EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6366 - MR FINAL

# FINAL REPORT OF AN AUDIT

# CARRIED OUT IN

# SLOVAKIA

# FROM 26 NOVEMBER TO 07 DECEMBER 2012

# IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MEAT, MILK AND THEIR PRODUCTS

***In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.***

***Executive Summary***

*The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Slovakia from 26 November to 7 December 2012. The main objectives of the audit were to evaluate the official controls related to production and storage of food of animal origin and the follow-up action taken by the competent authorities (CAs) with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products.*

*The CAs are clearly designated for the areas covered by this audit and the system for official controls is generally capable of delivering the standards required by the European Union (EU) legislation.*

*Overall progress can be noted since the previous mission DG(SANCO)/2008-7815 in several areas but not all the recommendations from the report have been satisfactorily addressed. Problems were still identified regarding the approval of establishments. Non-compliances were also detected in the area of identification marking.*

*A number of deficiencies were noticed regarding conditional approvals, compliance with the conditions for approval and in maintaining up-to-date lists of approved establishments. The non-compliances and shortcomings found by the FVO audit team had not been detected during the official controls.*

*Despite the recommendation made in the General Audit report DG(SANCO)/2008-8380, official controls are still not risk-based.*

*The official controls over the general and specific hygiene requirements were generally capable of ensuring that the requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 were met. However, in two establishments visited significant deficiencies were detected: corrective actions were requested and copies of action plans were provided to the FVO audit team before the final meeting.*

*Water control was not fully carried out in accordance with the requirements of Council Directive 98/83/EC.*

*Compliance with requirements for Hazard Analysis of Critical Control Points (HACCP), microbiological testing, traceability, labelling, Food Chain Information (FCI), ante- and post-mortem inspection, health marking and raw milk quality control was in most cases found to be satisfactory.*

*In the slaughterhouses visited the FVO audit team did not identify any shortcomings regarding animal welfare and the performance of stunning was satisfactory.*

*The official controls in the sectors evaluated and level of compliance by the food business operators (FBOs) were in general satisfactory but in several cases significant deficiencies had not been detected and documented in the completed check lists by the CAs.*

*A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.*

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## Abbreviations and definitions used in this report

| Abbreviation | Explanation |
|---|---|
| CA(s) | Competent Authority(ies) |
| CCA(s) | Central Competent Authority(ies) |
| CCP(s) | Critical Control Point(s) |
| COM | European Commission |
| DG(SANCO) | Health & Consumers Directorate General |
| DVFA | District Veterinary and Food Administration |
| EC | European Community |
| EU | European Union |
| FBO(s) | Food Business Operator(s) |
| FCI | Food Chain Information |
| FVO | Food and Veterinary Office |
| GHE | Game handling establishment |
| HACCP | Hazard Analysis of Critical Control Points |
| Hygiene Package | Regulations (EC) No 852/2004, No 853/2004 and No 854/2004 |
| MANCP | Multi-Annual National Control Plan |
| NRL | National Reference Laboratory |
| OV | Official Veterinarian |
| RVFA | Regional Veterinary and Food Administration |
| SCC | Somatic Cell Count |
| SVFA | State Veterinary and Food Administration |
| TPC | Total Plate Count (Plate count at 30 °C) |

## 1 Introduction

The audit took place in Slovakia from 26 November 2012 to 07 December 2012 as part of the planned audit programme of the FVO. The audit team comprised 2 auditors from the FVO.

The FVO audit team was accompanied throughout the audit by a representative from the Central Competent Authority (CCA), the State Veterinary and Food Administration of the Slovak Republic (*Štátna veterinárna a potravinová správa Slovenskej republiky*)

The opening meeting was held on 26 November 2012 with the CCA in Bratislava. At this meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

## 2 Objectives

The main objectives of the audit were to evaluate the official controls related to the production and storage of food of animal origin and the follow-up action taken by the CAs in response to the recommendations made in report DG(SANCO)/2008-7815– MR Final (hereafter referred to as report 2008-7815) with regard to:

- CA organisation and operation;
- official controls over FBOs' compliance with general and specific rules on the hygiene of food of animal origin.

In particular, controls over meat of domestic ungulates, farmed game, wild game, minced meat, meat preparations, mechanically separated meat, meat products, raw milk and dairy products in the framework of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 were subject to this evaluation.

