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

JUN 18 2004

Dr. Josef Holejsovsky
Director General
State Veterinary Administration
of the Czech Republic
Tesnov 17
117 05 PRAHA 1
Prague
Czech Republic

Dear Dr. Holejsovsky:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Czech Republic's meat inspection system from April 9 through May 2, 2003. 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,

Steven McDermott
for

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:
Alejandro Checchi-Lang, Director, Directorate E, European Commission, Brussels
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
Tony Van der haegen, EU Mission to the US, Washington
Robert Curtis, Minister Counselor, American Embassy, Vienna
Jiri Kulis, Economic Attaché, Embassy of The Czech Republic
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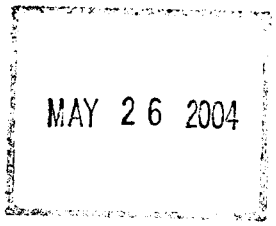
Mary Stanley, Director, IID, OIA
Shannon McMurtrey, IES, OIA
Country File

FINAL



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

APRIL 9 THROUGH MAY 2, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority – State Veterinary Administration (SVA)
FSIS	Food Safety and Inspection Service
IIC	Inspector-in-Charge
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species

1. INTRODUCTION

The audit took place in the Czech Republic from April 9 through May 2, 2003.

An opening meeting was held on April 9, 2003 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 regarding government oversight 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, State Veterinary Administration (SVA), and representatives from the 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 establishments 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 SVA, one laboratory performing analytical testing on United States-destined product, two meat slaughter and processing establishments, and two district offices.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	District	2	
Laboratories		1	
Meat Slaughter/Processing Establishments		2	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss government oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's local inspection headquarters. The third part involved on-site visits to two slaughter/processing establishments. The fourth part involved a visit 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*.

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 (SSOP's), (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 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 that the Czech Republic's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations that have been made for Czech Republic. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP and SSOP's, and testing for generic *E. coli* and *Salmonella* species.

Equivalence determinations are those that have been made by FSIS for the Czech Republic under provisions of the Sanitary/Phytosanitary Agreement. Currently, the only equivalence determinations the Czech Republic has requested is 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 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.) and the Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofo/tsc.

The following deficiencies were identified during the FSIS audit of the Czech Republic's inspection system conducted in July/August 2001:

- Heavy condensation over product in the coolers.
- Insect and rodent problems.

- Non-random testing selection for *E. coli* and *Salmonella*.
- Not denaturing condemned carcasses.
- Testing for the presence of *E. coli* by the sponging method, but using the excision performance criteria for evaluation.
- The Inspector-in-Charge (IIC) performing monthly supervisory reviews.
- Pre-shipment reviews not being properly documented.
- The SSOP not signed or dated.

These deficiencies had all been corrected by the time of the September 2002 audit.

The following deficiencies were observed during the FSIS audit of the Czech Republic's meat inspection system conducted in September 2002:

- A need for documentation of preventive actions in SSOP.
- One establishment had a loading dock to the outside not properly sealed to prevent the entry of rodents.
- Meat combos with product residues from previous days' uses on product-contact surfaces.
- One establishment did not address all of the hazards in the risk analysis of its HACCP plan.
- One of the establishments did not have proper documentation of the Critical Control Point for the control of feces/ingesta on carcasses.

These deficiencies had all been corrected by the time of this audit.

6. MAIN FINDINGS

6.1 Government Oversight

The Czech Republic is divided into 77 administrative districts. Each district has local offices, as needed. The personnel in these district offices supervise and oversee all field inspection personnel and in-plant functions. In the near future, the district offices will be divided into regional and area offices.

In the SVA headquarters in Prague, the CCA has a Director and coordinators for meat inspection. In order to gather more information on oversight, interviews were conducted with the officials responsible for:

- Field operations and inspection services.
- Export programs and U. S. regulations.
- Enforcement and compliance.
- Government staffing.

