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

NOV 8 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 May 19 through June 3, 2004. 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 more information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc: Quintin Gray, Minister Counselor, U.S. Embassy, Vienna
Jiri Kulis, Economic Attaché, Embassy of the Czech Republic
Norval Francis, Minister-Counselor, U.S. Mission to the E.U. in Brussels
Tony Van der Haegen, E.U. Mission to the U.S., Washington, D.C.
James Dever, FAS Area Officer
Amy Winton, State Department
Barbara Masters, Acting Administrator, FSIS
Linda Swacina, Executive Director, Institute of the Americas, FSIS
Karen Stuck, Assistant Administrator, Office of International Affairs (OIA), FSIS
Bill James, Deputy Assistant Administrator, OIA, FSIS
Donald Smart, Director, Review Staff, OPEER, FSIS
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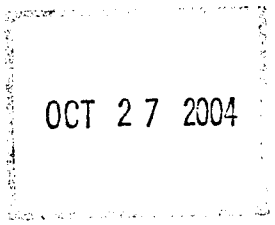
Armia Tawadrous, FSIS Codex Staff, OIA
Shannon McMurtrey, IES, OIA
Nancy Goodwin, IES, OIA
Country File (Audit: FY 2004)

FINAL



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

MAY 19 THROUGH JUNE 03, 2004

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]
SVA	State Veterinary Administration
DG	Director General
DVHPHE	Department of Veterinary Hygiene, Public Health and Ecology
DAHW	Department of Animal Health and Welfare
RVA	Regional Veterinary Administrations
DRVA	Director of Regional Veterinary Administrations
DVA	District Veterinary Administration
DDO	Director of District Office
VD	Veterinary Doctor
VA	Veterinary Assistant
VT	Veterinary Technician
FSIS	Food Safety and Inspection Service
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 Czech Republic from May 19 through June 04, 2004.

An opening meeting was held on May 20, 2004, 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 district inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing 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 the CCA (SVA), one regional veterinary administration office, two district offices, two local offices at the establishment level, one laboratory performing analytical testing on United States-destined product, and two swine slaughter and processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Headquarters (SVA)
	Regional	1	Ceske Budejovice (RSVA) office
	District	2	Jindrichuv Hradec and Tabor (DVA) offices
	Local	2	Establishment level
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 oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters, regional, and district offices. The third part involved on-site visits to two establishments: both slaughter and processing establishments. The fourth part involved visits to one government laboratory. The government laboratory, the State Veterinary Institution (Statni Veterinarni Ustav, Jihlava) was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*), *Salmonella* species (*Salmonella*), and *Listeria monocytogenes*. This laboratory also was conducting analyses of field samples for the Czech Republic's national residue control program.

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

During all on-site establishment visits, the 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 made for the 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, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those 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.

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 September 2002:

- Corrective/preventive actions in SSOP were not adequately documented in both establishments.
- 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 were found 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 (CCP) for the control of feces/ingesta on carcasses.

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

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

6. MAIN FINDINGS

6.1 Government Oversight

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

The first level is the State Veterinary Administration (SVA), which includes the Department of Veterinary Hygiene, Public Health and Ecology (DVHPHE), the Department of Animal Health and Welfare (DAHW), the Department of Veterinary Protection of State Territory and Foreign Relations (DVPSTFR), the Institute of State Control of Veterinary Biological and Medicaments (ISCVBM), seven State Veterinary Institutes (SVI), 13 Regional Veterinary Administrations (RVA), and one Municipal Veterinary Administration (MVA) in Prague. The SVA, with regard to meat inspection, is staffed with approximately 1,354 personnel. These personnel are scattered throughout the 14 Regions of the Czech Republic.

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

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

6.1.1 CCA Control Systems

An official of the RVA staff, district director and in-plant supervisor 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.

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

6.1.2 Ultimate Control and Supervision

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

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

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

6.1.3 Assignment of Competent, Qualified Inspectors

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

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

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

6.1.4 Authority and Responsibility to Enforce the Laws

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

6.1.5 Adequate Administrative and Technical Support

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

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at headquarters, regional, district and local offices at the establishment level. 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 United States
- Training records for inspectors and laboratory personnel.
- 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, 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.

