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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

BULGARIA

FROM 30 SEPTEMBER TO 08 OCTOBER 2010

IN ORDER TO EVALUATE IMPORT CONTROLS ON FOOD OF PLANT ORIGIN

IN THE CONTEXT OF A GENERAL AUDIT

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Bulgaria that took place between 30 September and 8 October 2010, as part of the general audit of Bulgaria carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls. The objectives of the specific audit were to check that official controls are carried out in accordance with the principles of the above Regulation and in line with the multi-annual national control plan (MANCP) as specified in Article 41 of the Regulation. Accordingly, the specific audit evaluated the implementation of EU legislation in the areas of import controls on food of non -animal origin (FNAO).

The competent authorities (CAs) have been designated. Horizontal communication between and within the CA and Customs is ensured, however deficiencies were identified in cooperation between the two main CAs (Ministry of Health (MH) and Ministry of Agriculture and Food). The MH has a sufficient number of qualified staff available. There is a training system in place, but some deficiencies were identified. Procedures for verifying official controls are established; however, no audits were carried out in 2009 and 2010 in the scope of this mission.

Designated points of entry (DPEs) and designated points of import (DPIs) have been designated by the CAs. As three of the DPEs do not meet all requirements of Article 4 of Regulation (EC) No 669/2009, the CA has nominated Control Points (CPs) at the food business operators (FBOs), but not all of them were adequately authorised, as provided for in Article 19 of Regulation (EC) No 669/2009. Consignments from Turkey subject to Regulation (EC) No 669/2009 bound for another MS, which had been selected at the DPE for identity and physical checks at the CP, in certain cases bypassed the CP. The onward transportation to another MS does not fully follow Article 8(2) of Regulation (EC) No 669/2009.

The frequency of sampling of some products subject to Regulation (EC) No 669/2009 was lower than required by the Regulation (the first two quarters were reported). The documentary checks on products subject to Regulation (EC) No 1152/2009 are not always carried out properly.

The observed sampling procedures for pesticide residues were adequate, but problems in sampling for aflatoxins were identified.

Laboratories for import controls of FNAO have been designated, but there are problems with accreditation and validation of analytical methods. In the laboratory for mycotoxins, deficiencies in quality assurance system (QAS) were identified and some requirements of Regulation (EC) No 401/2006 and Annex III of Regulation (EC) No 882/2004 were not followed. The laboratory visited by the mission team for pesticide residues does not implement fully SANCO Guideline Document No SANCO/10684/2009. The National Reference Laboratory (NRL) for mycotoxins in food has not been designated, and the NRL for pesticide residues analysis in fruit and vegetables does not perform all the tasks required by Article 33 of Regulation (EC) No 882/2004.

Overall, although there is an import control system in place in Bulgaria, major shortcomings were identified concerning cooperation between the CAs, authorisation of CPs, laboratories performance and methods validation, lack of NRL for mycotoxins (in food), procedures used for CPs, onward transportation and documentary checks.

The report makes a number of recommendations to the Bulgarian CAs, 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
BAS	Bulgarian Accreditation Service
BGN	Bulgarian Lev (currency)
BIP	Border Inspection Post
CA	Competent Authority
CCA	Central Competent Authority
CED	Common Entry Document
CP	Control Point
CLCTC	Central Laboratory for Chemical Testing and Control
DG(SANCO)	Health and Consumers Directorate-General
DPE	Designated Point of Entry
DPI	Designated Point of Import
EC	European Community
ELISA	Enzyme-Linked Immunosorbent Assay
EU	European Union
EURL	European Union Reference Laboratory
FA	Food Additive
FAPAS	Food Analysis Performance Assessment Scheme
FBO	Food Business Operator
FCM	Food Contact Material
FNAO	Food of Non–Animal Origin
FPI	First Point of Introduction
FSA	Food Safety Agency
FVO	Food and Veterinary Office
GC-MS	Gas Chromatography/Mass Spectrometry
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography with Tandem Mass Spectrometry
MAF	Ministry of Agriculture and Food
MANCP	Single Integrated Multi-Annual National Control Plan
MATRA	(Dutch) Social Transformation Project (Maatschappelijke Transformatie)
MF	Ministry of Finance
MH	Ministry of Health
MRM	Multi-Residue Method

MS	Member State
NBR	National Bulgarian Railways
NRL	National Reference Laboratory
NVS	National Veterinary Service
PCP	Pentachlorophenol
PHD	Public Health Directorate
PT	Proficiency Test
QAS	Quality assurance system
RASFF	Rapid Alert System for Food and Feed
RIPHPC	Regional Inspectorates for Public Health Protection and Control
SOP	Standard Operating Procedure
TARIC	Integrated Tariff of the European Community
TC	Third Country

1 Introduction

The Specific Audit formed part of the FVO's planned mission programme. It took place in Bulgaria from 30 September to 8 October 2010. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and two experts from Member States (MSs). The MT was joined also by a representative of DG(SANCO) Directorate E. Representatives from the Central Competent Authority (CCA) accompanied the mission team for the duration of the audit. An opening meeting was held on 30 September 2010 with the CCAs. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the mission team and the control systems were described by the authorities.

2 Objectives Of The Mission

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

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

- to evaluate the implementation of EU legislation in relation to import controls of food of non-animal origin (FNAO), in particular:

  - Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and FNAO and amending Decision 2006/504/EC;
  - Regulation (EC) No 1152/2009 imposing special conditions governing the import of certain foodstuffs from certain third countries (TC) due to contamination risk by aflatoxins and repealing Decision 2006/504/EC;
  - Emergency measures other than Regulation (EC) No 1152/2009, adopted on a basis of Article 53(1)(b)(ii) of Regulation (EC) No 178/2002.

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

- As regards Regulation (EC) No 882/2004, the organisation of official controls (Articles 3-7,) control and verification procedures and methods (Articles 8-10), registration of food establishments (Art. 31), enforcement (Articles 54-55), and MANCP (Articles 41-42);
- The implementation of Community legislation regarding FNAO import controls.

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

MEETINGS/VISITS			COMMENTS
COMPETENT AUTHORITIES	**Central**	**4**	Public Health Directorate (PHD), National Veterinary Service (NVS), Ministry of Agriculture and Food (MAF), Customs Authorities
	Regional	**2**	Inspectorates for Public Health Protection and Control (RIPHPC) in Varna and Haskovo
LABORATORIES		**2**	RIPHPCs laboratories in Sofia and Pleven
DESIGNATED POINTS OF ENTRY/DESIGNATED POINTS OF IMPORT/CONTROL POINTS		**6**	Designated Points of Entry (DPE) in Kapitan Andreevo and Varna Two Control Points (CPs) in Varna, one CP in Sofia, CP in the vicinity of DPE Kapitan Andreevo
ESTABLISHMENTS		**1**	Importer of products subject to Reg. (EC) No 669/2009 in Plovdiv

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 MSs. The main purpose of such audits is to verify that, overall, official controls take place in MSs in accordance with the multi-annual 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 sector specific issues.

4.1 Background to the series of missions on import controls of food of non-animal origin

A series of missions on import control of FNAO was carried out by the FVO between 2002 and 2004 to major importing MSs, to assess controls at import on food products of non-animal origin. The second series of mission was undertaken between 2006 and 2008 and it covered most of the MSs not included in the first series and follow-up of the previous missions. The scope of these series of missions covered emergency measures for foodstuffs imported from TCs adopted on a basis of Article 53(1)(b)(ii) of Regulation (EC) No 178/2002.

The overview report of the last series of missions is available on the Health and Consumers Directorate General (DG SANCO) Internet site at:

http://ec.europa.eu/food/fvo/specialreports/gr_2009-8328_aw_en.pdf

This third series of missions has started in year 2010. The scope covers Regulation (EC) No 669/2009 adopted on the basis of Art 15(5) of Regulation (EC) No 882/2004 as well as emergency measures adopted during the last few years (Regulation (EC) No 1152/2009, Regulation (EC) No 1151/2009, Regulation (EC) No 258/2010).

The last mission on import controls on FNAO DG(SANCO)/2008-7847, carried out by the FVO in Bulgaria from 26 to 30 May 2008 can be found at: http://ec.europa.eu/food/fvo/ir_search_en.cfm

Increased level of official controls

The relevance of imports of non-animal origin products from a food safety perspective is witnessed

by trade figures and number of notifications of non-compliant products notified to the European Commission via the Rapid Alert System for Food and Feed (RASFF). In 2008 products of non-animal origin represented more than 90% of total EU food imports. In the same year nearly 67% of RASFF notifications were triggered by import controls on feed and FNAO.

Based on Article 15(5) of Regulation (EC) No 882/2004, Regulation (EC) No 669/2009 requires MS to carry out an increased level of official controls on imports of certain feed and FNAO from specific Third Countries (TC).

Following its publication in July 2009, the Regulation is applicable since 25 January 2010. This Regulation introduces a set of uniform rules for performing official checks on food and feed imports of non-animal origin.

Emergency measures

During the past years risks were identified concerning some imported products including:

- mycotoxins in different foodstuffs such as nuts, almonds, dried fruit and derived products from different TC. Mycotoxins are naturally occurring metabolites produced by certain species of moulds (e.g. Aspergillus spp, Fusarium spp). Therefore, EU legislation establishes:
    - Maximum limits and sampling procedures for mycotoxins in foodstuffs and feedstuffs;
    - General criteria to ensure that the laboratories in charge of analysis use methods of analysis with comparable levels of performance.
- Sunflower oil from Ukraine contaminated by mineral oil. Sunflower oil originating from Ukraine was found contaminated with high levels of mineral oil in the year 2008. Based upon exposure estimates, EFSA concluded that the exposure of sunflower oil contaminated with high viscosity mineral oil, although being undesirable for human consumption, would not be of public health concern in this case.
- Guar gum and its food and feed compounds containing at least 10% originating in or consigned from India contaminated by pentachlorophenol (PCP) and dioxins. The RASFF received in 2007 a notification from a MS concerning a finding of a serious contamination by dioxins and PCP in guar gum originating from India.