It was found that, in both establishments audited, only government-paid employees were performing inspection duties.

6.1.1 CCA Control Systems

An official of the CCA on the Prague headquarters staff and the district and in-plant supervisors oversee the maintenance of eligibility to export to United States. These supervisors have the authority, under Czech Republic regulations, to enforce the necessary requirements to export to a 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. A checklist was used to record this information in one establishment, but no checklist was used in the other establishment.

6.1.2 Ultimate Control and Supervision

Control in both slaughter and processing establishments is accomplished by the Veterinarian-in-Charge. These Veterinarians-in-Charge are supervised by officials from the respective District Offices. Overall control and supervision is the responsibility of the headquarters office in Prague. Permits to export to other countries are granted or withdrawn by the headquarters office.

6.1.3 Assignment of Competent, Qualified Inspectors

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

6.1.4 Authority and Responsibility to Enforce the Laws

The SVA has the authority and responsibility to enforce U.S. requirements. Each establishment has copies of the pertinent SVA and U.S. rules and regulations.

6.1.5 Adequate Administrative and Technical Support

The SVA has adequate administrative and technical support in the central and district offices and in the field to operate and support its inspection system, including experts, specialists and adequate facilities.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the local SVA offices at establishments. These records reviews focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.

- 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, cysticercosis, 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.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited two establishments; both were slaughter and processing establishments.

One establishment received a notice of intent to delist the establishment from Czech Republic inspection officials. The notice was given because of poor sanitary operations, ineffective implementation of HACCP, and inadequate daily record keeping. This establishment may retain its certification for export to the United States provided that it corrects all deficiencies noted during the audit within 30 days of the date the establishment was audited.

Specific deficiencies are noted in the attached individual establishment review forms.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audit, 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. If private laboratories are used to analyze samples from products produced for export to the United States, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following laboratory was audited:

State Veterinary Institute, Jihlava. This is a government laboratory that conducts residue and microbiology testing for SVA.

No concerns arose from the audit of this laboratory.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess the Czech Republic's meat and poultry inspection system. The first of these risk areas that the FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of the establishments, 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 practices, and good product handling and storage practices.

In addition, and except as noted below, the Czech Republic's inspection system also 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

Each 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 both establishments audited were found to meet the basic FSIS regulatory requirements. The following deficiencies regarding SSOP implementation were noted:

- 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 old carcass cooler in two establishments.
- Daily records did not sufficiently describe observed deficiencies in one establishment.
- In one establishment, daily records did not include all deficiencies observed during this audit.
- Condensate was dripping adjacent to product in the cooler in one establishment.

9.2 Sanitation

No other sanitation deficiencies were noted.

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, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned products. 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 dispositions, post-mortem inspection procedures, post-mortem dispositions, 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.

- Trimming of foreign particles from carcasses was not properly performed in one establishment.

11.1 Humane Handling and Slaughter

Electrical stunning procedures and the use of carbon dioxide were properly carried out in both establishments.

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

The HACCP programs were reviewed during the on-site audits of both establishments. The following deficiency regarding HACCP requirements was observed:

- The HACCP plans did not include on-site verification of monitoring activities in both establishments.

11.3 Testing for Generic *E. coli*

The Czech Republic has adopted the FSIS regulatory requirements for testing for generic *E. coli* testing with the exception of the following different equivalent requirements:

1. LABORATORIES. Government laboratories.

   The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping facilities.

   Results of analyses including all permanently recorded data and summaries are reported promptly to the establishment.

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

Testing for generic *E. coli* was properly conducted in both slaughter establishments.

11.4 Testing for *Listeria monocytogenes*

Both establishments audited were producing ready-to-eat products approved for export to the United States. In accordance with United States requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

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 SVA State Veterinary Institute in Jihlava, a government laboratory, was audited. No deficiencies were noted.

The Czech Republic's National Residue Testing Plan for 2003 was being followed and was on schedule.

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 all slaughter and processing establishments.

13.2 Testing for *Salmonella* species

The Czech Republic has adopted the FSIS regulatory requirements for testing for *Salmonella* with the exception of the following equivalent measure:

1. *SALMONELLA* TESTING STRATEGY.

   The Czech Republic uses a continuous, on-going sampling program to determine when to initiate additional *Salmonella* testing. All U.S. export establishments are included in the sample pool. The on-going random sampling is continuous and part of a uniform system approach. The sampling program is based on each establishment's production, with a minimum of one bovine sample per week (small establishments) or two bovine samples per week (small establishments). If seven positives are found during the on-going program, the government requires the establishment to take corrective action and immediately initiates a second sample set of one sample per production day for 55 consecutive days.

   The Czech Republic uses a continuous, on-going sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is an U.S. performance standard are included in the sample pool.

   The Czech Republic's testing program has statistical criteria for evaluating test results.

   The percentage of *Salmonella* positives over time meets the FSIS performance standard.

2. ANALYTICAL METHODS: Different methods.

   The laboratories use ISO 6579 to analyze *Salmonella.* ISO 6579 is an internationally recognized method of analysis for detecting *Salmonella* and is closer to the FSIS method than the AOAC methods.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

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

13.5 Inspection System Controls

The CCA had controls in place for 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 2, 2003, in Prague with the CCA. At this meeting, the primary findings conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Oto Urban
International Audit Staff Officer

15. ATTACHMENTS

Individual Foreign Laboratory Review Reports
Individual Foreign Establishment Audit Forms
Foreign Country Response to the Draft Final Audit Report

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
4-28-03	State Veterinary Institute (Statni Veterinarni Ustav)

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
State Veterinary Administration	Jihlava, Czech Republic	Rantirovska 93, 586 05 Jihlava

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Oto Urban	Dr. Martinkova

	Residue Code/Name ▶		EVALUATION CODE	100	111	200	203	300	400	500	800	E.co	Sal	List	SP
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #													
	Sample Handling	01		A	A	A	A	A	A	A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O	O
	Data Reporting	06		A	A	A	A	A	A	A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A	A	A	A	A	A	A	A
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	O	O	O	O
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	A	A	A	A	O	O	O	O
	Recovery Frequency	12		A	A	A	A	A	A	A	A	O	O	O	O
	Percent Recovery	13		A	A	A	A	A	A	A	A	O	O	O	O
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	A	A
	International Check Samples	17		A	A	A	A	A	A	A	A	A	A	A	A
REVIEW	Corrected Prior Deficiencies	18	EVAL CODE	A	A	A	A	A	A	A	A	A	A	A	A
OTHER REVIEW		19	EVAL CODE												
		20	EVAL CODE												

SIGNATURE OF REVIEWER: [signature] for Oto Urban DATE: 7/24/03

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
Masna Studena, a.s. Masna 480 37856 Studena 2	04 – 24 - 03	12	Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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.	X
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.	X
19. Verification and validation of HACCP plan.	X
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	
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

Czech Republic, Continuation Est.12

10. Dripping condensation close to the product was observed in the cooler. This was corrected by the establishment management..

11. Flaking paint from rails was observed in the cooler. This deficiency was scheduled for correction by the establishment officials.

18. Trimming of carcasses from foreign particles was not properly performed. This deficiency was corrected by the inspection officials.

19. HACCP on-site verification of monitoring activities was not properly performed. This was scheduled for correction by the establishment management.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
7/24/03

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 Plana a.s. Prumyslova 499 39111 Plana nad Luznici 92	04 - 22 - 03	15	Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Oto Urban		[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.	X
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.	X
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.	X
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.	
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24. Labeling - Net Weights	
25. General Labeling	
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Salmonella Performance Standards - Basic Requirements	
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32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
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51. Enforcement	
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.	

80. Observation of the Establishment

Czech Republic Est. 15 04-22-03

10. Condensation was observed over exposed product and exposed product traffic areas (product moving hall, and cooler). This deficiency was corrected by the establishment officials.

11. Flaking paint over carcasses from carcass rails observed in the old carcass cooler. This deficiency was scheduled for correction by the establishment.

13. Daily records did not sufficiently describe observed deficiency. This was scheduled for correction by the establishment. Daily records did not include all deficiencies observed during this audit. Veterinary Services also described this deficiency with required corrective action.

19. No verification of the monitoring of critical limits was written in the HACCP plan or performed (implementation non-compliance with HACCP requirements).

* This establishment was issued a NOID for SSOP and HACCP deficiencies.

81. NAME OF AUDITOR
Dr. Otto Urban

82. AUDITOR SIGNATURE AND DATE
2/24/03

STATE VETERINARY ADMINISTRATION OF THE CZECH REPUBLIC
Slezská 7, 120 56 PRAHA 2
Phone : (+420) 227 010 184
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Your letter d/d	:	March 9, 2004	Attachment	:	
Your reference	:	None	File handled by	:	Dr. J. Kuna, DVM
Our reference	:	ZAH0129/usda/04Rc/498/04	Department	:	Foreign Relations

Dr. Sally STRATMOEN, DVM
Director, International Equivalence Staff
Office of International Affairs
USDA – FSIS
1400 Independence Ave.
Washigton D.C. 20250 USA

Prague :Monday, 05 April 2004

Re: FSIS audit in Czech plants exporting to the U.S. – comments.

Dear Dr. Stratmoen,

This is in reference to your letter of March 9, 2004 referring about the draft final audit report reflecting an on-site audit carried out from April 9 through May 2, 2003 in two Czech plants exporting to the U.S. and the meat inspection system therein in force.

As for the guarantees regarding rectifications and the elimination of failures found during the above audit and the relevant response of central competent authorities you have already been informed in our letter ZAH1506/usda/03 of May 23, 2003.

Copy of the letter enclosed for your reference.

Please be informed as well the Central Competent Authority (SVA CR) has already informed the managements of establishments in question i.e. CZ 15 and CZ 12 and the local veterinary offices in charge of supervision about the forthcoming FSIS audit scheduled for 19.5. through 3.6.2004.

Yours sincerely,

MVDr Josef Holejšovský
Director General (CVO)

c.c.: ing.Petra Chotěborská, Agricultural Specialist, U.S. Embassy, Prague

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Your letter d/d	:	Attachment	:
Your reference	:	File handled by	: Dr. J. Kuna, DVM
Our reference	: ZAH1506/usda/03	Department	: International Negotiations

Mrs.
Sally STRATMOEN
USDA – FSIS
1400 Independence Ave
Washington D.C. 20250
USA

Prague :Friday, 23 May 2003

Re: FSIS audit in Czech plants exporting to USA, results – comments.

Dear Mrs. Stratmoen,

In reference to the audit carried out by Dr. Otto Urban, DVM, FSIS audits inspector, during the end of April-May 2003 in two Czech plants approved for exports to the U.S. and based on written statements from district veterinary authorities in charge of supervision in these plants (DVA Tabor and DVA Jindřichův Hradec) please be informed as follows :
State Veterinary Administration of the Czech Republic hereby confirms and gives the following guarantees :

1. CZ 12 Studená a.s. – all failures found during the audit have been rectified as till 15.5.2003
2. CZ 15 MASO Planá a.s. – all failures found during the audit have been rectified as till 20.5.2003. The management of the plant reconsidered its approach to the SSOP records keeping espec. the verification system has been completely revised. As from the above date the evidence of all failures will be on files. Water condensation on rails in the transport room has been solved and rails painted again. Each failure will be exactly described in the protocol together with rectifying and preventative measures .

Please accept the above guarantees as the rectifying results of the above USDA-FSIS mission.

Kind regards.

Yours sincerely,

MVDr Josef Holejšovský
Director General (CVO)