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

APR 22 2002

Dr. Josef Holejsovsky
Acting Director General
State Veterinary Administration
Tesnov 17
117 05 Praha 1
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 July 23, 2001 through August 2, 2001. Enclosed is a copy of the final audit report. The Czech Republic's comments on the draft final audit report have been included as an attachment to the enclosed final audit 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 email at sally.stratmoen@usda.gov. You may also contact Richard F. Brown by telephone at (202) 690-2679, by fax at (202) 690-4719, or by e-mail at richard.brown@fsis.usda.gov.

Sincerely,

Richard F. Brown

/s/ Sally Stratmoen
Chief, Equivalence Section
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosure

cc: Robert Curtis, Minister Counselor, American Embassy, Vienna
Jiri Kulis, Economic Attaché, Embassy of The Czech Republic
Allen Burst, FAS Area Officer
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Country File (FY 2001 Audit)

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Food Safety And Inspection Service
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AUDIT REPORT FOR CZECH REPUBLIC
JULY 23 THROUGH AUGUST 2, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Czech Republic's meat inspection system from July 23 through August 2, 2001. Two establishments certified to export meat to the United States were audited. Both establishments were conducting slaughter/processing operations.

The last audit of the Czech Republic meat inspection system was conducted in June 2000. Two establishments were audited: one, Est. 15, was found to be acceptable, and one, Est. 12, was evaluated as acceptable/re-review. Several major concerns were reported at that time:

1. Inadequately inspected lymph nodes in both establishments. *This deficiency was corrected by the State Veterinary Administration (SVA).*
2. Monthly supervisory report did not document the findings/corrective actions in Est. 12, in Est. 15; the findings were recorded into a database that was not accessible to the IIC. *This was corrected by SVA; all data are accessible in the District Veterinary Administration offices.*
3. Hair, flaking paint and oil on carcasses in Est. 12 with no immediate corrective action taken by Est. or inspection personnel. *This deficiency was corrected by the company officials.*
4. Flaking paint and rust was found on carcasses in Est. 15. *These deficiencies were corrected by both establishments.*
5. Zero tolerance for fecal contamination was not enforced. *Corrected by both companies.*
6. On-site verification of HACCP plans not performed in both establishments. *Corrected in both establishments.*
7. There was not random selection of carcasses for generic *E. coli* testing. *This deficiency was not corrected and carcasses for Salmonella and E. coli samples were not randomly selected by the IIC. This will be corrected in both establishments.*
8. Sponging method was performed for generic *E. coli* testing, but the excision performance criteria were used for evaluation. *This practice was still used in Est.15, but the company is going to work out Statistical Process Control for their sponging method.*

Two species, bovine and porcine, were approved for export to the U.S. The Czech Republic is currently evaluated as a high-risk country for BSE.

During calendar year 2000, Czech Republic's establishments did not export any product to U.S.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with Czech Republic's national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second was conducted by on-site visits to establishments. The third was a visit to the government laboratory, performing analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella*.

Czech Republic's 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 the two establishments audited; both were evaluated as acceptable. 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, several major concerns had been identified during the last audit of the Czech Republic meat inspection system, conducted in June 2000. During this new audit, the auditor determined that the concerns had been addressed and corrected.

1. Pathogen Reduction testing random sample selection deficiencies had been found in two establishments visited (Ests. 12, and 15). During this new audit, implementation of the required random testing was again found to be deficient (this was a repeat finding), in both

(Ests. 12 and 15) establishments visited. Details are provided in the Slaughter/ Processing Controls section later in this report.

2. Statistical Process Control for generic *E. coli* testing for sponging method has been used in Est. 12, in Est. 15, the excision performance criteria have been still used.

Major concerns from the current audit included heavy condensation, insect and rodent problems, not denaturing condemned carcasses, non-random testing for *E. coli* and *Salmonella*, testing of *E. coli* by using the sponging method while evaluated by the excision performance criteria, IIC performing reviews, pre-shipment reviews, SSOP deficiency (preventive action) and *E. coli* sampling and dating and signing SSOP.