In all the cases specific Commission Decisions on emergency measures were adopted on the basis of Article 53(1)(b)(ii) of Regulation (EC) No 178/2002. They specify conditions of import, pre-notification of consignments arrival and official controls to be carried out by MSs such as documentary, identity and physical checks including sampling with a specific frequency. In most cases Decisions were revised and repealed by Regulations.

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 MSs to designate the Competent Authorities (CAs) responsible for official controls.

Findings

The Ministry of Health (MH) is responsible for import controls of FNAO. The implementation of the official controls is coordinated by the Public Health Directorate (PHD) and is carried out by 28 Regional Inspectorates for Public Health Protection and Control (RIPHPCs).

The National Veterinary Service (NVS), under the Ministry of Agriculture and Food (MAF), is responsible for import controls of feedingstuffs including products subject to Regulations (EC) No 669/2009 and 258/2010. These controls are organised at eight veterinary Border Inspection Posts (BIPs). Since June 2010, the NVS has been responsible also for feedingstuffs control on the market (previously the National Grain and Feed Service was responsible for this task).

More information on the structure of the PHD and the NVS can be found in the Country Profile: http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=BG

In total, there are 66 Customs offices in Bulgaria. Customs do not perform official food control tasks; however upon a suspicion they may request the RIPHPC to perform official controls of consignments.

The CCAs informed the mission team on the progress in establishing the Food Safety Agency (FSA) under the MAF. The draft of the legal act on the creation of the FSA has been sent for inter-ministerial consultations on 5 October 2010. Its adoption is expected in December 2010. Based on that Act it is anticipated that all responsibilities of the MH in relation to food safety would be moved to this new Agency, excluding official control of natural mineral waters. In total 3,055 staff would be employed in the FSA. Laboratories subordinated currently to RIPHPCs would remain in the MH structures. The FSA is expected to be operational in 2011. The MAF intends to use veterinary BIPs for import controls of FNAO within the framework of the new created Agency.

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.
Article 24 of Regulation (EC) No 882/2004 for the organisation of the official controls the CAs and the customs services shall cooperate closely.

Findings

The same agreement between the Customs and the PHD is in place as described in the FVO report on import control of FNAO DG(SANCO)/2008-7847. CAs exchange information by letters, joint meetings at local and central level. Letters sent to RIPHPCs concerning import controls of FNAO are also sent in parallel to the Customs. Daily cooperation is based on phone conversations and e-mails. The mission team obtained copies of instructions on the implementation of EU Regulations on import controls of FNAO sent to Customs by PHD in 2010 and 2009. A specific instruction letter of 16 February 2010 concerning detailed procedures on implementation of Regulation (EC) No 669/2009 was prepared in cooperation between the PHD and Customs. At the local level RIPHPCs cooperate closely with the Customs. In the case of consignments subject to Regulation (EC) No 669/2009 selected for sampling at the Control Points (CPs), Customs are notified about their arrival by the RIPHPCs, and sampling is undertaken in the Customs presence (see also Section 6.2.3).

There was communication between the MAF and the MH about nomination of DPEs under Regulation (EC) No 669/2009. Nevertheless there was no communication in relation to designation of CPs under Regulation (EC) No 258/2010.

Due to the lack of facilities in the Kapitan Andreevo DPE to perform identity and physical checks of products subject to Regulation (EC) No 669/2009, in February 2010 the MH sent a letter to the MAF requesting cooperation regarding BIP's facilities available in this border crossing. The MAF replied in March that due to problems with the maintenance of the BIP in Kapitan Andreevo, already addressed in the FVO report DG(SANCO)/8552-2010 on import/transit control system and BIPs, this solution could not be implemented at that moment. According to the MAF's letter, the situation in the BIP must be adequately assessed before any decision is taken. Since this time there has been no communication between CAs on that subject.

The Central Laboratory for Chemical Testing and Control (CLCTC), under the National Plant Protection Service at the MAF, has accredited methods for pesticide residue analyses: methomyl and oxamyl in fresh, chilled or frozen vegetables: peppers, courgettes and tomatoes. The laboratory also implemented a method for amitraz in pears, but it has been neither accredited nor validated. The MH informed the mission team, that the CLCTC could be used for import controls if the capacity of RIPHPC laboratory in Pleven was exceeded, but this was not the case to date. However the MH is not aware of the possible analytical capacities of the CLCTC, and no specific agreement is in place. The lack of cooperation between the MH and the MAF, in particular regarding analytical resources, was already highlighted in the Report DG(SANCO)/2008-7837 concerning controls of pesticide residues in food of plant origin.

In Bulgaria, an Inter-ministerial Council for Border Control is established. During the first meeting of the Council in 2010, the MH presented the problem with the Kapitan Andreevo DPE concerning lack of adequate facilities. The MH sent also a letter to the Ministry of Finance (MF) concerning a specific project on the new infrastructure of the border crossing in Kapitan Andreevo being implemented by the MF. The MH proposed to include facilities for import controls for FNAO in this project. In April 2010 the MF replied that the project is already too advanced to include this new proposal. The CCAs stated that the future solution for the DPE can be decided after the FSA is created.

Since 23 June 2010, one CP located 7 km from the DPE in Kapitan Andreevo has been authorised by the CA to solve the situation with lack of facilities in the Kapitan Andreevo DPE. Currently, all consignments from Turkey, which arrive in the Kapitan Andreevo DPE, are directed to this CP,

where the sampling takes place. Other CPs are not currently used for products from Turkey, but in the period of high volumes of import (February-May) they might be used again, because the resources at Kapitan Andreevo DPE and the CP are not sufficient for this peak period, and resources of MAF are not available to the MH (see Section 6.2.3).

The mission team visited a railway border crossing in Svilengrad, which was removed from the lists of DPIs and DPEs in June 2010. The MH based its decision on the information received from the National Bulgarian Railways (NBR) that the import volume of products subject to Regulations (EC) No 669/2009 and 1152/2009 is very low. According to the CA only five Common Entry Documents (CEDs) for products under Regulation (EC) No 1152/2009 and one CED for products subject to Regulation (EC) No 669/2009 were notified in 2010 in Svilengrad. During the meeting the railway companies informed the mission team that, recently, transport of all FNAO from Turkey (including products not covered by the EU legislation) was stopped at this border crossing. This situation arose because of a lack of communication between the CAs. The mission team was also informed by the Customs, that railway companies use simplified customs procedures. In such cases information available to the Customs concerning imported products is very limited, as the full TARIC code does not have to be mentioned in the declared documents.

5.1.3 Co-operation within Competent Authorities

Legal Requirements

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

Findings

Instruction letters, meetings and training are the main means of communication between the PHD and RIPHPCs. On 18 December 2009 a meeting was organised at central level to discuss import control procedures and new legislative changes, where representatives of RIPHPCs were present. Two similar meetings were organised in 2010. In 2009 and 2010, a number of instructions concerning new regulations on import controls of FNAO, including recent changes, were sent from the PHD to RIPHPCs. A specific instruction letter on laboratories designated for import controls and detailed procedures for organization of controls at CPs authorised under Article 19 of Regulation (EC) No 669/2009 was distributed on 23 March 2010 by the PHD to all RIPHPCs involved in these controls.

The Customs communicate internally via intranet, letters and meetings. The mission team obtained evidence of internal letters and the PHD instructions on EU legislation on import control of FNAO distributed to Customs offices in 2010. A specific letter was sent by the CCA to the local officers concerning procedures in relation to Regulation (EC) No 669/2009 including sampling of consignments in CPs. The mission team was informed that an electronic system for clearance of goods is available to the Customs, where risk profiles for products are launched. Profiles include specific requirements for foodstuffs such as the CED. The CCA informed the mission team that all products covered by EU Regulations on import control are included in this system. However, the mission team could not verify this information, because profiles could only be launched in the case of processing real consignments. In the Customs Office Varna-West the system was unavailable due to problems with internet connection, but the mission team obtained evidences of release of consignments (peanuts from Argentina and China) based on CEDs, as required by EU

legislation. In the Customs office in Kapitan Andreevo, a consignment of Turkish peppers subject to Regulation (EC) No 669/2009 was processed by the Customs system. The risk profile was launched and the CEDs were requested from the truck driver. In the visited importer of products subject to Regulation (EC) No 669/2009 in Plovdiv, the mission team obtained evidences of Customs release of consignments after the CED had been issued by the CA.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

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

Findings

The PHD informed the mission team that concerning analyses of PCP in guar gum and mineral oil in sunflower oil from the Ukraine samples may be sent to laboratories in other MS. This is not considered by the CA as a delegation of tasks.

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 MSs 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

Implementation of the contingency plan was already described in the FVO report on import controls of food and feed No. DG SANCO/2008-7847. As described in the MANCP, a general crisis management plan, in the context of general food safety, has been developed by the MH where the roles, responsibilities and procedures are defined.

Conclusions on Competent Authorities

The CAs in the context of this mission have been designated.

Horizontal communication between the PHD and Customs is ensured.

Deficiencies were identified in cooperation between the MH and the MAF in relation to import controls of FNAO.

Problems with coordination and communication between the RHD, NBR and Customs were notified to the mission team.

Cooperation within the CAs is adequate.

There is no delegation of tasks related to the official controls in the context of this mission, however

laboratories in other MSs may be used for official control purposes.

There is a general contingency plan which could be used in the event of an emergency as required by Articles 4 and 13 of Regulation (EC) No 882/2004.

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal Requirements

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

Findings

The legal powers for import controls of FNAO are based on Article 29 § 2.4 of the Food Law (SG No 102 / 2003), which gives responsibility for official controls of imported FNAO to the PHD and RIPHPCs. The Food Law provides the CAs' staff with the necessary powers of entry to establishments and access to FBOs documentation.

5.2.2 Staffing provision and facilities

Legal Requirements

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

Findings

Qualifications of staff, involved in import controls of FNAO are the same as for other food safety responsibilities. In the MH, staff qualifications are mainly medical doctors, food technologists and health inspectors.

Currently, in the PHD, five employees are responsible for food hygiene of FNAO, food contact materials (FCMs), food additives (FA), import controls of FNAO, dietetic products, food supplements, bottled waters. Two of them deal with import controls, among other food safety areas. They also perform verification and reporting activities.

In the visited RIPHPC in Varna, five officials were employed in the special unit dealing with import controls including sampling for aflatoxins and pesticides. Their responsibilities are described in job profiles.

Eight people are currently employed in the RIPHPC in Haskovo to perform their duties for import controls of FNAO in the Kapitan Andreevo DPE and in the CP located in the vicinity of the DPE. They work in pairs seven days a week: two shifts/12 hours. Due to the nomination of the mentioned CP, in July 2010 four people were redirected from other positions to work in this DPE and the CP.

The mission team noted that the two RIPHPCs visited have adequate facilities and sufficient

sampling equipment in place.

The Law on conflict of interest and Law on civil servants which applies to all CAs, lays down provisions to avoid any conflict of interest (see also FVO Report DG SANCO/2010-8584 on FCM and FA control).

5.2.3 Staff qualifications and training

Legal Requirements

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

Findings

The MH uses a cascade system whereby one inspector in each region is invited for a specific training, and this individual is responsible for training the other staff in that region. Training needs are identified according to the results of verification and audits, results of FVO missions and other experts and new legislation. However, in 2010 no training was organised on import controls at central level due to lack of funds.

In 2007-2009 a specific (Dutch) Social Transformation Project/Maatschappelijke Transformatie (MATRA) was carried out in Bulgaria where training on sampling and analysis of mycotoxins was included as a priority. One training session concerning import controls of FNAO including new EU legislation was organised in 2009 at central level. A number of internal training sessions were carried out in 2010 concerning import control procedures and sampling in the RIPHPCs visited. Inspectors responsible for sampling for mycotoxins from RIPHPCs in Varna and Sofia participated in specialised sampling training within the MATRA project as well as in internal courses during the last two years.

In the Kapitan Andreevo DPE all inspectors recently redirected to work on import controls received three-days introductory training, and in the first month they assisted more experienced colleagues during sampling for pesticide residues.

All inspectors met were aware of the new legislative changes and participated in the internal training sessions on import controls in 2009 and 2010. However, some problems with documentary checks and sampling for aflatoxins were observed by the mission team (see Sections 6.2.3 and 6.2.8).

In total, 17 employees from the MH, RIPHPCs, MAF and NVS participated in the two training sessions on import controls of FNAO within 'Better Training for Safer Food' organised by the European Commission, Health and Consumers Directorate-General DG(SANCO) in January and April 2010.

Staff involved in the aflatoxins analyses from the laboratory in RIPHPC Sofia have not received any training in relation to mycotoxins in 2009, and this issue was not included in plans for 2010. In this laboratory problems were identified concerning the quality assurance and validation of methods (see Section 6.2.8).

Conclusions on Resources for Performance of Controls

The CAs have adequate legal powers to carry out official controls and legal procedures in place to have access to premises of and documentation kept by the FBOs as required by Articles 4 and 8 of Regulation (EC) No 882/2004.

There are adequate staffing provisions, facilities and equipment available.

There are adequate provisions in place to avoid conflict of interest.

There is a training system established in the CA. No training at the central level was organised, but specific training on import controls has been undertaken at RIPHPCs. The staff in the visited laboratory has not received training on mycotoxins testing since 2008 and problems were identified in the laboratory performance (see Section 6.2.8).

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 MSs 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

Importers and establishments storing imported FNAO, including customs warehouses, are registered with RIPHPCs. All companies visited by the mission team (the importer in Plovdiv, warehouses in Sofia, Varna and Kapitan Andreevo used as CPs under Article 19 of Regulation (EC) No 669/2009) have registrations granted by the relevant RIPHPC.

5.3.2 Prioritisation of official controls

Legal Requirements

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

Article 16 of Regulation (EC) No 882/2004 requires that physical checks on import of FNAO shall be carried out at frequency depending on the risk associated with different types of feed and food.

Findings

In addition to controls of products subject to harmonised controls, soy beans, maize and derived products imported from TCs are subject to 50% physical, identity and documentary checks for GMO content, before release for free circulation. These products have to be sampled at the designated warehouses under the Customs supervision. Upon a suspicion, Customs may also request checks to be performed by the RIPHPCs.

Apart from import controls prior to release for free circulation, according to the current annual national sampling plan, 30% of samples taken from the market originate from TCs. Samples are tested for different parameters – based on legislative requirements.

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

Official controls are carried out by inspection, audit, sampling and analysis. Documentary, identity and physical checks including visual inspection, temperature control and sampling are used as control methods during everyday duties of the RIPHPCs inspectors responsible for import controls of FNAO.

5.3.4 Sampling and Laboratory analysis

Legal Requirements

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

Findings

There are six RIPHPCs laboratories designated for import controls of FNAO: in Vieliko Tarnovo, Varna, Burgas, Pleven, Plovdiv and Sofia. They all are designated to carry out analyses for pesticide residues, mycotoxins, cadmium and lead. Five of these laboratories analyse Sudan Dyes and two of them Ochratoxin A.

In reply to the recommendation DG(SANCO) 2008-7847 concerning accreditation of laboratories, significant progress was achieved. All six laboratories are accredited to EN ISO/IEC 17025, but in four of them some analytical methods are not included in the scope of accreditation: laboratory in Veliko Tarnovo – for Ochratoxin A, laboratories in Varna and Plovdiv for Sudan I, laboratory in Pleven – methods for amitraz, oxamyl, methomyl and Sudan I-IV. In both laboratories visited by the mission team in Pleven and Sofia, the assessed methods were not fully validated (See Section 6.2.8.).

Two laboratories were designated for control of cadmium and lead in trace elements used in feed as required by Regulation (EC) No 669/2009. At the present moment mycotoxins analysis of feed is performed with the Enzyme-Linked Immunosorbent Assay (ELISA) method by the National Reference Laboratory on Mycotoxicology and Ecotoxicology within the National Diagnostic Research Veterinary Medical Institute.

Findings and conclusions concerning sampling observed and performance of laboratories visited are described in Section 6.2.8.

5.3.5 Procedures for performance and reporting of control activities

Legal Requirements

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

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

Internal procedures for import controls of FNAO as well as instructions developed by the CCA are in place in the visited RIPHPCs in Varna and Haskovo/Kapitan Andreevo. In the RIPHPC Haskovo a detailed procedure for import controls of products subject to Regulation (EC) No 669/2009, which are sampled in the CP designated in the vicinity of the Kapitan Andreevo DPE, was introduced on 1 September 2010.

The national procedure for sampling of food for pesticides residues analyses prepared by the PHD was used by inspectors in Varna, Sofia and Kapitan Andreevo. Similar procedure for mycotoxins sampling was available for inspectors in Varna and Sofia, but it has not been updated following the recent legislative changes (Regulation (EC) No 178/2010 amending Regulation (EC) No 401/2006, Regulations (EC) No 105/2010 and 165/2010 amending Regulation (EC) No 1881/2006). Nevertheless, inspectors involved in sampling were aware of these latest amendments.

In 2010, the PHD prepared harmonised import control procedures, but they have not been distributed yet, as no meeting could be organised to discuss them with regional units. It is planned to organise such a meeting by the end of 2010, but the CCA is not certain whether funds would be available. In the case it cannot be organised, the procedure will be distributed with the detailed instruction letter.

The mission team noted that the '*Guidance document for CAs for the control of compliance with EU legislation on aflatoxins*' of DG SANCO was not used by inspectors as only the English version is available.

5.3.6 Transparency and confidentially

Legal Requirements

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

Findings

The mission team obtained examples of transparency in the scope of this mission. On the MH web-

site relevant legislation, list of DPEs, DPIs and CPs as well as the quarterly reports on sampling of products subject to Regulation (EC) No 1152/2009 are published. A special information note on all legislation concerning import control of FNAO is also published at the PHD website. In the RIPHPC in Varna information on new import control legislation was made available on their website, as well as in the bulletin displayed in the inspectorate for the customers. Information letters have also been sent by the RIPHPC to the main importing companies in Varna.

The information concerning DPEs (under Regulation (EC) No 669/2009) and CPs (under Regulation (EC) No 258/2010) for feed was not clearly posted on the NVS website. During the mission the CCA updated the website, and this information is now available. The list of legislative acts in relation to import controls has also been updated.

The CCA provided documentary evidence of meetings held in 2010 between the PHD and Turkish representatives concerning problems in implementation of import control procedures for products from Turkey subject to Regulation (EC) No 669/2009.

The DPEs, CPs and DPIs are listed on the website of the MH. However the mission team noted that this information was not transparent enough to clearly identify all of the FBOs warehouses authorised as CPs under Article 19 of Regulation (EC) No 669/2009 (see also Section 6.2.1).

Conclusions on Organisation and Implementation of Official Controls

FBOs, including importers, are subject to registration requirements.

In the scope of this mission official controls are organised in accordance with the requirements and criteria laid down in Article 3 of Regulation (EC) No 882/2004.

Tasks related to official controls are generally carried out using appropriate methods and techniques.

The official controls are carried out in accordance with the documented procedures, however the procedure used for mycotoxins sampling has not been updated (Article 8(3)(b) of Regulation (EC) No 882/2004).

Laboratories for import controls of FNAO have been designated, but not all of them use accredited and fully validated methods, contrary to provisions of Article 12 of Regulation (EC) No 882/2004.

Provisions have been put in place to ensure adequate transparency and confidentiality as required by Article 7 of Regulation (EC) No 882/2004, however information on CPs authorized under the Article 19 of Regulation (EC) No 669/2009 is not transparent enough to identify all of them clearly.

5.4 Enforcement Measures

5.4.1 Measures in the case of non-compliance

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Findings

Measures are in place when a non-compliance is identified, such as detention, prohibition of the placing the product on the market, closure of establishment and recall from the market of non-compliant food. (See also Section 6.2.6).

5.4.2 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 states that MSs 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 legal basis for imposition of administrative sanctions by the CAs arises from the Food Law as amended and the Sanction and Infringement Administrative Act 92/1963 (see also Section 6.2.6).

Conclusions on Enforcement Measures

Legal provisions are in place and provide for measures in the case of non-compliance and sanctions (see also Section 6.2.6).

5.5 Verification and review of official controls and procedures

5.5.1 Verification procedures

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the CAs to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure the effectiveness of corrective action and to update documentation where needed.

Findings

In the two RIPHPCs visited in Varna and Haskovo internal verification was carried out by heads of departments. Verification consisted of documentary check of inspection files, interview with the inspector concerned and on-the-spot observation of inspections and sampling. Such activities were carried out in 2010 in the Kapitan Andreevo DPE. Also, an on-site visit of the CCA took place in the Kapitan Andreevo DPE in 2010 to assess the situation on-the-spot and verify the implemented procedures.

The sampling frequency is verified based on reviewing of quarterly reports of RIPHPCs by the CCA. Due to problems with frequency of products subject to Regulation (EC) No 669/2009 in the

first half of 2010, the CCA currently monitors this situation by reviewing monthly reports on sampling of these products.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

An audit system within the MH is in place, as already described in the FVO report on FCM/FA DG(SANCO)/2010-8584. The MH planned five audits concerning official controls for 2009, but only one was completed due to financial and staff constraints. Due to the lack of funds no such audits have been performed in 2010 either. The most recent audit on import controls of FNAO was carried out in 2008.

Conclusions on Verification Procedures

Verification procedures are in place.

There is an audit system in place within the meaning of Article 4(6) of Regulation (EC) No 882/2004, but no audits have been carried out in the scope of this mission since 2008.

5.6 Multi Annual National Control Plan

Legal Requirements

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

Findings

The integrated MANCP for 2008-2010 has been received by the Commission from the Bulgarian Authorities. It covers, in general, horizontal issues for official food safety control. The control systems applied to import controls of FNAO is not described in detail and it is not updated in relation to new legislative changes.

Conclusions on Multi-Annual National Control Plan

The MANCP does not contain some of the information required in Article 42(2)(e) of Regulation (EC) No 882/2004.

6 Sector Specific findings and conclusions

6.1 Legislation

Findings

As described in the FVO report on FCM/FA No DG(SANCO)/2010-8584, the drafting of legislation in relation to food safety is undertaken by the responsible ministry and drafts are distributed to all other ministries for their input. The MH is responsible for the transposition of EU legislation in the area of food safety including import controls of FNAO. Once officially approved, all new legislation is available on the website of the MH.

The PHD informed the mission team that, there is no national legislation on import controls in place laying down additional requirements regarding sampling frequency for FNAO products from TCs. However there is specific legislation in place concerning fees for import controls of FNAO adopted in 2010 (see chapter 6.2.5).

All the relevant legislation is available on the website of the PHD and RIPHPCs.

Conclusions

In addition to EU legislation, there is no national legislation on import controls in relation to specific products from TCs.

National legislation is in place to establish fees for import controls.

6.2 Requirements along the food chain for import controls of food of non-animal origin

6.2.1 Designated places of import

Legal Requirements

Article 15(2) of Regulation (EC) No 882/2004 requires performing official controls at an appropriate place, including Point of Entry of goods, point of release for free circulation, warehouses, the premises of the importing FBOs, or other points of the food chain.

Article 17 of Regulation (EC) No 882/2004, Article 3(b) and 5 of Regulation (EC) No 669/2009 establish definition and specific requirements for designation of designated points of entry (DPEs) by MS. Article 4 of Regulation (EC) No 669/2009 provides minimum requirements for DPEs.

For a period of five years transitional measures are established by Article 19 of Regulation (EC) No 669/2009. On that basis, when DPE is not adequately equipped with all the facilities, another Control Point(s) can be authorised by the MS.

Under Article 9 of Regulation (EC) No 669/2009, on a request of the MS, the Commission may authorise the CA of the certain DPE operating under specific geographical constraints to carry out physical checks at the premises of FBOs.

Article 2(a) and Article 6 of Regulation (EC) No 1152/2009 establish definition and specific requirements for Designated Points of Import (DPI) for products subject to this Regulation.

According to Article 5(4) and (5) of Regulation (EC) No 258/2010 the checks of products subject to this Regulation shall be carried out at control points specifically designated by the MSs for that purpose and the list of control points shall be made available to the public and communicated to the Commission.

Article 4 of Commission Decision 2008/47/EC requires that the documentary check, as referred to in Article 16(1) of Regulation (EC) No 882/2004, shall be performed at the point of first arrival in the Community and evidence of this check will accompany the consignment.

Findings

Under Regulation (EC) No 669/2009, five DPEs have been established for food, which are also at the same time First Points of Introduction (FPIs) under Regulation (EC) No 1152/2009, namely Sofia airport, the port of Burgas, Kapitan Andreevo and the ports of Varna–West and Varna. The last three DPEs mentioned do not meet certain requirements of Article 4 of Regulation (EC) No 669/2009 and therefore, according to the MH website, 13 CPs were designated under Article 19 of Regulation (EC) No 669/2009. These CPs are FBOs warehouses supervised by six RIPHPCs.

The NVS informed the mission team that, for the purposes of Regulations (EC) No 669/2009 and 258/2010, all eight veterinary BIPs are designated for feedingstuffs. This information was made available on the MAF website during the mission.

There are eight DPIs designated under Regulation (EC) No 1152/2009 which are customs warehouses supervised by the designated RIPHPCs.

These warehouses are at the same time CPs for foodstuffs falling under Regulation (EC) No 258/2010. They are also designated as first points of entry for imports of sunflower oil under Regulation (EC) No 1151/2009.

Veterinary BIPs are not used for import controls on FNAO.

The PHD informed the mission team that there were no imports of peanuts from the USA subject to Decision 2008/47/EC in Bulgaria.

Designated points of entry/ import or control points visited

- *DPEs/CPs in Varna*

At the two DPEs at the ports of Varna–West and Varna there are no CA offices and facilities at the border. The RIPHPC in Varna is designated for prior notification by the importer and performs the documentary checks. Sampling and identity checks are carried out at the CPs by inspectors from the RIPHPC Varna supervising them.

One of the visited CPs was a FBO warehouse used for sampling of fruit and vegetables from Turkey (imported via the DPE in Kapitan Andreevo) before June 2010. The CCA informed the mission team that the second CP visited was recently registered by RIPHPC as a warehouse for dry products falling under Regulations (EC) No 669/2009 and 1152/2009. The registration document issued by the RIPHPC on 11 June 2010 states that this CP is a customs warehouse.

The two CPs could not be clearly identified and matched with the CPs/DPEs listed on the MH website (see Section 5.3.6).

- *DPE/CP in Kapitan Andreevo*

In the Kapitan Andreevo DPE there is a small office for inspectors, where the documentary checks are performed. In this DPE, there are no CA's facilities to perform identity and physical checks.

The CP visited by the mission team is located 7 km from the DPE. This CP was designated by the RIPHPC in Haskovo on 23 June 2010, since when consignments from Turkey subject to Regulation (EC) No 669/2009 are sampled there. The capacity of this warehouse is 300 square meters (around four truckloads). The facility is equipped for electric charging of the cooling units of containers/trucks. An appropriate parking area for trucks is available. A separate room for inspectors has also been made available by the FBO in the warehouse.

- *CP in Sofia*

The CP visited in Sofia is a complex of warehouses rented by different FBOs, of which four can be used mainly for identity and physical checks of products from Turkey subject to Regulation (EC) No 669/2009 entering Bulgaria via the Kapitan Andreevo DPE. The CA informed the mission team that one specific warehouse is designated for products bound for other MSs. This warehouse is not used currently, because consignments are sampled in the CP close to the Kapitan Andreevo DPE. The information on the list of DPEs/CPs available on the MH website is not detailed enough to identify these warehouses, as only a general indication of the warehouse area is given (see Section 5.3.6).

All the CPs visited by the mission team comply with the following requirements of Article 4 of Regulation (EC) No 669/2009: (b) appropriate facilities for the CA to undertake checks; (d) facilities to store consignments; (e) unloading equipment; and (f) possibility to perform unloading. Other requirements of Article 4 are met by the RIPHPCs, i.e. (a) adequate staff; (c) instructions for sampling and laboratories; (e) sampling equipment; and (g) designated laboratory.

- *DPIs in Sofia and Varna*

The DPI in Sofia visited by the mission team is a customs warehouse used by the companies importing consignments of products subject to Regulation (EC) No 1152/2009. The DPI in Varna was, at the same time, the CP for dry products falling under Regulation (EC) No 669/2009, as described above.

These DPIs comply with the following requirements of Article 6 of Regulation (EC) No 1152/2009: (c) possibility to perform unloading and storage; (d) availability of storage rooms; and (e) unloading equipment. Other requirements of Article 6 are met by the RIPHPC in Sofia, i.e. (a) adequate staff; (b) instructions for sampling and laboratories; (e) sampling equipment; and (f) designated laboratory.

Authorisation of CPs

Authorisation of the CP in the vicinity of the Kapitan Andreevo DPE was based on a specific assessment procedure implemented for this purpose by the CA.

Other CPs visited by the mission team were subject to regular registration by the relevant RIPHPCs. The registration indicates which products can be stored in these warehouses, taking into account storage conditions. No authorisation procedure under Article 19 of Regulation (EC) No 669/2009 has been established and none of the FBOs received a formal evidence of such authorisation from CAs for use as CPs.

Shared use of facilities at the BIPs/DPEs

Currently DPEs for food and BIPs do not share any facilities (see Section 5.1.1).

Conclusions

Five DPEs have been designated, but three of them do not comply with minimum requirements established by Article 6 of Regulation (EC) No 669/2009.

13 CPs in the FBOs' premises are established under Article 19 of Regulation (EC) No 669/2009, together with the RIPHPCs supervising them.

DPIs for products subject to Regulation (EC) No 1152/2009 are designated at the customs warehouses for controls on products subject to the same Regulation.

CPs under Regulation (EC) No 258/2010 and first points of entry for imports of sunflower oil under Regulation (EC) No 1151/2009 have been designated.

The CPs visited comply with Article 4 of Regulation (EC) No 669/2009.

The DPIs visited comply with Article 6 of Regulation (EC) No 1152/2009.

Not all CPs were adequately authorised by the CA for carrying out identity and physical checks, as provided for in Article 19 of Regulation (EC) No 669/2009.

6.2.2 Prior notification of consignments

Legal Requirements

According to Article 17(1) of Regulation (EC) No 882/2004, for organisation of official controls subject to Article 15(5), MS shall require from FBO responsible for consignments to give prior notification of their arrival and nature.

Article 5 of Regulation (EC) No 1152/2009, Article 6 of Regulation (EC) No 669/2009 and Article 3 of Regulation (EC) No 1151/1009 establish detailed rules of prior notification requirements for products subject to these Regulations.

Article 4 of Regulation (EU) No 258/2010 requires FBO responsible for consignments of products subject to this Regulation to provide prior notification to the CA of the MS before their physical arrival.

Findings

In case of the DPE in Varna the prior notification of products subject to Regulation (EC) No 669/2009 and 1152/2009 follows the legislative requirements. The importer or his representative submits notification (part I of the CED) to the CAs at least one working day prior to the physical arrival of the consignment. At the Kapitan Andreevo DPE, for products subject to Regulation (EC) No 669/2009, it is common practice for truck drivers to submit the CED on the spot, pending the customs controls at the border.

For products subject to Regulations (EC) No 1151/2009 and 258/2010, before the consignment arrives at the first point of entry or CP, the importer (or his representative) must pre-notify the CA about the date and time of arrival, as required by the legislation. A model notification of arrival of

the consignment has been developed by the CA and placed at FBOs' disposal for use to notify the responsible RIPHPC. Upon receipt of the notification, the RIPHPC faxes it to the customs office for information.

Conclusions

Adequate prior notification procedures are in place for FNAO subject to Regulations (EC) No 669/2009, 1152/2009, 1151/2009 and 258/2010. However, in the Kapitan Andreevo DPE these procedures are not always followed by the FBOs for products subject to Regulation (EC) No 669/2009.

6.2.3 Procedures for import controls

Legal Requirements

Article 15(1) of Regulation (EC) No 882/2004 establishes that CA shall carry out regular official controls on food and feed of non-animal origin imported into the EU.

Article 8 of Regulation (EC) No 669/2009, Article 7 of Regulation (EC) No 1152/2009, Article 4 of Regulation (EC) 1151/2009 specify official controls to be carried out by the CA on products subject to these Regulations before products are released for free circulation.

According to Article 10 of Regulation (EC) No 669/2009 release for free circulation of consignments shall be subject to the presentation by the FBOs or their representatives to the custom authorities of a CED duly completed by the CA and favorable results from physical checks, where such checks are required, are known.

Article 5 of Regulation (EU) No 258/2010 specify checks to be carried out by the CA on products covered by this Regulation presented for first placing on the market.

Findings

The main road border crossing for products from Turkey subject to Regulations (EC) No 1152/2009 and 669/2009 is in Kapitan Andreevo.

In the case of products released in Bulgaria, importers are registered by RIPHPCs, and they are responsible for prior notification and delivery of the documents required to the Customs authorities. These tasks can also be performed by logistics companies.

The RIPHPCs perform official controls on imported foodstuffs. After receiving prior notification from FBOs, RIPHPCs perform documentary checks, which takes up to two working days. For products subject to Regulation (EC) No 669/2009, other documents accompanying the consignment, proving that the information on the CED is correct, are checked, e.g. the phytosanitary certificate, the invoice, reports on laboratory tests (when presented), health certificates and/or declarations, where available. The CED is accepted in Bulgarian and/or English.

Procedures for products subject to Regulation (EC) No 669/2009

The following procedures have been implemented at the CP and the Kapitan Andreevo DPE. After receiving the notification (CED, part I) inspectors at the DPE in Kapitan Andreevo carry out

documentary checks. Based on a special chart, which allows for a random selection, inspectors decide whether samples should be taken. If only documentary checks are carried out, part II of the CED is filled in and signed. If the consignment is chosen for sampling, part II of the CED is issued, with an indication that the consignment was selected for sampling, and the identity and physical checks are performed at the CP. For that purpose, the inspector informs the Customs by sending them a request to attend. At this stage the inspector retains the copy of parts I and II of the CED. In parallel, the truck driver presents to the Customs the original CED, which already contains an indication about sampling. At this point the driver receives from the Customs documents allowing release for transfer under customs procedures to the destination in Bulgaria or in the other MS.

The truck, accompanied by Customs and RIPHPC officials, travels to the CP facility located 7 km away from the DPE. At the CP the customs official removes the seals from the vehicle and the RIPHPC inspector takes samples in the presence of the Customs official. After sampling is finished, the Customs official re-seals the consignment. The number of the new seal is indicated in the CED. In the customs transfer document the Customs official indicates that samples were taken, and that a new seal was affixed. A joint report on the action taken is written by both RIPHPC and customs officials.

The truck driver then has two possibilities – either wait for the results of the analysis or continue the journey to the destination declared. The RIPHPC in Haskovo informed the mission team that 60 % of drivers prefer to stay at the CP and wait for the results. In most cases where onward transportation is requested, the final destination of the products is in other MSs. If the driver prefers to continue the journey, he is given a certified copy of parts I and II of the CED. The original is kept at the CP in the special office of the RIPHPC inspectors. Once the results are available, the finalised original CED and the results of the analysis are handed over to the driver. If the truck has already left the CP for onward transportation, the original CED is handed over to the manager of the facility at the CP who has a special letter of authorisation signed by the importers or the importers' agents. The manager then transmits these documents to the agents or to the final destination of the importer. All controls are finalised in three days (during the working days and when the consignments is not detained) and four - five days if the consignments arrives during the weekend or if it is detained by the CA.

If the goods are transferred to another CP, the procedure is different. The inspector at the DPE in Kapitan Andreevo issues a certified copy of the CED indicating that samples should be taken. The document is left at the DPE. The original CED is given to the driver. On this basis, the Customs release the truck for transfer to the next customs point, which is not necessarily the CP, but the next destination declared in the customs documents. The Kapitan Andreevo DPE informs the RIPHPC supervising the CP by faxing parts I and II of the CED. A special information note is given to the driver, which he has to sign, informing him about the procedure and the location of the CP. The truck, not accompanied by customs officials and inspectors, then leaves the DPE. After it arrives at the CP samples should be taken. The local RIPHPC informs the customs authorities when and where this will happen. After agreeing with the Customs RIPHPC inspectors take samples in the presence of Customs officials. The sampling procedure is similar to that followed in the previous case. The original CED is retained at the RIPHPC and a certified copy is given to the driver. In most cases, if the products are bound for other MSs, after sampling the trucks continue their journey to the final destination. The original CED and analytical report are sent to the destination indicated in the CED. This procedure could take more time than the previous one. In the obtained cases it took up to seven days from the prior notification until the final CED was issued.

The procedure described above does not ensure that consignments which leave the Kapitan Andreevo DPE will arrive at the CP because, according to the customs documents, these consignments are already in the process of transfer to the next destination. This led to around 120 consignments selected for sampling not arriving at the CP and not being sampled. This was mainly the case with products bound for Romania. Since nomination of the CP in the vicinity of Kapitan Andreevo that procedure is not used, but it may be followed again if the Kapitan Andreevo DPE would be overloaded with sampling of vegetables from Turkey. This may happen in late February to May, when the biggest volume of imports is expected.

At the DPEs in Varna consignments are usually sampled in the CPs (warehouses) supervised by the RIPHPC in Varna and customs officers participate in this procedure in a similar way. However, in some cases goods could be transmitted to other CPs in Bulgaria, but only when they are intended for the Bulgarian market.

Identity and documentary checks performed by the inspectors were generally considered satisfactory for products subject to Regulation (EC) No 669/2009.

As described above, onward transportation is commonly used for consignments imported from Turkey subject to Regulation (EC) No 669/2009 and bound for other MSs (mainly Germany, Romania, the Netherlands and Austria), but the Bulgarian CA which allows onward transportation does not inform the CA in the MS of the final destination.

Procedures for products subject to Regulation (EC) No 1152/2009

The mission team visited the FPIs in Varna and in Kapitan Andreevo and the DPIs in Sofia and Varna. The mission team observed that control procedures followed Regulation (EC) No 1152/2009. The CED and all documentary checks were performed at the FPI of Regulation (EC) No 1152/2009, and consignments were transferred to the DPIs which are customs warehouses. After receiving the CED faxed by the FPI, the RIPHPC inspector decide on the sampling frequency and samples are then taken under customs supervision. The Customs authorities can release consignments after part II of the CED was finalised.

Some problems concerning documentary checks of products subject to Regulation (EC) No 1152/2009 were observed by the mission team. Inspectors in Kapitan Andreevo DPE were not always aware that the number of samples indicated in the analytical report attached to the health certificate should correspond to the quantity of consignments specified in Regulation (EC) No 401/2006. In the Kapitan Andreevo DPE, which is the main FPI for Turkish products, where all documentary checks are performed CEDs are commonly accepted without indicating the DPI for which consignments are bound. Inspectors informed the mission team that this information is not available to them, and they do not use the DG SANCO '*Guidance document for CAs for the control of compliance with EU legislation on aflatoxins*' since only the English version is available.

Sampling frequency

The sampling frequency laid down for products subject to Regulation 669/2009 (10 % of vegetables from Turkey) was not met during the first two quarters of 2010. In the first quarter the main reasons were problems with implementation of procedures. During the second quarter, once CPs had been designated, the frequency improved, especially for products intended for the Bulgarian market. The CCA informed the mission team that after 23 June 2010 the situation improved significantly, as almost all consignments of vegetables from Turkey were sampled at the CP in the vicinity of the

Kapitan Andreevo DPE. Based on internal verifications, the third quarterly report is expected to meet the sampling frequency of 10 % required for these products. Also the frequency of sampling of chili and chili products for Sudan Dyes and spices from India for aflatoxins was lower than required Regulation (EC) No 669/2009.

The information on import controls of products subject to EU legislation in 2009, provided by the Bulgarian CA, is presented in Table 1. In 2009 the sampling frequency for products subject to Decision 2006/504/EC, as repealed by Regulation (EC) No 1152/2009, was generally met. In 2009 no samples had been taken from four consignments of guar gum subject to Decision 2008/352/EC, as repealed by Regulation (EC) No 258/2010.

A special chart developed by the RIPHPC was available for inspectors in Kapitan Andreevo for random selection of the consignments subject to physical checks under Regulation (EC) No 669/2009. The sampling arrangements for other products are decided by the inspectors at local level. During sampling of Turkish hazelnuts at the DPI, the inspector had internal instructions for selection of consignments for sampling. He explained that whenever random sampling is required every first consignment imported by a company would be chosen and then samples would be taken, based on the level of consignments imported by different importers and previous experience.

Table 1 Import and sampling data for 2009 (January to December) – products coming under Commission Decisions

Product	**CN - code**	**Country of origin**	**Number of consignments imported**	**Samples analysed**	**Number of non-conformant consignments**
a) Products subject to **Commission Decision 504/2006 (repealed by Regulation (EC) No 1152/2009**):					
Peanuts and peanut products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96, 2008 11 94, 2008 11 98	EGYPT	10	2	-
Peanuts and peanut products	1202 10 90, 1202 20 00, 2008 11 92, 2008 11 96, 2008 11 94, 2008 11 98	CHINA	**129**	**20**	-
Pistachios	0802 50 00, 2008 19 13, 2008 19 93	IRAN	-	-	-
Dried figs	0804 20 90	TURKEY	**17**	**2**	-
Hazelnuts	0802 21 00, 0802 22 00	TURKEY	**12**	**2**	-
Pistachios	0802 50 00, 20081993	TURKEY	**1**	-	-
Figs, hazelnuts, pistachios and derived products	0813 50, 2007 99 98, 2008 19, 1106 30 90	TURKEY	**71**	**9**	**1**(document)
Peanuts and peanut products	12021090, 1202 20 00, 2008 11 94, 2008 11 98, 2008 11 92, 2008 11 96	BRAZIL	-	-	-
Brazil nuts in	0801 21 00	BRAZIL	-	-	-

shell					
Mixtures of nuts or dried fruits containing Brazil nuts In shell	081350	BRAZIL	-	-	-
Almonds (subject to Voluntary Aflatoxin Sampling Plan(VASP)	080211, 080212, 2008 19 13, 2008 19 93, 081350	USA	**21**	**3**	-
Almonds (not subject to VASP)	080211, 080212, 2008 19 13, 2008 19 93, 081350	USA	**2**	**2**	-
b) Products subject to Commission Decision 2005/402/EC (repealed by Regulation (EC) No 669/2009):					
Chilli and chilli products, curcuma (for Sudan dyes)	0904 20 90, 0910 50, 0910 30	Third Countries	12	9	**2**(document)
Palm oil **(for Sudan dyes)**	1511 10 90	Third Countries	11	2	**2**(document)
c) Products subject to **Commission Decision 2008/ 352/EC repealed by Regulation (EC) No 258/2010)**					
Guar gum **for PCP** For human or animal consumption	1302 32 90	India	4	-	-
Compound foodstuffs and feedingstuffs containing at least 10 % guar gum originating in or consigned from India **(for PCP)**.		India	-	-	-
d) Products subject to **Commission Decision 2008/433/EC (repealed by Regulation (EC) No 1151/2009**):					
Sunflower oil for **contamination with mineral oil**	15121191, 1512199010	Ukraine	2	1	-

On-site visits to the FBOs

The mission team visited one importer of vegetables from Turkey subject to Regulation (EC) No 669/2009. The importer had been instructed about the new legislative requirements during the visit by the RIPHPC in 2009. All the clearance procedures are entrusted to the forwarding agent who represents the importer before the Customs and the CA. The mission team obtained evidence of CEDs issued by the CAs and of customs releases at a later stage.

Conclusions

Customs release for free circulation complies with Article 10 of Regulation (EC) No 669/2009 and Article 8 of Regulation (EC) No 1152/2009.

When the CA allows onward transportation to the other MS, the CA at the DPE does not notify the CA at the point of destination and no arrangements are in place to ensure that the consignment remains under the continuous control of the CAs, as required by Article 8(2) of Regulation (EC) No 669/2009.

Consignments from Turkey subject to Regulation (EC) No 669/2009, transported by truck and bound for another MS which had been selected at the DPE for identity and physical checks at the CPs (other than the CP located 7 km from Kapitan Andreevo) did not always reach the CPs, and the checks were not carried out (Article 8(1)(b) of Regulation (EC) No 669/2009).

The documentary checks on products subject to Regulation (EC) No 1152/2009 are not always carried out properly (Article 7(2) of Regulation (EC) No 1152/2009).

In the first two quarters of 2010 the sampling frequency for some products subject to Regulation (EC) No 669/2009 was lower then required by the same Regulation.

In 2009 the sampling frequency for products subject to Decision 2006/504/EC, as repealed by Regulation (EC) No 1152/2009, was followed.

No samples of four consignments of guar gum had been taken in 2009.

6.2.4 Splitting of consignments

Legal Requirements

According to Article 12 of Regulation (EC) No 669/2009, Article 8 of Regulation (EC) No 1152/2009 consignments shall not be split until the official controls and CED is completed by the CA. In case of subsequent splitting an authenticated copy of the CED shall accompany each part of the consignment until released for free circulation.

Article 5 of Regulation (EC) No 1151/2009 provides that consignments shall not be split until the official controls by the CA have been completed. In case of subsequent splitting a copy of official documents provided for in Article 3(2) authenticated by the CA of the MS on whose territory the splitting has taken place, shall accompany each part of the consignment until released for free circulation.

Article 6 of Regulation (EU) No 258/2010 requires that if consignment of products subject to this Regulation are split, a certified copy of the health certificate provided for in Article 2(1)(a), shall accompany each part of the split consignment until its release into free circulation.

Findings

The CA informed the mission team that consignments may not be split until all the checks have been finalised by the CAs. The instructions issued by the CA include splitting procedures and follow the relevant legislation. Products arriving by truck can be partially unloaded on the way to the final destination, as different products and consignments are transported together, but the consignments subject to import controls may not be split until the final CED is issued.

Conclusions

In Bulgaria procedures for subsequent splitting of consignments follow EU requirements.

6.2.5 Fees and costs

Legal Requirements

Article 14 of Regulation (EC) No 669/2009 establishes that MSs shall ensure the collection of fees occasioned by the increased level of official controls provided for in this Regulation in accordance with Article 27(4) and criteria laid down in Annex VI of Regulation (EC) No 882/2004.

Article 7 of Regulation (EU) No 258/2010 establishes that all costs resulting from the official controls referred to in Article 5(1), including sampling, analysis, storage and any measures taken following non-compliance, shall be borne by the feed and food business operator.

According to Article 7 of Regulation (EC) No 1151/2009 and Article 10 of Regulation (EC) No 1152/2009 all costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance shall be borne by the FBO.

Findings

Decree No 96 of the Council of Ministers of 18 May 2010 amending the tariff of fees to be collected for public health controls under the Health Act, adopted by Decree No 242 of the Council of Ministers, establishes specific fees for products subject to Regulations (EC) No 1152/2009 and 669/2009. Under this Decree the following costs apply: (a) reviewing and evaluating the documentation and filling in the CED: 30 BGN (15.3 EUR); (b) identity and physical checks, including filling in the CED: 35 BGN (18 EUR); (c) sampling: 40 BGN (20.5 EUR); (e) laboratory analysis — aflatoxins: 186 BGN (95 EUR); cadmium and lead: 16 BGN (8.2 EUR); ochratoxin A: 69 BGN (35.3 EUR); residues of pesticides: from 32 BGN (16.4 EUR) to 321 BGN (164 EUR); Sudan dyes: 64 BGN (32.7 EUR).

For products subject to Regulations (EC) No 1151/2009 and 258/2010, on the basis of the Health Act the importer is charged 2.4 BGN per working hour of the inspector and for the laboratory analysis.

Concerning other costs related to products subject to EU Regulations on imports of FNAO, the importers cover costs such as unloading, storage and courier services.

Conclusions

Costs and fees concerning import controls on FNAO are established for products subject to specific EU legislation.

6.2.6 Procedures for non-compliant lots

Legal Requirements

Article 19 of Regulation (EC) No 882/2004 establishes that CAs shall place under official detention consignments that do not comply with the food or feed law, and that a number of measures shall be taken in respect of such feed or food. These measures include destruction, special treatment, re-dispatch or use for other purposes. Some of these measures are described in Articles 20 and 21 of the above mentioned Regulation.

Findings

The procedures for non-compliant lots are the same as described in the previous report DG(SANCO)/2008-7847 on import controls of FNAO. Importers can re-dispatch a non-compliant consignment to the TC, it may be used as feed, or it can be destroyed. The costs of destruction are borne by the importer. Examples of such cases were reviewed by the mission team. In the case of diversion of food into feed, the CA responsible for controls of feedingstuffs on the market is informed.

Conclusions

Procedures for non-compliant lots are in line with Articles 19 and 21 of Regulation (EC) No 882/2004.

6.2.7 Rapid Alert System for Food and Feed

Legal Requirements

Article 50 of Regulation (EC) No 178/2002. Where a MS has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information must be immediately notified to the Commission under the rapid alert system.

Article 19(3) of Regulation (EC) No 882/2004. Where it does not permit the introduction of feed or food, the CA shall notify the Commission and other MS of its findings and of the identification of the products concerned in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decision to the customs services, together with information as regards the final destination of the consignment.

Findings

The organisation and procedures for the RASFF system are in place and have not changed since the last mission on import controls of FNAO. The operation of the RASFF network was demonstrated to the mission team by means of documentation in relation to previous RASFF notifications. The information concerning the latest version of Turkish signatures from 13 September 2010 was available in the FPI/DPI Kapitan Andreevo.

Conclusions

The RASFF procedures are in place in the framework of import controls and comply with the legal requirements.

6.2.8 Sampling and laboratories visited

Legal Requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires CA to ensure that they have access to an adequate laboratory capacity.

Article 11(1) of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant Community rules.

Article 12(1) of Regulation (EC) No 882/2004 requires CA to designate laboratories that may carry out the analysis of samples taken during official controls.

Article 33 of Regulation (EC) No 882/2004 requires MS to designate National Reference Laboratories (NRL) for each European Union Reference Laboratory (EURL) referred to in Article 32. The NRL shall collaborate with the EURL, coordinate activities, organise comparative tests, ensure dissemination of information, and provide scientific and technical assistance.

Findings

6.2.8.1 Sampling

Sampling for pesticides residues analyses

A Standard Operation Procedure (SOP) on sampling for pesticide residues has been developed by the CCA and is provided to all RIPHPCs. Regulation (EC) No 396/2005, Commission Directive 2002/63/EC and Ordinance No 31 on MRLs of pesticides in food are listed in the SOP as the main documents to be followed.

The mission team observed sampling for pesticide residues at the CP in the vicinity of the Kapitan Andreevo DPE and at the CP in Sofia. A uniform approach was demonstrated by the sampling inspectors met during the mission. The requirements of Commission Directive 2002/63/EC on the number of primary samples, number of units and weight of the sample were largely followed. Lots were identified correctly. Some deficiencies were identified in preparation of the bulk samples for peppers (pre-packed in small packages of 500 grams) when it came to combining and mixing the primary samples. The sampling inspectors in the second region confirmed that, in the case of pre-packed fruit and vegetables, they do not mix the content, but only combine and mix individual packages. The samples were properly sealed and labelled.

A standard sampling protocol was used by the sampling inspectors. In both cases, the sampling protocol was drafted after completion of the sampling. One copy is always provided to the FBOs, one copy is kept by the sampling inspector and the original accompanies the samples to the laboratory. An additional photocopy is provided to the Customs officer who is present at the CP during the physical check on the consignment (including sampling).

The samples were properly sealed and labelled, as required by Article 11(7) of Regulation (EC) No 882/2004.

Sampling for aflatoxins analyses

In the DPI in Sofia the mission team observed sampling of a 4 000 kg consignment of pistachios (160 vacuum packs of 25 kg each). The inspector from the Sofia RIPHPC followed Annex I.D.2.7.1 to Regulation (EC) No 401/2006. He reduced the number of incremental samples to be taken from 60 to 30, and the weight of an incremental sample was 400 g. Following Annex I.A.4 to the same Regulation, the inspector used the calculation formula to decide on the sampling frequency. After having sampled about 15 packs with full spear, the sampler realised that the aggregate sample weight was already too high since he had forgotten to subtract the weight of the basket in which the aggregate sample was weighed. The inspector then considered continuing with a 25 % smaller incremental sample (resulting in an incremental sample of around 300 g). A total aggregate sample of 12 kg was taken and, after mixing, the inspector divided it into two samples of 6 kg each. The samples were put in non-transparent bags, each of which was sealed. The sampling report was prepared. One copy was given to the importer and one was sent to the laboratory. The FBO was asked if it would request a confirmatory sample. The inspectors sent the sample to the laboratory.

6.2.8.2 Laboratories visited

Specific laboratory for pesticide residue analysis

During the mission, the laboratory of the RIPHPC in Pleven was visited. This laboratory is one of the six official laboratories carrying out official control analyses for pesticide residues in food of plant origin in Bulgaria. On 23 March 2010 this laboratory was designated by the MH as the sole laboratory in charge of testing foodstuffs subject to Regulation (EC) No 669/2009 for pesticide residues.

The laboratory in Pleven is designated as the NRL for pesticide residues analysis in fruit and vegetables. This NRL performed some training for other pesticides residues laboratories but focusing mainly on laboratory equipment. It coordinated also participation of these labs in the Proficiency Tests (PTs) carried out by the European Union Reference Laboratory (EURL), but did not carry out any such tests itself.

The laboratory is equipped with liquid chromatography with tandem mass spectrometry (LC-MS/MS) (since the end of 2009) and gas chromatography/mass spectrometry (GC-MS) for multi-residue analysis of pesticides. The laboratory has limited facilities for implementing some of the quality control/assurance procedures required for this type of analysis (mainly those related to preparation/storage/control of pesticide standards and method validation).

Six employees (three chemists and three technicians) are responsible for routine analyses. The staff are experienced and qualified and training is provided regularly.

Analytical coverage of 108 pesticides was reported by the CA (53 analysed by GC-MS and 55 by LC-MS/MS). The main focus is on analyses using multi-residue methods (MRMs). The analytical method routinely used by the laboratory consists of extraction with QuEChERS, followed by GC-MS and LC-MS/MS analysis. The limit of quantification (LOQ) established by the laboratory for all pesticides is 0.01 mg/kg, except for four pesticides analysed by GC-MS (0.04-0.05 mg/kg).

Samples from import controls on FNAO are analysed by LC-MS/MS only for oxamyl, methomyl and thiodicarb (compound included in the residue definition of methomyl). Import control samples are considered the priority. The time taken between sampling and reporting analytical results is usually one day. In cases where the maximum residue level (MRL) is exceeded, this time is

extended to two days for confirmation purposes.

In 2009, the laboratory analysed some 356 samples by GC-MS. In the first half of 2010, a total of 1,171 samples were analysed, 474 of them for import controls.

The single-residue method (SRM) used in the laboratory for amitraz in pears is not validated and does not cover the metabolites included in the residue definition. In 2009, six cases of non-compliance were identified and reported via the EU RASFF for amitraz in pears, even though the method was not accredited and validated.

The laboratory is accredited in line with EN ISO/IEC 17025 in accordance with Article 12 of Regulation (EC) No 882/2004. The first accreditation was granted in December 2009 by the Bulgarian Accreditation Service (BAS) for the GC-MS method. An application was submitted to the BAS for extension of the scope of accreditation to include the LC-MS/MS method. Laboratory staff stated that the first external audit is expected by the end of the year.

The mission team reviewed the oxamyl and methomyl method used by the laboratory and observed that the Document No SANCO/10684/2009 on 'Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed' is only partly followed. The pure standards available in the laboratory exceeded the expire date. The comparison of old and new standards is not performed by the laboratory, controls are not performed on the stock solutions and records are not kept. Laboratory uses also inadequate containers for the working solutions. Calibration/verification of the balance and pipettes used for standards preparation was inadequate. Cross-contamination cannot be avoided during the sample preparation by the laboratory because pure standards and laboratory samples are weighed in the same small room and the same equipment is used.

Validation of the GC-MS method for many of the pesticides covered has not been completed yet, and validation of LC-MS/MS method for oxamyl, methomyl and amitraz is not finalised. The LC-MS/MS determination system is not calibrated for every batch of analysis and the quantification is achieved with matrix-matched standards. A spiked sample is analysed with every batch. Measurement uncertainty has been introduced recently for reporting results for methomyl and oxamyl only, but the method of estimating the uncertainty is unrealistic (within-laboratory reproducibility is not taken into account).

The laboratory has participated in the last two European proficiency tests (PTs) for fruit and vegetables (EUPT-FV-11 (2009) and EUPT-FV-12 (2010)), as required by Article 28 of Regulation (EC) No 396/2005. In 2009, the results for the substances reported were good, but the number of pesticides analysed was insufficient (neither oxamyl nor methomyl was analysed). As a result, the laboratory was classified as category B. The results of EUPT-FV-12 have not been officially reported yet. However, preliminary evaluations show that the laboratory did not manage to analyse amitraz.

In reply to the recommendation given in the Report DG(SANCO) 2008-7847 on import controls of FNAO, this laboratory implemented the method for Sudan I-IV based on the LC-MS/MS equipment used for pesticides residues. This method is not accredited and validated yet.

Specific laboratory for mycotoxins

The mission team visited the RIPHPC laboratory in Sofia, where a specialised Unit for Chemical Analysis is responsible for testing for mycotoxins. Two chemists with university degrees and two

laboratory assistants are designated for mycotoxins analysis. Since January 2010 the laboratory has been accredited by the BAS as in line with EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'. Analytical methods for aflatoxin B1 and total aflatoxins in nuts and dried fruit are included in the scope of the accreditation. The laboratory was audited by the BAS in June 2009 with a positive result. After six months, its final accreditation certificate was granted. During the first half of 2010, the laboratory analysed around 110 samples for mycotoxins, 13 of which were import control samples (aflatoxins). No non-compliant samples were identified in this period. In-house training and audit programmes are in place. However, no training relating to mycotoxins was given in 2009 and none is planned in 2010. The laboratory is equipped with High Performance Liquid Chromatography (HPLC) for aflatoxins analysis.

The laboratory used a dry method for sample preparation. A SOP was available for grinding and homogenising the laboratory sample.

No SOP for handling the trade (defence) and reference (referee) samples was in place. The samples observed were stored at ambient temperature in fragile plastic bags that did not prevent possible changes in the composition of the samples. The mission team was shown another storage room where old positive samples were stored on the floor in leaking packages while waiting to be incinerated. There was consequently a risk that the laboratory could be contaminated by mycotoxins brought in from this storage room on staff's shoes (no shoe change is required when moving between the storage room and the analysis room). According to the laboratory staff, non-compliant samples should be stored in a freezer, at least within three months after the date of analysis. There was no SOP or relevant quality document describing this procedure.

The quality assurance system (QAS) does not fully meet the requirements of EN standard ISO/IEC 17025 and of points 4.2 and 4.3 of Annex II to Regulation (EC) No 401/2006:

- No certified reference material (CRM) or other suitable control sample is available to verify the method checked.
- The latest participation in a suitable PT was in 2006 for aflatoxins in peanut paste, organised by the EURL on 'Mycotoxins in food and feed'. The PT z-score was <-2.0 (underestimating the actual content) for both B1 and the sum of B1+B2+G1+G2. No corrective action was taken by the laboratory, as it did not consider the results of this PT as non-compliant. In the official report on the PT, all z-scores <-2.0 or >2.0 were, however, explicitly regarded as non-satisfactory and corrective action was required from the laboratories concerned.
- The recovery rate is not assessed during routine analyses; the final results are therefore reported without correction for recovery.
- The equipment used for the aflatoxins analysis (analytical and technical weights and pipettes) is not calibrated with appropriate frequency; the frequency reported was once every three years.
- The traceability of the QAS is inadequate. Some of the documents requested were missing or were not available.

A validation report for the aflatoxin method was presented. The method was not fully defined, as the following criteria were not assessed: accuracy, reproducibility and measurement uncertainty.

The analytical results are reported without correction for recovery; recovery rates are not available for such correction. Measurement uncertainty is reported together with the analytical results, but a procedure to calculate measurement uncertainty is missing.

According to the chapter 4.4.1 of the MANCP, laboratory of the RIPHPC in Sofia has been designated as the NRL for the analysis of mycotoxins in food within the system of the MH. During the visit the mission team noted that the laboratory was not aware of this nomination. Laboratory management explained that before 2009 they performed some activities as the NRL. Since 2008 no laboratory performed tasks of the NRL for mycotoxins in food. The CCA informed the mission team that this issue would be addressed within the near future.

Conclusions

During the sampling procedures observed for mycotoxins and pesticides, samples were properly sealed and labelled, as required by Article 11(7) of Regulation (EC) No 882/2004.

The sampling requirements for pesticide residues set out in Commission Directive 2002/63/EC were generally followed.

Possible changes of the weight of the incremental samples during the sampling procedure for aflatoxins analyses could lead to obtaining a non-representative aggregate sample. This is not in compliance with point A.1 of Annex I to Regulation (EC) No 401/2006.

The NRL for mycotoxins in food is not designated and currently no laboratory performs NRL's tasks required by Article 33 Regulation (EC) No 882/2004.

The NRL for pesticide residues analysis in fruit and vegetables under the MH does not perform all the tasks required by Article 33(2) (b), (c) and (e) of Regulation (EC) No 882/2004.

In the visited laboratory for pesticide residues the SANCO Guidelines (Document No SANCO/10684/2009) on ‘Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed’ are only partially followed, and the sample preparation does not ensure avoidance of cross-contamination.

The staff at the laboratory visited in Pleven are suitably qualified and receive regular training. At the RIPHPC laboratory in Sofia problems with training staff were identified (see Section 5.2.3 'Findings' and 'Conclusions').

The laboratory is accredited as in line with ISO 17025, as required by Article 12 of Regulation (EC) No 882/2004. However, the accreditation does not cover the LC-MS/MS method, which is mainly used for the routine analyses.

The laboratory participates in the European PTs for fruit and vegetables, as required by Article 28 of Regulation (EC) No 396/2005. Nevertheless, based on the results and its performance, it was classified as category B.

The analytical method used for Sudan Dyes I-IV is not validated and accredited as required by Article 12 of Regulation (EC) No 882/2004.

The laboratory for mycotoxins analyses does not operate fully in accordance with standard EN ISO/IEC 17025, as required by Article 12(2) of Regulation (EC) No 882/2004.

Validation of the aflatoxin method is limited and does not fully follow Annex III to Regulation (EC) No 882/2004 (no studies on accuracy, reproducibility and measurement uncertainty).

The storage of the trade (defence) and reference (referee) samples observed was inadequate to avoid any change in the composition of the sample, which might arise during storage. This routine is not in compliance with point A.3.7 of Annex I to Regulation (EC) No 401/2006.

The analytical results reported are not corrected for recovery; recovery rates are not available for such correction. This is not in compliance with point 4.4 of Annex II to Regulation (EC) No 401/2006.

7 Overall Conclusion

Overall, although there is an import control system in place in Bulgaria, major shortcomings were identified concerning cooperation between the CAs, authorisation of CPs, laboratories performance and methods validation, lack of NRL for mycotoxins (in food), procedures used for CPs, onward transportation and documentary checks.

8 Closing Meeting

A closing meeting was held on 8 October 2010 with representatives of the CCAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The representatives of the CAs provisionally accepted these findings and offered some clarifications and comments.

9 Recommendations

The CAs 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.	Ensure efficient and effective cooperation between the CAs in relation to import controls of food of non-animal origin as required by Article 4(3) of Regulation (EC) No 882/2004.
2.	Continue with the training of staff performing import controls of FNAO, in particular laboratory staff, to ensure that they receive appropriate training for their area of competence, as established in Article 6 and Annex II of Regulation (EC) No 882/2004.
3.	Ensure that the procedure used for mycotoxins sampling is updated as required by Article 8(3)(b) of Regulation (EC) No 882/2004.
4.	Ensure that all methods used by laboratories designated for import controls of FNAO, are validated and they are included in the scope of accreditation as required by Article 12 of Regulation (EC) No 882/2004.
5.	Ensure that the information on all CPs authorised under the Article 19 of Regulation

N°.	Recommendation
	(EC) No 669/2009 is transparent enough to identify them clearly as required by Article 7 of Regulation (EC) No 882/2004.
6.	Ensure that audits are carried out in the units of the MH responsible for import controls as required by Article 4(6) of Regulation (EC) No 882/2004.
7.	Ensure that the MANCP contains all the information required in Article 42(2)(e) of Regulation (EC) No 882/2004.
8.	Ensure that all control points are adequately authorised by the CA for the purpose of carrying out identity and physical checks as provided for in Article 19 of Regulation (EC) No 669/2009.
9.	Ensure that the prior notification procedure is followed by FBOs at the Kapitan Andreevo DPE as required by Article 6 of Regulation (EC) No 669/2009.
10.	Ensure that, when the consignments are bound for identity and physical checks at the CPs, these checks are always carried out as required by Article 8 (1) (b) of Regulation (EC) No 669/2009.
11.	Ensure that the sampling frequency complies with Annex I of Regulation (EC) No 669/2009.
12.	Ensure that documentary checks are properly carried out in accordance with Article 7 of Regulation (EC) No 1152/2009.
13.	Ensure that, when the CA allows for the onward transportation to the other MS, the CA at the DPE notifies the CA at the point of destination and appropriate arrangements are put in place to ensure that the consignment remains under the continuous control of the CAs as required by Article 8(2) of Regulation (EC) No 669/2009.
14.	Ensure that the NRL for mycotoxins in food is clearly designated and both, the NRL for mycotoxins and the NRL for pesticide residues analyses in fruit and vegetables under the MH, carry out all tasks required by Article 33(2) of Regulation (EC) No 882/2004.
15.	Ensure that SANCO Guidelines 10684/2009 on method validation and quality control procedures for pesticide residue analysis in food and feed, adopted on the basis of Article 28(2) of Regulation (EC) No 396/2005, are fully followed, including samples preparation, especially in the case of laboratory performing analyses of amitraz, metomyl and oxamyl in products originating from Turkey.
16.	Ensure that the analytical method used for Sudan Dyes I-IV is validated and is

N°.	Recommendation
	included in the scope of accreditation as required by Article 12 of Regulation (EC) No 882/2004.
17.	Ensure that laboratory performing mycotoxins analyses complies with Annex I point A.3.7 and Annex II point 4.4 of Regulation (EC) No 401/2006, completes validation of the aflatoxins method with studies on accuracy, reproducibility and measurement uncertainty as required by Annex III in Regulation (EC) No 882/2004 and operates fully in accordance with EN ISO/IEC 17025 as required by Article 12(2) of Regulation (EC) No 882/2004.
18.	Ensure that aggregate sample obtained can be considered as representative of the lot, as required by Annex I point A.1 of Regulation (EC) No 401/2006.

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2010-8592.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 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. 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. 315/93	OJ L 37, 13.2.1993, p. 1-3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official

Legal Reference	Official Journal	Title
		controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC
Reg. 1151/2009	OJ L 313, 28.11.2009, p. 36-39	Commission Regulation (EC) No 1151/2009 of 27 November 2009 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil and repealing Decision 2008/433/EC
Reg. 1152/2009	OJ L 313, 28.11.2009, p. 40-49	Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC
Reg. 258/2010	OJ L 80, 26.3.2010, p. 28-31	Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Dec. 2006/677/EC	OJ L 278, 10.10.2006, p. 15-23	2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules
Dec. 2008/47/EC	OJ L 11, 15.1.2008, p. 12-16	2008/47/EC: Commission Decision of 20 December 2007 approving the pre-export checks carried out by the United States of America on peanuts and derived products thereof as regards the presence of aflatoxins