, 2007 in Prague with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Nader Memarian, 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 Plana & Luznici	05/10/2007	CZ15	The Czech Republic
	5. NAME OF AUDITOR(S) Nader Memarian, 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.	
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.	X
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	
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	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 05/10/2007 Est #: CZ15 (Maso Planá a.s. [S/P/CS]) (Plana & Luznici, The Czech Republic)

15/51 The establishment's 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. [Regulatory references: 9CFR 417.2(c)(7), 417.4(a)(2), and 417.8]

22/51 A) Verification records for CCP seven (zero tolerance for fecal, ingesta, and foreign materials) and CCP eight (product temperature) did not document the type of the verification procedures performed or the results of the verification. [9CFR 417.5 (a)(3) and 417.8]

B) Verification records for CCPs seven and eight did not document the times when the specific events occurred. [9CFR 417.5(a)(3) and 417.8]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	05-10-2007

STATE VETERINARY ADMINISTRATION
Czech Republic

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Dr. Donald Smart, Director
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Prague, October 2, 2007

COMMENTS TO THE DRAFT REPORT FSIS MISSION

Dear Dr. Smart,

Many thanks for your information on the draft of final audit report carried out in the Czech Republic from May 2 to May 17, 2007.

Below please find one formal comment to:

Page 9:

Point 6.2.2. We suggest to delete the last sentence in the third paragraph - "Permits to export to other countries are granted or withdrawn by the SVA headquarters office."

If our understanding is correct we would like to propose the following wording which will replace the previous sentence:

"The OVIC is responsible for certification of products to be exported."

Many thanks for your kind co-operation.

Kind regards.

MVDr. Milan Malena, Ph.D.
Director General (CVO).

Advanced copies to:
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