FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BULGARIA

FROM 03 TO 07 JUNE 2013

IN ORDER TO EVALUATE THE SYSTEMS PUT IN PLACE TO GIVE EFFECT TO THE PROVISIONS OF ART. 8(3) OF REGULATION 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Bulgaria from 3 to 7 June 2013. The objective of the audit was to evaluate the systems put in place to implement article 8(3) 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.

The scope of the audit covered the procedures put in place by the Bulgarian Food Safety Agency which is the competent authority (CA) and responsible for the majority of official controls falling under Regulation (EC) No 882/2004.

The report concludes that the CA has procedures in place for the purposes of verification of effectiveness of official controls, as required by Article 8(3) of Regulation (EC) No 882/2004. These procedures cover qualitative and quantitative assessments and were largely implemented at central and regional levels. Various feedback mechanisms are in place within CA that are mostly used to adjust the annual plans and support the system for verification and management decision making.

However, the verification of effectiveness is undermined by several factors. The CA does not have measurable targets and/or indicators in order to measure the processes and compare the results against the expected results and to ascertain differences. The unavailability of quantitative assessments of official control programmes in certain sectors and lack of analyses, establishment of trends as regards official controls of the past years, for further input into the planning process, creates difficulties for the CA in exploiting available control data. No IT tools are developed to facilitate such assessments.

In most cases the CA demonstrated its ability to take corrective actions when shortcomings were identified. There are examples of good practice, in particular the feed sector, where regular, comprehensive overview reports are prepared for CA management, and the outcome of supervision visits results in corrective measures at the national level. The corrective measures taken at central level in most other sectors resulted only in limited instances in the development/modification of control procedures and/or other means of improvements. The effectiveness of verification system is also affected by limited communication of identified or potential shortcomings in official control procedures, thus affecting appropriate corrective actions.

Various other instruments, such as internal audits, "complex checks", and supervisory controls by individual Directorates, reinforce the verification of effectiveness of official controls. These three internal control instruments were mostly implemented as planned. There is, however, a potential overlap of effort concerning these internal control activities at central level, as these controls have similar objectives and all of them include on-the-spot components.

The report makes a number of recommendations to the Bulgarian authorities aimed at rectifying the identified shortcomings, and enhancing the verification measures in place.
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<td>AHWD</td>
<td>Animal Health and Welfare Directorate</td>
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<td>APV</td>
<td>Authorised private veterinarian</td>
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<tr>
<td>BCD</td>
<td>Border Control Directorate</td>
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<td>BFSA</td>
<td>Bulgarian Food Safety Agency</td>
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<td>CA</td>
<td>Competent Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<td>CCD</td>
<td>Co-ordination and control Directorate</td>
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<tr>
<td>DG SANCO</td>
<td>Directorate General for Health and Consumer Protection</td>
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<tr>
<td>DPE</td>
<td>Designated Points of Entry</td>
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<td>EC</td>
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<td>EU</td>
<td>European Union</td>
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<td>FBO</td>
<td>Food Business Operator</td>
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<td>FeCD</td>
<td>Feed Control Directorate</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<tr>
<td>HACCP</td>
<td>Hazard Analysis Critical Control Point</td>
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<td>LAD</td>
<td>Laboratory Activities Directorate</td>
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<td>MAF</td>
<td>Ministry of Agriculture and Food</td>
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<tr>
<td>MANCP</td>
<td>Multi-Annual National Control Plan</td>
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<td>MS</td>
<td>Member States</td>
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<td>OMV</td>
<td>Official Municipal Veterinary</td>
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<td>QMD</td>
<td>Quality management Directorate</td>
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<td>RFSD</td>
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<td>SA</td>
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<tr>
<td>TQD</td>
<td>Training and Qualifications Directorate</td>
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<tr>
<td>VETIS</td>
<td>Veterinary information system</td>
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<td>VMPCD</td>
<td>Veterinary Medicines Products Control Directorate</td>
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1 INTRODUCTION

This audit took place in Bulgaria from 3 to 7 June 2013, as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two officials from the FVO.

The audit team was accompanied throughout the audit by representatives from the Central Competent Authority (CCA).

An opening meeting was held with the CCA on 3 June 2013 at Bulgarian Food Safety Agency (BFSA) headquarters in Sofia, at which the audit team confirmed the objective of and itinerary for the audit.

2 OBJECTIVES

The objective of the audit was to evaluate the systems put in place to implement article 8(3), on control and verification procedures, 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\[1\]:

Competent authorities shall have procedures in place:

(a) to verify the effectiveness of official controls that they carry out; and

(b) to ensure that corrective action is taken when needed and that the documentation referred to in paragraph [8](1) is updated as appropriate.

The paragraph 1 referred to above is Article 8(1) of the Regulation, which states:

(c) "Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, inter alia, the areas referred to in Annex II, Chapter II".

The scope of the audit was limited to the procedures put in place by the Central Competent Authority (CCA) the BFSA, which is responsible for the majority of official controls falling under Regulation 882/2004;

as well as the procedures put in place by the RFSDs of BFSA, who are responsible for implementing those official controls.

In pursuit of these objectives, the itinerary included meetings with the following CAs:

<table>
<thead>
<tr>
<th>Competent Authorities</th>
<th>No.</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Central</td>
<td>1</td>
<td>BFSA: Meeting with following BFSA Directorates in Sofia: Animal health and welfare Directorate (AHWD) Feed Control Directorate (FeCD) Food Control Directorate (FCD) Border Control Directorate (BCD) Quality Management Directorate (QMD) Co-ordination and control Directorate (CCD) Laboratory Activities Directorate (LAD)</td>
</tr>
<tr>
<td>Regional authorities</td>
<td>2</td>
<td>Regional Food Safety Directorates (RFSDs) in Varna and Vratsa</td>
</tr>
<tr>
<td>Municipalities</td>
<td>2</td>
<td>Municipality of Provadia and Vetrino in the region of Varna</td>
</tr>
</tbody>
</table>

3 **Legal Basis**

The audit was carried out under the general provisions of the legislation of the European Union (EU) and, in particular, Article 45 of Regulation (EC) No 882/2004.

4 **Background**

4.1 **Systems Audit**

Regulation 882/2004 basically provides for a management system for official controls, setting out the requirements that the various elements of this management system must meet in order to allow for the delivery of controls of consistently high quality and which are delivered uniformly. Consequently, deficiencies in or incorrect implementation of core elements of this management system manifest themselves in problems and non-compliances as these are *inter alia* identified in FVO audits. The Systems Audit (SA) approach focuses upon and addresses these core issues. The purposes of the SA are to:

- examine the operation of selected "horizontal" control system elements across the EU
- identify good practice as well as difficulties encountered in their implementation
- promote and contribute to a coherent EU-wide approach towards systems aspects of official controls, without imposing excessive burden on Member States
- contribute to a systems-based approach to FVO audits
- further expand the FVO's specific Member States knowledge base, thus providing useful additional input into the prioritisation process for audits by the FVO;
• provide useful background information to other FVO audit teams on the overall progress made by the Member state in the operation of the selected control system elements

The SA model consists of an initial phase of desk analysis (including review of Multi-Annual National Control Plans, Member State Annual Reports, FVO reports and Country Profiles, and other relevant information), followed by a short and targeted series of audits of a sample of Member States for each selected topic, with a view to drawing valid general conclusions and, where appropriate, to issue recommendations which are relevant to all Member States.

4.2 **Verification of Effectiveness**

Regulation (EC) No. 882/2004 sets out a number of over-arching requirements for the operation of control systems, including, in Article 8(3), on control and verification procedures. Official controls must be carried out uniformly, and must be of consistently high quality. In order to ensure this, they must a) be carried out in accordance with documented procedures, and b) Member States (MS) must have procedures in place to verify that they are effective, and to correct them where shortcomings are identified, including the updating of control procedures and/or documentation. The "verification" requirement features as an issue in almost all FVO reports, across all Member States, although, it would appear, more often than not in terms of "verification of compliance with planned arrangements" rather than "verification of effectiveness of official controls".

Investigation of this theme in recent FVO General Follow-up Audits as well as the MS annual reports cf. Article 44 of Regulation 882/2004 demonstrate that CCAs do gather control data, but there appears to be limited on-going evaluation of that data. In the MS annual reports, the degree of evaluation, in terms of effectiveness of the official controls performed, varies greatly. Given the above, and considering the importance of ensuring uniform and consistently high quality controls it was decided to focus on procedures to verify the effectiveness of official controls in the first round of SAs.

4.3 **Previous Audits**

FVO has carried out numerous inspections and audits in Bulgaria, the reports of which can be found at:


While the topic of the current audit, procedures to verify the effectiveness of official controls, has not been the specific objective of any previous FVO audit, the subject has been considered within the scope of numerous sectoral audits carried out since 2006, as well as the general audit carried out in 2010 (reference number DG(SANCO)/2010-8713). The general audit report contained a horizontal recommendation to the Bulgarian competent authorities in relation to this issue. FVO is continuing to follow up action taken in response to recommendations in relation to verification of effectiveness of official controls arising from sectoral audits on poultry meat (2010-8456), bovine spongiform encephalopathy (2011-8944), fishery products (2010-8498), feed (2012-6491), Salmonella national control plan (2012-6438) and animal welfare (2012-6454).
5 FINDINGS AND CONCLUSIONS

5.1 LEGAL REQUIREMENTS

Article 8(3) of regulation (EC) No 882/2004 requires that:

*Competent* authorities shall have procedures in place:
(a) to verify the effectiveness of official controls that they carry out; and
(b) to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate.

The paragraph 1 referred to above is Article 8(1) of the Regulation, which states:

"Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, inter alia, the areas referred to in Annex II, Chapter II".

5.2 COMPETENT AUTHORITIES

5.2.1 Findings

Detailed information on the structure and organisation of the Bulgarian competent authorities can be found in the Country Profile for Bulgaria at:

http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=BG

The Ministry of Agriculture and Food (MAF) and the Ministry of Health (MH) set the state policy in the field of food safety. The Animal Health and Food Safety Directorate within MAF is responsible for development and co-ordination of the implementation of policy in the field of food safety and quality, feed safety, animal health and welfare.

The CCA falling within the scope of this audit is BFSA under the MAF. It is the competent authority performing official control of food safety and food quality (with exception of bottled natural mineral, spring and table water; food contact materials and the quality compliance of fresh fruits and vegetables), feed, plant protection products and fertilizers, animal by-products, animal health and welfare, and plant health.

The BFSA is responsible, inter alia, for drafting legislation, developing the programmes of official controls, contingency plans and setting control priorities and objectives (see planning under 5.3.1). Directorates within BFSA are also responsible for drafting control procedures and instructions for Regional Food Safety Directorates (RFSD). Each Directorate has a direct chain of command with its corresponding RFSDs Departments.

The territory of the Republic of Bulgaria is divided into 28 regions which execute the regional policy of central government bodies. The Regional Governor is appointed by the Council of Ministers. Local government in Bulgaria is organised through 264 municipalities. The administration in the food safety sector is organised in line with the territorial division of the country. BFSA structure comprise of 28 RFSDs which are distributed across the country. RFSDs are responsible for implementation of official control programmes in the areas of food, feed, animal health, animal welfare and plant health.

At local/district level, there are 264 municipalities each supported by an official municipal veterinarian (OMV) which carries out controls on farms in the areas of animal health, animal welfare and supervises the performance of the authorised private veterinarians (APV). OMV join
feed inspectors for official controls at farms. A total of 1,025 APV implement animal health monitoring programmes, transmissible spongiform encephalopathies (TSE) surveillance and animal welfare controls at farms.

5.2.2 Conclusion

Competences of the competent authority (CA) are clearly defined and responsibility has been allocated for the activities necessary for the development and implementation of programmes of official controls.

5.3 Verification Procedures

5.3.1 Planning process and development of the programmes of official controls

5.3.1.1 Findings

BFSA organises their official controls on the basis of a Multi-Annual Control Plan (MANCP). The BFSA national general strategic and sector-specific objectives are set out in the MANCP in a descriptive manner (e.g. to ensure effective implementation of the relevant Union legislation, in particular Regulation (EC) No 882/2004, achieve a high level of protection of public health, animal health through effective monitoring of all feed chain).

Directorates within BFSA develop annual official control programmes (control frequencies and sampling, vaccination plans) for each sector. In general, these programmes are developed taking into account of new information, risks or new legal requirements. In turn, the RFSDs and OMV develop their own annual control programmes based on criteria from the central level and local knowledge. In feed and animal welfare sectors, RFSDs annual control programmes are sent to BFSA for approval.

In addition to annual control plans, the FCD establishes specific, more targeted, thematic and specific controls. On an annual basis, FCD schedules such thematic controls that are targeting specific FBOs at particular time period of the year or at festivals. Several examples were presented to the audit team in relation to the planning specific official controls in the food sector. During the joint inspections between BFSA and Red Cross organisation, it was identified that food for charities are usually of a lower quality and are potentially risky for the recipients of such food. Therefore, the decision had been agreed with the Red Cross to notify RFSDs when a new shipment of foodstuffs is received, in order to take samples and evaluate safety and quality parameters. The BFSA in 2012 targeted specific FBOs that provide catering services for children outside the school activities (e.g. children sports events, school camps, excursions). Following the control campaign in 2012, FCD established that focus is required during 2013 to further improve food quality, safety and reduce food borne outbreaks amongst the children population. The outcomes of these thematic and specific controls reported systematically to the BFSA after finalisation of each series. However, the audit team did not receive evidence from FCD, if these controls were effective and results were used to modify next planning cycle.

The BFSA use different mechanisms to provide feedback information for use in the planning process. Information from these BFSA activities (annual official controls, audits, supervision controls and complex checks) at the central level were used to adjust the future planning arrangements. The audit team noted several examples of such mechanisms in operation.

Regular reports were being used to provide feedback on the outcome of official controls to the central level. The audit team noted that official control reports had been used to adjust animal health programmes (i.e. rabies eradication programme – redistribution of vaccination). In the feed sector the audit team saw regular overview reports that were submitted to the management for
further decisions and modification of plans (see also chapters 5.3.2 and 5.3.4).

Information from supervision checks also was used to feed back into planning process. Based on results of supervision visits in feed sector FeCD decided to amend the Feed Act in order to facilitate implementing Regulation EC (No) 225/2012. Following changes in the Fees Act the plan was adjusted and RFSDs were requested to control implementation of this provision (see also chapter 5.3.4).

The outcome of internal controls (audits, complex checks) also provides valuable information in order to adjust the plans. The audit team noted an example where the future training programme was adjusted to take into account problems identified in RFSDs (see also chapter 5.3.6).

The audit team saw no evidence that official control results from the past years at central level or regional level were being used systematically for analyses and identification of trends. In the RFSDs it was confirmed that information from previous years is available, however it is not being used. The BFSA acknowledged that there is a problem exploiting the all available control data in order to identify trends and indicated that this issue is currently being reviewed under a project (Optimization of the structure and improvement of the newly established BFSA) implemented with financial support of the EU. On the basis of the findings of this the executive director of BFSA created a working group in order to establish procedures for determining the effectiveness of official controls, as required by Article 8 of Regulation (EC) No 882/2004. The aim of this working group is to analyse the existing procedures in each sector and establish an integrated approach to official controls in all areas related to the food chain. The BFSA also confirmed that an IT strategy has been developed after a major re-organisation, which includes development of IT tools for official controls. This strategy was submitted to the Ministry of Agriculture and Food, but no decision has been taken yet to implement it. At the moment, VETIS is the only IT system available in BFSA; it contains information on identification, movement and health status (Classical swine fever, Bovine tuberculosis, Bovine brucellosis, Enzootic bovine leukosis) of animals, but is not being used to monitor implementation of control programmes. Other sectors within BFSA do not have IT tools (databases) available to record and exploit control data. Several RFSDs identified the need for such an IT tool and have initiated development thereof. The Director of one RFSD acknowledged that such an IT tool was a necessity for them to facilitate better management of official controls, especially as such large amount of information is available.

The BFSA recently started setting up criteria in several sectors (e.g. food and veterinary medicine products) to enable measuring of the effectiveness of official controls. The audit team noted that FCD is considering eight criteria to measure effectiveness: a) controls carried out based on risk and appropriate frequency, b) quality of official controls, c) consistency of official controls, d) incidences of food borne diseases, e) findings of internal or external audits, f) amendments of legislation, g) RASFF notifications, h) feedback from stakeholders. These criteria are already included in the procedure on verification of effectiveness of official control, but are not yet quantified. According to FCD the work is in progress of quantifying these criteria.

5.3.1.2 Conclusions

The CA had defined its strategic national and sector specific descriptive objectives necessary to deliver results in accordance with MANCP. Annual official control programmes, including targeted specific controls in food sector, are established at central and regional levels which are the main instrument to implement these objectives. Various feedback mechanisms are in place within the CA that are mostly used to adjust the annual plans and supports the system for verification and management decision making. However, information in relation to the official controls of the past years is not being used systematically for analyses or to establish trends and it does not feed back
into the planning process. At the moment, the CA do not have established measurable targets and/or indicators in order to measure the processes and compare the results against the expected results and to ascertain differences. IT tools are not being developed in most control areas to facilitate recording and exploiting available control data.

5.3.2 Monitoring of implementation of official control programmes

5.3.2.1 Findings

Following the adoption of annual control programmes RFSDs carry out official controls and report the outcomes to the central level. These controls are carried out by officials, namely inspectors and official veterinarians and only some tasks (monitoring of the animal health programmes, TSE surveillance and animal welfare controls at farms) are performed by APVs. Methods for carrying out inspections and sampling are laid down in specific control procedures and instructions prepared by the central level. The RFSDs use these control procedures, guidance and check-lists, but in certain cases have flexibility to develop their own documentation. In one instance, the audit team saw check-lists developed by one RFSD as none were available from the central level. The audit team noted that, in visited RFSDs the official controls were carried out based on the annual programmes. The monitoring of implementation of control programmes was carried out by the Heads of Departments in RFSDs and, in certain cases, by BFSA officials at the central level. Results of official controls were reported by RFSDs on a weekly, monthly, quarterly basis (sent by e-mail and post) depending on defined frequency in control procedures.

In the area of animal health the audit team had seen examples of monthly monitoring of implementation of control programme done by the central level and Animal Health and Welfare Department in RFSDs. In one of the RFSD, the Head of Animal Health and Welfare Department identified under-implementation of Classical swine fever, Bovine brucellosis monitoring and Anthrax vaccination programmes based on monthly reports from OMV. Measures were undertaken to rectify implementation in the following months and also discussed during the meetings with OMV.

At the central level AHWD also monitors implementation of the plan on a monthly basis (quantitative check of implemented controls against planned). The audit team had seen examples where some minor shortcoming were identified in monthly reports (i.e. use of old reporting templates, errors in calculations, positive samples not indicated at the end of report) and feedback with the guidance was provided to RFSDs.

The FeCD performs a documentary check of monthly, annual reports and all other records of inspections and laboratory analysis which are submitted by RFSDs. On a weekly basis, all inspectors send to the FeCD scanned copies of inspection and sampling protocols, laboratory reports and other supporting documentation. Each month the FeCD summarize these results of official controls, and provides a monthly report to BFSA Executive Director. Such overview reports are also provided summarizing annual activities. The analysis involves quantitative assessment as to whether sampling and inspection plans have been implemented as planned and documentary qualitative check of feed inspections (e.g. if deadlines had been respected in cases of non compliances and followed up in the next inspection, sanctions, administrative measures imposed). The audit team checked the monthly report of April 2013 which contained a detailed analysis of implementation of planned arrangements by each RFSD and also contained comparative analysis with the previous period of 2012. The sampling plan for that period was implemented - 99%, but inspections in feed business operators - 78% (reasons indicated - problems with transport arrangements in RFSDs).
In relation to the food sector, reports have to be submitted by RFSDs on weekly, monthly, quarterly and annual basis. The weekly reports are not used to monitor implementation of programmes, but rather to gather statistical information on official controls performed (i.e. controls carried out in establishments and enforcement measures applied). According to FCD this data is used for media purposes and to inform BFSA executive director about controls carried out during that week. FCD indicated that officials at central level regularly monitor implementation of official programmes, including thematic and specific controls, but the audit team did not see any evidence of this. In both RFSDs visited, the audit team saw that programme implementation is monitored by the Heads of Food Control Departments and in certain cases problems were identified by them as regards inadequate implementation of control frequencies. Corrective measures were applied in order to address these problems (see chapter 5.3.4).

RFSDs are required to send weekly informative notes and quarterly reports to Veterinary Medicine Products Control Directorate (VMPCD) as regards the official controls that had been finalized, the deficiencies and infringements registered and corrective measures prescribed. VMPCD analyses and summarise information received. The quantitative assessment consists of comparing the number of implemented controls with the planned arrangements.

In relation to import controls, the Border Control Directorate (BCD) receive monthly/quarterly reports on inspections and sampling of consignments. The sampling plan was implemented for the year 2012 according to the annual report.

The Laboratory Activities Directorate (LAD) receives monthly reports from all BFSA laboratories. These reports contain vast amounts of information on laboratory analysis performed (number of samples taken, analysis performed and positive cases). No further assessment is done by Laboratory Activities Directorate based on these reports. The turnaround time are set for National Residues Control Plan, 30 days for contracted private laboratory and 14 days for Central Laboratory for Veterinary Sanitary Expertise and Ecology (CLVSEE). Reports do not contain information on compliance with the turnaround times and such requirements are not monitored.

The audit team noted that in most of the sectors the quantitative assessments at central level were carried out in a systematic way. Procedures to verify the effectiveness of official controls included detailed instructions for the staff. The FCD and LAD could not demonstrate to the audit team that quantitative assessments at central level were systematically performed, though information (through reports) was regularly received. In addition, there were no documented procedures or guidance available in those two Directorates as regards quantitative assessment.

5.3.2.2 Conclusions

The CA has adequate internal control procedures developed in different sectors and these are being used by RFSDs. The implementation of official control programmes are monitored in most cases at the central and regional levels. However, not all Directorates at central level (i.e. FCD, LAD) make use of regular reports from RFSDs or laboratories in order to perform quantitative assessment. Moreover, these Directorates had not prescribed quantitative assessment requirements in their documented procedures.
5.3.3 Checking performance – supervision

5.3.3.1 Findings

The Directorates within BFSA have recently adopted individual procedures to verify the effectiveness of official controls, which include supervision of staff performance. Though several Directorates had supervision arrangements in place previously (FCD, AHWD, BCD), not all of them had an on-the-spot supervision component. The supervision process comprises an appropriately qualified and designated person supervising control staff documentation (plans, inspection reports, sampling forms, etc.) based on the checks on-the-spot. The main purpose of these checks is to assess skills and abilities of control staff to apply and use the methods and techniques of official controls, ability to identify non-compliances and take appropriate enforcement measures. According to the procedure, staff from Directorates at central level and each Head of Department/Head of sector/MOV within RFSDs should carry out supervision checks using developed check-lists in accordance with defined frequencies. These requirements and their application are summarized below:

<table>
<thead>
<tr>
<th>Supervision</th>
<th>Feed</th>
<th>Food</th>
<th>Animal health and animal welfare</th>
<th>Imports</th>
<th>Veterinary Medicine Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>BFSA Feed Control</td>
<td>BFSA Feed Control Directorate annual on-the-spot check of feed inspector in RFSD</td>
<td>BFSA FCD every 2 years on-spot-check of each Food Control Department in RFSD</td>
<td>BFSA AHWD once every 2 years documentary and if necessary on-the-spot check of each Animal Health Department in RFSD</td>
<td>BFSA BCD on-the-spot check twice per year BIPs, designated points of entry (DPE)</td>
<td>BFSA VMPCD annual on-the-spot check of VMP inspector in RFSD</td>
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<td>B.C.</td>
<td>Joint checks with VMPCD</td>
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<tr>
<td>BFSA FCD</td>
<td></td>
<td>Head of FCD/Head of Sector annual on-the-spot check of official</td>
<td></td>
<td>Heads of BIP/ DPE twice per year each inspector</td>
<td>Head of Animal Health and Welfare Department monthly documentary check</td>
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<tr>
<td>BFSA AHWD</td>
<td></td>
<td>Head of Animal Health and Welfare Department documentary and annually on-spot-check of MOV</td>
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<td>BFSA BCD</td>
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<td>BFSA VMPCD</td>
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The audit team noted that all individual procedures for verification of effectiveness of official control (5 separate procedures in FCD, AHWD, BCD, FeCD, VMP) had similar principles in relation to quantitative and qualitative assessments. The audit team noted that all these procedures have separate specific criteria developed by each Directorate (e.g. different criteria as regards supervision frequencies (on-the-spot visits from annual to once every two years), different reporting obligations, frequencies to the line management (from RFSDs to the BFSA and Directorates to the executive director), conducting the supervision checks. Such fragmented approach by each Directorate indicates the lack of co-ordination at the procedures development stage.

The audit team observed that, at the central level, supervision checks had been planned and performed with only some exceptions (e.g. Food Control Directorate). In general, the defined frequencies have been respected by Directorates at central level with exception of Border Control Directorate (BCD). During 2012, BCD completed on-the-spot checks in 5 out of 8 BIPs and 1 out of 4 DPE. Another example was provided to the audit team as regards feed supervision for 2013.
During the period between February and April 2013, all 8 planned supervision controls had been implemented. These checks were carried out jointly with the experts of BFSA VMPCD, especially where visits included on-the-spot checks at farm level.

Heads of Departments and Heads of Sectors in RFSDs are responsible for supervising their own staff. The audit team observed that standardised procedures for the quantitative and qualitative assessment of the performance of individual official controls carried out by the line management were consistently implemented in both RFSDs visited.

For all these supervision controls, standardised check-lists were used which contained conclusions, recommendations and deadlines for corrective measures. Implementation of recommendations was followed up by way of assessing submitted documentation or during the next supervision visit. The audit team saw examples of such qualitative assessments in both RFSDs (e.g. observation of inspection in food and feed business operators, observation of Salmonella and feed sampling).

According to the Heads of RFSDs they occasionally supervise their staff and perform on-the-spot checks depending on need (e.g. when new Head of Department Unit is appointed, complaints received from FBOs). These supervisions are not systematically recorded.

The audit team noted that in one RFSD, the established frequency of controls in confectionary (inspection frequency set by central level – once every month) could not be implemented due to other priorities and emergencies. In this particular case, an experienced inspector was pulled back to perform the normal routine monthly inspection, even after the follow-up inspection reported that shortcomings were eliminated. In both visited RFSDs it was confirmed that officials are obliged to follow instructions provided by the central level and frequency can be adjusted only to increase and not reduce controls based on the previous control results. It was confirmed to the audit team that rigid inspection frequency regime has been in place for several years and has not yet been reviewed or changed by the FCD to take into account previous years experience. However, FCD indicated that it would be subject for review. There was no communication from RFSD to inform FCD about the existing problems to respect rigid control frequencies.

The audit team visited two municipalities and reviewed documentation available to MOV. The MOV performed supervision of APV on an annual basis and check-lists were used in all occasions. The audit team saw an example of MOV report as regards supervision of blood sampling and intradermal test for tuberculosis. In most cases investigated by the audit team, no major non compliances had been detected by MOV.

The audit team noted that, in one municipality visited, official controls have been planned according to set frequencies by the central level. Backyard farms were not part of official control tasks in this municipality (though over 2000 such farms are known to MOV). It was confirmed by the MOV that they visit backyard farms only in case of complaints. APVs are obliged to report animal identification shortcomings if these are identified during sample taking or certification of movements off farms. APV have not reported any such shortcomings. The audit team noted that, in the case of one complaint (February 2013), there were 13 small ruminants not identified in one farm. The RFSD in this particular case is still pursuing these non-compliances as the owner refused to comply with animal identification requirements. The case is being dealt with the judicial authorities. There was no communication from RFSD to inform AHAWD about the existing unidentified animals in the backyard farms. AHAWD indicated that certain eradication programmes (e.g. Classical swine fever, Avian Influenza) include percentage of official controls in backyard farms. However, the audit team did not receive any indication if control procedures were reviewed in order to increase the compliance in the backyard farms (e.g. reduce unidentified animals).
5.3.3.2 Conclusions

The BFSA have procedures in place for the qualitative assessment of the performance of individual official controls carried out by inspectors and official veterinarians. The defined supervision frequencies were mostly respected or carried out based on the recently adopted procedures. The effectiveness of verification system is undermined by lack of communication, a failure to identify problems in certain official control procedures (whether procedures are fit for purpose) and not taking corrective actions to rectify the shortcomings.

5.3.4 Feedback and corrective action

5.3.4.1 Findings

The main mechanism within BFSA for feeding back information to the line management is through regular reports, internal audits, complex checks and results of supervisions carried out. The audit team noted, that in the feed sector, regular and comprehensive feedback is provided to the management which includes a detailed overview of the situation in the sector, status of implementation of official programme, comparison with the previous year results, outcome of supervision visits and suggestions for improvement. In most other Directorates, the audit team had not observed it to be done in such a comprehensive way. Another way used to feed back information to the BFSA management is by having regular weekly management meetings, where risk management issues are discussed (e.g. number of controls conducted, unsafe food cases, emergency situations).

In the RFSDs, the feedback to management as regards status of implementation of programmes is provided every month when reports are submitted to the central level. Other essential information on activities of different Departments is provided during the weekly management meetings.

According to the procedures for verification of effectiveness of official controls, supervision check-lists should be used and contain conclusions, recommendations and deadlines for corrective measures. The audit team observed many examples where these requirements had been recorded in the check-lists and corrective actions had been undertaken and followed up.

In one of the RFSD, during supervision controls the lack of knowledge of MOV in the feed area had been identified. The Animal Health and Welfare Department undertook to organise additional training sessions in that area for MOV. In another example, during on-the-spot controls it was noted that an inspector did not follow set frequencies and could not identify certain legal provisions (e.g. labelling) in food business operators (FBO). Following the investigation it was identified that his work load was substantial. Therefore, a decision was made to re-distribute his work load between other inspectors. The frequencies were later re-established and implementation of corrective measures followed up in the particular FBO.

In another RFSD, the Food Control Department, based on supervision controls on-the-spot, identified that Trichinella tests were not recorded in a register in the slaughterhouse; one inspector did not follow defined frequencies of controls and in one case an inspector did not perform controls according to plan for identified themes (i.e. food contact materials). Appropriate measures were undertaken by Food Control Department to address these shortcomings.

In the area of feed official controls, the audit team was provided with several examples where supervision controls resulted in changes to procedures at national level. Based on the first round of supervision visits, the FeCD identified that there is lack of guidance for inspectors in HACCP controls and interpretation of laboratory results which led to the procedures being developed. Also,
following results of supervision visits it was decided to amend the Feed Act in order to facilitate implementing Regulation EC (No) 225/2012, where certain operator activities should be approved. The audit team observed another example where the AHWD verification procedure had been amended based on results from supervision visits. New elements had been included on checking animal welfare of animals used for scientific purposes.

5.3.4.2 Conclusions

Where problems had been identified during verification of effectiveness of official controls the corrective actions had been undertaken and followed up in all cases seen by the audit team. The BFSA management makes use of feedback mechanisms either through regular reports, supervision or other internal controls. Only in limited instances did the outcome result in development/modification of control procedures and/or other means of improvements at national level. However, there are good examples in several sectors where regular comprehensive overview reports are being prepared for the CA management and the outcome of supervision visits has resulted in corrective measures at the national level.

5.3.5 Internal controls within BFSA

5.3.5.1 Findings

Internal audits

The QMD within BFSA is responsible for conducting internal audits required by Art. 4(6) of Regulation (EC) No 882/2004. Experts from Animal Health and Food Safety Directorate within MAF also participate in activities on performance of audit of the official control carried out by the BFSA. All BFSA audits have an on-the-spot element at FBO level. BFSA laboratories have their own internal audit systems based on ISO standard 17025 requirements and are audited by an accreditation body.

The overall process of internal audits of official controls (planning, organising, implementing, documenting and follow-up audits) is defined in internal BFSA audit guidelines. A more detailed description of the BFSA audit system is provided in the country profile at:


According to the multi-annual audit plan 2012-2016, the QMD planned to carry out 26 audits in 2012 and 54 audits in 2013. Due to resource constrains, QMD in 2012 carried out 14 audits (53%) and the 2013 plan has been reduced to 17 audits (32%).

According to the QMD, auditors check if control procedures are fit for purpose and this information is fed back to the central level. In one example provided to the audit team, the control procedure in the food sector did not contain detailed guidance on enforcement actions to be taken by inspectors. Ultimately, this information was indicated in the audit report and forwarded to the FCD at central level, which in turn clarified and modified the procedure.

Since April 2012, the QMD has amended provisions in the audit guideline and each audit now includes a point on verification of effectiveness of official controls. The QMD identified the following shortcomings in verification of effectiveness of official controls:

- On-spot checks in the FBOs contained only evaluation of inspector's documentation;
- There were no records on the results of the verification performed;
- The evaluation of verification did not cover the entire control activity;
The verification system had failed to establish if official controls were effective. The audit team had seen examples of audit reports of RFSD Veliko Tarnovo, Blagoevgrad, Dobrich and Sofia that contained information in relation to verification of effectiveness of official controls. These reports contained findings and recommendations in relation to quantitative and qualitative assessments of official controls. The audit reports did not indicate if corrective measures have been undertaken by RFSDs to comply with Article 8.3 (b).

**Complex checks**

Occasional "complex checks" are carried out by a BFSA group of experts, determined on case-by-case basis depending on the scope and objective, to evaluate the performance of all subordinate BFSA authorities, in particular whether staff in those authorities had adequately implemented legislation and applied control procedures. Co-ordination and Control Directorate (CCD) within BFSA carries out these complex checks, based on an approved annual control plan. These complex checks are performed in one or more areas: animal health and welfare, feed controls, foodstuffs controls, VMP controls, plant protection, legal affairs, financial and other economic activities, laboratory and testing activities, border control activities. At the moment, there is no written procedure describing processes as regards carrying out these “complex checks”.

The CCD co-operates with the officials from the Ministry of Interior, the Commission for Consumer Protection, NGOs for animal welfare and all authorities of BFSA. Based on notifications about non-compliant or illegal activities, due to lack of controls by certain RFSD official(s), the CCD undertake the checks, in order to validate the confirmation or denial of this information.

Within the period from 01.03.2011 to 31.05.2013, the CCD has organised and performed a total of 14 complex checks in RFSD and one in National Diagnostic and Research Veterinary Institute. The 2013 plan contains 12 “complex checks” to be carried out; however by the end of May 2013 only one was finalised (Vidin RFSD).

During these checks, a nominated expert team evaluates the performance of the selected authority, sometimes only in a specific area. The process involves the evaluation of available documentation for official controls and always includes on site checks in FBOs. Following the “complex checks” a report is drafted which includes evidence and specific recommendations for improving the activity of the RFSD. The report is forwarded to the Director of RFSD, who in turn has to present an action plan on the measures and actions foreseen, in order to eliminate the non-compliances identified. Implementation of recommendations of “complex checks” is monitored by the CCD. The audit team saw reports containing information for different sectors and recommendations issued to these authorities.

Based on the outcome of such “complex checks”, the CCD proposed to impose disciplinary measures against certain BFSA officials. At the end of May 2013, in total 66 officials had received such sanctions (postponement of promotion, warnings etc.).

The “complex check” reports, besides the scope to evaluate implementation of legislation and application of procedures, include also evaluation of effectiveness and efficiency of official controls. These reports also contain recommendations that might be linked to further improvement of verification of effectiveness of official controls (e.g. improve supervision of official veterinarians, provide training to officials in a specific sector).

**5.3.5.2 Conclusion**

The CA audits and “complex checks” are valuable instruments that are used to evaluate performance of all authorities and these contribute to improving verification of effectiveness of official controls. However, there is potential duplication of efforts in internal control activities by
the central level. Both these instruments are geared towards checking whether RFSDs and laboratories implement legislation, internal procedures and whether controls are effective. Moreover, there are no procedures available as regards conducting the “complex checks”, and planned activities for 2012 and the first semester of 2013 have not been implemented as planned.

5.3.6 Training and competence management

5.3.6.1 Findings

Training and Qualifications Directorate (TQD) within BFSA is responsible for the staff training. TQD develops the annual training plan for the Agency. The main criteria for development of training plan: new legislation, results of annual attestation of inspectors, analysis of previous training, results from internal audit reports and FVO reports.

During 2012, training was conducted in all areas of activities of Regulation (EC) No 882/2004, including animal health, animal welfare, food, feed and plant health. In total 251 training sessions were delivered for 3672 participants. These consist of internal, external and cascade training. Training had also been delivered to laboratory staff.

A national register exists within BFSA of all staff that were trained.

An internal audit was carried out in September 2012 on training. It concluded that TQD should establish rules and methods for qualification of all BFSA staff and improve effectiveness of training. TQD has already initiated additional measures for further improvement of the training system. Feedback information from all BFSA authorities was taken into account in developing the 2013 training programme. The training programme was provided to the audit team.

In one case provided to the audit team, the auditors from QMD identified that some inspectors responsible for food of non-animal origin controls have limited knowledge on Regulation (EC) No 852/2004 and recommended that training on the topic should be provided at the national level. This training for inspectors had been planned by TQD and implemented in the second quarter of 2013. Information from supervisions visits is also used to develop training programme (e.g. HACCP in feed sector, import controls).

There is a staff appraisal system for control staff in BFSA. Inspectors or official veterinarian performance should be evaluated by means of interviews by the line manager at the end of the year. During the appraisal, the line manager and official discuss whether objectives were achieved during the year and whether training is needed for further knowledge development.

5.3.6.2 Conclusion

There is a system in place for the training of staff performing official controls. The results of internal controls and feedback from the regions are taken into account when developing training programmes. The training system supports the verification of effectiveness of official controls.

6 Overall Conclusions

The CA has procedures in place for the purposes of verification of effectiveness of official controls, as required by Article 8(3) of Regulation (EC) No 882/2004. These procedures cover qualitative and quantitative assessments and were largely implemented at central and regional levels. Various feedback mechanisms are in place within CA that are mostly used to adjust the annual plans and support the system for verification and management decision making.
However, the verification of effectiveness is undermined by several factors. The CA does not have measurable targets and/or indicators in order to measure the processes and compare the results against the expected results and to ascertain differences. The unavailability of quantitative assessments of official control programmes in certain sectors and lack of analyses, establishment of trends as regards official controls of the past years, for further input into the planning process, creates difficulties for the CA in exploiting available control data. No IT tools are developed to facilitate such assessments.

In most cases the CA demonstrated its ability to take corrective actions when shortcomings were identified. There are examples of good practice, in particular feed sector, where regular, comprehensive overview reports are prepared for CA management, and the outcome of supervision visits results in corrective measures at the national level. The corrective measures taken at central level in most other sectors resulted only in limited instances in the development/ modification of control procedures and/or other means of improvements. The effectiveness of verification system is also affected by limited communication of identified or potential shortcomings in official control procedures, thus affecting appropriate corrective actions.

Various other instruments, such as internal audits, "complex checks", and supervisory controls by individual Directorates, reinforce the verification of effectiveness of official controls. These three internal control instruments were mostly implemented as planned. There is, however, a potential overlap of effort concerning these internal control activities at central level, as these controls have similar objectives and all of them include on-the-spot components.

7 Closing Meeting

A closing meeting was held on 7 June with the central authorities of BFSA. At this meeting the FVO audit team presented their findings and preliminary conclusions and advised the authorities of the relevant time limits for production of the report and their response.

The representatives of the BFSA acknowledged the findings and conclusions presented by the FVO audit team.

8 Recommendations

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

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| 1.  | In order to ensure the effectiveness and appropriateness of official controls, as required by Article 4 (2) a of Regulation (EC) No 882/2004, the Competent authorities should enhance the procedures in place to verify the effectiveness of controls cf. Art. 8.3 (a) and (b) of that Regulation. Specifically, the CA should: a) take measures to ensure improved use and analysis of data from previous official controls, in terms of both qualitative and quantitative assessments of delivery and outcomes; b) investigate in which other control areas and to what extent, the verification system as currently applied in the feed area can be implemented; c) ensure that appropriate and documented corrective action is taken where it is established that controls are not
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<td>2.</td>
<td>In order to facilitate the verification of effectiveness of official controls, the CA should consider establishing control indicators and/or targets, as appropriate, in order to measure their delivery in terms of implementation and outcome.</td>
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The competent authority's response to the recommendations can be found at:

### ANNEX 1 - LEGAL REFERENCES

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