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Directorate F - Food and Veterinary Office

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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

BULGARIA

FROM 04 TO 12 MARCH 2010

IN ORDER TO EVALUATE THE FOOD SAFETY CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF POULTRY MEAT AND POULTRY MEAT PRODUCTS

IN THE CONTEXT OF A GENERAL AUDIT

Executive Summary

This report describes the outcome of a Food and Veterinary Office specific audit in Bulgaria, which took place from 4 to12 March 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.

This specific audit covered the Bulgarian food safety control system covering the poultry meat and poultry meat products sector.

The report concludes that there is a comprehensive and well documented system of official controls of poultry meat and poultry meat products, however it is not fully implemented. Although, training programmes and verification procedures are in place and documented, the effectiveness of official controls is compromised by the fact that some major deficiencies regarding sanitary conditions and post-mortem inspection found in two out of the five establishments visited by the audit team during this audit, had not been detected by any level of competent authority supervision. The results of proficiency tests and some routine tests in one official laboratory raise some concern on the reliability of Salmonella testing. Current procedures for the notification of laboratory analyses result do not allow the food business operator to adopt prompt measures in cases of non-compliant results.

The report makes a number of recommendations to the Bulgarian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AHFSD	Animal Health and Food Safety Directorate
AMI	Ante-mortem Inspection
AT	Audit Team
AV	Approved Veterinarian
CA	Competent Authority
CCA	Central Competent Authority
CP	Cutting Plant
CRL	Community Reference Laboratory
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
GA	General Audit
GDCVA	General Directorate for the Controls on Veterinary Activity
GHP	Good Hygiene Practices
HACCP	Hazard Analysis Critical Control Points
MAF	Ministry of Agriculture and Food
MANCP	Multi-Annual National Control Plan
MS	Member State
NCCC	National Council for Co-ordination of Controls
NDRVI	National Diagnostic and Research Veterinary Institute
NRCFS	National Reference Centre of Food Safety
NRL	National Reference Laboratory
NVS	National Veterinary Service
OA	Official Auxiliary
OV	Official Veterinarian
PH	Public Health Department
PHD	Public Health Directorate
PM	Poultry Meat
PMI	Post-mortem Inspection
PMP	Poultry Meat Products
PT	Proficiency Testing

RASFF	Rapid Alert System for Food and Feed
RVS	Regional Veterinary Service
SA	Specific Audit
SH	Slaughterhouse
SOP	Standard Operating Procedure

1 Introduction

The specific audit formed part of the Food and Veterinary Office's (FVO) planned mission programme. It took place in Bulgaria from 4 to 12 March 2010. The audit team (AT) was comprised of two inspectors from the FVO and one national expert from a Member State. Representatives from the central competent authority (CCA) accompanied the AT for the duration of the audit. An opening meeting was held on 4 March 2010 with the CCA. At this meeting, the objectives of, and itinerary for the specific audit were confirmed by the AT and the control systems were presented by the Bulgarian authorities.

2 Objectives Of The Mission

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

- verify that official controls of poultry, poultry meat (PM) and poultry meat products (PMP) are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the national multi-annual control plan (MANCP) prepared by Bulgaria.
- evaluate the food safety control system in place governing the production and placing on the market of PM and PMP.

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

- As regards Regulation (EC) No 882/2004, the organisation of official controls (Art. 3-7,) control and verification procedures and methods (Art. 8-10), enforcement (Art. 54-55), and MANCP (Art. 41-42);
- As regards the specific area under review and in the framework of Regulations (EC) Nos 178/2002, 852/2004, 853/2004 and 854/2004, the controls over PM and PMP.

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

MEETINGS/VISITS		**n**	**COMMENTS**
COMPETENT AUTHORITIES	**Central**	**2**	Opening and closing meeting (National Veterinary Service)
	Regional	**4**	Regional Veterinary Services (RVS)
LABORATORIES		**1**	National Reference Laboratory (NRL)
FARMS		**1**	Broiler farm
SLAUGHTERHOUSES (SHs)		**3**	In one of them only a documentary check was carried out
OTHER ESTABLISHMENTS		**5**	4 cutting and meat products establishments (3 of them integrated in SHs) and 1 independent cold store

3 Legal Basis for the Mission

The mission 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 multi-national control plans 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 poultry sector specific issues.