6.3.1 Audit of Regional Site

The FSIS auditor reviewed one regional SVA office in Ceske Budejovice and interviewed the regional director. The purpose of the interview was to review the meat inspection records and determine the level of government oversight and control provided by the regional offices relative to the certified establishments.

The auditor concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters through the regional offices to two district offices and certified establishments (local inspection sites). This was accomplished by hard copy.
- Copies of all relevant regulations, notices, and other inspection documents and records were maintained at the regional offices.
- The regional director was knowledgeable of U.S. import requirements relative to the two certified establishments producing or exporting meat to the United States.
- The regional official demonstrated adequate administrative assistance to ensure that official inspection personnel were assigned to the two certified establishments.
- Records for training programs for inspectors in PR/HACCP and SSOP system implementation, *E. coli*, *Salmonella*, and *Listeria monocytogenes* testing were reviewed.

The auditor found that the instructions had been received and implemented by the regional office visited.

6.3.2 Audit of District Sites

The FSIS auditor reviewed the Czech Republic's meat inspection records at the SVA's two DVA offices in Tabor and Jindrichuv Hradec. The auditor interviewed the district directors of the Tabor and Jindrichuv Hradec offices. The purpose of the interviews was to review the meat inspection records and determine the level of government oversight and control provided by the DVA offices relative to the certified establishments.

The auditor concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters through the regional offices to the two district offices and certified establishments (local inspection sites). This was accomplished by hard copy.
- Copies of all relevant regulations, notices, and other inspection documents and records were maintained at the district offices.
- Both district directors were knowledgeable of U.S. import requirements relative to the two certified establishments producing or exporting meat to the United States.
- Both district offices demonstrated adequate administrative assistance to ensure that official inspection personnel were assigned to the two certified establishments.

6.3.3 Local Inspection Sites (Certified Establishments)

The FSIS auditor reviewed the Czech Republic's meat inspection records maintained at the local inspection sites certified to produce or export meat to the United States. In addition, the auditor interviewed the senior veterinarian official at each establishment and their inspection teams, which consisted of veterinary inspectors, senior veterinary assistant and meat inspectors.

The auditor concluded that:

- All relevant regulations, notices, and other inspection documents and records were adequately disseminated from headquarters through the regional, district offices to the two local inspection sites. This was accomplished by hard copy.
- Inspection personnel demonstrated adequate knowledge of inspection requirements relative to the export and distribution of meat to the United States.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two establishments. Both were slaughter and processing establishments. None of the establishments were delisted by the SVA and none of the establishments received a Notice of Intent to Delist (NOID). Specific deficiencies are noted in the attached individual establishment review forms.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratory was reviewed:

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

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

9. SANITATION CONTROLS

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

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

9.1 SSOP

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 were found to meet the basic FSIS regulatory requirements with no deficiencies.

9.2 Sanitation

The Sanitation Performance Standards (SPS) were not effectively implemented in one of the two establishments audited.

- A build up of rust, pieces of fat, and meat was observed at various spots on the two ducts and a beam over the hog carcass rail in the hallway leading to carcass cooler. No evidence of product contamination was observed.

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

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

11.1 Humane Handling and 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 a HACCP program. 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 deficiencies were noted in one of the two establishments audited.

- The establishment employee signs or initials the monitoring records once a day when the frequency of monitoring of CCP for carcass temperature in the chiller is every two hours. The records do not include the signatures or initials of the establishment employee performing the monitoring activity each time under the HACCP plan.

11.3 Testing for Generic *E. coli*

The Czech Republic has adopted the FSIS requirements for generic *E. coli* testing with the exception of the following equivalent measure(s).

- Government laboratories were conducting the testing rather than private laboratories.

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 not properly conducted in one of the two slaughter establishments.

- The establishment is sponging hog carcasses and is not using statistical process control techniques to evaluate *E. coli* test results. The SVA inspection officials ordered establishment personal to take corrective action.

11.4 Testing for *Listeria monocytogenes*

Both establishments audited were producing ready-to-eat products for export to the United States. One of the two establishments audited was not required to meet the testing requirement for *Listeria monocytogenes* in RTE products because it was producing thermally processed/commercially sterile product. In the other establishment, the HACCP plan had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur in accordance with United States requirements.

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 laboratory, located in Jihlava, is a government laboratory which conducts analyses of field samples for the Czech Republic's national residue program and analyses of field samples for the presence of *Salmonella* and the generic *E. coli* sampling program.

The following deficiencies were noted:

- The temperature of incoming samples of chlorinated hydrocarbons, polychlorinated biphenyls, antibiotics, organophosphates, trace elements, and sulfonamides was not recorded on the form, as specified, by the laboratory employee in the sample receiving room.

The Czech Republic's National Residue Testing Plan for 2004 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*

The Czech Republic has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

- Testing strategy is once a week for bovine and twice a week for swine, continuously until violation, then sample set is taken.
- Uses different method for analysis; specifically, ISO 6579.

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

Testing for *Salmonella* was properly conducted in both establishments.

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 both 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.

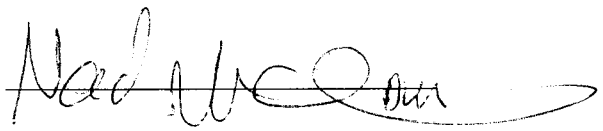
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on June 3, 2004, 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.

For Faizur R. Choudry, DVM
International Audit Staff Officer



15. ATTACHMENTS

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

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
05/21/2004	State Veterinary Institute (Statni Veterinarni Ustav)

FOREIGN GOVT AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
State Veterinary Administration	Jihlava, Czech Republic	Rantirovska 93, 586 06 Jihlava

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faizur R. Choudry, DVM	N/A

	Residue Code/Name ►			100	111	300	400	200	800	Eco	Sal	Lit	Sp		
SAMPLING PROCEDURES	REVIEW ITEMS Sample Handling	ITEM # 01	EVLUATION CODE	C	C	C	C	C	C	A	A	N	N		
	Sample Frequency	02		A	A	A	A	A	A	A	A	N	N		
	Timely Analysis	03		A	A	A	A	A	A	A	A	N	N		
	Compositing Procedure	04		O	O	O	O	O	O	O	O	N	N		
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	N	N		
	Data Reporting	06		A	A	A	A	A	A	A	A	N	N		
ANALYTICAL PROCEDURES	Acceptable Method	07	EVLUATION CODE	A	A	A	A	A	A	A	A	N	N		
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	N	N		
	Equipment Operation	09		A	A	A	A	A	A	A	A	N	N		
	Instrument Printouts	10		A	A	A	A	A	A	O	O	N	N		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVLUATION CODE	A	A	A	A	A	A	O	O	N	N		
	Recovery Frequency	12		A	A	A	A	A	A	O	O	N	N		
	Percent Recovery	13		A	A	A	A	A	A	O	O	N	N		
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	N	N		
	All Analyst W/Check Samples	15		A	A	A	A	A	A	A	A	N	N		
	Corrective Actions	16		A	A	A	A	A	A	A	A	N	N		
	International Check Samples	17		A	A	A	A	A	A	A	A	N	N		
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A	A	A	A	A	A	N	N		
OTHER REVIEW		19	EVAL. CODE												
		20													

Signature of reviewer: Faizur R. Choudry

Date: 06/28/04

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 05/21/2004	NAME OF FOREIGN LABORATORY State Veterinary Institute (Statni Veterinarni Ustav)
FOREIGN GOVT AGENCY State Veterinary Administration	CITY & COUNTRY Jinlava, Czech Republic	ADDRESS OF LABORATORY Rantirovska 93, 586 05 Jinlava
NAME OF REVIEWER Dr. Faizur R. Choudry, DVM	NAME OF FOREIGN OFFICIAL N/A	

RESIDUE	ITEM NO.	COMMENTS
100,111 200,300 400,800	01	The temperature of incoming samples of chlorinated hydrocarbons, polychlorinated biphenyls, antibiotics, organophosphates, trace elements, and sulfonamides was not recorded on the form, as specified, by the laboratory employee in the sample receiving room.