In pursuit of these objectives, the audit itinerary included the following meetings and visits:

*Table 1*

| **COMPETENT AUTHORITIES** | | | **Comments** |
|---|---|---|---|
| Competent authorities | Central | 1 | |
| | Regional | 3 | Administrative regions: Zilina, Trencin, Banska Bystrica |
| | Local | 10 | One district office was visited and the responsible officials were always present during the visits to the individual establishments |
| **FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES** | | | |
| Slaughterhouses | | 3 | |
| Cutting premises | | 5 | All integrated |
| Minced meat / meat preparation establishments | | 1 | Integrated |
| Meat products establishments | | 3 | Integrated |

| | | |
|---|---|---|
| Game handling establishments | 1 | |
| Cold stores | 5 | One independent |
| Laboratories | 2 | For analysis of raw milk, *Trichinella* |
| Milk processing plants | 3 | |

## 3 Legal Basis

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

*Full EU legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.*

## 4 Background

The previous audit concerning the safety of food of animal origin in Slovakia was carried out from 22 to 31 October 2008, the results of which are described in report 2008-7815. It was part of the General Audit carried out in Slovakia in 2008 (DG(SANCO)/2008-8380. These reports are accessible at:

http://ec.europa.eu/food/fvo/index_en.cfm

The action plan received from the Slovakian CCA provided satisfactory guarantees in response to all of the recommendations in Part B of the report.

## 5 Findings And Conclusions

### 5.1 Competent Authorities

#### *5.1.1 Designation of Competent Authorities*

**Legal requirements**

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs.

**Audit findings**

Following the amendment of the Veterinary Framework Act No 39/2007 (hereafter Veterinary Law) the distribution of responsibilities among CAs changed due to the abolition of the 8 Regional Veterinary and Food Administration (RVFA) at middle level. The State Veterinary and Food Administration (SVFA) is the CCA and directs the 40 District Veterinary and Food Administrations (DVFA) which perform the official controls in the dairy and meat sector. The range of competences remained the same but was re-allocated. Regarding the official controls, the internal audit of the DVFAs, verification of controls of the DVFAs, collecting of information, data, the results of

controls were transferred from the former RVFAs to the SVFA.

A Department for Audit and Control was created (under the Chief Veterinary Officer) and internal audits of the DVFAs in all sectors including dairy and meat have been performed by this Department since 1 November 2011 as required by Article 4 of Regulation (EC) No 882/2004.

The DVFAs are responsible for carrying out audits of meat and dairy establishments as required by Article 4 of Regulation (EC) No 854/2004.

### *5.1.2 Co-operation and co-ordination between and within Competent Authorities*

**Legal requirements**

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between CAs. Article 4(5) of the Regulation requires that, when, within a CA, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

**Audit findings**

Co-operation within the CAs takes place through regular information exchange, centrally organised training courses and meetings in the area covered by this FVO audit.

### *5.1.3 Registration/approval of Food Business establishments*

**Legal requirements**

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

**Audit findings**

In response to Recommendation 1 – *"To ensure that establishments are only approved if the FBO has demonstrated that it complies with the relevant requirements of the food law as required by Article 31 (2) (c) of Regulation (EC) No 882/2004 and to ensure that the deficiencies noted by the mission team in the establishments visited are corrected"* the CCA committed themselves to arranging a working meeting for CAs who transfer the information to the official veterinarians (OVs) and in the course of the internal audit the DFVA will focus on the findings of the previous FVO audit.

According to the Veterinary Law the DVFAs are responsible for conditional or full approval of establishments. Officials from the competent DVFA carry out the pre-approval inspection and write a report. On the basis of this report the DVFA issues the approval decision including the allocated approval number. This administrative decision is always sent to the SVFA. On the basis of the information received the SVFA develops, keeps and maintains the up-to-date list of approved establishments and makes them available through its website. The SVFA notifies in parallel the FBO and the DVFA about the inclusion in, or modification to, the national establishment list. The DVFA is also responsible for keeping the approval of establishments under review. It is also the DVFA that sends the administrative decision of suspension or withdrawal of the approval. The

documented procedure regarding the approval of establishments is available on the SVFA website. The last revision was in 2012 when different forms and check lists together with the flow chart of the approval procedure were made available.

The FVO audit team found the following deficiencies:

- After the announcement of the FVO audit the list of approved establishments was revised and out of 28 cold stores in the 3 regions visited 8 were deleted and 2 were added. At the request of the FVO audit team the administrative decisions for six of the de-listed establishments were checked and it was disclosed that one establishment should have been de-listed two and a half years earlier and another establishment two years earlier. Moreover, the establishment listed two and a half years earlier had only a conditional approval for three months. After the three months the conditional approval was not prolonged and full approval was never given.
- In one meat product establishment an approval for additional activities was given in 2005 under a different number. This number had already been allocated to another establishment in another region. This mistake was not detected during the official controls. The CA stated that the new additional number had never been used and that the activities covered had been included under the number already used by the establishment. The CA also stated that before the latest amendment of the Veterinary Law a new number had to be given in case the legal entity changed. A third number was therefore allocated to this establishment in 2011. At the request of the FBO a decision to retain the old number was granted and the third number had also never been used.
- In one case the FBO had been in operation for a month when the the SVFA received the decision about the approval. The CCA stated that these decisions have to be sent by post to the SVFA and sometimes a considerable delay could occur due to the postal services. This problem has been noted by the SVFA and they have drafted a new instruction which allows them to act on the basis of a scanned document.
- In a cold store visited the approval verification control was carried out without verifying the information on the national establishment list, which included remarks regarding activities (mp, aj CHS), that could not be explained by the OV[1].
- One game handling establishment (GHE) was approved for cutting meat of domestic ungulates without having the proper facilities for the reception of unprotected meat. In addition a conditional approval of this GHE for meat processing was issued in 2010 and this conditional approval was not prolonged and full approval was never given. This activity was only deleted from the national list after the announcement of the FVO audit.

#### *5.1.4 Prioritisation of official controls*

**Legal requirements**

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the EU, imports into the EU and to product placed on the EU market.

1 In their response to the draft report the CA noted that an explanatory note regarding these remarks has already been deleted from the up dated list of independent (stand-alone) cold stores.

**Audit findings**

Despite a previous recommendation made in the General Audit report DG(SANCO)/2008-8380, official controls are still not risk based, however they are carried out at a high frequency. The FBO's past records, reliability of their own checks and any information on non-compliances are not taken into account. Controls are carried out at least once per month as it is prescribed in the Slovakian Code of practice for official controls. Even a cold store with very limited activities concerning meat and dairy products was officially controlled and check lists were filled in at least once per month.

In addition since 2011 OVs have carried out at least one so called "passport control" in a year in order to evaluate the compliance with the approval decision. During this "passport control" the same check lists used for approval of establishments are filled in.

The decision is left to the DVFA on whether a "passport control" by an OV or an audit of the establishment with two or three members in the team is carried out. In both cases the same check lists have to be filled-in.

Each DVFA sends a summary report about fulfilled official controls to the SVFA every year. In one DVFA visited it was 100% fulfilled.

### *5.1.5 Official sampling and laboratory analysis*

**Legal requirements**

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for the laboratories so designated.

**Audit findings**

Each year the SVFA issues systematic instructions for official sampling which is sent to all DVFAs. It contains guidelines for planning of sampling on a risk basis. Each DVFA makes their own control plan based on the instruction.

The FVO audit team visited one private laboratory carrying out 70% of the raw milk quality control in Slovakia. The laboratory was accredited by the Slovakian National Accreditation Body which used validated methods and participated in proficiency testing. Raw milk samples were received from clients and the results were only communicated directly back to them. The laboratory did not make any calculation of geometrical average and had no responsibility in relation to sampling frequency and non-compliances. However, in case of a positive inhibitor test result the client, and both the competent DVFA and the SVFA, is informed immediately.

Slovakia has a National Reference Laboratory (NRL) for *Trichinella* testing and this laboratory provided ring test for the 3 accredited State laboratories and for 23 in-house laboratories in 2011. The in-house laboratories are approved by the SVFA and operated by the DVFA staff. No private laboratories are involved in *Trichinella* testing.

### *5.1.6 Procedures for performance of control activities*

**Legal requirements**

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

**Audit findings**

Reports on official controls were presented in all establishments visited. The FBO countersigns and receives an authenticated copy. In case non-compliances are detected the copy of the check list filled in during the official control, containing a reference to the legislation and a deadline for corrective actions is also provided to the FBO.

In all cases checked by the FVO audit team the frequency of official controls was in accordance with the annual control plan.

A number of detailed check lists both for approval and official control of all types were elaborated by the SVFA and distributed in 2012. To help with implementation a training session was organised in September 2012. Nevertheless, in several cases non-compliances or shortcomings were not recorded in the completed check lists.

Training programmes for 2011 and 2012 were made available to the FVO audit team.

### *5.1.7 Enforcement measures*

**Legal requirements**

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation. Article 55 of the Regulation states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

**Audit findings**

The legal basis (Veterinary Law) regarding enforcement measures has not been changed since the previous audit. Nevertheless the range was increased and the responsibilities were redistributed due to the elimination of the regional level.

In case of a non-compliance detected, the competent DVFA (inspectors and the director) evaluates the case and initiates administrative action with an imposition of fines. The CA follows up the corrective actions taken and the cost of the additional controls are to be covered by the FBO.

A full documentation of an imposed sanction in relation to beef labelling was presented to the FVO audit team.

#### *5.1.8 Verification and review of official controls and procedures*

**Legal requirements**

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed. Under Article 4 of the Regulation CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

**Audit findings**

The internal audit carried out by the SVFA over the DVFAs is designed to be the tool to monitor the performance of OVs and to evaluate the effectiveness of the official controls.

The FVO audit team visited one DVFA office which had planned and carried out systematic verification of the effectiveness of the official controls and the evaluation of the performance of the OVs.

The SVFA has not elaborated guidelines for the check lists to guarantee the uniform implementation and consistency, but training courses and meetings were organised to ensure appropriate use and effectiveness.

**Conclusions on Competent Authorities**

The CAs are clearly designated for the areas covered by this audit and the system for official controls is generally capable of delivering the standards required by the EU legislation.

Out of five recommendations from the report 2008-7815, two - regarding the approval of establishments and the identification marking (see under point 5.2.4) - have not been satisfactorily addressed.

There were a number of deficiencies noticed regarding conditional approvals, compliance with the conditions for approval and maintaining up-to-date lists of approved establishments.

Despite the recommendation made in the General Audit report 2008-8380, official controls are still not risk-based.

The SVFA has developed several check lists for official controls, but in a number of cases existing non-compliances or shortcomings had not been recorded in the completed check lists.

### 5.2 Official controls over food Business Operators' compliance with hygiene rules at establishment level

#### *5.2.1 General and specific hygiene requirements*

**Legal requirements**

Article 4(2) of Regulation (EC) No 852/2004 establishes that the FBO carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation

(EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, sitting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses.

Article 4(2) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify the FBO's compliance with these requirements.

**Audit findings**

The FVO audit team visited eleven establishments processing meat and milk. In general the layout, design and construction of the premises were satisfactory. With some exceptions maintenance and cleanliness were also acceptable.

Despite own check records never showing any problems regarding the temperature of knife sterilisers, similarly to the findings in 2008, some sterilisers were not functioning at 82°C and some were not in operation.

In two establishments additives or ingredients were found in a storage room with an expired best before date. The FBOs took immediate action.

The slaughter hygiene was generally satisfactory in the three slaughterhouses visited.

In a small slaughterhouse visited some shortcoming were seen during the operation – e.g. hide rolled back, carcass touched the floor of the work platform, and the cable of the saw was pulled over the carcass.

In one meat processing establishment the maintenance was generally satisfactory but some shortcomings were identified in relation to cleanliness. A broken pipe and condensation were observed in a chilling room for smoked products.

In a large meat processing establishment the trolleys were in very poor condition and therefore not easy to clean.

In two meat processing establishments intermediate and final products hanging on the lowest level of the smoking trolleys touched the floor and the wheels.

In a cold store visited wrapped pork rind on a wooden pallet was exposed due to the damaged wrapping.

In two establishments particular problems were identified:

1. In one slaughterhouse the FVO audit team found serious maintenance problems (gaps, broken covings, rusts, floor and wall damages). The changing rooms and the rest room were of a very poor standard, there were not enough lockers provided and the separation of street and clean clothes was not guaranteed. The slaughter hygiene was satisfactory during the slaughter of pigs but some shortcomings were noted during the evisceration (offal could touch the floor). Water hoses were frequently used for cleaning carcasses, offal, aprons and hands. In the room used for slaughtering bovine and ovine animals the knife steriliser and hand wash basin was not in operation. The bovine stunning box was rusty and was in very poor condition. Furthermore the conveyor was very low not allowing the suspension of large

bovine animals without touching the floor[2]. None of these non-compliances was detected during the "passport control" and monthly official controls in 2012. The adopted measures and an action plan were presented to the FVO audit team before the final meeting.

2. In the freezer of one meat processing establishment several plastic crates with uncovered meat, and exposed meat in damaged wrapping were together with wrapped carcasses placed directly onto uncovered meat. The CA requested immediate action and documentation was presented to the FVO audit team on the spot.

Microbiological testing of water was carried out in accordance with the EU requirements. In one establishment visited lay-out with numbered taps was available but the samples were always taken from the same tap in the operational area and no plan for sampling was set up and followed[3]. In another establishment samples were not taken in the operation area. The chemical analyses did not cover all the parameters listed in Council Directive 98/83/EC (implementing in national legislation No 354/2006, amended by 496/2010). In Slovakia the Public Health Authority is responsible for water testing and both the CA and the FBO stated that it would be very difficult to get a copy of chemical analysis of water from a public supply.

Pest control programmes were in place in all the establishments visited. In two establishments a potential risk of rodents was identified due to gaps under the doors and in one case due to the accumulation of old packaging and building materials in the courtyard.

**Conclusion**

The official controls over the general and specific hygiene requirements were generally capable of ensuring that the requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 were met. However, in two establishments visited significant deficiencies were detected: corrective actions were requested and copies of action plans were provided to the FVO audit team before the final meeting.

Water control was not fully carried out in accordance with requirements of Council Directive 98/83/EC.

### *5.2.2 HACCP-based systems*

**Legal requirements**

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Section II of Annex II to Regulation (EC) No 853/2004 lays down the specific requirements for HACCP-based procedures in slaughterhouses. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures (Article 4 (3)(a) and (5) of Regulation (EC) No 854/2004).

**Audit findings**

2 In their response to the draft report the CA noted that the FBO in a letter of 12 November 2012 which was presented to the FVO audit team had stated that the slaughtering of bovines had been discontinued and repairs of equipment had started. However, the FVO audit team disclosed that slaughtering activities had not stopped as stated in the letter (two bovine animals had been slaughtered two weeks later – one week before the FVO audit visit).

3 In their response to the draft report the CA noted that the FBO explained that he takes samples of water from the point of risk, where the water is added directly to food by the means of a flaked ice maker. The other taps in the operational area were not used for inlet of water which comes into direct contact with foodstuffs.

HACCP based procedures were in place in all establishments visited and were evaluated regularly during the official controls, in accordance with a detailed check list. In most cases HACCP plans were well developed and were tailor made.

The FVO audit team observed the following shortcomings:

- In one dairy establishment confusion with the revisions and some mistakes regarding the temperature limits were noted.
- In one cold store three critical control points (CCPs) were identified and each CCP comprised a lot of different control points but not all of them related to the identified risks. Two critical limits were temperature ranges that did not correspond to risks or legal requirements for the products which potentially could be stored.
- In a meat processing establishment modifications and revisions were not recorded, procedures for time separation in the reception chillers were not available, and for one CCP the record was not properly filled in.

**Conclusion**

HACCP based procedures were in place and regularly evaluated during the official controls. In most cases HACCP plans were well developed and only some minor shortcomings were detected by the FVO audit team.

### *5.2.3 Microbiological criteria for foodstuffs*

**Legal requirements**

Details on the microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005. Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation. These cover a range of items with regard to requirements for slaughterhouses, cutting plants, emergency slaughter, game handling, raw milk and dairy products and other products of animal origin.

**Audit findings**

In the slaughterhouses visited microbiological testing of carcasses was carried out in accordance with Regulation (EC) No 2073/2005. In one establishment the FVO audit team evaluated the microbiological testing of meat preparations and they were carried out in accordance with the Regulation.

The microbiological test results communicated to the FBOs confirmed that the methods used in the laboratories were in compliance with the required ISO methods.

During the audit the FVO audit team found that:

- In a slaughterhouse visited sampling places for a surface sanitation checks were not relevant as it was not possible for them to come into contact with the product.
- In one dairy establishment visited the FVO audit team followed up a Rapid Alert for Food and Feed notification regarding *Listeria monocytogenes* in cheese. The Slovakian CA notified the CA and the consignee in the receiving Member State, took all the necessary measures and carried out a satisfactory follow-up. After the incident the best before date of

the product was reduced from 14 days to 8 days and a microbiological study to clarify the risk of *Listeria* growth in the product was carried out in co-operation with the NRL. The FBO set up a sampling plan and the planned frequency was followed.

- In one small capacity slaughterhouse the carcass surface control was carried out once a year in accordance with the required frequency laid down in Order No 359/2011 establishing hygienic requirements for direct sale and supply of small amounts of primary products.
- In another slaughterhouse visited the results communicated to the FBO made reference to the laboratory procedure for *Salmonella* detection. The SVFA later provided documentation about the accreditation of the laboratory and about the methods compliance with the required ISO standard.

**Conclusion**

Microbiological sampling and testing was in general carried out in accordance with the requirements of Regulation (EC) No 2073/2005.

### *5.2.4 Traceability, labelling and identification marking*

**Legal requirements**

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires that the verification of compliance with traceability requirements takes place in all approved establishments.

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 and verification of compliance with these requirements is foreseen by Article 4(6) of Regulation (EC) No 854/2004. Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer. Regulations (EC) No 1760/2000 and 1825/2000 set out specific labelling requirements for beef meat.

**Audit findings**

Following recommendation No 3 of the report 2008-7815 "*To improve official controls in order to ensure that identification marking complies with the requirements of Article 5 of Regulation (EC) No 853/2004 and Annex II, Section I of Regulation (EC) No 853/2004",* the SVFA arranged working meetings to improve the official controls and analysed the findings written in the report. In addition the SVFA responded that the DVFAs will focus on the controls of identification marking during the performance of official controls and internal audit programmes will focus on the findings from the specific audit related to identification marking of meat and milk.

In response to recommendation 4 *"to improve official controls in order to ensure that traceability of food and food producing animals and any other substances incorporated into a food shell be established at all stage of production According to Article 18 of Regulation (EC) No 178/2002"* the SVFA organised a working meeting and analysed the findings of the specific audit in order to

ensure that traceability shall be established at all stages of production. In addition, the SVFA responded that the DVFAs perform special official controls on traceability in all approved cold stores and internal audit programmes will focus on the findings from the specific audit related to traceability of food and food producing animals and any other substances incorporated into a food.

The identification marking system in the establishments visited were with some exceptions satisfactory and reliable, providing an acceptable basis for the traceability. Specific labelling requirements for beef meat were implemented in accordance with Regulations (EC) No 1760/2000 and (EC) No 1825/2000.

During the FVO audit the following shortcomings were identified:

- In three meat processing establishments visited most of the cleaned plastic crates still had part of the old labels attached and, in some cases, clearly bearing identification marks from other establishments. The OVs had never requested corrective action.
- In one of these meat processing establishments casings were kept in barrels without any identification. The FBO took immediate action to remedy the situation.
- In one establishment approved as a cutting plant and re-wrapping establishment vacuum packed pork fillets received from other Member States were relabelled with their own approval number as a cutting and packaging establishment. Furthermore the approval number of a supplying cutting plant was indicated on the label as a slaughterhouse despite the commercial document clearly showing that the meat only was cut and packed in that establishment and slaughter took place in a different establishment.

None of these non-compliances was detected during the official controls even when including traceability exercises.

Traceability systems were in place in the establishments visited and when checked by the FVO audit team were found to be reliable.

Specific labelling requirements for beef meat were implemented in accordance with Regulations (EC) No 1760/2000 and (EC) No 1825/2000.

The official controls regularly included controls over traceability, labelling and identification marking and these topics had specific points in the check lists used during the controls.

**Conclusion**

The CAs did not fully address recommendation 3 of the previous report 2008-7815 and some non-compliances regarding identification marking were still detected by the FVO audit team and the verification of compliance with the requirements Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 concerning the application of identification marks was not properly carried out.

Regarding traceability the CAs addressed satisfactorily recommendation 4 of the previous report 2008-7815 and a traceability system was in place in all establishments visited.

Compliance with the requirements for labelling was in most cases found to be satisfactory.

### *5.2.5 Food Chain Information*

**Legal requirements**

According to Article 3 of Regulation (EC) No 853/2004, the FBO shall comply with the relevant provisions of Annexes II and III to this Regulation. In particular the FBOs operating slaughterhouses must as appropriate, request, receive, check and act upon FCI in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse. According to Article 5(1) of Regulation (EC) No 854/2004 the OV shall carry out inspection tasks in slaughterhouses also as regards FCI.

**Audit findings**

The FCI used in Slovakia complies with the relevant EU requirements. The format was recently revised and renewed.

In one slaughterhouse visited the declarations were duly signed and filled in but statements with possible yes or no answers were not ticked or were marked in a wrong way (instead of yes the no was ticked).

**Conclusion**

FCI was available in all slaughterhouses visited and, with the exception of some minor shortcomings, EU requirements were fulfilled.

### *5.2.6 Ante-mortem and post-mortem inspection*

**Legal requirements**

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including ante-mortem inspection of all animals before slaughter in accordance with the general requirements of Section I, Chapter II of Annex I to Regulation (EC) No 854/2004 and post-mortem inspection in accordance with the general requirements of Section I, Chapter II of Annex I and the specific requirements of Section IV, Regulation (EC) No 854/2004.

**Audit findings**

In the slaughterhouses visited only the OVs carried out ante-mortem and post-mortem inspections and kept records in accordance with the general and specific requirements of Regulation (EC) No 854/2004. No shortcomings were observed except in one slaughterhouse where the light was insufficient to perform adequate ante-mortem inspection.

Testing for *Trichinella* was carried out by the DVFA staff and found to be in compliance with the EU requirements. Only minor shortcomings were noticed by the FVO audit team as the working instruction in one case had no reference that the digestion process is considered satisfactory if not more than 5% of the starting sample weight remains on the sieve and no information was available on the spot about the magnification of the microscope.

It is the SVFA who maintains the list of trained persons and organises, via the Institute for further education of veterinarians, training courses for hunters. According to the new amendment of the Veterinary Law the first training course is for 2 days. It has to be repeated after 5 years and then lasts for 6 hours. A coloured manual for post-mortem inspection and a training DVD is distributed to the hunters.

**Conclusion**

Ante-mortem and post-mortem inspections and records maintained were generally satisfactory. *Trichinella* testing was performed in accordance with the requirements of Regulation (EC) No 2075/2005.

### *5.2.7 Health marking*

**Legal requirements**

Article 5(2) of Regulation (EC) No 854/2004 requires that health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs and large wild game as well as half-carcasses, quarters and wholesale cuts shall be carried out in slaughterhouses and game-handling establishments by, or under the responsibility of, the OV when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

**Audit findings**

In the three slaughterhouses visited health marks were correctly applied by the officials after post-mortem inspection had declared the carcasses fit for human consumption.

**Conclusion**

Health marking was carried out in accordance with the EU requirements.

### *5.2.8 Animal welfare at the time of slaughter or killing*

**Legal requirements**

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal welfare. Council Directive 93/119/EC sets out EU rules with regard to the protection of animals at the time of slaughter or killing.

**Audit findings**

In the slaughterhouses visited the FBO and the CA evaluated animal welfare during transport and at the time of slaughter in accordance with documented procedures.

**Conclusion**

In the slaughterhouses visited the FVO audit team did not identify any shortcomings and the performance of stunning was satisfactory.

### *5.2.9 Control of milk production holdings and of raw milk upon collection*

**Legal requirements**

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) No 854/2004. The CA shall carry out official controls to verify that health

requirements and hygiene requirements for raw milk and colostrum are complied with and monitor the checks carried out for plate count, somatic cell count (SCC) and residues of antibiotic substances.

**Audit findings**

Following recommendation No 2 of report 2008-7815 "*To ensure that criteria for raw cows' milk as laid down in Annex III, Section IX, Chapter I of Regulation (EC) No 853/2004 are met*" the SVFA stated that they would arrange a working meeting with all stakeholders involved in the national control scheme for milk in order to revise the computer system for counting total plate count (TPC) and SCC of raw milk.

The FVO audit team checked the raw milk quality controls in two dairy establishments, one raw milk testing laboratory and one DVFA office visited.

Observations:

- The DVFAs carry out official controls annually on all the holdings producing and supplying milk for human consumption. The reports including check lists from the controls carried out on raw milk suppliers were checked in the dairy establishments visited. The annual frequency of controls was respected. The DVFAs also verify the dairy processing establishment's controls over raw milk quality during the monthly inspections and the records seen were satisfactory.
- The DVFA office visited did not cover any milk processing establishments where raw milk was processed. The office was only involved in raw milk controls at farm level, e.g. in relation to seasonal producers of ice cream and cheese in remote areas. The seasonal producers receive an official control visit from the DVFA before the seasonal production starts and again during the season. It was explained that individual producers are responsible for the sampling and testing of own raw milk if they do not supply raw milk to a dairy establishment themselves. The producers provide copies of individual test results to the DVFA – in case of own sampling without any calculation of geometric averages. According to the DVFA it is the responsibility of the individual producer to calculate geometric averages and this would be checked during official controls on the farms.
- The results of this FBO's quality controls disclosed that raw milk samples for TPC and SCC testing were only collected on the first four days of the week (no samples were collected on Fridays, Saturdays or Sundays). It was explained that this was due to the working hours of the laboratory carrying out the laboratory tests. The FBO performs daily inhibitor tests on all the tanker trucks delivering raw milk using a rapid test and the CA considers this to be sufficient to guarantee compliance with the hygiene requirements.
- In the first large dairy establishment visited the CA stated that there had been no cases of non-compliance with the requirements of Annex III, Section IX, Chapter I of Regulation (EC) No 853/2004 during the past 3 years. In the second large dairy establishment visited there had been several cases of non-compliance with these requirements and documentation of the follow-up were available. The CA explained that in cases where the limits are exceeded the monthly reports sent to the producers are considered to be the notification in accordance with point 5 of Annex III, Section IX, Chapter I of Regulation (EC) No 853/2004. When the rolling geometric averages (TPC and/or SCC) have exceeded the limits for three consecutive months the dairy processing establishment sends a written warning to the raw milk producer requesting him to take corrective measures or face disruption in milk collection. A copy of this warning letter is sent to the DVFA for information and possible

further action.

- One small cheese producer only received blocks of cheese (cheese loaves) from another milk processor for further processing. The cheese loaves were received with supplier guarantees concerning the quality (e.g. that it had been produced from pasteurised bovine milk).

**Conclusion**

The raw milk quality controls were generally in line with the requirements but the corrective action taken in case of identified non-compliance with the raw milk quality requirements is not fully in line with the requirements of point 2 of Annex IV, Chapter II of Regulation (EC) No 854/2004 as the corrective action period exceeds three months since the initial non-compliance was identified.

### *5.2.10 Documentation of official controls*

**Legal requirements**

Article 9 of Regulation (EC) No 882/2004 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

**Audit findings**

Reports were drafted and check lists were filled in after each official control was carried out. These reports included what have been controlled, by whom and the results of the controls.

When needed requests for corrective action were produced including deadlines for the completion of necessary actions.

Evidence of the follow-up of these deadlines by the CA was, in general, available.

In several cases the Slovakian CAs did not identify or record shortcomings detected by the FVO audit team.

**Conclusion**

The documentation of official controls as well as the level of compliance FBOs with the legal requirements were in general acceptable. However, in several cases the CA failed to detect significant deficiencies seen by the audit team.

## 6 OVERALL CONCLUSIONS

Overall progress can be noted since the previous mission DG(SANCO)/2008-7815 in several areas but not all the recommendations from the report have been satisfactorily addressed. Problems were still identified regarding the approval of establishments and risk-based official controls. Non-compliances were also detected in the area of identification marking.

The official controls in the sectors evaluated and level of compliance by the FBOs were in most cases satisfactory but in several cases significant deficiencies had not been detected and documented in the completed check lists by the CAs.

The FVO audit team did not consider that the shortcomings identified lead to an immediate risk to public and animal health.

## 7 Closing Meeting

A closing meeting was held on 7 December 2012 with the CCA, the SVFA. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.

The representatives of the CCA acknowledged the findings and conclusions presented by the FVO audit team with one exception. The CCA expressed some disagreement with the findings regarding calculation of geometrical average for SCC and TPC. In addition, information on action already taken and planned in order to address particular findings in the establishments visited was provided.

## 8 Recommendations

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table to correct the deficiencies found should be presented to the Commission within 25 working days of receipt of the report.

| N°. | Recommendation |
|---|---|
| 1. | To ensure that only establishments in compliance with all relevant requirements of food law are approved and the approval of establishments is in line with Article 31 of Regulation (EC) No 882/2004. To ensure that when carrying out official controls, the review of approval conditions of the establishments is accurate and the list of establishments maintained is up-to-date. |
| 2. | To ensure that all relevant risks associated with establishments are taken into account in order to establish an appropriate official control frequency in all cases as required by Article 3 (1) of Regulation (EC) No 882/2004. |
| 3. | To improve the efficiency and the documentation of official controls in order to better detect the non-compliances of the individual establishments with the legal requirements so as to achieve the objectives of Regulation (EC) No 882/2004. |
| 4. | To ensure that water sampling and chemical analysis is carried out in accordance with the requirements of Council Directive 98/83/EC. |
| 5. | To ensure that identification marking complies with the requirements of Article 5 and Annex II, Section I of Regulation (EC) No 853/2004 and the verification of compliance with these requirements is carried out as foreseen by Article 4(6) of Regulation (EC) No 854/2004. |

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6366

## Annex 1 - Legal References

| Legal Reference | Official Journal | Title |
|---|---|---|
| Reg. 1760/2000 | OJ L 204, 11.8.2000, p. 1-10 | Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 |
| Reg. 1825/2000 | OJ L 216, 26.8.2000, p. 8-12 | Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products |
| Reg. 178/2002 | OJ L 31, 1.2.2002, p. 1-24 | Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety |
| Reg. 852/2004 | OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3 | Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs |
| Reg. 853/2004 | OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22 | Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin |
| Reg. 854/2004 | OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83 | Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption |
| Reg. 882/2004 | OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1 | Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules |

| Legal Reference | Official Journal | Title |
|---|---|---|
| Reg. 2073/2005 | OJ L 338, 22.12.2005, p. 1-26 | Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs |
| Reg. 2074/2005 | OJ L 338, 22.12.2005, p. 27-59 | Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 |
| Reg. 2075/2005 | OJ L 338, 22.12.2005, p. 60-82 | Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat |
| Reg. 1162/2009 | OJ L 314, 1.12.2009, p. 10–12 | Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council |
| Dir. 93/119/EC | OJ L 340, 31.12.1993, p. 21-34 | Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing |
| Dir. 96/93/EC | OJ L 13, 16.1.1997, p. 28-30 | Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products |
| Dir. 98/83/EC | OJ L 330, 5.12.1998, p. 32-54 | Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption |

| Legal Reference | Official Journal | Title |
|---|---|---|
| Dir. 2000/13/EC | OJ L 109, 6.5.2000, p. 29-42 | Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs |