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

APR 17 2003

4/21/03

Dr. Josef Holejsovsky
Acting Director General
State Veterinary Administration
Tesnov 17
117 05 Praha 1
Czech Republic

Dear Dr. Josef Holejsovsky:

Enclosed is a copy of the final report of the Food Safety and Inspection Service (FSIS) audit of the Czech Republic's meat inspection system from September 12 – 19, 2002. Comments by the Czech Republic on the draft final audit report have been included as Attachment "G" in the enclosed final audit report.

FSIS has carefully reviewed the assurances provided by the Czech Republic at the Exit Conference in Prague on September 19, 2002 and the comments contained in your December 30, 2002 response to the audit findings. We appreciate your commitment to correct all of the deficiencies found during the audit and will make every effort to work collegially with the Czech Republic to that end.

FSIS also apologize for the delay in transmitting the final report. We did not receive a copy of your letter until March 4, 2003 and were advised, at that time, that the letter represented your comments to the draft final audit report.

If you have any questions relative to the recent audit or this letter, or need additional information, please feel free to contact me at your convenience. My telephone number is (202) 720-3781, my email address is sally.stratmoen@fsis.usda.gov, and my fax number is (202) 690-4040.

Sincerely,

Sally Stratmoen JD

Sally Stratmoen, Acting Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc: Robert Curtis, Minister Counselor, American Embassy, Vienna
Jiri Kulis, Economic Attaché, Embassy of The Czech Republic
James Dever, FAS Area Officer
Linda Swacina, Associate Administrator, FSIS
Karen Stuck, Acting DAA, Office of International Affairs
Amy Winton, State Department
Donald Smart, Director, Review Staff, PEER, FSIS
Sally Stratmoen, Acting Director, IES, OIA
Clark Danford Acting Director, IEPS, OIA
Richard Brown, IES, OIA
Mostafa Eldakdoky, IES, OIA
Country File (FY 2002 Audit – Czech Republic)

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

AUDIT REPORT FOR THE CZECH REPUBLIC

SEPTEMBER 12 THROUGH SEPTEMBER 19, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of the Czech Republic's meat/poultry inspection system from September 12 through September 19, 2002. Both of the two establishments certified to export meat/poultry to the United States were audited. Both of these were slaughter/processing establishments.

The last audit of the Czech Republic meat inspection system was conducted in July/August 2001. Both certified establishments were audited. Several concerns were reported at that time.

1. Heavy condensation over product in the coolers. This deficiency was corrected by the State Veterinary Administration as it was not observed during this audit.
2. Inadequate insect and rodent controls. Items related to this issue and listed in the previous audit had been corrected.
3. Non-random testing selection for *E. coli* and *Salmonella.* This deficiency had been corrected by the use of computer generated randomized selections.
4. Not denaturing condemned carcasses. This deficiency was corrected by the State Veterinary Administration.
5. Testing for the presence of *E. coli* by using the sponging method for sampling and using excision performance criteria. This deficiency had been corrected by the State Veterinary Administration.
6. IIC performing monthly supervisory reviews. This deficiency had been corrected by the State Veterinary Administration as District Personnel were performing and documenting these reviews.
7. Pre-shipment reviews not being properly documented. This deficiency had been corrected by the State Veterinary Administration and they were now properly performed and documented.
8. SSOP not signed nor dated. This deficiency was corrected by the State veterinary Administration.
9. SSOP preventive actions not properly documented. This deficiency had not been satisfactorily corrected.

Fully cooked pork is eligible to be exported to the United States from the Czech Republic.

During the calendar year 2001, the Czech Republic establishments did not export any product to the United States.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with the Czech Republic national meat/poultry inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat/poultry inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to two establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella* and *E. coli*

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

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

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in both of the establishments audited. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, eight major concerns had been identified during the last audit of the Czech Republic's meat inspection system conducted in July/August 2001. During this new audit, the auditor determined that the all of the concerns had been addressed and corrected except for documentation of preventive actions.

SSOP documentation deficiencies had been found in both of the establishments. During this new audit, implementation of the required SSOP documentation was again found to be

deficient in both establishments (this was a repeat deficiency). Details are provided in the Sanitation Controls section later in this report.