Entrance Meeting

On July 24, 2001, an entrance meeting was held in the Prague offices of the State Veterinary Administration, and was attended by Dr. Josef Holejsovsky, General Direct, (Chief Veterinary Officer); Dr. Milan Malena, Head of Hygiene, Public Health and Ecology Department; Dr. Eduard Slanec, Head of Division, Department of Veterinary Hygiene, public Health and Ecology; Dr. Jiri Kuna, Senior Veterinary Officer, Department of International Negotiations and Veterinary Protection of the State Territory; all representing SVA, and Dr. Oto Urban, International Audit Staff Officer, FSIS, USDA. Topics of discussion included the following:

1. The itinerary arrangements were finalized.

2. The FSIS auditor discussed the export situation of the Czech Republic to the U.S., because the country has not exported to the U.S. since 1991.

3. The auditor provided the data-collection instruments he would be employing for compliance with the requirements of Standard Sanitation Operating Procedures, Hazard Analysis Critical Control Point, generic *E. coli* testing and the testing program for *Salmonella* species.

4. SVA provided information to update the FSIS country profile of the Czech Republic.

5. The current status of country regarding BSE diagnosis.

6. The auditor asked about the current state of SVA species verification program, *Listeria monocytogenes* and *E. coli* O157:H7 testing. All these are being performed in the Czech Republic.

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 inspection system in June 2000.

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. No documents were reviewed at the headquarters because only two plants were visited. This records review was conducted at the IIC office, since the Czech Republic had only two establishments approved for export to the U.S. The records review focused primarily on food safety hazards and included the following:

- Supervisory visits to establishments that were certified to export to the U.S.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- 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.
- 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.

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

1. The SSOP preventive action was not recorded in both establishments and the procedure was not dated and signed by the person with overall on-site authority in Est. 15.

2. Both establishments were not aware of the pre-shipment review. In case they resume export to U.S., they will perform this requirement.

3. The sample for *E. coli* and *Salmonella* testing was not selected randomly.

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 SVA 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 time this audit was conducted. Both establishments were visited for on-site audits. In the establishments visited, both SVA 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 laboratory*;* intra-laboratory quality assurance procedures, including sample handling; and methodology.

The State Veterinary Institute Laboratory in Jihlava was audited on July 26, 2001. 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. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been accredited by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the two establishments:

Beef and pork slaughter, boning, cutting, grinding, cured (dried) smoked products, cooked sausage, shelf stable canned products, and convenience foods – Est. 12.
Beef and pork slaughter, boning, cutting, grinding, cured (dried) smoked products, cooked sausage, shelf-stable and non-shelf stable canned products – Est. 15.

SANITATION CONTROLS

Based on the on-site audits of establishments, the 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, antemortem 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 of records.
2. Est.15 did not have the procedure dated and signed by the person with overall on-site authority.

Condensation in Cooler

In Est. 12, heavy condensation was observed over exposed and non-exposed product in the expedition cooler. *This was corrected immediately by the establishment management.*

Hand Washing Facilities

In Est.15, most of the hand-washing facilities in production areas did not have wastebaskets. *This deficiency was corrected immediately by the establishment officials.*

The hand-washing facility in the packaging room had a hand-operated wastebasket in Est.15. *This was immediately corrected by the company officials.*

Personnel Hygiene and Practices

In Est.12, a company employee was wearing his street clothes over his protective clothing. *No corrective action was taken either by the company management or inspection officials.*

Pest Control

Numerous flies were observed in various areas of the Est. 12. *Officials are investigating the possible entrance of flies and increasing preventive action.*

Bait stations did not have specified fecal droppings documented in their rodent control program in Est.12. *The company is going to correct this deficiency.*

In Est.15, numerous flies were observed in the slaughter room. *Officials are investigating the possible entrance of flies and increasing preventive action.*

Lighting

Lighting was inadequate over the boning table in swine boning room in Est. 15. *Installation of an additional light in the boning room was scheduled by the establishment officials.*

ANIMAL DISEASE CONTROLS

With the exception listed below, the Czech Republic's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

- Condemned carcasses were properly identified but not denatured in Est.12. *The SVA asked IIC to denature the condemned carcasses.*

There was a reported outbreak of Bovine Spongiform Encephalopathy (BSE) in the late spring of 2001 in Czech Republic. The status of other animal diseases with public-health significance: Swine Vesicular Disease was never recorded in the country, the last occurrence of Foot and Mouth Disease was in 1975 and vaccination was officially terminated in 1991, and outbreaks of Classical Swine Fever in domestic pigs was eradicated by stamping out method in June, 1997. Recent national serological surveys gave negative results. Serological examination of the wild boar population indicated a low incidence of infection. Vaccination was officially terminated in 1992.