NOTE: Listeria and species verification testing was not reviewed due to inadequate time

NOTE: A (acceptable), C (comments), O (not applicable) N.(Not Reviewed)

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	05/27/04	12	Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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	X
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	X
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	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment # 12 Date of Audit: 05/27/04 Slaughter & Processing Operations

29/51. The establishment is sponging hog carcasses and is not using statistical process control techniques to evaluate *E.coli* test results. The SVA inspection officials ordered establishment personnel to take corrective action. 9 CFR 310.25(5)(ii).

39/51. A build up of rust, pieces of fat and meat was observed at various spots on the two ducts and a beam over the hog carcass rail in the hallway leading to carcass cooler. No evidence of product contamination was observed. 9 CFR 416.2(b)

61. NAME OF AUDITOR
Dr. Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
Faiz R Choudry 05/27/04

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	05/26/04	15	Czech Republic
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
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	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Eetablishment # 15 Dated 05/26/04 Slaughter/processing operation

22/51. The establishment employee signs or initials the monitoring records once a day when the frequency of monitoring of CCP for carcass temperature in the chiller is every two hours. The records do not include the signatures or initials of the establishment employee performing the monitoring activity each time under the HACCP plan. 9 CFR 417.5(b)

61. NAME OF AUDITOR
Dr. Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE
06/27/04

STATE VETERINARY ADMINISTRATION OF THE CZECH REPUBLIC
Slezská 7, 120 56 PRAHA 2
Phone : (+420) 227 010 184
Fax.: (+420) 227 010 198
Web : www.svscr.cz
Email:zahr@svscr.cz

Your letter d/d	: July 22, 2004	Attachment	: None
Your reference	: 2630-9 (6/86)	File handled by	: Dr. J. Kuna, DVM
Our reference	: ZAH1034/fsis/04Re1414	Department	: Foreign Relations

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

Prague :Monday, 13 September 2004

Re: FSIS audit in Czech plants exporting to USA.

Draft final report - results – comments.

Dear Sally White,

In reference to your letter and to the audit conducted May 19 through June 3, 2004 and carried out by FSIS audit inspector Dr. Faizur R. Chouldry please be informed the State Veterinary Administration of the Czech Republic, based on written reports and safeguards from the Regional Veterinary Administration for South-Bohemian region (supervising the audited Czech plants) and from the State Veterinary Institute, Jihlava, provides the following guarantees :

1. All shortcomings and oversights found during the audit at the plant CZ 12 have been rectified till the date 28.5.2004. Statistical process control to evaluate generic *E.coli* test results has been implemented. The overall cleaning measures have been carried out on the two ducts and a beam over the hog carcass rail in the hallway leading to the carcass cooler where the buildup of rust and pieces of fat and meat ware observed during the audit.
2. All deficiencies found at the plant CZ 15 have been rectified till the date 26.5.2004. Employees in charge of monitoring records of critical control points for carcass temperature in the chiller have been re-trained and advised to sign or initiate monitoring records every two hours as stated as the monitoring frequency in the establishment's HACCP plan. This frequency is being currently observed.

3. Deficiencies found at the State Veterinary Institute, Jihlava have been rectified. In each incoming sample to the samples receiving room - the time of arrival, number of transporting line, the temperature in the transporting vehicle are being recorded as well as the temperature of incoming samples carried out by the infra-red thermometer. Records are affirmed by a responsible person.

Your offices are kindly requested to accept these guarantees provided by the SVA CR for and on behalf of the government of the Czech Republic.

In case of any additional information or query please feel free to contact our Administration.

Yours sincerely,

MVDr Josef Holejšovský, PhD
Director General (CVO)

c.c.:

Ing.P.Chotěborská, Foreign Agricultural Service, Embassy of the USA, Prague