Entrance Meeting

On September 12, 2002, an entrance meeting was held in the Prague offices of the State Veterinary Administration, and was attended by Dr. Milan Malena, Head of Hygiene, Public Health And Ecology Department; Dr. Jiri Kuna, Senior Veterinary Officer, Department of International Negotiations and Veterinary Protection of the State Territory, both of the Czech Republic; and Dr. Judd Giezentanner, International Audit Staff Officer, FSIS, USDA. Topics of discussion included the following:

1. Recent audit issues.

2. The country's current status

3. Objective of this audit.

4. Scope of this audit.

5. Audit procedures of a systems audit.

6. Audit selection.

7. Audit Standards.

8. Final decision by FSIS.

9. Exit Conference.

10. Audit report.

11. Establishment audits.

12. Reporting findings.

13. Corrective actions for audit findings.

14. Delistments.

15. Security of Auditors.

16. Conflict of interest issues.

17. Communications.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of the Czech Republic's meat inspection system in July/ August 2001.

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

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the headquarters of the inspection service and at a district or regional office. The records review focused primarily on food safety hazards and included the following:

- ? Internal review reports.
- ? Supervisory visits to establishments that were certified to export to the U.S.
- ? Training records for inspectors and laboratory personnel.
- ? Sampling and laboratory analyses for residues.
- ? Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- ? 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.

The following concerns arose as a result the examination of these documents:

1. In both establishments, SSOP preventive actions for found deficiencies were not listed.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by the Czech Republic as eligible to export meat products to the United States were full-time State Veterinary Administration employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Two establishments were certified to export meat products to the United States at the time this audit was conducted. Both establishments were visited for on-site audits. In both of the

establishments visited, both State Veterinary Administration inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

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

The State Veterinary Institute Laboratory in Jihlava was audited on September 17, 2002. Effective controls were in place for 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 methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

The Czech Republic's microbiological testing for *Salmonella* and *E. coli* was being performed in the SVI government laboratory in Jihlava.

Establishment Operations by Establishment Number

The following operations were being conducted in the two establishments:

Pork slaughter, boning and canning - two establishments (Est. 12 and 15)

SANITATION CONTROLS

Based on the on-site audits of establishments, Czech Republic’s inspection system had controls in place for: water potability records, chlorination procedures, back siphonage prevention, sanitizers, establishment separation, pest control program, temperature control, operations work space, inspector work space, ventilation, facilities approval, over-product equipment, product contact equipment, other product areas, dry storage areas, ante-mortem facilities, welfare facilities, outside premises, personal dress and habits, sanitary dressing procedures, cross contamination prevention, equipment sanitizing, product handling and storage, product reconditioning, product transportation, effective maintenance program, pre-operational sanitation, operational sanitation and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations:

1. Both establishments did not include prevention in the documentation records.

Pest Control

1. Establishment 15 did not have the loading dock doors leading to the outside properly sealed to preclude the entry of rodents. This was to be corrected that day.

Equipment and Facilities

1. Establishment 12 had combos in the boning room with product residues from previous day's use adhering to product contact surfaces.

ANIMAL DISEASE CONTROLS

No findings.

RESIDUE CONTROLS

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

SLAUGHTER/PROCESSING CONTROLS

The Czech Republic's inspection system had controls in place to ensure adequate ante-and post-mortem inspection procedures and dispositions, control and disposition of dead, dying, diseased or disabled animals, humane handling and slaughter, pre-boning trim, boneless meat reinspection, ingredients identification, control of restricted ingredients, formulations, packaging materials, laboratory confirmation, label approvals, special label claims, inspector monitoring, processing schedules, processing equipment, processing records, empty can inspection, filling procedure, container closure exam, interim container handling, post-processing handling, incubation procedures, processing defect actions - plant, and processing control - inspection.

HACCP Implementation

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

The HACCP programs were found to meet the basic FSIS regulatory requirements except:

1. Establishment 15 did not address each hazard in their hazard analysis. This was to be corrected within one week.

2. Establishment 12 did not have proper documentation of the CCP for zero tolerance, which stated that each carcass would be monitored for feces/ingesta. Documentation was only for deficiencies. This was to be corrected.

Testing for Generic *E. coli*

The Czech Republic has adopted the FSIS regulatory requirements for E. coli testing with the exception of the following equivalent measures. The data collection instrument used accompanies this report (Attachment C).

1. LABORATORIES: Government Laboratories. The criteria used for equivalence decisions for use of government laboratories in lieu of private laboratories are:
   - The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
   - Results of analyses, including all permanently recorded data and summaries, are reported promptly to the establishment.

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

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

ENFORCEMENT CONTROLS

Inspection System Controls

The State veterinary Authority inspection system controls [control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs

and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

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

The Czech Republic has adopted the FSIS regulatory requirements for *Salmonella* testing. *Salmonella* samples were collected by the Czech Inspection Service and processed in the government laboratory in Jihlava.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification Testing

At the time of this audit, the Czech Republic was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by the District Supervisor of SVA. He was a veterinarian with many years' experience.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers, at least once monthly on the District level, and once a year from the headquarter in Prague. The records of audited establishments were kept in the inspection offices of the individual establishments, in the District offices of the SVA, and copies were also kept in the central SVA offices in Prague, and were routinely maintained on file for a minimum of one year.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again

qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to the headquarters in Prague for evaluation; they formulate a plan for corrective actions and preventive measures.

Enforcement Activities

All organizations with the State Veterinary Authority of the Czech Republic conform to the provisions laid down in the Act No. 166/1999 regarding state operated and budget-dependant organizations. Their budget comes from state budget through the Ministry of Agriculture of the Czech Republic. The essential assignments of the SVA CR with regard to Animal Health are to fight against animal diseases and to ensure the well being of the animal population. In regards to Food Hygiene, the basic assignments are to promote and monitor the wholesomeness and not adulteration of animal and animal-based foods with the aim of protecting public health. The SVA can impose verbal warnings and fines to Animal Health violators. The fines are paid to federal financial institutions. Repeated violators must pay higher fines. After the serious violation, the individual is suspended from producing product in the meat industry.

Exit Meetings

An exit meeting was conducted in Prague on September 19, 2002. The participants included Dr. Jiri Kuna, Senior Veterinary Officer, International Relations and Veterinary Protection; Dr. Milan Sehnal, Branch Chief, International Relations and Veterinary Protection, Petra Chotrborska, Agricultural Specialist, FAS, FSIS; and Dr. Judd Giezentanner, International Audit Staff Officer, FSIS. The following topics were discussed:

1. Still a need for documentation of preventive actions in SSOP documentation. To be corrected with oversight from SVA.

2. One establishment had a loading dock door to the outside not properly sealed to prevent the entry of rodents. Programmed for correction.

3. Meat combos with product residues from previous day's use on product contact surfaces. Corrected immediately.

4. One establishment did not address all of the hazards in the risk analysis of its HACCP plan. Programmed for correction.

5. One of the establishments did not have proper documentation of the Critical control Point for the control of feces/ingesta on carcasses. Programmed for correction.

CONCLUSION

The inspection system of the Czech Republic was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Two establishments were audited. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Judd Giezentanner
International Audit Staff Officer

ATTACHMENTS

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

Attachment A

Data Collection Instrument for SSOPs

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

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

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
15	?	?	?	?	?	?	?*	?
12	?	?	?	?	?	?	?*	?

* Both establishments did not include prevention in the documentation records.

Attachment B

Data Collection Instrument for HACCP Programs

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

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

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conduct-ed	3. Use & users includ-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. proced-ures	10. Adequate documentation	11. Dat-ed and signed	12. Pre-shipmt .doc. review
15	?	?	?	no	?	?	?	?	?	?	?	?
12	?	?	?	?	?	?	?	?	?	no	?	?

(4) Establishment 15 had not addressed each hazard in the risk analysis.

(10) Establishment 12 did not have proper documentation of the CCP for zero tolerance, which stated that each carcass would be monitored for feces/ingesta. Documentation was only for deficiencies.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

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

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

Est. #	1.Written procedure	2. Sampler designated	3.Samp-ling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
15	?	?	?	?	?	?	?	?	?	?
12	?	?	?	?	?	?	?	?	?	?

Attachment D

Data Collection Instrument for *Salmonella* testing

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

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

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

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

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
15	?	?	N/A	?	?	?
12	?	?	N/A	?	?	?

Attachment E

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
9/16/02	Czech Republic Jihlava

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
State Veterinary authority	Jihlava, Czech Republic	Rantirouska 93

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Judd Giezentanner	Josef Brychta

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

SIGNATURE OF REVIEWER

DATE 9/16/02

Designed on FormFlow Software

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
9/16/02	Jihlav . Czech Republic

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
State veterinary Authority	Jihlava, Czech Republic	Rantir ɔuska 93

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Judd Giezentanner	Alena Honzlova

	Residue Code/Name ▶			PC	HC	Sulf	Chlo	Pen	Tetr	Stre	Ars	Hg	Pb	Zn
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		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
	Timely Analyses	03		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
	Interpret Comp Data	05		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
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	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
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A	A	A
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	A	A
	Percent Recovery	13		A	A	A	A	A	A	A	A	A	A	A
	Check Sample Frequency	14		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
	Corrective Actions	16		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
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A	A	A	A	A	A	A	A	A
OTHER REVIEW		19	EVAL. CODE											
		20												

SIGNATURE OF REVIEWER

DATE 9/16/02

Designed on FormFlow Software

Attachment F

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 Plana, Czech Republic	9/13/02	15	Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Judd Giezentanner		[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 SSOPs have failed to prevent direct product contamination or adulteration.	X
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 Sampl	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Gr unds and Pest Control	X
39. Establishment Co struction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sev age	
43. Water Supply	
44. Dressing Rooms/L avatories	
45. Equipment and Ut nsils	
46. Sanitary Operatio s	
47. Employee Hygien	
48. Condemned Produ t Control	
Part F - Inspection Requirements	
49. Government Staffi g	
50. Daily Inspection C verage	
51. Enforcement	
52. Humane Handling	
53. Animal Identificatio n	
54. Ante Mortem Inspe tion	
55. Post Mortem Inspe tion	
Part G - Other Regulatory Oversight Requirements	
56. European Communi y Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

CZECH REPUBLIC – Est. 15

12. SSOP preventive actions not documented.

38. Loading dock doors to outside not sealed to prevent entry of rodents.

61. NAME OF AUDITOR

Judd Giezentanner

62. AUDITOR SIGNATURE AND DATE

9/13/02

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 Studena, Czech Republic	9/16/02	12	Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Judd Giezentanner		[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.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
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 Operation	X
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 – Est. 12

12. SSOP preventive actions not documented. To be corrected.

22. HACCP plan indicates monitoring of each carcass for fecal contamination or zer tolerance. Only documented deficiencies. HACCP plan to be corrected.

46. Combos had product residues from previous day's use. Corrected immediately.

61. NAME OF AUDITOR

Judd Giezentanner

62. AUDITOR SIGNATURE AND DATE

9/16/02

Attachment G

STATE VETERINARY ADMINISTRATION OF THE CZECH REPUBLIC
Těšnov 17, 117 05 PRAHA 1
Phone : (+420) 2 2181 2974
Fax.: (+420) 2 2181 2738
Web : www.svscr.cz
Email:zahr@svscr.cz

Your letter d/d	: Dec. 30, 2002	Attachment	:
Your reference	: none	File handled by	: Dr J. Kuna, DVM
Our reference	: ZAH1503/usda/03	Department	: International Negotiations

Mrs. Sally STRATMOEN
Acting Director , Equivalence Staff
Office of International Affairs
USDA – FSIS
Washington, D.C. 20250
USA

Prague :Monday, 03 March 2003

Re: Supplement to the FSIS inspection team report on the inspection of meat processing plants in Masna Studená, a.s. and Maso Planá, a.s. carried out on 12-19 September 2002

Dear Dr. Stratmoen,

On the basis of information provided by management and the DVA, the SVA CR guarantees the rectification of the shortcomings detected during the FSIS inspection carried out on 12-19 September 2002 in plants Maso Planá a.s. and Masná Studená a.s. as referred to in the report.

The rectification of the shortcomings detected in Maso Planá a.s , Planá nad Lužnicí will be arranged in the following way:

1) Missing documentation on preventive measures in SSOP will be rectified by the replacement of reports intended for the recording of the monitoring of operational and pre-operational hygiene. Such reports are used in all centres. Preventive measures are also included in further documentation - "Notification form on the state of the sanitation and the HACCP system" and "Monthly report on the state of the sanitation and the HACCP system".
2) Not complete HACCP programme has been supplemented by the analysis of all risks; the HACCP system will be further extended in connection with the reconstruction of the slaughterhouse.
3) In order to prevent the access of rodents to the operational premises, all external entries have been sealed up. The problem will be completely solved within planned reconstruction of external walls (the first six months of 2003).

The rectification of the shortcomings detected in Masna Studená a.s. will be arranged in the following way:

1) The SSOP documentation has been extended by detail :d description of preventive measures. Forms used for the recording of preventive measures were modified in November 2002 in main centres and the appropriateness a ıd efficiency of the proposed measures will be evaluated by the end of February 2003; tl .e revised type of the records will be used in all centres then.
2) The HACCP plan has been modified in order to docume ıt all cases which are to be monitored in prescribed intervals, i.e. including proper cases
3) Within preventive measures, a special monitoring of the qua ity of washing of packagings at the output from washing room has been established.

Thank you very much for your cooperation, I remain

Yours faithfully,

MVDr. Jose f H o l e j š o v s k ý
Director (eneral (CVO)