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

- The NVS under the Ministry of Agriculture and Food (MAF) is the designated competent authority (CA) responsible to carry out official controls of PM and PMP. The NVS has a pyramidal structure with a direct line of command between central and regional level. The NVS has 28 RVSs.
- The Public Health Directorate (PHD) of the NVS and Public Health Departments (PH) of the RVSs are responsible for the organisation of official controls within the scope of this specific audit.
- A more detailed description of the CA can be found in the country profile for Bulgaria on the following website: http://ec.europa.eu/food/fvo/country_profiles_en.cfm .

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 competent authorities.

Findings

- The National Council for Co-ordination of Controls (NCCC) has been established. Its main function is the co-ordination and planning of control activities at all stages of the food chain

and the exchange of information between the different CAs involved. Regular monthly meetings were envisaged, however, the first and only meeting so far was held in October 2008. The AT was informed by a representative of the MAF that this co-ordination function is currently exercised by the Animal Health and Food Safety Directorate (AHFSD) of the MAF (especially concerning MANCP).

- In the regions visited it was explained by the CA that in emergency situations co-ordination is ensured through the Regional Emergency Council which is headed by the regional governor. In emergency situations the procedures to be followed are laid down in the contingency plan. (General Crisis Management Plan; see section 5.1.5 below).

5.1.3 Co-operation within Competent Authorities

Legal Requirements

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, 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

- There is continuous co-operation between the central office of the NVS and the RVSs. This is done by written correspondence (letters, circulars, faxes and e-mails) and by phone in urgent matters.
- There are regular meetings organised by the CCA for the regional services. The AT saw evidence that these meetings took place. However, the AT was informed by the CCA that due to budgetary constraints the frequency of such meetings has been reduced since 2009.
- A system of reporting between NVS and RVSs is in place (see also section 5.5.1).

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 competent authority must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Findings

- The NVS has not delegated any specific tasks to any control body that carries out audits and controls on poultry establishments.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities 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

- There is no specific contingency plan required under Community legislation in the field of PM/PMP. However, the AT was informed by the CA that a general crisis management plan is in place to address situations involving direct or indirect risks to human health deriving from food and feed as required by Regulation (EC) No 178/2002.

Conclusions on Competent Authorities

The NVS is clearly designated as the CA to perform official controls within the scope of this specific audit. The CA has procedures in place to ensure co-ordination and co-operation.

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 to undergo inspection by the competent authorities. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

Findings

- The Veterinary Activity Law and the Food Law provide the CA with the necessary legal powers to carry out official controls, including the powers of access to food business premises and documentation. There is an obligation on food business operators (FBOs) to submit to inspection by the CA.

5.2.2 Staffing provision and facilities

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority 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

- The AT was informed by the CA that in 2009 staffing levels were reduced by at least 10 percent due to budgetary cuts. Nevertheless, as the CCA informed the AT it had no significant impact on the official controls carried out in the PM/PMP sector. It had originally been planned for the CA to audit once per year the HACCP system in every meat production establishment, including slaughterhouses, however, in two out of the four regional CA offices visited the AT was informed that the planned number of poultry sector audits of Hazard Analysis and Critical Control Points (HACCP) systems and Good Hygiene Practices (GHP) was not fully achieved in 2009 as the resources had been focused on the

approval of establishments under the provisions of Commission Decision 2007/716/EC.

- There were appropriate facilities and equipment available to CA staff in all offices and establishments visited by the AT.
- The law on conflict of interest and the law on the civil service sets obligations for public officials as regards independence and involvement in other activities. Each public official has to sign annually the declaration that he/she has no conflict of interest in relation to assets held and income received.
- No situation that could likely result in a conflict of interest was noted during the audit.

5.2.3 Staff qualifications and training

Legal Requirements

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

Findings

- An annual training programme is drawn up by the NVS Directorate "Science, Laboratory Control and Training" for NVS and RVSs employees taking into account different aspects e.g. conclusions of previous FVO missions, recommendations of audits carried out by central level of NVS or by MAF, proposals from RVSs, etc.
- The AT saw evidence that several training sessions were held for the different levels of official control i.e. NVS, RVS and OV at municipal level.
- Several CA staff had participated in seminars and workshops organised by the European Commission (e.g. "Better training for safer food") and by other institutions.
- The AT was informed by the CCA that the available budget for training purposes has been significantly reduced and consequently, compared to 2008, they had less training courses in 2009 and planned less training sessions in 2010.
- Some major deficiencies noted by the AT in establishments in relation to their structure and operations had not been previously reported by the official supervision in establishment by in-house OVs or by regular RVS control visits. The CA in one region put this lapse down to inadequate training in one case (see Section 6.3).

