



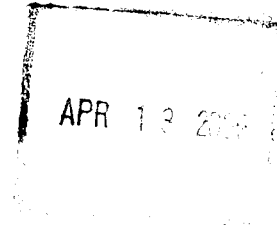
United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Don

Prof. Dr. Josef Bires
Chief Veterinary Officer
State Veterinary Administration
Botanicka 17
84213 Bratislava
Slovak Republic



Dear Dr. Bires:

The Food Safety and Inspection Service (FSIS) conducted an annual audit of the Slovakia meat inspection system October 19 through October 25, 2005. The comments from Slovakia have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:

Quintin Gray, Counselor, US Embassy, Vienna

Frantisek Rucrcka, First Secretary, Embassy of Slovakia

Norval Francis, Counselor, US Mission to the EU, Brussels

Canice Nolan, First Secretary, EU Mission to the US, Washington

Bob Macke, Assistant Deputy Administrator, International Trade Policy, FAS

Amy Winton, State Department

James Dever, FAS Area Director

Barbara Masters, Administrator, FSIS

Karen Stuck, Assistant Administrator, OIA

William James, Deputy Assistant Administrator, OIA

Linda Swacina, Executive Director, FSIA, OIA

Donald Smart, Director, Review Staff, OPEER

Sally White, Director, IES, OIA

Clark Danford, Director, IEPS, OIA

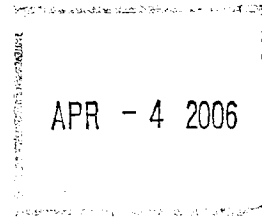
Mary Stanley, Director, IID, OIA

Barbara McNiff, Director, FSIS Codex Staff, OIA

Shannon McMurtrey, IES, OIA

Country File

FINAL



**FINAL REPORT OF AN AUDIT CARRIED OUT IN SLOVAKIA
COVERING SLOVAKIA'S MEAT INSPECTION SYSTEM**

October 19 through October 25, 2005

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 and Food Administration) |
| DVFA | District Veterinary and Food Administration |
| <i>E. coli</i> | <i>Escherichia coli</i> |
| EU | European Union |
| FSIS | Food Safety and Inspection Service |
| PR/HACCP | Pathogen Reduction/Hazard Analysis and Critical Control Point Systems |
| RVFA | Regional Veterinary and Food Administration |
| <i>Salmonella</i> | <i>Salmonella</i> species |
| SSOP | Sanitation Standard Operating Procedures |
| SVFA | State Veterinary and Food Administration |
| SVI | State Veterinary and Food Institute |
| VEA | European Community/United States Veterinary Equivalence Agreement |

1. INTRODUCTION

The audit took place in Slovakia from October 19 through October 25, 2005.

An opening meeting was held on October 19, 2005, in Bratislava 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 Slovakia's meat inspection system.

The audit team was accompanied during the entire audit by representatives from the CCA, the State Veterinary and Food Administration (SVFA).

2. OBJECTIVE OF THE AUDIT

This audit was the initial audit following U.S. approval of Slovakia to export meat and meat products to the United States. The objective of the audit was to evaluate government oversight and enforcement capabilities of the CCA with respect to controls over slaughter and processing establishments, as well as laboratories. At the time of this audit, no establishments were certified by the CCA as eligible to export meat products to the United States; therefore no establishments were audited.

In pursuit of the objective, the following sites were visited: The headquarters of the CCA, one regional inspection office, one district inspection office, and two laboratories performing analytical testing on European Union destined-product and domestic product.

| Competent Authority Visit | | | Comments |
|---------------------------|----------|---|--|
| | Central | 1 | Bratislava |
| | Regional | 1 | Trenčín |
| | District | 1 | Nové Mesto/Váhom |
| Laboratories | | 2 | Residue-Košice Microbiology-Dolný Kubín |

3. PROTOCOL

This on-site audit was conducted in three 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 located in Bratislava, one regional office located in Trenčín and one district office located in Nové Mesto/Váhom. The third part involved visits to two government laboratories. The State Veterinary and Food Institute Microbiology Laboratory, located in Dolný Kubín was conducting analyses of field samples for the presence *Salmonella spp.*, *Listeria monocytogenes*, *Listeria spp.*, *Escherichia coli (E. coli) O157:H7*, generic *E. coli*, and other pathogens and the State Veterinary and Food Institute Residue Laboratory, located in Košice was conducting analyses of field samples for Slovakia's national residue control program.

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

At the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations of individual sanitary measures that have been made by FSIS for Slovakia under provisions of the World Trade Organization (WTO) Sanitary and Phytosanitary Agreement. No equivalence determinations have been made by FSIS for Slovakia.

At the time of this audit, no establishments were certified by the CCA as eligible to export meat products to the United States; therefore no establishments were audited.

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 (PR)/HACCP regulations.

In addition, compliance with the following European Community Directives was assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat.
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products.

- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

June 15-22, 2000 Audit

The following deficiencies were identified during the FSIS initial equivalence determination audit of Slovakia's meat inspection system conducted June 15 through June 22, 2000:

Government Oversight

- In two establishments, odd hour inspection was not conducted.
- In two establishments, official inspection was not provided for the second shift.
- In two establishments, U.S. requirements were not enforced.

Sanitation Controls

- Product contamination deficiencies, such as paint chips and product residue from the previous days' production on product contact surfaces were observed.
- Several potential product cross-contamination issues were also observed and included deficiencies such as, rods used for hanging sausages had not been cleaned of residues and were stored outside, carcasses located on the beef slaughter floor were in contact with a metal employee work stand, lack of proper sanitation of a viscera conveyor belt and offal trays.
- In one establishment, the hide puller was contaminating skinned carcasses.
- In one establishment, the SSOP did not clearly define procedures to be performed during pre-operational and operational sanitation, while in another establishment corrective actions were not adequately documented in their sanitation records.
- In one establishment, spider webs were observed in the processing room.
- Maintenance and construction issues that presented potential product contamination hazards were also observed.
- Condensation, another product contamination hazard, was observed in several locations and such as the offal cooler, in the pork cooler and beef suspect cooler, on overhead refrigeration units in the beef cooler, and over swine carcasses in the carcass cooler.
- Pieces of metal were found on swine carcasses in the carcass cooler.
- In one establishment, stick wounds were not trimmed and reconditioning by trimming was not performed.
- In one establishment, establishment employees unwrapping frozen block meat, were cross-contaminating product by touching unclean non-product surfaces and then touching meat product without washing their hands.
- In one establishment, inedible product stored in the freezer, had not been decharacterized or denatured.

Slaughter/Processing

- In one establishment, swine were not adequately stunned.
- HACCP implementation deficiencies were routinely observed and included such things as no development of a hazard analysis, monitoring frequencies were not written in the HACCP plan, lack of ongoing verification, inadequate corrective actions, no development of a CCP for zero tolerance for fecal contamination, and the HACCP plans did not provide for a recordkeeping system.
- In one establishment, fecal contamination was found on three carcasses.
- In one slaughter establishment, generic *E. coli* testing had not been implemented.
- The method for analyzing product for *E. coli* O157:H7 had not been submitted for an equivalence determination.
- The four-plate microbiological screening method for antibiotic residue detection had not been submitted for an equivalence determination.
- The SVI microbiology laboratory did not have a documented plan for the number of each proficiency samples they expected to analyze each year.
- In one slaughter establishment, official government inspectors were not incising the lateral and medial retropharyngeal lymph nodes and some inspectors were chopping rather than slicing lymph nodes.

Residue Controls

- The SVI residue laboratory did not have a centralized chemistry guide book.
- None of the analysts were certified for the accreditation of methods.
- Training records were not available.
- In-plant screening methods had not been developed.
- Residue test reports were not available for verification.

Enforcement

- In one slaughter establishment, *Salmonella* testing was not performed.
- In neither establishment audited, species verification testing was not performed.

December 4-8, 2000 Audit

FSIS conducted a follow-up initial equivalence audit and determined that all audit findings identified during the June 2000, audit had been corrected with the exception of the following:

- In one establishment, critical limits did not adequately measure the CCPs.
- In one establishment, preventive measures were not included the establishment's HACCP plan.
- The SVI residue laboratory did not have a centralized chemistry guide book; however SVA officials informed the auditor that a centralized Chemistry Laboratory Guidebook is in the process of completion..

In addition to those deficiencies previously identified above and not corrected, the following deficiencies were identified during the FSIS audit of Slovakia's meat inspection system, which was conducted December 4 through December 8, 2000:

Residue Controls

- Pages in the laboratory logbook were not numbered.
- Expiration dates on some of the standards were missing.

Enforcement

- In one establishment, species verification testing was not performed as required.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

6.2.1 CCA Control Systems

The organizational structure of the SVFA has changed from the last audit of Slovakia's meat inspection system conducted December 4 through December 8, 2000. During this audit, the State Veterinary Administration (SVA) was identified as the CCA. The SVA was restructured and the SVFA was established by an amendment to Food Act 23/2002.

The SVFA is considered the CCA. The formation, development, administration and coordination of inspection regulations and guidelines take place at the headquarters of the SVFA in Bratislava.

The Ministry of Agriculture of the Slovak Republic oversees the SVFA. The Director General of the SVFA is the Chief Veterinary Officer (CVO). There are five divisions under the CVO: Information and Veterinary Database Administration Division, Economic Section, European Integration Legislation and Foreign Affairs Department, Animal Health Section, and Food Supervision and Food Hygiene Section.

Organized under the Food Supervision and Food Hygiene Section are the Animal Origin Foodstuffs Department, Plant Origin Foodstuffs Department, Special Commodity Regime Department, and Laboratory Diagnostic, Certification and Rapid Alert System Department. There are 6 State Veterinary and Food Institutes (laboratories) organized under the Laboratory Diagnostic, Certification and Rapid Alert System Department. Five of six State Veterinary and Food Institute (SVI) laboratories are responsible for the testing of food products and the sixth SVI laboratory is a diagnostic laboratory responsible for animal diseases. Each of the six SVI laboratories is audited one time per year by the Laboratory Diagnostic, Certification and Rapid Alert System Department. The Food Supervision and Food Hygiene Section in conjunction with the Animal Origin Foodstuff Department are responsible for official control of Slovakia's Meat Inspection System. This department is also responsible for the approval and registration of food enterprises.

Slovakia is further divided into eight Regional Veterinary and Food Administration offices (RVFA). Each RVFA contains a Department of Animal Health and a Department of

Inspection and Hygiene. The Division of Animal Health is subdivided into the Department of Animal Health and Welfare and the Department Hygiene of Feed, Ecology, and Veterinary Pharmacy. The Division of Food Inspection and Hygiene is subdivided into the Department of Food Inspection and Hygiene of Animal Origin and the Department of Food Inspection and Hygiene of Plant Origin. The Department of Food Inspection and Hygiene of Animal Origin is responsible for the meat inspection program and the supervision of 40 District Veterinary and Food Administration offices (DVFA). The primary responsibilities of the RVFA offices are to coordinate the activities of the DVFA, collect and report inspection data, supervise the implementation of the SVFA inspection program and for tracking the process of microbiological, economic and residue sampling.

Each DVFA has an administrative structure similar to the RVFA. The Division of Food Inspection and Hygiene in conjunction with the Department of Food Inspection and Hygiene of Animal Origin is responsible for the delivery and implementation of the SVFA meat inspection program. The DVFA is also responsible for the supervision of veterinary inspectors in-charge of one or more establishments. Veterinary inspectors are responsible for the supervision of veterinary technicians. Veterinary technicians perform post-mortem inspection and assist the veterinary inspector with his responsibilities, but do not work independently in other areas, except for post-mortem inspection.

6.2.2 Ultimate Control and Supervision

The SVFA headquarters in Bratislava has ultimate control and supervision of Slovakia's meat inspection system. The SVFA transposes European Union (EU) legislation and related regulations into Slovakia's legislation with related guidelines. Although Slovakia's inspection system is implemented by the DVFA and the DVFA's implementation program is supervised by individual RVFA offices, the SVFA develops and distributes official legislation to the RVFA and DVFA. The SVFA coordinates the implementation of inspection activities through the RVFA offices and provides for training programs for the regional and district staff. The RVFA assesses the performance of the DVFA with regard to food and veterinary control by planned visits to each DVFA and selected establishments.

Meetings to coordinate inspection activities and delivery of new inspection regulations and guidelines are scheduled on a regular basis. The SVFA will meet with the directors of the RVFAs two times per year, or more often if needed. The RVFA will conduct monthly meetings with DVFA directors. The SVFA will meet with DVFA directors two times per year and all district meetings, including veterinary inspectors are conducted on a monthly basis.

The DVFA in conjunction with the RVFA are responsible for recommending to the SVFA headquarters in Bratislava, the certification or decertification of establishments eligible to export to the EU or third countries. Representatives of the SVFA will participate with the RVFA and DVFA for the final official certification or decertification of establishments. The SVFA is responsible for maintaining the official list of establishments eligible to export to the EU or third countries.

6.2.3 Assignment of Competent, Qualified Inspectors

The SVFA is responsible for the hiring, training and payment of veterinary inspectors. The Office of State Service is the official government office for the hiring of all state employees. The SVFA will submit a request for the hiring of Veterinary Inspectors to the Office of State Service and this office, with the aid of an expert selection panel, will select a qualified candidate. Veterinary Technicians are hired by the District Director.

Students of veterinary medicine interested in a career in public health can specialize in hygiene courses as an option offered as part of the requirements to obtain a degree in veterinary medicine. Initial training, for veterinary inspectors, is received at the Institute for Postgraduate Studies of Veterinary Surgeons located in Košice. Practical training is received by working under the supervision of an experienced veterinary inspector. On-going training is offered by the CCA and is organized and delivered by the Institute for Postgraduate Studies of Veterinary Surgeons located in Košice.

Veterinary Technicians receive on the job training by working under the supervision of an experienced veterinary inspector. Periodic training for specific topics is received at the Institute for Postgraduate Studies of Veterinary Surgeons located in Košice.

Veterinary Inspectors and Veterinary Technicians, as well as all state employees, are paid by the Slovakia State Treasury.

A yearly performance conference for each State employee is required by Slovak law. Performance conferences are documented and retained in a confidential personnel file by the supervisor of the employee.

The Director of the Department of Food Inspection and Hygiene of Animal Origin, within the RVFA, develops a yearly plan to visit a selection of establishments within each DVFA supervised by the RVFA. The purpose is to evaluate the supervision and implementation of the SVFA meat inspection program and to report the results to the SVFA in Bratislava.

6.2.4 Authority and Responsibility to Enforce the Laws

Although the CCA has the legislative authority and the responsibility to enforce the FSIS requirements, based on the FSIS audit observations, the CCA was not prepared to enforce all of the FSIS requirements. For example:

- FSIS requirements and other related material have not been translated into the Slovak language.
- The CCA has not developed, organized or delivered specialized training programs tailored to government oversight and enforcement of FSIS requirements to inspection personnel.

6.2.5 Adequate Administrative and Technical Support

The CCA has the resources and ability to support a third-party audit and has adequate administrative and technical support to operate Slovakia's inspection system. Financial

resources for third country export programs, such as resources needed for the update of inspection programs for establishments requesting certification for the export of meat products to the United States, are derived from fees assessed by the SVFA to individual establishments requesting export certification.

The SVI microbiology laboratory located in Dolný Kubín is ISO 17025 accredited by the Slovak National Accreditation Service (SNAS). This SVI microbiology laboratory is audited one time per year by the SVFA Laboratory Diagnostic, Certification and Rapid Alert System Department. A SVI microbiology laboratory was not audited during the December 4 through December 8, 2000 audit, but all SVI microbiology audit findings identified during the June 15 through June 22, 2000 audit, were found to have been corrected during the current October 19 through October 25, 2005 audit. At the time of this audit, no establishments had been certified to export meat products to the United States by the SVFA; therefore this microbiology laboratory was not testing meat products destined for export to the United States. Laboratory testing methods currently in use were not the same methods used to test meat products in microbiological laboratories in the United States and have not been submitted to FSIS for equivalent determinations. For example:

- Slovakia was not using FSIS laboratory testing methods for the identification of *Listeria monocytogenes* and *Salmonella* in meat products.
- Laboratory testing methods ISO 11290-1 and ISO 11290-2 for *Listeria monocytogenes* and ISO method 6579 for *Salmonella* are currently used to test meat products in SVI microbiology laboratories, but have not been submitted to FSIS for equivalence determinations.

6.3 Headquarters, Regional and District Offices Audit

The auditor conducted a review of inspection system documents at the headquarters of the SVFA located in Bratislava. The auditor also conducted a review of records at the RVFA located in Trenčín and the DVFA located in Nové Mesto/Váhom for the purpose of determining the organizational and supervisory structure of the RVFA and DVFA and to review records pertinent to the audit of Slovakia's meat inspection system. Other records reviewed focused on food safety hazards and included the following:

- Internal review reports.
- Training records for inspectors.
- Training programs for inspection 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 disease conditions and of inedible and condemned materials.
- Export product inspection and control.
- Enforcement records, including examples of recalls, seizure and control of noncompliant product.

Programs and procedures were in place for the registration of new establishments, for the certification of establishments for compliance with EU requirements and for compliance with third country export requirements, but there was not an active program in place for government oversight and enforcement of FSIS requirements as reported in section 6.2.4 of this report.

7. ESTABLISHMENT AUDITS

At the time of this audit, no establishments were certified by the CCA as eligible to export meat products to the United States; therefore no establishments were audited.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the 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 evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements. The following laboratories were reviewed: One SVI microbiology laboratory located in Dolný Kubín and one SVI Residue Laboratory located in Košice. Audit findings have been reported under section six or will be reported under other sections of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas is Sanitation Controls. At the time of this audit, no establishments were certified by the CCA as eligible to export meat products to the United States; therefore no establishments were audited.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, procedures for sanitary handling of returned, reconditioned product and the implementation of the requirements for the control of Bovine Spongiform Encephalopathy. Based on the observations made during this audit, the auditor determined that Slovakia's inspection system had adequate animal disease controls in place.

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 was scheduled to review was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

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

At the time of this audit, no establishments were certified by the CCA as eligible to export meat products to the United States; therefore no establishments were audited.

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.

12.1 FSIS Requirements

The SVI Residue Laboratory located in Košice was audited. All SVI residue laboratory audit findings identified during the December 4 through December 8, 2000 audit were found to have been corrected during the current October 19 through October 25, 2005 audit. No deficiencies were observed.

Slovakia's National Residue Control Program for 2005 was being followed and was on schedule.

12.2 EC Directive 96/22

In SVI Residue Laboratory located in Košice, the provisions of EC Directive 96/22 were effectively implemented.

12.3 EC Directive 96/23

In SVI Residue Laboratory located in Košice, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*. At the time of this audit, no establishments were certified by the CCA as eligible to export meat products to the United States; therefore no establishments were audited.

- The SVFA has not established a testing program for *Salmonella* testing for pathogen reduction performance standards that would meet FSIS requirements.

14. CLOSING MEETING

A closing meeting was held on October 25, 2005, in Bratislava 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.

Don Carlson, DVM
Senior Program Auditor

A handwritten signature in cursive script that reads "Don Carlson DVM". The signature is written in black ink and is positioned to the right of the typed name.

15. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Draft Final Audit Report

Jozef Bireš
Chief Veterinary Officer
State Veterinary and Food Administration
of the Slovak Republic
Bratislava



Bratislava, 14.03.2006
Our letter: 888/2006-110

Dear Sally White ,

we are sending you the Standpoint to the Report from the Mission Performed by the American Experts in the Slovak Republic in Autumn 2005

We are inform you , that the conclusions from the mission of American experts found out in the field of residues in October 2005 did not contain any comments to the expertness to which it would be necessary to take a standpoint.

The comments from the year 2000 as indicated on the page 7 in the Part Residue control, all the findings were corrected as follows:

- requirement for centralization of chemical methods (chemistry guide book) was fulfilled by issuing of the Methods of determination of foreign substances in raw materials of animal origin, in foodstuffs, feeding stuffs and in water, issued by SVA SR, Bratislava 2001 and at present in the register of official methods published in the Bulletin of the Ministry of Agriculture No. 1 from the year 2004.
- Requirement of certification of analytical operators for accredited methods and mainly obligations and way of validation of analytical methods is modified in pursuance of the valid legislation ISO STN 17025.
- Requirement for so called training records was fulfilled, each analytical operator has full documentation including experimental and training tests, records on inclusion of workers into accredited activity in pursuance of ISO EN STN 17025, directed documentation, record SL 21.
- Requirement for the use of screening validated tests in production and processing establishments is not in the competence of SVFI.
- Requirement for availability of records on examinations was corrected by the obligation of the diagnostics workplace to keep records for the period of 5 years in a written and electronic form.

Please find enclosed for comparison ISO standards valid in the Slovak Republic with American standards for

1. detection and identification E. coli O157:H7
2. isolation and identification Listeria monocytogenes
3. isolation and identification of Salmonella

Yours sincerely,

Sally White
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Washington DC 20250 ,USA
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15. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Draft Final Audit Report