There was a short visit to a fattening pig production farm in Jarosov. There was a brief discussion with farm officials, including the company veterinarian, but the farm facilities could not be visited.

The company veterinarian is responsible for distribution of medication/drugs at the farm. Pharmaceuticals are received only from one supplier. Antibiotics are not regularly added to feed, drugs are added to feed as a curative/preventive action in certain time period. No animal drugs are allowed to be distributed by farmers. Veterinary technicians under instruction from a veterinarian will provide medication to animals. Attending veterinarians are required to provide written guarantees of the residue-free or drug withdrawal status for any purpose for each animal with the date the drug was administered.

RESIDUE CONTROLS

The Czech Republic's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Czech Republic 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 inspection system had controls in place to ensure adequate humane 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 with the following exception:

- Both establishments did not have knowledge of performing and documenting pre-shipment document reviews. *In this case, when they resume export to the U.S., the companies will perform pre-shipment reviews.*

Testing for Generic *E. coli*

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

1. SAMPLE COLLECTOR: Government Takes Samples. The criteria used for equivalence decisions for use of government employees in lieu of establishment employees are:
   - There is a clearly written sampling plan with instructions for sample and collection that will be universally followed.
   - The government has a means of ensuring that sample collection activities are appropriate.
   - The government uses the test results to verify establishment slaughter processing and dressing controls for fecal contamination.

2. 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 promptly reported to the establishment.

The E. coli testing programs were found to meet equivalent FSIS requirements, except as follows:

- Samples were not randomly selected.
- Government Officials were taking the samples. *This is contrary to the program previously determined equivalent by FSIS in which establishment employees took the samples*

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 SVA inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, 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

Two 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 with the following exception:

- Samples were not being randomly selected.

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/she was a veterinarian with many years of experience. In case of the U.S. audit, it was performed by the IIC in both establishments. This was discussed at the exit meeting.

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 in the establishment, 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 1 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 within of the SVA Czech Republic conform to the provisions laid down in the Act No. 166/1999 regarding state operated and budget-dependable 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. SVA can impose verbal warnings and fines to Animal Health or Public 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 August 1, 2001. The participants included Dr. Josef Holejsovsky, General Director (Chief Veterinary Officer); Dr. Milan Malena, Head of Hygiene, Public Health and Ecology Department; Dr. Jiri Kuna, Senior Veterinary Officer; and Dr. Oto Urban, International Audit Staff Officer. The following topics were discussed:

1. In Est. 12, heavy condensation was observed over exposed and non-exposed product in the expedition cooler. *This was corrected immediately by the establishment management.*

2. Several flies were observed in various areas of the Est. 12. *This deficiency was corrected immediately by establishment officials.*

3. Bait stations did not have specified fecal droppings documented in their rodent control program in Est.12. *The company is going to correct this deficiency.*

4. In Est.15, several flies were observed in the slaughter room. *This deficiency was corrected immediately by establishment officials.*

5. Condemned carcasses were properly identified but not denatured in Est.12. *The SVA asked IIC to denature the condemned carcasses.*

6. Pathogen Reduction testing random sample selection deficiencies had been found in the two establishments visited (Ests. 12 and 15) during the last audit. During this new audit, implementation of the required random testing was again found to be deficient in both establishments (this was a repeat finding). *This deficiency was scheduled for correction by both government and establishment officials.*

7. Statistical Process Control for generic *E. coli* testing for sponging method was being used in Est.12; in Est. 15, the excision performance criteria was being used. *It was scheduled for correction by the establishment.*

8. Reviews of the U.S. audited establishments were being repeatedly performed by the IIC. *This practice is going to be change during the next audit.*

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. The general impression of the auditor regarding the Czech Republic meat inspection system as a whole was one of considerable improvement, compared with the findings resulting from the previous audit. Two establishments were audited and both were found to be acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Oto Urban — (signed) Dr. Oto Urban
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. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
12	√	√	√	√	√	√	√*	√
15	√	√	√	√	√	√	√*	N

Ests.15 and 12/7* The preventive action was not recorded.
Est. 15 The procedure was not dated and signed by the person with overall on-site authority.

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 conducted	3. Use & users included	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. Procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
12	√	√	√	√	√	√	√	√	√	√	√	N
15	√	√	√	√	√	√	√	√	√	√	√	N

Ests. 12 and 15/12 Did not know about the pre-shipment review. In case they would export to the U.S., they will perform this requirement.

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.Sampling 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
12	√	√*	√	√	√	√	N	√	√	√
15	√	√*	√	√	√	√	N	√	√	√

Ests. 12 and 15/2* The local SVA government inspector collect samples for generic *E. coli*.
Ests. 12 and 15/7 The sample was not selected randomly.

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
12	√	√	√	N	√	√
15	√	√	√	N	√	√

Ests. 12 and 15/4 - The samples were not taken randomly.

Attachment E

U.S. Department of Agriculture Food Safety & Inspection Service Field Operations / Review Staff	Date of Review 07.26.2001	Laboratory State Veterinary Institute City, Country Jihlava, CZ
Reviewer Dr. O. Urban	Foreign Official Dr. Zámek. director	☐ Acceptable ☐ Acceptable / Re-Review ☐ Refer to Science

Codes *(Enter one for each review with items listed below)* ☐ Acceptable ☐ Marginally Acc. ☐ Unacceptable ☐ Exempt ☐ Not Applicable ☐ Not Reviewed ☐ Comments on Reverse

		Residue Code	100	111	200	203	300	400	500	800	Species verification	IVM			
	Sample Procedures														
01	Sample Handling		A	A	A	O	A	A	O	A	A	A			
02	Sampling Frequency		A	A	A	O	A	A	O	A	A	A			
03	Timely Analysis		A	A	A	O	A	A	O	A	A	A			
04	Compositing Procedure		O	O	O	O	O	O	O	O	O	O			
05	Interpretation of Comp. Data		O	O	O	O	O	O	O	O	O	O			
06	Data Reporting		A	A	A	O	A	A	O	A	A	A			
	Analytical Procdedures														
07	Acceptable Method		A	A	A	O	A	A	O	A	A	A			
08	Correct Tissue(s)		A	A	A	O	A	A	O	A	A	A			
09	Equipment Operation		A	A	A	O	A	A	O	A	A	A			
10	Instrument Printouts		A	A	O	O	A	A	O	A	O	A			
	Quality Assurance/Control Procedures														
11	Minimum Detection Level		A	A	A	O	A	A	O	A	O	A			
12	Recovery Frequency		A	A	A	O	A	A	O	A	O	A			
13	Percent Recovery		A	A	O	O	A	A	O	A	O	A			
14	Check Sample Frequency		A	A	A	O	A	A	O	A	A	A			
15	All Analysts with Check Samples		A	A	A	O	A	A	O	A	A	A			
16	Corrective Actions		A	A	A	O	A	A	O	A	A	A			
17	International Check Samples		A	A	A	O	A	A	O	A	A	A			
18	Corrected Prior Deficiencies														
19	Other Review Findings														

Science Program Evaluation ☐ Acceptable ☐ Acc./Re-Review ☐ Unacceptable	Signature of Evaluator(s)	Date

* Certain standards (prepared or manufactured by Sigma company) did not have the expiration dates but company (Sigma) gaurantee it's standards up to two years.

State Veterinary Institute; Jihlava Czech Republic

From: Urban, Otto
Sent: Friday, February 16, 2001 3:39 PM
To: Bolstad, Gary
Subject: micro

Questions for Auditing Laboratories

General

Name & location of lab:

Private or gov't lab? Government

How & when was accreditation obtained? Czech Institute for Acreditations 14. 9. 2000 - for five years

How & how often is accreditation maintained? Every year is a control fro CIA

When and how is payment for analysis provided? Complete (Accomplished) res are paid after finish (monthly pay

Are results released before payment is received? Yes

What are the qualifications of the analyst(s) performing the individual tasks within a method? Universi Specializ high school degr for middle Corta help

What are the qualifications of the direct supervisor of the analyst(s)? University and post-gradual degrees, seminars, congresse

Methodology for HACCP *Salmonella* samples (regulatory labs)

Does this lab analyze HACCP *Salmonella* samples? Yes

How are HACCP *Salmonella* samples received & recorded? Under SVI control by SVI special sample delive car - maintaining requir 5°C. Recorded number from the place of collection to the lab

Are HACCP *Salmonella* samples analyzed on the day of receipt? Yes, in some cases next day

What method(s) is used for HACCP *Salmonella* samples?

Is it a qualitative method (i.e. +/- result)? Yes

Are HACCP ground beef samples analyzed for *Salmonella*? Yes

What is the size of the ground beef test portion? 250gr

What buffer (and what volume) is used for:

Sponge samples for *Salmonella*? Buffered Pepton Water

Poultry rinsates for *Salmonella*? N/A

Salmonella ground beef sample homogenates? Classical physiological solution

What is the formulation of the Buffered Peptone Water you use?

What analytical controls are used for *Salmonella* analyses(i.e. control cultures, etc.)? National collection bank in Brno, Salmonella enterid — " — typhy muriu

Are they employed for each sample set? Yes

How are HACCP *Salmonella* results expressed? +/− in 25gr, original sampl

How are HACCP *Salmonella* results recorded:

Data sheets/work sheets? Log books

and/or Log books?

How and to whom are HACCP *Salmonella* results reported? (1) District Veterina Office (2) Headquarter of SI (3) If the sample is paid by company, they receive a copy of the res

Are "check" samples periodically used to test the proficiency of the lab and analysts for *Salmonella* testing?

Intra
Inter
International (FAPAS)
tests samples

1. For individual analysts or for the lab as a whole?
2. What species/strains are used? According to the provider
3. How many samples are analyzed and how often? Up to 10 samples / yearly
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Yes, negative & positive control
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? Not used cfu but +/−

* Frequency is set only for intralaboratory check sample

Methodology for HACCP generic *E. coli* samples (in-plant or other private labs)

Does this lab analyze HACCP generic *E. coli* samples? Yes

How are HACCP *E. coli* samples received & recorded?

Are HACCP *E. coli* samples analyzed on the day of receipt?

What method is used for HACCP generic *E. coli* samples?

Is it a quantitative method? Yes

What buffer (and what volume) is used for: Butterfield

E. coli sponge samples?

Poultry rinsates for generic *E. coli*? N/A

What analytical controls are used? The same source from Brno

Are they employed for each sample set? Yes, negative, Positive and samples

How are HACCP *E. coli* results calculated and/or expressed? Calculated for gr or ml for cfu

How are *E. coli* results recorded:

Data sheets/work sheets? Log book

Log books?

How and to whom are HACCP *E. coli* results reported? The same as Salmonel

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic *E. coli* testing?

Intra } check
Inter }

6. For individual analysts or for the lab as a whole?
7. What species/strains are used? generic E.coli
8. How many samples are analyzed and how often? Up to 5 for a year
9. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Negative & Positive
10. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts?

NOTE: IF YOU HAVE ANY QUESTIONS REGARDING THIS, FEEL FREE TO CALL EITHER VICTOR COOK OR BONNIE ROSE AT 202-501-6022.

Chromogene media - E. coli
Immunomagnetic separation
Listeria
E. coli 0157

Attachment F

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

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
7/25/01	Est. 12 Masna Studena a.s.	Studena
		COUNTRY: Chech Republic

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Drs. Milan Malena & George Kuna	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 M	**2. DISEASE CONTROL**		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 O	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 O
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 M	Ingredients identification	53 A	E.Coli & Salmonella	83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	7/25/01	Est. 12 Masna Studena a.s.	Studena
			COUNTRY Chech Republic

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Drs. Milan Malena & George Kuna	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

7 Few flies were observed in various areas of the establishment.

9 Bait stations did not have specified fecal droppings documented in their rodent control program. The company is going to correct this deficiency.

17 Heavy condensation buildup was observed in the expedition cooler, above some exposed but mostly not exposed product. This was corrected immediately by the establishment management.

26 The company's employee in the boning room was observed to wear his working cloth outside of his protective clothing. No corrective action was taken either by the company management or inspection officials.

43 Condemned carcasses were properly identified but not denatured. The SVA asked IIC to denature the condemned carcasses.

82 Pre-shipment review is going to be performed on product exported to the U.S.A. This company hasn't exported to the U.S. since 1991.

83 Randomness of the carcass selection needs to be changed to exclude the human factor. It is going to be changed by the IIC.

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

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
7/27/01	Est. 15 Maso Plana a.s.	Plana n/Luzici
		COUNTRY: Czech Republic

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Drs. Kuna & Martinkova	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A*
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 M	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 O	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 O
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 A	E.coli & Salmonella	83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	7/27/01	Est. 15 Maso Plana a.s.	Plana n/Luzici
			COUNTRY Czech Republic

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Drs. Kuna & Martinkova	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

4 Most of the hand-washing stations in production areas did not have waste baskets. This deficiency was corrected immediately by the establishment officials.

4 The hand-washing facility in packaging room had hand-operated waste basket. This was immediately corrected by the company officials.

7 Several flies were observed in slaughter room.

11 Lighting was inadequate over the boning table in swine boning room. Installation of light in the boning room was scheduled by the establishment officials.

82 The pre-shipment review of the exporting product to the U.S. will be performed.

83 The randomization of pathogen reduction samples will be performed.

Attachment G

STATE VETERINARY ADMINISTRATION OF THE CZECH REPUBLIC
Těšnov 17, 117 05 Praha 1
Phone : (+420.2) 2181 2738
Fax.: (+420.2) 2181 2974
Web : svs.aquasoft.cz
Email:zahr@svs.aquasoft.cz

Your letter d/d	: Feb. 11, 2002	Attachement	:
Your reference	: none	File handled by	: Dr. J. Kuna, DVM
Our reference	: ZAH0139/u.s./02 Re265/02	Department	: International Negotiations

Mrs. Sally STRATMOEN
Chief, Equivalence Section
International Policy Staff
Office of Policy, Program Development and Evaluation
USDA – FSIS
20250 Washington, D.C. USA

Prague, March 21, 2002

Re : Comments to Draft Final Audit Report (FSIS on-site audit July 23 through August 2, 2001).

Dear Mrs Stratmoen.

This is in reference to your letter and the above Draft Final report enclosed therein. As you invite us to provide written comments to this, please be informed as follows .

State Veterinary Administration of the Czech Republic after the due consideration given to the Report and due negotiations held with relevant management staff and district veterinary offices in charge of supervision of the audited plants has already set the deadlines for rectification of deficiencies described in your letter.
As per the rectifying actions and the deadlines already set :

- Problem regarding a random selection of carcasses for generic *Escherichia coli (E. coli)* and *Salmonella* testing programs will be solved with the managements of both plants (CZ 12 and CZ 15) through a purchase of computerized programme.
  Deadline : 31.5.2002.
- Sponging method of sampling for generic *E. coli* (statistical process control) in establishment CZ 15 is being already performed. As per the unified system in both plants
  Deadline : 30.4.2002.
- System of the insect and rodent controls and the evaluation of this system will be changed. In the framework of re-construction works in the plant CZ 12 the more strict separation of barns and slaughter premises will be implemented.
  Deadline : 30.4.2002
- Heavy condensation over exposed and unexposed product in establishment CZ 12 – Rectified regimes of cooling and product flow – rectified immediately.

- Full implementation of HACCP in establishments CZ 12 and CZ 15 regarding pre-shipments reviews.
  Deadline : 31.3.2002.

Remaining deficiencies found during the audit and described in the Final Draft have already been rectified just during and immediately after the inspection.

It is our firm belief that the above described rectifications and the deadlines already set will contribute to an achievement of full compliance with U.S. legislative requirements in both approved Czech establishments.

In case of any additional query please do not hesitate to contact our Administration.

Kind regards.

Yours sincerely.

MVDr Josef Holejšovský
Director General (CVO)

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