Conclusions on Resources for Performance of Controls

The AT noted that the CAs has appropriate facilities and equipment to carry out official controls.

A training system for officials is in place at both central and regional levels, although training sessions are being reduced. However, training has not been effective since some major deficiencies in establishments, noted by the AT, had not been detected by any level of CA.

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.

Findings

- Articles 135-137 of the Veterinary Activity Law, Ordinance No 44 of the MAF and Ordinance No 7 of the Ministry of Health provide the legal basis for the registration of commercial broiler farms. Registration procedure involves on-site visit(s) of the CA. If the farm operator complies with all requirements, the RVS director issues the registration document. The register of broiler farms is publicly available on the NVS website.
- Article 12(2) of the Food Law provides the legal basis for approval of food businesses (including PM/PMP establishments). According to the procedures in place FBOs have to obtain a preliminary approval of technical documents/ drawings related to structures and processes of the proposed operations from the RVS Director. When construction works are completed, a regional commission appointed by the RVS Director performs an on-site visit in the establishment. The establishment concerned must be in operation and fully in compliance with all the infrastructure and equipment requirements during this inspection visit. HACCP plan and GHP must be available but may not be fully in compliance. As a result of the on-site visit a conditional approval may be granted to the FBO. The period of conditional approval cannot exceed six months. The AT was informed by the CA that during the period of conditional approval stricter official supervision is exercised over the establishment by the RVS which includes sampling for laboratory analyses. If the establishment meets all of the relevant requirements full approval will be granted.
- The AT noted that in the establishments visited the approval was correctly granted and the approval procedures were adequately followed.
- A special approval procedure (details can be found in the country profile for Bulgaria) was used for those establishments which were under the provisions of Commission Decision 2007/716/EC. The AT was informed by the CCA that in total 147 establishments handling PM (83 only PM; 64 PM and red meat) were approved under this special procedure by 31 December 2009.

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 Community, imports into the Community and to product placed on the Community market.

Findings:

- By NVS Director General 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 put in place a new risk assessment system to classify food-businesses into risk groups. The minimum frequency of inspections (once per week; twice per month; once per month) depends on the risk group (High, Medium, Low) into which the establishment falls. It takes into account twelve risk

elements: e.g. establishments' structure and equipment, capacity, type of product produced, raw materials, reliability of own control systems, past records of non-compliance, etc.

- The AT noted that this risk assessment instruction was followed in all establishments visited and that the number of documented inspection visits usually exceeded the required frequency.
- Although some major deficiencies were noted by the AT in an establishment in relation to its structure and operation, the establishment concerned had been evaluated as low risk concerning structures and maintenance when the CA carried out its risk assessment (see Section 6.3).
- The AT was informed by the CA that there is no minimum frequency (e.g. once per year) determined in the instructions for updating the risk categorisation of an establishment. A risk assessment can be updated whenever needed.
- The AT noted that a full audit of FBOs' HACCP and GHP systems is carried out by a team of inspectors at least once per year. However in 2009, this frequency was not achieved in the poultry sector in two of the four regions visited (see section 5.2.2).
- The AT was informed that routine inspection visits are unannounced while audits are carried out with advance notice.

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 AT found that NVS had carried out official controls throughout the food chain "from farm to fork" in the poultry 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 competent authorities 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 competent authority 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 National Diagnostic and Research Veterinary Institute (NDRVI) in Sofia provides laboratory support to the NVS. It has two National Reference Centres:

National Reference Centre of Food Safety (NRCFS) - containing five NRLs, covering the most important food-borne pathogens, including *Listeria* and *Salmonella*, marine biotoxins and water

content in PM and the National Reference Centre for Animal Diseases.

The CCA informed the AT that samples for official controls are sent for testing exclusively at laboratories that are accredited.

- The AT visited the NRCFS which is accredited in accordance with EN ISO/IEC 17025:2006 by the Bulgarian Accreditation Service.
- The NRL visited participated regularly in proficiency testing (PT) organised by the Community Reference Laboratories (CRLs) with adequate results.
- Only two PTs (neither of them on poultry meat matrix) have been organised during the last two years (2008/2009) by the NRL for the regional official laboratories (30 laboratories at that time). Five of 30 regional laboratories failed in the recent (2009) PT for *Salmonella* detection and most of the rest also had poor performance. According to the NRL no repeat tests were done due to financial constraints and no follow-up training or meetings were organised by the NRL for the regional laboratories to examine the reasons for the non-compliance and improve their performance. This practise is not in line with Point 2(c) of Article 33 of Regulation (EC) No 882/2004.
- The NRL visited had qualified staff. The AT was provided with documentary evidence that NRL staff regularly participate in training (including training organised by CRLs).
- Currently there are 24 accredited Regional Veterinary Laboratories under the umbrella of the RVS carrying out analyses of samples taken during official control and FBOs' own-check samples. No audits or supervisory visits have been carried out by the NRL on these RVS laboratories.
- The AT was informed and noted on several occasions that when testing for *Salmonella* and *E.coli* the analytical reference methods as laid down in Regulation (EC) No 2073/2005 were used. The AT noted in one establishment visited that the *Salmonella* analyses were completed within two days. A representative of the laboratory claimed that the method used was the reference method (EN ISO 6579) however, the incubation time of the media had been reduced at her own initiative. This amended method had not been validated against the reference method as required by Point 5 of Article 5 of Regulation (EC) No 2073/2005.
- The AT was informed that FBOs may, when appropriate, ask for a supplementary sample for analyses (provided by Ordinance No 22 of the Ministry of Health) and this sample may be sent to a different accredited laboratory. The supplementary sample is taken at the same time as the official sample and sealed by the Official Veterinarian (OV). The documentation accompanying the official sample to the laboratory always indicates when a supplementary sample has been taken for analysis. This documentation (protocol) is signed both by the OV and by the FBO.

5.3.5 Procedures for performance and reporting of control activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities 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 competent authorities 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 AT noted that there are various instructions, checklists, questionnaires, templates used during official controls. Some of them were provided by the CCA and some of them were drafted by the RVSs.
- 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 control, 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 competent authorities 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 AT was informed by the CA that some information is publicly available on the CA's website: e.g. annual audit plan, audit procedures, list of establishments, registered poultry farms, legislation, Rapid Alert System for Food and Feed (RASFF) notifications if applicable, etc.
- The AT was informed in one of the RVS visited that they have weekly meetings with the local media to provide updated information on RVS activities including food safety.
- Provisions regarding professional secrecy and personal data protection are contained in Article 29 of the Food Law.

Conclusions on Organisation and Implementation of Official Controls

There is a comprehensive, risk based and well documented system of official controls covering the sector. However, there are some deficiencies in its implementation related to the risk assessment of establishments' structure and maintenance.

The NRL does not fulfil all the functions set out in Article 33 of Regulation (EC) No 882/2004 in organising the work of the 24 RVS laboratories in that the results of PTs were not followed up. Furthermore some routine tests (using an erroneously implemented ISO 6579 method) in one official laboratory raise a concern as regards the reliability of *Salmonella* testing.

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 competent authority which identifies a non-

compliance to take appropriate action to ensure that the operator remedies the situation.

Findings

- The AT was informed that apart from the provisions contained in Regulation (EC) No 882/2004, the Food Law and the Veterinary Activity Law provide the legal bases for the CA to take enforcement measures in case of non-compliances.
- The AT was informed by the CCA that 259,147 official checks were performed in the sector of food of animal origin by the CA in 2009 which resulted in about 19,000 enforcement orders ("prescriptions").
- Documentary evidence was seen by the AT of requests for corrective actions, with deadlines established, and of inspection visits for verification of implementation of corrective action.

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 Community 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 Food Law and the Veterinary Activity Law provide the legal bases for the CA to impose fines in case of non-compliances.
- The AT was informed by the CA that a fine can range from 250 to 70,000 Bulgarian Levas (from approximately 125 to 35,000 EURO).
- Fines are proposed by the OVs but are imposed by the RVS Director.
- The AT saw evidence that fines were imposed by the RVS director.

Conclusions on Enforcement Measures

There is a system in place for applying enforcement measures and fines in case of non-compliances and the CA exercised its powers both in relation to enforcement orders and fines.

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 competent authorities 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 AT was informed that OV's performance is reviewed by the RVS Head of the PH once a year and by the Head of the PH Sector twice a year. The AT noted that this review covers mainly the implementation of annual control plan.
- In spite of the fact that the performance of the inspectors was evaluated by the RVS, major deficiencies (structural, maintenance, operational hygiene, post-mortem inspection) found by the AT during establishment visits, had not been detected by this review process.
- There is a reporting system in place between the RVSs and the PHD at NVS headquarters. The AT was informed that there are seven different types of report dealing with public health official controls which are transmitted by RVSs to NVS PHD on a regular basis (weekly, monthly, quarterly, etc.). The AT was informed that these reports are analysed by the PHD and feedback to RVSs is provided where needed.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 competent authorities 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 the Controls on Veterinary Activity (GDCVA) is responsible for carrying out audits within NVS.
- The AT was informed that nine RVSs were audited in 2009 and 14 disciplinary actions involving 23 officials were carried out. Ten audits are planned for 2010 by GDCVA.
- AHFSD of the MAF is responsible for carrying out audits in services under the umbrella of MAF including the NVS.
- According to the information received from AHFSD six audits were carried out in the RVSs in 2009 and a further six are planned for 2010 (out of the total 13 planned audits).
- No audits have been carried out so far specifically targeting official controls related to PM/PMP.

Conclusions on Verification Procedures

There is a well documented system in place which covers all the relevant checks required under Community law. However not all major deficiencies had been noted by the various CA levels.

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 multi-annual national control plan (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 MANCP 2008–2010, (version SMANCP BG 16.10.2008.doc. rev.2) contains a description of the control system for food of animal origin in general but with no specific reference to controls of PM/PMP establishments. However, the frequency of controls in establishments described in the MANCP is not the one currently being used as the risk assessment system classifying establishments into risk groups was amended after this version of the MANCP was issued.

Conclusions on Multi-Annual National Control Plan

The MANCP, drafted in accordance with the provisions of Article 41 of Regulation (EC) No 882/2004. There is no specific reference in the MANCP to the implementation of official controls in the PM/PMP sector. The MANCP requires updating in order to be in line with current practices as regards risk assessment.

6 Sector Specific findings and conclusions

6.1 Controls at farm level

Legal Requirements

Annex I to Regulation (EC) No 852/2004.

Findings

- The broiler farm visited was appropriately registered (see section 5.3.1 for registration procedure).
- Inspection visits are carried out by the OV (municipality level) at least four times per year and by the RVS at least once per year. The OV's visits include sampling for *Salmonella* analysis when need be. A comprehensive checklist, issued by the General Director of the NVS, has been in use for official controls since May 2009. The checklist covers a broad range of issues including inter alia biosecurity measures, farm management, feed and water supply, cleaning and disinfection, record keeping, sampling for *Salmonella* analysis.
- The approved veterinarian (AV) is responsible for the health status of the animals, implementing national prevention programmes, own-check *Salmonella* sampling, keeping records of the treatments (i.e. veterinary medicinal products used), signing and issuing documents accompanying the birds when they are sent to the SH.
- In the broiler farm visited the AT noted that official controls and own-checks were adequately documented.

Conclusions

Broiler farms are adequately registered and under regular official supervision in accordance with Regulation (EC) No 852/2004.

6.2 Controls in slaughterhouses: Ante-mortem and post-mortem inspection

Legal Requirements

Annex II to Regulation (EC) No 852/2004. Section II of the Annex III to Regulation (EC) 853/2004. Regulation (EC) No 854/2004 Chapter V of Section IV of Annex I.

Findings

- In the SHs visited the AT noted that ante-mortem inspection (AMI) was carried out by OVs. This includes checks on the documents accompanying the birds when they arrive. There are three types of documents which accompany poultry to the SH: (1) food chain information; (2) veterinary certificate which certifies that the birds were examined by the AV and found fit for transport; (3) the declaration on medical treatment of the birds. All three documents are issued and signed by the AV. In a broiler SH visited the AT noted that the results of *Salmonella* tests performed on the flock were always included in the veterinary certificate. The AT was informed by the CA that the test results are usually communicated to the SH one week prior to the arrival of the birds. According to the OV, in the broiler SH visited, they have never slaughtered a broiler flock testing positive for *Salmonella*.
- The AT noted that in SHs visited AMI was well documented and the records were available for inspection.
- In a duck SH visited the AT noted that the space for the reception of the animals and for the AMI was not covered as required by paragraph 1, Chapter II, Section II of Annex III to Regulation (EC) No 853/2004. This deficiency had not been noted in the official reports.
- In all SHs visited the AT noted that the post-mortem inspection (PMI) was carried out by OVs and in one case the OV was assisted by an official auxiliary (OA). The AT saw evidence that the OA had adequate qualifications and training to carry out PMI on poultry. The AT was informed by the CCA that there are only 10 OAs in Bulgarian SHs (including red meat ones).
- In a broiler SH visited the AT noted on several occasions that carcases were not properly presented for PMI (i.e. they had not been fully eviscerated). This evisceration task was completed by the OA preventing her from carrying out adequate PMI on the other birds. Moreover, the AT observed, that while the OA was removing intestines, spillage of digestive tract on to the carcase and on the OA's hands occurred. In the absence of hand washing facilities in close proximity to the PMI site, the OA became a source of contamination by handling further carcases during their inspection. This is not in line with paragraph 4, Chapter II, Section II of Annex III and paragraph 6, Chapter IV, Section II of Annex III to Regulation (EC) No 853/2004) and paragraphs 1 and 4 of part D, Chapter II, Section I of Annex I to Regulation (EC) No 854/2004.
- The AT noted that in the same broiler SH, poultry carcases were washed after evisceration, before the PMI, preventing the OV or the OA from assessing properly possible faecal contamination (paragraph 5, Chapter IV, Section II of Annex III to Regulation (EC) No 853/2004). In the absence of a specific control to verify adherence to the provisions of the aforementioned paragraph, the PMI becomes the only point in the process where the possible contamination can be assessed. The practise of washing and/or rinsing makes that assessment impossible.
- The AT noted in a duck SH visited that during PMI not all the offal of the birds was

inspected by the OV because in some cases, the offal did not accompany the birds to PMI. This is not in line with paragraph 1, part D, Chapter II, Section I of Annex I to Regulation (EC) No 854/2004.

- The AT noted in all SHs visited that PMI was documented and the records were available.

Conclusions

AMI and PMI were well documented. However, several deficiencies concerning PMI were identified in the SHs visited.

6.3 Controls in other establishments (cutting plants, cold stores, PMP establishments)

Legal Requirements

Annex II to Regulation (EC) No 852/2004; Chapter III of Section II of the Annex III to Regulation (EC) 853/2004; Section VI of Regulation (EC) 853/2004;

Findings

There is a comprehensive, regular and well documented system of official controls of poultry establishments which includes thematic inspection visits, HACCP and GHP audits, sampling of products, water and surfaces for laboratory analyses. The AT saw evidence in all establishment visited that these checks were performed.

Five establishments were visited by the AT: three integrated establishments which included SH, cutting plant (CP) and meat processing units; one standalone CP with meat processing unit and one standalone cold store.

- All establishments visited had HACCP based procedures in place and relevant records were kept.
- The AT noted that comprehensive HACCP audits were carried out in all establishments visited at least once in 2010 by a team of experts from the RVS (see also Section 5.2.2). A specific CA drafted checklist is used for this purpose.

Three out of the five establishment visited were generally compliant with Community requirements. However the AT found major deficiencies in one of the integrated establishments visited. e.g.:

- Surfaces (floors, walls and equipment) were not maintained in a sound condition and were not easy to clean and disinfect in contravention of paragraph 1 (a), (b), (f) Chapter II of Annex II to Regulation (EC) No 852/2004;
- Premises were not protected against the formation of condensation in contravention of paragraph 2(b), Chapter I of Annex II to Regulation (EC) No 852/2004; Condensation was observed by the AT in some instances above exposed products.
- Crates used for storing fresh meat were not properly washed in some instances in contravention of paragraph 1(a), Chapter V of Annex II to Regulation (EC) No 852/2004;
- The AT observed splashing of water when hearts were washed on the evisceration line posing a risk to contaminate hearts and duck carcasses which is not in line with Point 3, Chapter IX, Annex II to Regulation (EC) No 852/2004;
- Packaging materials (cardboard boxes) were stored in a building outside of the main

premises of the establishment and were not protected from contamination. The AT also noted that in another building used for storing glass jars for final product, the storage conditions were not in compliance with Community requirements (floor was not clean and was made of material which is not possible to clean and disinfect; the building was not pestproof; in several instances the protective packaging of the jars was broken). These are not in line with the provisions of Chapter X of Annex II to Regulation (EC) No 852/2004;

- The AT also noted several non-compliances related to GHPs (unsanitary delivery conditions of cardboard boxes to the packing room from the outside storage area; wrapping and packing of exposed meat at the same place; use of scales with dirty surface in contact with exposed products; carcases touching the curtain at the door of the carcase chiller when they are unloaded; accumulation of ice in the freezer containing packed product and in some cases on the product). These are not in line with the provisions of paragraph 3 Chapter IX of Annex II to Regulation (EC) No 852/2004.

The majority of the non-compliances found by the AT in this establishment (apart from storage of cardboard boxes and condensation in the cooking room) had not been noted by the OV in the inspection reports nor during the HACCP/GHP audit carried out by the RVS. Although the AT pointed out these deficiencies during the establishment visit, the OV involved who, until recently had worked in the area of animal by-products, was not fully trained in poultry matters and did not regard them as non-compliances.

The AT noted some deficiencies in the cold store visited:

- Missing hand-washing facilities near the toilets in contravention of paragraph 4, Chapter I of Annex II to Regulation (EC) No 852/2004;
- Product storing and handling practices do not prevent products from contamination (damaged wrapping/packaging exposing products to contamination) not in line with paragraph 3, Chapter IX of Annex II to Regulation (EC) No 852/2004;
- During the visit to the cold store neither the AT nor the OV were requested by the FBO to wear protective clothing in contravention of paragraph 2, Chapter IX of Annex II to Regulation (EC) No 852/2004.

Although, several inspection visits and a HACCP/GHP audit had been carried out by the CA, these deficiencies had not been detected and nor recorded in the official reports.

Traceability systems were in place in all establishments visited and subject to official controls.

Conclusions

There is a comprehensive and well documented system of official controls of PM/PMP establishments in place. Despite the fact that premises visited by the AT presented in general a good level of compliance with Community requirements, some major deficiencies had not previously been recognised and not addressed in the official reports by the CA and therefore had not been corrected by FBOs.

6.4 Official sampling

Legal Requirements

Point 8 (c) of Article 4 of Regulation (EC) No 854/2004.

Findings

Based on the instructions of the NVS on implementation of the MANCP for raw materials and foodstuffs of animal origin, RVS draws up an annual sampling programme. This programme includes:

- Sampling and testing for the food safety and process hygiene criteria, in accordance with Regulation (EC) No 2073/2005, in each establishment, once a month, selected from one group of products for one criterion.
- Swab samples from food contact surfaces (posing high risk) for verifying the effectiveness of FBOs' cleaning and disinfection procedures in accordance with Ordinance No 5 (25.05.2006) once a month.
- Sampling and testing for microbiological criteria of the quality of potable water in accordance with requirements of Ordinance No 9 (16.03.2001) once a year. The Ordinance transposes the requirements of Council Directive 98/83/EC.

According to the data provided by the CA in 2008 out of 16,573 PM/PMP samples 84 tested positive for *Salmonella* and out of 1467 samples 9 tested positive for *Listeria*.

The CA explained that laboratory monitoring of food additives is carried out by the Ministry of Health mainly in wholesale establishments. Nevertheless, the AT saw evidence in one processing establishment visited that an official sample had been taken from PMP and analysed for phosphates with satisfactory results.

The AT noted that in each RVS office and establishment visited the official sampling programmes were available and followed by the CA. The samples were analysed in accredited laboratories.

Conclusions

The system in place for the monitoring of the microbiological criteria by the CA complies with the provisions of Regulation (EC) No 2073/2005.

Potable water is tested by the CA in compliance with the requirements of Directive 98/83/EC.

6.5 Own-checks sampling

Legal Requirements

Article 4 of Regulation (EC) No 2073/2005.

Findings

- The AT noted that each establishment visited had an annual sampling programme for laboratory analyses including products, water and surfaces.
- The AT noted that the FBOs' sampling programmes are broken down into monthly schedules and were fully implemented in all establishments visited. The samples were analysed in accredited laboratories (in the RVS laboratories or in one case in an accredited private laboratory).
- The AT noted that although it is not a Community requirement, neck skin samples are also taken and analysed for *Salmonella* in duck SHs in accordance with the provisions laid down in Regulation (EC) No 2073/2005 for broilers and turkeys. In all SHs visited the frequency

for sampling was reduced to fortnightly (from weekly) with the permission of the CA because no positive results for *Salmonella* had been obtained over 30 consecutive weeks. This is in line with Regulation (EC) No 2073/2005.

- The AT also noted that PM preparations were sampled and analysed for *Salmonella* (in 25 g) and *E. coli* in compliance with Community requirements. However, the AT reviewed a case when *Salmonella* was detected in a PM preparation and noted that it took ten days for the FBO and for the RVS to receive the positive results of the this laboratory analysis. Although the FBO initiated immediate action to recall the product after the positive results had been received, the product concerned was neither available in the FBO's premises nor at retail level any more. The CA explained that according to the procedures in place, all *Salmonella* spp. isolated in a RVS laboratory shall be submitted to NRL for confirmation and serotyping (despite the fact that RVS laboratories are accredited and use the reference method). The results are only made available to the CA and to the FBO once confirmatory analysis has been completed by the NRL. In case of positive results this procedure may cause unnecessary delays for the FBO in taking prompt action (including recall of products). This is neither in compliance with Article 3 (1) of Regulation (EC) No 2073/2075 nor with Article 19 (1) of Regulation (EC) No 178/2002.
- Each establishment visited had a water sampling plan which included analyses for microbiological and chemical parameters and in some cases radiology.

Conclusions

The FBO own-check samples of PM and PMP are taken and analysed in compliance with Regulation (EC) No 2073/2005. However, current procedure of laboratory analyses result notification does not allow the FBO to adopt prompt measures in case of non-compliant results.

Potable water is tested by the FBOs in compliance with the requirements of Directive 98/83/EC.

6.6 RASFF

Legal Requirements

Article 50 of the Regulation (EC) No 178/2002.

Findings

There has been no RASFF notifications linked to PM or PMP from Bulgaria in the past three years.

7 Overall Conclusion

There is a comprehensive and well documented system of official controls of PM and PMP, however it is not fully implemented. Although, training programmes and verification procedures are in place and documented, the effectiveness of official controls is compromised by the fact that some major deficiencies regarding sanitary conditions and PMI found in two out of the five establishments visited by the AT during this audit, had not been detected by any level of CA supervision.

The results of PTs and some routine tests of one official laboratory raise some concern on the reliability of *Salmonella* testing. Current procedures for the notification of laboratory analyses result do not allow the FBO to adopt prompt measures in case of non-compliant results.

8 Closing Meeting

A closing meeting was held on 12 March 2010 with representatives of the CCA. At this meeting, the AT presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take whatever actions were necessary in order to correct all deficiencies presented by the AT.

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.	The CA should ensure that adequate training is provided to official inspectors to ensure competency in the identification of all non-compliances during inspections of establishments thereby improving the effectiveness of official controls as required in Article 4.2(a) of Regulation (EC) No 882/2004.
2.	The CA should ensure that all laboratories involved in the official analyses of PM and PMP regularly participate in PTs coordinated by the NRL and that the results of these PTs are adequately followed-up by the NRL in accordance with Article 33 of Regulation (EC) No 882/2004.
3.	The CA should ensure that the analytical method used for Salmonella analyses is the reference method in conformity with Article 5 (1) of Regulation (EC) No 2073/2005 or if an alternative method is to be used it should be validated against the reference method in accordance with Article 5 (5) of the same Regulation.
4.	The CA should take measures to improve verification procedures in order to ensure that the lack of effectiveness of the official controls, noted by the AT in establishments, are also detected by those verification procedures, as required by Article 8 of Regulation (EC) No 882/2004.
5.	The CA should ensure that the MANCP is regularly updated in the light of the evolution of the control systems involved in accordance with Article 42.1(b) of Regulation (EC) No 882/2004
6.	The CA should ensure that OVs carry out PMI in SHs in conformity with paragraphs 1 and 4 of part D, Chapter II, Section I of Annex I to Regulation (EC) No 854/2004 and with paragraph 5 and 6, Chapter IV, Section II of Annex III to Regulation (EC) No 853/2004.
7.	In order to comply with the requirements of Annex II to Regulation (EC) No 852/2004

N°.	Recommendation
	and Annex III to Regulation (EC) No 853/2004, the CA should ensure that the deficiencies found by the AT are corrected in the establishments visited and are not present in other approved ones.
8.	The CA should ensure that FBOs are immediately notified of the non-compliant results of laboratory analyses to enable them to take immediate measures in accordance with Article 3 (1) of Regulation (EC) No 2073/2075 and with Article 19 (1) of Regulation (EC) No 178/2002.

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2010-8456.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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
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
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. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives