EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2010-8513 - MR FINAL

FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

BULGARIA

FROM 07 TO 17 DECEMBER 2010

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 THE CONTEXT OF A GENERAL AUDIT

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Bulgaria, which took place from 7 to 17 December 2010, as part of the general audit of Bulgaria carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The specific audit evaluated the implementation of national measures, aimed at the control of the Hygiene package 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 Bulgarian National Veterinary Service (NVS) replied satisfactorily to most of the 11 recommendations of the previous mission report DG(SANCO)/2009-8235 with the main exception of a lack of a clear strategy for improving raw milk quality.

Staff resources remain unchanged since the last mission and seem adequate. A comprehensive training system for officials is in place and evidence of staff participation was provided. The frequency of official controls is based on risk and the frequencies set are followed and often exceeded. An annual and well documented supervision system is in place from the Regional Veterinary Services (RVS) to all meat and dairy establishments and all official veterinarians. However, in spite of the training provided and the supervision carried out the system failed to detect some important deficiencies in establishments noted by the FVO team, mainly related to significant shortcomings in structure of establishments and food business operators (FBOs) own check programmes or failure to take action when the bacteriological parameters indicated it.

The Central Competent Authority (CCA) stated that all transitional establishments as regards structural requirements (meat, milk and their products) covered by Commission Decision 2007/716/EC have either been upgraded in line with Regulations No (EC) No 852/2004 and (EC) No 853/2004 or, if non-compliant, been closed down. In some regional services visited it was confirmed that a comprehensive documented control system was in place to ensure that these establishments were actually closed including quarterly inspection visits from the CAs.

There has been a change in the structure of the laboratory network responsible for testing of official samples for public health purposes implemented since July 2010. The number of laboratories performing public health tasks in the laboratory network has been reduced from 28 to 11 (including both National Reference Laboratories (NRLs) and regional laboratories). All 11 remaining laboratories are accredited. According to the information received from the CAs the reduction in the number of laboratories has led to an improvement in their overall performance.

Bulgaria is in the final phase of the transitional period for raw milk parameters. The somatic cell count (SCC) is in line with the requirements of Regulation (EC) No 853/2004 and the plate count (PC) is currently set for 200 000 cfu/ml, to be in line with the EU requirements at the end of 2011 (100 000 cfu/ml). In the dairy establishments visited the respect of the raw milk requirements was assessed and was found in principle to be satisfactory and in line with the national plan based on the Commission Decision 2009/861/EC.

A number of recommendations have been made to the Bulgarian Competent Authorities with a view to address the deficiencies identified during this mission.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
ABP	Animal by-products
CA	Competent Authority
CCA	Central Competent Authority
CCP	Critical Control Point
CRL	Community Reference Laboratory
DG(SANCO)	Health and Consumers Directorate-General
EU	European Union
FBO	Food Business Operator
FCI	Food Chain Information
FVO	Food and Veterinary Office
GDCVA	General Directorate for Control of Veterinary Activity (in NVS)
HACCP	Hazard Analysis Critical Control Points
MAF	Ministry of Agriculture and Food
MANCP	Single Integrated Multi-Annual National Control Plan
NRL	National Reference Laboratory
NVS	National Veterinary Service
OV	Official Veterinarian
PC	Plate count
Report 2009-8235	Report DG(SANCO)2009-8235 of a mission carried out in Bulgaria from 14 to 25 September 2009 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
RVS	Regional Veterinary Service
SCC	Somatic cell count

1 Introduction

The Specific Audit formed part of the FVO's planned mission programme. It took place in Bulgaria from 7 to 17 December 2010. The FVO team comprised four inspectors from the FVO. Representatives from the central competent authority (CCA), the National Veterinary Service (NVS) accompanied the FVO team for the duration of the audit. An opening meeting was held on 7 December 2010 with the CCA. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the FVO team and the control systems were described by the authorities.

2 Objectives Of The Mission

The **objectives** of the specific audit were to:

- verify that official controls are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by Bulgaria,

- evaluate the follow-up action taken by the competent authorities (CA) in response to the recommendations made in report DG(SANCO)/2009-8235 (hereafter referred to as report 2009-8235), and

- evaluate the controls over meat of domestic ungulates, wild game, minced meat, meat preparations, meat products, raw milk and dairy products.

In terms of **scope**, the audit concentrated primarily on:

- Regulation (EC) No 882/2004, in particular the organisation of official controls (Articles 3-7), control and verification procedures and methods (Articles 8-10), enforcement (Articles 54-55), MANCP (Articles 41-42) and registration and approval of establishments (Article 31), and
- the specific area under review and in the framework of Regulations (EC) No 178/2002, No 852/2004, No 853/2004 and No 854/2004, in particular the controls over meat of domestic ungulates, wild game, minced meat, meat preparations, meat products, raw milk and dairy products.

The table below lists sites visited and meetings held in order to achieve that objective:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	**Central**	**1**	Initial and final meeting.
	Regional	**10**	Officials at regional level were met at four regional offices visited and in establishments in six other regions visited.
SLAUGHTERHOUSES		**6**	These activities were performed in different combinations in the 13 meat processing establishments visited.
MEAT PRODUCT ESTABLISHMENTS		**7**	
MINCED MEAT/ MEAT PREPARATIONS		**4**	
CUTTING PLANTS		**5**	
COLD STORES		**1**	

MEETINGS/VISITS	n	COMMENTS
WILD GAME ESTABLISHMENTS	**1**	
DAIRY ESTABLISHMENTS	**5**	
MILK COLLECTION CENTRE	**1**	
CLOSED ESTABLISHMENTS	**6**	Establishments with structural derogations previously on the lists of Commission Decision 2007/716/EC.
LABORATORIES	**1**	National Reference Laboratory (NRL) for raw milk in Sofia.

3 Legal Basis for the Mission

The specific audit was carried out under the general provisions of Community 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.

A full list of the legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in Member States. The main purpose of such audits is to verify that, overall, official controls take place in Member States in accordance with the MANCPs referred to in Article 41 and in compliance with Community law.

This specific audit was carried out as a component of a General Audit to Bulgaria. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

4.2 Summary of previous FVO mission results

The previous mission concerning the safety of food of animal origin in Bulgaria was carried out from 14 to 25 September 2009, the results of which are described in report DG(SANCO)2009-8235 -MR Final (hereafter referred to as report 2009-8235). This report is accessible at:

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

The action plan received from the Bulgarian CCA in response to the report's recommendations provided unsatisfactory responses to one of the 11 recommendations made.

The recommendation with the unsatisfactory response related to a lack of strategy for improving

raw milk quality. The recommendations and a short summary of the CA response can be found under the relevant heading in this report.

A detailed description of the CAs can be found in the country profile for Bulgaria which is accessible at:

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

5 Findings And Conclusions related to implementation of Regulation (EC) no 882/2004

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

- There have been no changes since the last mission: The NVS under the Ministry of Agriculture and Food (MAF) is the designated CA responsible for carrying out official controls of meat and milk and their products. The NVS has a pyramidal structure with a direct line of command between central and regional levels. The NVS has 28 RVS. The Public Health Directorate of the NVS and Public Health Departments of the RVS are responsible for the organisation of official controls within the scope of this specific audit.
- The NVS informed that it is anticipated that two new institutions related to food safety - the Bulgarian Food Safety Agency (under the MAF) and the Risk Assessment Centre will open in January 2011. The draft Law for these organisational changes was adopted in the Council of Ministers at the end of October 2010. The new Agency will combine administrative units of the Ministry of Agriculture and Food i.e. NVS, the National Service for Plant Protection, the National Grain and Feed Service and parts of the Ministry of Health (official controls with food of non-animal origin). The Food Safety Agency will be headed by one General Director and three deputy directors and will include a total number of 3000 staff (including regional and local levels). The Risk Assessment Centre will be an independent body to assess the risk in the food chain.

5.1.2 Co-operation between 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.

Findings

- No evidence was detected during this mission of inadequate cooperation and coordination

between CAs.

- In the previous mission and in spite of the coordination foreseen in the MANCP between all central level authorities the Ordinance No. 4 (SG 23 of 19.2.2008) contained provisions on the disposal of milk positive for residues (animal by-products (ABP) category 2) that were not in line with the provisions in the Environment and Water Act of 2004 (as amended) issued by the Ministry of Environment, and with the provisions of Regulation (EC) No 1774/2002. In this mission it was confirmed that NVS has amended Ordinance No 4, Art. 23 (2) (SG 27 of 9.4.2010) to ensure compliance with the requirements of Art. 3.3. of Regulation (EC) No 1774/2002 as regards disposal of liquid waste (ABP category 2 and 3) from dairy plants (see also chapter 6.3.7.).

5.1.3 Co-operation within Competent Authorities

Legal Requirements

Article 4(5) of Regulation (EC) No 882/2004 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.

Findings

- The system remains the same as described in report 2009-8235. The NVS (Directorate for Veterinary Public Health) is responsible for the MANCP and the drawing up of the annual inspection programme and the heads of Units in the public health sections of the RVS are responsible for implementing the annual control plans for the veterinary officers in their region covering all establishments. The RVS are then obliged to send weekly, monthly and quarterly reports to the NVS on all the control activities carried out.
- No evidence was detected during this mission of inadequate co-operation and co-ordination between animal health and public health officers at central or regional levels.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating CA must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Findings

- No official tasks have been delegated to any control bodies in the area covered by this FVO audit.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that CAs have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

- According to the MANCP national contingency plans have been drawn up for different food emergencies (by the Ministry of Health) and the NVS has drawn up an operation plan for emergency situations. However, none of these contingency plans cover *Trichinella* outbreaks specifically as required by Article 7 to Regulation (EC) No 2075/2005.
- The NVS informed the FVO team that the RVS were responsible for drawing up contingency plans for *Trichinella*. However, some examples of these contingency plans were seen in the RVS and these differed in quality and some were seen to be rudimentary. In particular they did not all contain provisions concerning traceability of infested carcasses and parts thereof, for the epidemiological investigations of the source of infestation and the spreading among wildlife and for the determination of the *Trichinella* species.

Conclusions on Competent Authorities

The NVS has been clearly designated as the CCA for the areas covered by this mission. A new Food Safety Directorate including the NVS is anticipated to start up in January 2011.

Satisfactory co-ordination and co-operation was seen. The previous recommendation regarding a change of Ordinance No 4 on disposal of liquid waste from dairy plants in order to bring the legal basis in line with Regulation (EC) No 1774/2002 has been addressed.

There is no national contingency plan in place for *Trichinella,* but the RVS has drawn up such plans, however, they differed in quality and did not fulfil all the requirements of Article 7 to Regulation (EC) No 2075/2005.

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators (FBOs) to undergo inspection by the CAs. Article 8 of the above Regulation requires that CAs have the necessary powers of access to food business premises and documentation.

Findings

- There have been no changes to what was described in report 2009-8235. The framework legislation (the Veterinary Activity Law (SG No. 87/2005 as amended) and the Food Law

(SG No.102/2003 as amended) provides the CAs with the necessary legal powers to carry out controls, including powers of access to FBOs and documentation. There is an obligation on FBOs to undergo inspection by the CAs.

5.2.2 Staffing provision and facilities

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings

- All inspectors employed by the NVS and the RVS carrying out official controls in meat and milk establishments are veterinarians. The NVS informed the FVO team that in order for a veterinarian to be appointed as an Official Veterinarian (OV), they must have worked at least three years without infringements, they must undergo relevant training, and the Director of the RVS must propose them to the Director General of the NVS.
- The FVO team was informed that there have been no staff reductions since the last mission. However, staff has been re-assigned from the closed laboratories to other work in the same RVS (see chapter 5.3.3).
- A comprehensive system for the prevention of conflict of interest is in place. It includes a requirement for all civil servants to annually sign two declarations: the first should identify their property and the in the second the civil servant must declare that they have no direct or indirect links to private, commercial or political entities that could cause conflict of interest.
- The NVS informed the FVO team that since January 2010 an Order issued by the Director General introduced a new system to prevent a conflict of interest, which consisted of three months rotation within the same RVS to be implemented amongst the OVs working in the RVS, in order that they would change responsibility for their establishments (slaughterhouses were exempted, the system was introduced in cutting plants, meat product plants and dairy plants). In addition, each inspector would personally follow up their own prescriptions to the food establishments also after their three month period had elapsed.

5.2.3 Staff qualifications and training

Legal Requirements

Article 6 of Regulation (EC) No 882/2004 requires CAs to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

The relevant recommendation of report 2009-8235 was to ensure that staff responsible for official controls were able to identify non-compliances in order to prevent a lack of effectiveness of the official controls. In response to this recommendation the CCA undertook to provide training for

OVs regarding general hygiene, animal welfare, meat control and microbiological sampling of carcasses. In addition, the CCA undertook to strengthen the verification procedures of the performance of the OVs operating in the plants where the FVO team had identified major non-compliances.

- The NVS informed the FVO team that all 15 staff at central level in the Public Health Directorate in the NVS have participated in at least one training session for Better Training for Safer Food in 2010. In addition, in some RVS visited OVs had also participated in these training courses. Afterwards knowledge cascades had been organised for colleagues.
- According to information received from the NVS the Directorate for Research, Laboratory and Training (part of the NVS) is in charge of establishing a list of relevant subjects for training related to food safety and the PHD can comment on this list. The criteria for establishing this list is according to NVS: 1. Results from FVO reports, 2. Legislative changes, 3. The situation as regards laboratories and their results, 4. Discussions with the PHD about current problems. This list as amended of training subjects is then sent to the RVS that are in charge of implementing the training sessions.
- In one RVS visited the FVO team went through the implemented training sessions in 2010. These included official controls in milk and milk products (including recent changes in Regulation (EC) No 2073/2005), approval procedures, animal welfare (in particular stunning and transport) and official controls in meat establishments (including meat control). For each seminar an attendance list was available and copies of training material could be provided.
- In one RVS visited where training on meat control had recently been provided significant deficiencies were seen in relation to post-mortem inspection of bovines (see section 6.3.3).
- In some RVS visited where training had recently been provided regarding requirements of Regulation (EC) No 2073/2005, deficiencies in microbiological testing were identified by the FVO team in most establishments visited that were not identified by the CA (see section 6.2.2.).
- In one RVS visited the FVO team was informed that 14 inspectors (out of 51 inspectors in the Public Health sector in that RVS) had received training on auditing in a three day course in December 2009 (see section 5.2.2.).

Conclusions on Resources for Performance of Controls

The CA has the necessary legal powers to carry out official controls.

Adequate resources are in place to carry out official controls and a national system for prevention of conflict is in place.

A comprehensive training system for officials is in place at both central and regional levels and evidence of staff participation was provided. However, training has not always been fully effective since some major deficiencies in establishments, noted by the FVO team during the mission, had not been detected by any level of supervision.

5.3 Organisation and implementation of official controls

5.3.1 Registration / approval of food business operators

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 operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

Furthermore Commission Decision 2007/716/EC has allowed certain establishments in the meat and milk sector in Bulgaria not to apply some structural requirements provided for in Regulations (EC) No 852/2004 and No 853/2004 until 31 December 2009, subject to certain conditions. Products from these establishments should only be placed on the domestic market.

Findings

The system for upgrading of establishments covered by Commission Decision 2007/716/EC has remained the same as described in report 2009-8235.

- The legal basis for approval of food establishments is Article 12 in the Food Law and approvals are granted on a permanent basis. Ordinance No. 909 dated 22.10.2007 from the NVS establishes the detailed procedures for approvals and registrations of food establishments and the conditions and deadlines are in line with Article 31 of Regulation (EC) No 882/2004.
- The RVS issues the approval and gives the approval number to food establishments. Each month the RVS in obliged to send a list with all changes (i.e. new or closed establishments) to the NVS in order for them to update the national list of establishments.
- The list of approved establishments has been made publicly available. In addition, lists of milk collection centers and milk storages are available on the NVS homepage.
- Blue prints were not always fully up-to-date. A few cases were seen where it was difficult to establish exactly what buildings or parts of a building that were covered by the approval.
- During a visit to a slaughterhouse the FVO team noted the presence of two other meat establishments (see section 6.2.1.). One of them was not fulfilling EU structural requirements and since 2009 had been suspended for an unlimited time by the CA but was still carrying out some storage activities in spite of the suspension. The other meat establishment was operating without any approval and was unknown to the CA.
- The NVS informed the FVO team that all establishments covered by Commission Decision 2007/716/EC had either been upgraded in line with Regulations (EC) No 852/2004 and (EC) No 853/2004 or, if non-compliant, been closed down. Initially a total of 378 meat establishments were included in the derogation list (including poultry slaughterhouses), and 330 of these had fulfilled the EU requirements. The initial number of dairy plants was 207, and 188 of these had met the structural requirements.
- The NVS provided the FVO team with a list of 67 establishments which have closed that had previously been on the list of Commission Decision 2007/716/EC of which 41 were red meat establishments (11 slaughterhouses and 30 meat processing plants), 19 dairy plants and seven poultry slaughterhouses. In some of the RVS visited it was confirmed that a

comprehensive documented control system was in place to ensure that these establishments were actually closed including quarterly inspection visits from the RVS. For the closed establishments orders had been issued by the RVS regarding a ban on production in the case of a lack of upgrading or other breaches of the legislation and orders on delisting of the establishment from the national lists.

- The FVO team visited six closed establishments (four slaughterhouses for red meat, one meat processing plant for red meat and one dairy plant) in three different RVS and verified that they were actually closed down and that no food processing activities were taking place.

5.3.2 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 products placed on the EU market.

Findings

- Official controls are carried out on a risk basis (see also report 2009-8235).

- Since the last mission the instruction in place to carry out risk assessment and determine the corresponding frequency of inspection has been through a hearing procedure with the RVS and has been changed. With the Order No RD 11-51 of 27 January 2010 "On the implementation of the MANCP for raw materials and foodstuffs of animal origin" the CA has put in place a revised risk assessment system to classify food-businesses into risk groups. The main points changed are that the very low risk category has been removed (instead of four there are only three categories of risk today, i.e. high, medium and low risk). In, addition, there are only 12 parameters for risk assessment (previously 13 parameters) and new parameters include results of own-checks carried out, internal monitoring for results of bacteriological testing and messages from the Rapid Alert System for Food and Feed.

- The FVO team verified that the risk assessment instruction had been followed in the RVS visited and that the set inspection frequencies were being respected and very often exceeded.

5.3.3 Control activities, methods and techniques

Legal Requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

- The FVO team found that the RVS had carried out official controls throughout the food chain in the meat and dairy sector. This included inspections of establishments and farms, auditing of FBO's own-check systems based on HACCP principles, interviews with FBOs

and sampling for laboratory analyses.

5.3.4 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 laboratories so designated.

Findings

- The NVS informed the FVO team about a change in the structure of the laboratory network responsible for the testing of official samples for public health purposes (*Salmonella*, *Trichinella*, raw milk etc.) implemented by an Order dated July 2010 from the NVS. The number of laboratories performing public health tasks has been reduced from 28 to 11 laboratories. (including National Reference Laboratories (NRLs) and regional laboratories.
- According to information received from the NVS all staff from the closed laboratories have been re-assigned to other tasks in the same RVS either in the public health or animal health section. In addition, equipment and reagents have been sent to remaining laboratories.
- All eleven remaining laboratories are accredited by the Bulgarian Accreditation Agency according to ISO-17025 standards. According to information received from the NVS all laboratories will be re-accredited after 1 January 2011.
- The NRL for raw milk was visited. According to the information received the laboratory participated in three international ring-tests in 2010 organised by the Community Reference Laboratory (CRL) for PC with satisfactory results and for SCC and for alkaline phosphatase test where the results has not yet been received at the time of the audit. In addition, the laboratory had participated in the same ring tests organised by the CRL in 2008 and 2009 with satisfactory results. So far the NRL had not organised ring-testing for regional laboratories performing raw milk controls but was in the process of organising such a test. The NRL informed the FVO team that three of the eight regional laboratories were using Bactoscan/Fossomatic method and two more were about to install this method. According to the responsible person for the NRL, the reorganisation of the laboratory network had increased the quality of testing. However, so far no audits have been carried out to the local laboratories and there were no actual plans, but training sessions had been organised.
- Since the last mission the NRL for *Trichinella* has been accredited. The CCA provided documentation for the NRLs participation in international ring-testing by the CRL from 2008 to 2010, however, the results were not always satisfactory: In 2009 the CRL evaluated three out of ten samples found to be not satisfactory by the NRL, in 2010 two out of ten samples were not satisfactory. So far the NRL for Trichinella has not organised ring-testing for the eight remaining regional *Trichinella* laboratories and no audits have been carried out from the NRL to these laboratories.
- Annual sampling plans were made in each RVS for official sampling of final products, water and hygiene swabs and in establishments visited samples were taken on a monthly basis. The official sampling had been carried out according to the plan and the results seen were within the requirements of EU legislation.

5.3.5 Procedures for performance and reporting 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.

Article 9 of the above Regulation 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.

Findings

- The FVO team noted that there are various instructions, checklists, questionnaires and templates used during official controls. Some of them were provided by the CCA and some of them were drafted by the RVSs.
- The NVS has recently revised the instruction on risk assessment of establishments (see also 5.3.2.), that also contains some limited elements of instruction to inspectors on what issues should be covered during a hygiene inspection in meat and milk establishments. However, there are no detailed guidelines made by NVS for the RVS to carry out official controls to cover all aspects of Regulations (EC) No 854/2004 and No 882/2004 in order to ensure uniform controls in the 28 RVS.
- Following official controls, detailed reports are prepared by the official inspectors and countersigned by the FBOs. These reports include the description of the purpose of the official controls, the methods applied, the results obtained and any actions to be taken by the FBO concerned. Copies of these reports were available in all FBOs visited.

5.3.6 Transparency and confidentially

Legal Requirements

Article 7 of Regulation (EC) No 882/2004 requires that CAs carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

- The CA website includes a section on public health with details on the relevant legislation, annual audit plans, audit procedures, lists of establishments, etc.
- Provisions regarding professional secrecy and personal data protection are contained in the Food Law.

Conclusions on Organisation and Implementation of Official Controls

The approval procedure for new establishments is in line with Article 31 of Regulation (EC) No 882/2004. However, some inconsistencies were seen as regards contents of approvals mainly in

relation to blue prints that were not always accurate or updated.

The CA has managed to upgrade transitional establishments or has closed them down completely in line with Commission Decision 2007/716/EC. A comprehensive and documented control system has been implemented for the closed establishments.

Official controls are carried out on a risk basis and instructions for carrying out risk assessment of establishments have been further improved. However, instructions on how to carry out official controls in order to cover all aspects of Regulations (EC) No 854/2004 and No 882/2004 for performing hygiene inspections in meat and milk establishments are not fully developed.

The laboratory network has been reduced from 28 to 11 laboratories including the NRLs. All these laboratories are accredited. The NRL for *Trichinella* has participated in ring-testing organised by the CRL but not always with satisfactory results. The NRL for raw milk has participated in ring-testing organised by the CRL with satisfactory results. There has not been ring-testing organised for the regional laboratories from the NRL for *Trichinella* and the NRL for raw milk to the regional laboratories.

5.4 Enforcement Measures

5.4.1 Measures in the case of non-compliance

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.

Findings

- The legal basis for the CA to enforce legislation is the Veterinary Activity Act and the Food Law. When a non-compliance is noted, a report is written, including recommendations and deadlines for correction. There is a follow-up carried out by the OV, who must stamp and date the report when the FBO had corrected the deficiency.
- The FVO team detected significant non-compliances in the structure of establishments, in FBOs' own check programmes and regarding microbiological testing (see sections 5.5.1., 6.2.1., 6.2.2. and 6.2.3.) that had not been detected and reported by the CAs.
- Several examples were seen of enforcing measures including suspension of activities for one meat-product plant (for 10 days) and in this period the OV performed ad-hoc visits to ensure that no food production was taking place.

5.4.2 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 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.

Findings

- The Veterinary Activity Law provides the legal basis for administrative fines.
- In one RVS visited 95 administrative fines had been issued in 2010 to amongst others one milk establishment and five meat processing plants (the rest were mainly issued to retailers and cold stores). Most of the fines had been given due to lack of documentation and the range of fines was between 1 500 to 3 000 LEVA (around 750 to 1 500 EURO).
- Each month the RVS must send a report to the NVS with information on the number of administrative fines given, and information on the type of infringement. Each RVS is also obliged to report the total sum of money collected in fines to the NVS in January each year.
- NVS has issued an instruction dated 5 July 2006 on how administrative fines should be imposed by RVS. This also includes a template for the reporting of the infringement that should be used for issuing fines.

Conclusions on Enforcement Measures

The CA has the necessary legal powers and do take appropriate action as required by Article 54 of Regulation (EC) No 882/2004 when non-compliances are identified. Bulgarian national legislation providing detailed rules on sanctions is in place in line with the requirements laid down in Article 55 of the Regulation and the sanctions provided appear to be effective and proportionate.

However, several significant non-compliances detected by the FVO team regarding structure of one establishment, HACCP and microbiological testing had not been detected previously by the CA.

5.5 Verification and review of official controls and procedures

5.5.1 Verification 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.

Findings

The relevant recommendations of report 2009-8235 was to take further measures to improve verification procedures in order to prevent the lack of effectiveness of the official controls seen in four establishments visited and urgently to address the inadequate official supervision that failed to report on the serious deficiencies of animal welfare of horses, animal identification and ante-mortem inspection. In response to these recommendations the CCA undertook to provide training for OVs in the specific establishments regarding animal welfare, meat control and microbiological sampling of carcasses. In addition, the CCA undertook to strengthen the verification procedures of the performance of the OVs operating in the four plants and a new guideline sets out that each FBO must now be audited based on risk, but at least once a year.

- The CA has carried out intensified checks on the every day performance and work of OVs operating in the four plants where major non-compliances were seen at the last mission. In

addition, the expert team from the NVS have carried out a detailed supervision check of the RVS and the problematic establishments which has resulted in disciplinary procedures against the OVs. Moreover, training has been provided for the OVs in question on animal welfare, animal identification and registration of animals, meat controls and microbiological sampling.

- Order No RD 11-51 of 27 January 2010 "On the implementation of the MANCP for raw materials and foodstuffs of animal origin" (see also Chapter 5.3.2.) sets out a minimum frequency for supervision of all establishments. Based on this instruction the annual regional official control programmes are elaborated for the RVS including frequency of inspections and supervisions (audits of establishments by the same RVS).
- The system of verification of official controls is direct supervision each year on the spot over the FBOs and the OVs from the regional level. Each time such a verification visit is carried out two reports are made, one concerning the establishment and one concerning the OV. The reports contain recommendations and deadlines for correction.
- The supervision and verification system did not detect significant structural deficiencies in one meat establishment and one dairy establishment. It had also not detected a hidden and illegal meat establishment found by the FVO team (see also Chapter 6.2.1.).
- Some significant deficiencies noted by the FVO team in establishments in relation to their structure and operation (see section 6.2.1.) had not been previously reported by the official supervision at establishment or RVS level.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 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.

Findings

- The General Directorate for Control of Veterinary Activity (GDCVA) within the NVS is responsible for internal audits at central level over the activities of the RVS.
- The audit teams consist of representatives from the GDCVA as well as representatives from the RVS, other than the audited RVS, mainly the Heads of Public Health from the RVS.
- The NVS informed the FVO team that the GDCVA prepare an audit plan each year. In 2010 ten audits were planned to ten different RVS, however the CA stated that only six of these audits had been carried out due to budgetary constraints. According to the overall plan all 28 RVS should be covered in a four-year period.
- In one RVS visited an audit had been carried out in 2010 where the FVO team went through the audit report. The audit team consisted of two representatives from the GDCVA and three representatives from an RVS, other than the audited RVS. The audit lasted three days and included two establishment visits (one dairy plant and one meat product plant). The remarks seen on the Public Health activities included description of staff and establishments in the RVS, compliance checks with procedures, reporting and legislation, compliance with procedures for assessment of risk, and total number of inspections, supervision visits, prescriptions, sanctions, samples taken, compliance with MANCP, verification procedures in

place and programme for training. The report concluded that an insufficient number of inspections had been carried out.

- In addition, the Public Health Directorate in the NVS can decide to carry out audits or supervision visits to the RVS in case of complaints or alerts.
- Comprehensive training sessions had been carried out for a high number of staff on the auditing principles as set out in Regulation (EC) No 882/2004 since the last mission (see also Chapter 5.2.3.).

Conclusions on Verification Procedures

A well documented system of verification procedures including follow-up is in place. However, the system did not detect or report significant deficiencies detected by the FVO team in some RVS visited, where the verification procedures failed to ensure the effectiveness of official controls.

A documented system of central level audits over the RVS is in place, however, so far only some of the 28 RVS have been audited.

5.6 Multi Annual National Control Plan

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated MANCP. According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

Findings

- The Bulgarian MANCP is valid for the period from 2008 to 2010. It includes all control authorities responsible for feed and food safety, animal health, animal welfare and plant health controls. The MANCP has been drawn up in co-operation between the MAF, and in particular by the Directorate for Quality and Safety of Food as regards the products within the scope of this mission, and the Ministry of Health.
- The MANCP includes information on the organisation of official controls of meat and milk establishments.

Conclusions on Multi-Annual National Control Plan

The Bulgarian MANCP for 2008 to 2010 has been prepared as required by Articles 41 and 42 of Regulation (EC) No 882/2004.

6 Sector Specific findings and conclusions

6.1 National measures and derogations

Legal Requirements

According to Article 10 of Regulation (EC) No 853/2004 Member States may, without compromising the achievement of the objectives of Regulation (EC) No 853/2004 adopt national measures adapting the requirements laid down in Annex III. The national measures refer to continued use of traditional methods and regions subject to geographical constraints and are subject to notification to the Commission and other Member States. National rules may be maintained or established for placing on the market of raw milk or raw cream for direct human consumption and to permit the use of raw milk not meeting the criteria for PC and SCC. Article 7 of Regulation (EC) No 2074/2005 allows Member States to grant establishments manufacturing foods with traditional characteristics derogations from certain requirements set out in Regulation (EC) No 852/2004.

Findings

- The CA stated that they have so far not notified any national measures and derogations to the Commission Services.
- As mentioned in the report 2009-8235 derogations have been given at national level since Ordinance No. 4 (SG 23 of 20.2.2008) includes a derogation for the use of non-compliant milk with regard to PC and SCC.
- Some meat products (amongst others a meat product called Lukanka produced by cold smoking and afterwards formed into a special shape between wooden plates) are considered as traditional products.

Conclusions

The Bulgarian authorities have not notified the Commission and other Member States of national measures and derogations in place as required by Article 10 (5) of Regulation (EC) No 853/2004 and Article 7 of Regulation (EC) No 2074/2005.

6.2 Food business operators obligations and official controls

The relevant recommendation of report 2009-8235 was to take further measures to ensure that the FBOs comply with their obligations as laid down in Chapter II of Regulation (EC) No 853/2004 and with the general and specific hygiene requirements set out in Article 4 of Regulation (EC) No 852/2004. In response to this recommendation the CCA has guaranteed that each establishment with noted deficiencies has been followed up by the responsible OV and deficiencies have been eliminated.

6.2.1 General hygiene requirements

Legal Requirements

Article 4(2) of Regulation (EC) No 852/2004 establishes that FBOs 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 of Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design,

construction, sitting and size of food premises. Article 4(4) 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 FBOs' compliance with these requirements.

Findings

- Evidence of action taken by the CAs in establishments with noted problems seen on the mission in 2009 as regards general hygiene requirements was received by the FVO team on this visit.
- During a visit to a slaughterhouse the FVO team noted the presence of two other meat establishments around the same yard: one did not fulfil EU structural requirements. In 2009 it had been suspended for an unlimited time by the CA but was still carrying out some storage activities, and another was hidden in a workshop building and was of an unacceptable standard, and, according to the CA's statement, was unknown to them. The FBO of the slaughterhouse did not provide full information and delayed the FVO team access to both other establishments. The CA took action by suspending the slaughterhouse, prohibiting activity and seizing meat in the other establishments. They initiated the withdrawal of one establishment from the list of establishments and imposed administrative and legal sanctions.
- Some establishments visited were not sufficiently protected against pests with doors and openings to the exterior not always tight.
- Different maintenance problems were seen, in particular equipment so worn that it was difficult to maintain, very worn and leaking and rusty cold units with risk of contamination of products, leaking pipes and rusty or mouldy ventilation systems with a risk of spreading airborne contamination.
- Some problems were seen with condensation on overhead structures and ceilings sometimes also over exposed products due to inadequate ventilation.
- In an old and very large establishment visited the middle of the building contained an old slaughter room, not in use, but practically beyond control (leakage from the roof, no evidence of pest control, and the situation was difficult to assess due to a lack of electricity).
- In one big dairy plant visited crates were stored outside of the building and there were insufficient washing facilities before they went into the establishment with the result that the crates for keeping finished products were very dirty.
- In all the establishments visited where non-compliances were noted, in most cases the CAs initiated corrective actions immediately after the FVO visit.

Conclusions

The establishments were generally constructed in a way that allowed them to comply with the general hygiene requirements. However, a number of shortcomings were identified, mainly in relation to maintenance, pest proofing and cleaning.

As regards the previous recommendation evidence of action undertaken in establishments where deficiencies were found was received and was found to be satisfactory.

6.2.2 Specific requirements

Legal Requirements

Article 3 of Regulation (EC) No 853/2004 sets out that the FBOs 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. Details on microbiological criteria for foodstuffs are set out in Regulation (EC) No 2073/2005 and Article 4(4) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify FBOs compliance with these requirements. 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.

Findings

The relevant recommendation of report 2009-8235 was to ensure that the FBOs sampling and microbiological analysis of carcasses is done in line with the requirements of Regulation (EC) No 2073/2005 and to improve the official controls on this issue. In response to this recommendation the CCA undertook to provide training of OVs concerning the requirements of Regulation (EC) No 2073/2005.

- In the establishments visited evidence of OV's training in the requirements of Regulation (EC) No 2073/2005 was presented to the FVO team. Moreover, in all the establishments visited extensive microbiological testing in line with Regulation (EC) No 2073/2005 was taking place as part of the FBOs own check programme and the official control sampling plan. However, deficiencies in this regard were noted in most of the establishments visited.
- In all slaughterhouses microbiological sampling of carcasses was carried out in accordance with Regulation (EC) No 2073/2005. However, in three slaughterhouses visited the FBO did not analyse the trends of the results obtained as required by Article 9 of Regulation (EC) No 2073/2005. Therefore, when the microbiological test results tended towards unsatisfactory results no action was taken by the FBO to remedy the situation. These shortcomings were not identified by the CA in spite of regular audits carried out with regard to Regulation (EC) No 2073/2005.
- In one game handling establishment with associated minced meat production activities the FBO had an extensive microbiological sampling plan in place. In addition, the CA also performed frequent microbiological sampling as part of the official control plan. However, in several cases the *E. coli* test results for minced meat were above the acceptable limit. These deficiencies were not identified either by the FBO or by the CA and therefore no corrective actions had taken place.
- Knife sterilisers were not always in operation at the required temperature (82ºC) and this had not been identified in two slaughterhouses visited by the FVO team.
- In one large and one medium size slaughterhouse the procedures in place did not ensure that the carcasses produced were free from faecal contamination and hair. Moreover, the carcasses were health marked after the post-mortem inspection. Furthermore, in one cutting plant pig carcasses were found with extensive faecal contamination in the chilling room and in the de-boning area. The documentation regarding official controls presented to the FVO team during the visits in these establishments did not identify these issues.

Conclusions

Some shortcomings were identified in relation to specific hygiene requirements, mainly as regards microbiological testing and carcase hygiene which was unsatisfactory in three establishments visited. The training provided by the CA did not ensure that the sampling, microbiological analysis and follow-up is done in line with the requirements of Regulation (EC) No 2073/2005 and therefore the relevant recommendation has not been fully addressed.

6.2.3 HACCP-based systems

Legal Requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. In Section II of Annex II to Regulation (EC) No 853/2004 the specific requirements for HACCP-based procedures in slaughterhouses are specified. 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(5) of Regulation (EC) No 854/2004).

Findings

The relevant recommendation of report 2009-8235 was to ensure that the FBOs' HACCP based systems were in line with Article 5 of Regulation (EC) No 852/2004. In response to this recommendation the CCA undertook to deliver documented and individual measures in the establishments to ensure a more efficient implementation of the HACCP based systems.

- HACCP-based procedures were in place in all the establishments visited but shortcomings were identified in eight out of the 13 HACCP programmes seen in individual establishments.
- The HACCP programmes were not always supported or sufficiently adapted to the individual establishment activities.
- In some cases the critical limits were not properly established (range of temperatures), the monitoring of CCPs was not carried out as described and when the monitoring identified that the process was not within the critical limit the prescribed corrective action was not carried out. The latter case was identified in an establishment visited during the last mission and where shortcomings with the HACCP procedures were highlighted.
- In one establishment the HACCP plan did not include verification procedures.
- In one establishment the CA had identified deficiencies in the HACCP plan. The deadline given for correction expired the day after the visit of the FVO team. The CA informed the FVO team that subsequently the production was suspended due to the deficiencies not being corrected within the required time frame. The FVO team noted some other deficiencies in the HACCP based procedures not identified by the CA.

Conclusions

HACCP–based procedures were implemented in all the establishments visited. However, the FVO team found shortcomings not identified by the CA. Moreover, in the establishment visited by the FVO during the previous mission the implementation of the HACCP plan was still not satisfactory. Therefore, the relevant recommendation has not been fully addressed.

6.2.4 Identification marking and labelling

Legal Requirements

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 No 1825/2000 set out specific labelling requirements for beef meat.

Findings

- Labels and identification marks were generally applied in a satisfactory way in the establishments visited. However, in one meat product establishment visited the identification mark applied to the final products was not legible.
- Meat from wild boar and dairy products not eligible for intra-Community trade were identified with a hexagonal national identification mark in line with Article 8b of Commission Decision 2008/855/EC and Article 4 of Commission Decision 2009/861/EC respectively.
- Evidence of verification of compliance by the CA with the requirements of labelling including identification marking was presented to the FVO team in the establishments visited.

Conclusions

Labels and identification marks were generally applied in accordance with the requirements and regular verification by the CA was carried out.

6.2.5 Traceability

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 FBOs 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 verification of compliance with traceability requirements takes place in all approved establishments.

Findings

- Traceability exercises were carried out in three establishments during the visits. The FBOs were in all cases able to provide documented evidence linking the batches of the final products to the incoming batches of fresh meat or carcasses and in the case of slaughterhouses to the incoming animals. In all the establishments visited internal traceability was guaranteed by identifying the products at the different stages of the process.
- In the establishments visited the CA carries out regular official controls of the traceability

procedures including full traceability exercises in some cases.

Conclusions

In the establishments visited by the FVO team the CA carried out regular verification of the traceability procedures.

6.3 Official inspection tasks in establishments for verification of the food business operators compliance

6.3.1 Food Chain Information

Legal Requirements

According to Article 3 of Regulation (EC) No 853/2004, the FBOs 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 food chain information (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 official veterinarian shall carry out inspection tasks in slaughterhouses also as regards FCI.

Findings

The relevant recommendation of report 2009-8235 was to review the current FCI system in order to fully implement the requirements for FCI for large and small ruminants and horses as required by Annex II, Section III of Regulation (EC) No 853/2004. In response to this recommendation the CCA undertook to make the necessary changes in the standard document accompanying each consignment of animals to the slaughterhouse in line with the requirements of Regulation (EC) No 853/2004.

- Since the last mission the template forms used for accompanying animals for slaughter has been amended. It now includes information on diseases on the farm with food safety aspects, results of samples taken and the name and address of the private veterinarian attending the holding of provenance in line with the requirements of Regulation (EC) No 853/2004.
- In the slaughterhouses visited the animals arriving for slaughter were accompanied by the relevant FCI, which was controlled by the FBO as well as the CAs.
- In one slaughterhouse visited FCI was not available for a consignment of 335 slaughter sheep from Romania as relevant information was missing; nevertheless the consignment was accompanied by a certicate covering animal health aspects as required by Council Directive 91/68/EEC.

Conclusions

The recommendation on FCI of the previous mission report has been fully addressed and the FCI system is adequate. However, FCI was not available for slaughter sheep from Romania.

6.3.2 Ante-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 of Regulation (EC) No 854/2004.

Findings

- In the slaughterhouses visited by the FVO team the ante-mortem inspection was carried out by the OV before slaughter.
- Records in the form of ante-mortem registers were presented to the FVO team in all the slaughterhouses visited.
- Furthermore, animals arriving at slaughterhouses are accompanied by an animal health certificate issued by the private veterinary practitioner responsible for the holding of provenance.

Conclusions

The ante-mortem inspection and registers were in compliance with the requirements of Regulation (EC) No 854/2004.

6.3.3 Post-mortem inspection

Legal Requirements

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

Findings

The relevant recommendation of report 2009-8235 was to ensure that post-mortem examination of pigs is carried out in compliance with Article 5(1)(d) and Annex I, Section IV of Regulation (EC) No 854/2004. In response to this recommendation the CCA undertook to provide training of OVs concerning post-mortem examination and in addition, to strengthen the verification procedures to ensure compliance as regards meat control.

- The post-mortem records including records of *Trichinella* results were found to be sufficient.
- Post-mortem inspections were carried out by OVs in line with EU-legislation. However, in one large slaughterhouse some necessary examinations were not performed on bovines, e.g.: the retropharyngeal, submandibular and parotid lymph nodes were not examined and incised, the masseters were not properly incised, the tongue was not freed to allow the full inspection of the mouth and fauces, bronquial and mediastinal lymph nodes were examined but not incised in all cases, the trachea and the main branches of the bronchi were not opened lengthways (the lungs were destined for human consumption), the gastrointestinal tract was not inspected and the mesenteric and gastric lymph nodes were not palpated. In addition, carcasses with obvious contamination (faeces and hair) were declared fit for human consumption at post-mortem inspection and health marks were applied. Moreover, the OVs responsible in this slaughterhouse had received recent documented training of performing post-mortem inspection (see also section 5.2.3.).
- In one pig slaughterhouse visited the hearts were not incised and the gastro-intestinal tract was not inspected.
- Systems were in place in the slaughterhouses visited to ensure that all carcasses of pigs were sampled and that samples were sent to regional laboratories for *Trichinella* testing.

Carcasses were were only released after a negative result for *Trichinella*.

Conclusions

Post-mortem registers were in line with EU legislation. The previous recommendation on post-mortem inspection has been adressed by providing training. However, the training has not been efficient in all cases as significant deficiencies were found in two slaughterhouses in relation to post-mortem inspection.

6.3.4 Health marking

Legal Requirements

Article 5(2) of Regulation (EC) No 854/2004 requires that health marking shall be carried out in slaughterhouses and game-handling establishments by, or under the responsibility of, the official veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

Findings

- In most establishments visited health marking was applied correctly.
- However, in two slaughterhouses and in one cutting plant visited health marks were applied to carcasses with faecal contamination.

Conclusions

In most cases health marks were applied correctly. However, some cases were seen where health marks had been applied to carcasses with faecal contamination, which is not in line with Article 5(2) of Reg. (EC) No 854/2004.

6.3.5 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.

Findings

The relevant recommendation of report 2009-8235 was urgently to improve official controls of animal welfare during transport and slaughter to ensure that animal welfare conditions at the time of slaughter or killing are in accordance with Regulation (EC) No 1/2005 and Council Directive 93/119/EC. In response to this recommendation the CCA undertook to provide training to OVs concerning animal welfare and in addition, to strengthen the verification procedures to ensure compliance as regards animal welfare.

- In two slaughterhouses visited, the FVO team noted that pigs were not properly stunned even though adequate facilities were present (electrical stunning not applied in the right place of head or not for sufficient time).
- A documented system for official controls in relation to animal welfare is in place at

slaughterhouse level. However, the shortcomings noted by the FVO team in the stunning of pigs had not been detected by the OVs.

- In an establishment visited by the FVO at the previous mission in 2009 and where serious deficiencies in relation to animal welfare were seen, new improved procedures were seen as well as evidence of extensive training to the responsible OVs. The FVO team had no opportunity to see if this action was efficient in practice due to a lack of slaughtering activity.

Conclusions

Training on animal welfare has been provided to the responsible OVs in the slaughterhouse where problems had been detected by the FVO team in 2009 and to other slaughterhouse OVs. However, in two other slaughterhouses visited pigs were not stunned properly and the official controls had not detected the shortcomings, which means that the training provided had not been efficient in all cases.

6.3.6 Criteria for raw milk

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) 854/2004 and the CA carries out official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with and monitors the checks carried out for PC, SCC and residues of antibiotic substances.

Findings

The relevant recommendation of report 2009-8235 was to continue efforts to improve the quality of the milk collection system, dairy holdings and raw milk quality in order to bring them in line with the requirements of Chapter I (II and III), Section IX of Annex III to Regulation (EC) No 853/2004, within the deadlines prescribed in Chapter 4 of Section B of Annex VI of the Act of Accession of Bulgaria and Romania. In response to this recommendation the CCA undertook to take action to improve raw milk quality and achieve the criteria laid down in Regulation (EC) No 853/2004, within the deadline specified in Commission Decision 2009/861/EC, i.e. until 31.12.2011.

- Bulgaria is in the final phase of the transitional period for raw milk parameters specified in Commission Decision 2009/861/EC. The SCC is in line with the requirements of Regulation (EC) No 853/2004 and the PC is currently set for 200 000 cfu/ml, to be in line with the EU requirements at the end of 2011 (100 000 cfu/ml). According to the CCA the national legal basis for this strategy including deadlines is laid down in Ordinance No 4.
- The FVO team visited all the categories of dairy plants i.e. category 1 processing compliant milk, category 1 a (processing non-compliant milk for the production of white brine cheese only), category 2 (processing compliant and non-compliant milk on two separate lines until the end of 2011) and category 3 (processing non-compliant milk until the end of 2011). In the six dairy establishments visited the respect of the raw milk requirements was assessed in five (one carrying out only storage activities due to reconstruction) and was found in principle to be satisfactory and in line with the national plan based on Commission Decision 2009/861/EU.

Conclusions

In the dairy establishments visited the respect of the raw milk requirements was assessed and was found in principle to be satisfactory and in line with the national plan based on the Commission Decision 2009/861/EC. The previous recommendation on raw milk has been properly addressed.

6.3.7 Animal by-products

Legal Requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the official veterinarian carries out inspection tasks, including animal by-products (ABP). Annex II to Regulation (EC) No 1774/2002 sets out the requirements for the collection and transport of ABP, including requirements for identification, records and the use of commercial documents.

Findings

The relevant recommendation of report 2009-8235 was to ensure that adequate arrangements for collection and disposal of liquid waste (Category 2 and 3) from dairy plants are in place as required by Article 3 (3) to Regulation (EC) No 1774/2002. In response to this recommendation the CCA undertook to change the national legal basis for disposal of liquid waste to ensure compliance with Regulation (EC) No 1774/2002 as regards disposal of liquid waste (category 2 and 3) from dairy plants.

- The CAs were performing inspections covering ABP in establishments visited.
- The collection, transport and disposal of ABP as well as identification in the meat establishments visited were in line with Regulation (EC) No 1774/2002.
- Since the last mission Ordinance No 4 has been amended to ensure compliance with the requirements of Regulation (EC) No 1774/2002 as regards disposal of liquid waste (ABP category 2 and 3) from dairy plants (see also chapter 5.1.2.). In the dairy plants visited it was confirmed that the disposal of whey (category 2 and 3) was done in line with the requirements of Regulation (EC) No 1774/2002.

Conclusions

In establishments visited ABP were collected and identified correctly.

7 Overall Conclusion

Progress was noted since the last mission and the CA has addressed several of the recommendations of report DG(SANCO)/2009-8235. However, not all the recommendations of the previous mission have been properly implemented, in particular regarding the quality of training and supervision, HACCP and controls over microbiological testing. Despite the training provided and the supervision carried out the system failed to detect some important deficiencies in establishments noted by the FVO team, mainly related to significant shortcomings in structure of establishments, FBOs own check programmes or failure to take action when the bacteriological parameters indicated it.

All transitional establishments as regards structural requirements (meat, milk and their products) covered by Commission Decision 2007/716/EC have either been upgraded in line with Regulations

No (EC) 852/2004 and No (EC) 853/2004 or, if non-compliant been closed down.

The number of laboratories performing public health tasks in the laboratory network has been reduced from 28 to 11 laboratories (including both NRLs and regional laboratories) leading to an improvement in the overall performance of them. All 11 remaining laboratories are accredited.

Bulgaria is in the final phase of the transitional period for raw milk parameters. The SCC is in line with the requirements of Regulation (EC) No 853/2004/EC and the PC is currently set for 200 000 cfu/ml, to be in line with the EU requirements at the end of 2011 (100 000 cfu/ml). In the dairy establishments visited the respect of the raw milk requirements was assessed and was found in principle to be satisfactory and in line with the national plan based on Commission Decision 2009/861/EC.

8 Closing Meeting

A closing meeting was held on 17 December 2010 with representatives of the CCA. At this meeting, the FVO team presented the main findings and preliminary conclusions of the mission.

The representatives of the CCA acknowledged the findings and conclusions presented by the FVO team and they provided additional requested information and guarantees on action already taken and planned in order to address the shortcomings seen.

9 Recommendations

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this specific audit report.

N°.	**Recommendation**
1.	To prepare a national contingency plan for Trichinella outlining the action to be taken when samples test positive for Trichinella as required by Article 7 of Regulation No (EC) No 2075/2005.
2.	To continue the efforts to provide training to staff performing official controls and in particular to ensure that training provided is efficient and enables staff to undertake their duties competently as required by Article 6 of Regulation (EC) No 882/2004.
3.	To organise comparative testing at national level from the responsible NRLs to regional laboratories performing testing for Trichinella and criteria for raw milk in line with Article 33 of Regulation (EC) No 882/2004.
4.	To further develop instructions for staff performing official controls and to take the necessary steps in order to ensure uniform application in the regional veterinary services of the official controls in meat and milk establishments covering all relevant aspects of Regulation (EC) No 854/2004 as required by Article 8 (1) of Regulation (EC) No 882/2004.

N°.	Recommendation
5.	To take further measures to improve verification procedures in order to ensure the effectiveness of official controls in the RVS visited where significant deficiencies were detected by the FVO team in line with Article 8(3) of Regulation (EC) No 882/2004.
6.	To notify the Commission and other Member States of national measures and derogations as required by Article 10(5) of Regulation (EC) No 853/2004 and Article 7 of Regulation (EC) No 2074/2005.
7.	To take further measures to ensure that the FBOs comply with their obligations as laid down in Chapter II, Articles 3 to 6 of Regulation (EC) No 853/2004 and with the general and specific hygiene requirements set out in Article 4 of Regulation (EC) No 852/2004.
8.	To ensure that the FBOs sampling and microbiological analysis of carcasses is in line with the requirements set out in Articles 3 to 5 and 7 of Regulation (EC) No 2073/2005 and that the CA carries out official controls to verify the compliance in line with Article 4 (4) of Regulation (EC) No 854/2004.
9.	To ensure that the HACCP based systems in meat and milk establishments are in line with Article 5 of Regulation (EC) No 852/2004.
10.	To ensure that the post-mortem examination in bovines and pigs is carried out in compliance with Article 5 (1)(d) and Annex I, Section IV of Regulation (EC) No 854/2004.
11.	Urgently to improve the official controls on animal welfare of pigs during slaughter at the time of killing to ensure compliance with the stunning requirements set out in Council Directive 93/119/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2010-8513.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 91/68/EEC	OJ L 46, 19.2.1991, p. 19-36	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals
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. 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
Dec. 2007/716/EC	OJ L 289, 7.11.2007, p. 14-37	2007/716/EC: Commission Decision of 30 October 2007 laying down transitional measures for structural requirements of certain establishments in the meat and milk sectors in Bulgaria provided for in Regulations (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council
Dec. 2008/855/EC	OJ L 302, 13.11.2008, p. 19-25	2008/855/EC: Commission Decision of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States
Dec. 2009/861/EC	OJ L 314, 1.12.2009, p. 83-89	2009/861/EC: Commission Decision of 30 November 2009 on transitional measures under Regulation (EC) No 853/2004 of the European Parliament and of the Council as regard the processing of non-compliant raw milk in certain milk processing establishments in Bulgaria
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

Legal Reference	Official Journal	Title
		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. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
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
Reg. 1/2005	OJ L 3, 5.1.2005, p.	Council Regulation (EC) No 1/2005 of 22

Legal Reference	Official Journal	Title
	1-44	December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
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