EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2010-8584 - MR FINAL

# FINAL REPORT OF A SPECIFIC AUDIT

# CARRIED OUT IN

# BULGARIA

# FROM 21 TO 29 JUNE 2010

# IN ORDER TO ASSESS THE OFFICIAL CONTROL SYSTEMS IN PLACE FOR FOOD CONTACT MATERIALS AND FOOD ADDITIVES

# 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, carried out between 21 to 29 June 2010, as part of the general audit of Bulgaria undertaken under the provisions of Regulation (EC) No 882/2004 on official food and feed controls. The objective of the specific audit was to check that official controls are carried out in accordance with the principles of that Regulation and in line with the multi-annual national control plan (MANCP) as specified in Article 41 of the above Regulation. In order to achieve the overall objective the specific audit evaluated the implementation of the Community legislation in the area of food additives (FA) and food contact materials (FCM).*

*There are two competent authorities (CAs) clearly designated in the context of this mission, namely the Ministry of Health (MoH) and Ministry of Agriculture an Food (MAF). Effective coordination between the CAs is ensured. The EC Directives relevant to this mission are transposed and in force. In addition national legislation requiring registration of FCM manufacturers and traders came into force in 2009.*

*The MANCP lacks any information relating to designation of tasks regarding FCM and FA.*

*There is a training system established and although specific training on FCM and FA is included not all inspectors have been adequately trained in official control of FCM and FA as required by Article 6 and Annex II to Regulation (EC) No 882/2004.*

*In respect of inspections of food businesses and FCM manufacturers there were a number of shortcomings noted: inadequate assessment of declaration of compliance (DoC), level of FA in final products not being checked, failure to check the specific provisions relating to purity criteria and incomplete assessment of procedures on HACCP.*

*There is no information on the level of implementation of GMP as the registration of FCM manufacturer and traders only commenced two months ago.*

*There is no monitoring system for the consumption of FA and the monitoring system for the use of FA does not cover food of animal origin contrary to the requirements of Article 27 of Regulation (EC) No 1333/2008.*

*In the context of this mission, official control laboratories for testing FA and FCM have been clearly designated, including the National Reference Laboratory (NRL) for FCM. The performance of laboratories visited by the mission team was considered adequate, however, the range of accredited methods for FCM and FA is very limited. None of the designated official control laboratories in Bulgaria participate in Proficiency Tests. In addition, some shortcomings were identified in relation to the method and sampling for the determination of lead and cadmium in ceramic wares.*

*There is an adequate communication network established to transfer information to and from the RASFF national contact point.*

*It is concluded that the official control of FA and FCM is undertaken as part of the broader official control of foodstuffs. The system for FA is mainly carried out following the relevant EC legislation. However, the shortcomings identified regarding assessment of documentation and the limited scope of laboratory analysis might reduce the efficiency of the system. The official control system for FCM is newly set up and requires legal registration of FCM manufacturers and traders. However, a number of shortcomings have been identified in relation to the very limited scope of laboratory analysis, accreditation status and the incomplete assessment of the DoC, which may lead to ineffective controls.*

*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 |
|---|---|
| AHFSD | Animal Health and Food Safety Directorate (Previously FSQD) |
| CA | Competent Authority |
| CCA | Central Competent Authority |
| DEHA | Di(2-ethylhexyl) adipate |
| DG(SANCO) | Health and Consumers Directorate-General |
| DoC | Declaration of Compliance |
| EC | European Community |
| EU | European Union |
| EURL | European Union Reference Laboratory |
| FA | Food Additive |
| FAO | Food of Animal Origin |
| FBO | Food Business Operator |
| FCM | Food Contact Material |
| FNAO | Food of Non Animal Origin |
| FSA | Food Safety Agency |
| FSQD | Food Safety and Quality Directorate (Renamed to AHFSD) |
| FVO | Food and Veterinary Office |
| GA | General Audit |
| HACCP | Hazard Analysis Critical Control Points |
| ITX | Isopropyl Thioxantone |
| LOD | Limit of Detection |
| LOQ | Limit of Quantification |
| MAF | Ministry for Agriculture and Food |
| MANCP | Single Integrated Multi-Annual National Control Plan |
| MEW | Ministry for Environment and Water |
| MoH | Ministry of Health |
| MS | Member State |
| NRL | National Reference Laboratory |
| NCCC | National Council for Co-ordination of Controls |
| NCFS | National Council for Food Safety. |
| NGFS | National Grain and Feed Service |
| NSPP | National Service for Plant Protection |
| NVS | National Veterinary Service |

| | |
|---|---|
| PPA | Primary Aromatic Amines |
| PHD | Public Health Directorate |
| PT | Proficiency Tests |
| RASFF | Rapid Alert System for Food and Feed |
| RIPHPC | Regional Inspectorates for Public Health Protection and Control |
| RVS | Regional Veterinary Services |
| SA | Specific Audit |
| SEM | Semicarbazide |
| SOP | Standard Operating Procedure |
| TC | Third Counties |

## 1 Introduction

The Specific Audit formed part of the Food and Veterinary Office's (FVO) planned mission programme. It took place in Bulgaria from 21 to 29 June 2010. The audit team comprised two inspectors from the FVO and two experts from two different European Union (EU) countries. Representatives from one of the central competent authorities (CCAs), namely the Ministry of Health (MoH), accompanied the audit team for the duration of the audit. An opening meeting was held on 21 June 2010 with the CCAs, the MoH and Ministry of Agriculture and Food (MAF). At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit 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 in the sector currently being evaluated;

- to evaluate the implementation of the Community legislation in the area of food additives (FA), in particular Regulation (EC) No 1333/2008 and transposition and implementation of Annexes to Commission Directives 94/35/EC, 94/36/EC, 95/2/EC and related legislation concerning the purity of food colours, sweeteners and FAs other than colours and sweeteners;

- to evaluate the implementation of the Community legislation in the area of food contact materials (FCM), in particular implementation of Regulation (EC) No 1935/2004 and related legislation with regard to regenerated cellulose film, plastic materials, ceramic articles and active and intelligent food contact materials and articles.

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

- Regulation (EC) No 882/2004, the organisation of official controls (Art. 3-7,) control and verification procedures and methods (Art. 8-10), enforcement (Art. 54-55), and MANCP (Art. 41-42) in the sectors currently under evaluation;

- the implementation of Community legislation regarding FA and FCM.

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

| MEETINGS/VISITS | | No | COMMENTS |
|---|---|---|---|
| **COMPETENT AUTHORITIES** | **Central** | **2** | Opening and closing meeting with the MoH and MAF |
| | **Regional** | **2** | Regional Competent Authorities (CAs) in Plovdiv and Sofia |
| **LABORATORIES** | | **2** | Regional Inspectorates for Public Health Protection and Control (RIPHPC) laboratories for FA and FCM in Plovdiv (including National Reference Laboratory (NRL) for FCM) and Sofia City. |
| **FCM** | | **3** | Two FCM manufacturers, (one in Plovdiv and one in Sofia) and 1 FCM importer in Plovdiv. |

| MEETINGS/VISITS | No | COMMENTS |
|---|---|---|
| **FA Producer** | **2** | One in Plovdiv and one in Sofia |
| **FA user** | **1** | One meat producer in Sofia |

## 3 Legal Basis for the Mission

The mission was carried out under the general provisions of Community legislation, and in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

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

## 4 Background

### 4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in Member States (MS). The main purpose of such audits is to verify that, overall, official controls take place in MS in accordance with the MANCP 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 and it is the first FA/FCM audit undertaken to this MS after accession. It forms part of a series of audits to MS with similar objectives concerning the evaluation of the implementation of Community legislation on official controls for FA and FCM. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

### 4.2 Background to the series of missions on food additives and food contact materials

Article 50 of Regulation (EC) No 178/2002 requires that information on foodstuffs and feedingstuffs found to have public health implications is disseminated as notifications through the Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country.

As regards FCM, 767 notifications, mainly concerning materials originating from Third Countries (TC) and to a lesser extent in MS, have been notified through RASFF in the last four years. These break down as follows: 192 alerts in 2006, 172 in 2007, 206 in 2008 and 197 in 2009.

The following hazards were reported: primary aromatic amines (PAA), semicarbazide (SEM), di(2-ethylhexyl) adipate (DEHA), formaldehyde, heavy metals (lead, cadmium, chromium, nickel, iron,manganese or zinc), excessive total migration, organoleptic properties, isopropyl thioxantone (ITX), benzophenone, 4-methylbenzophenone and phthalates (e.g. DEHP, DBP).

As regards FA, around 600 notifications from TC and MS, have been notified through RASFF in

the last four years. The use of illegal dyes (e.g. Sudan) as well as the high content or unauthorised use of sulphites in foodstuffs have been notified frequently. Other FA notified were benzoic acid, sorbic acid and artificial sweeteners (e.g. Aspartame).

"Food additive" is defined as a substance not normally consumed as food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the internal addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods. Community legislation establishes a "positive list" of additives authorised for use in foodstuffs, usually specifying the maximum content thereof allowed in food or setting the permitted limit at a level necessary to achieve the technological purpose without misleading the consumer. Before authorisation, FA have to undergo appropriate toxicological testing and evaluation, leading to approval or rejection and to establishment of the maximum permitted levels in foodstuffs. This evaluation takes into account any cumulative, synergistic or potentiating effect of use thereof and the phenomenon of human intolerance to substances foreign to the body. It is illegal to use unauthorised additives in foodstuffs and to apply additives to foodstuffs without authorisation for each specific application.

# 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 MS to designate the CAs responsible for official controls.

**Findings**

The MoH and the MAF have overall responsibility for official controls in the context of this mission. Both CAs are listed in the MANCP.

The Ministry for Environment and Water (MEW) is the Competent Authority (CA) for recycled plastic materials. The audit team did not meet this CA as the MoH stated that currently there is no activity relating to this topic.

The MoH is responsible for the control of FCM and FA producers, distributers, importers and the users of FA and FCM in the field of Food of Non Animal Origin (FNAO). The implementation of the official controls is co-ordinated by the Public Health Directorate (PHD) and is carried out by the 28 Regional Inspectorates for Public Health Protection and Control (RIPHPC).

The MAF is responsible for the control of the users of FA and FCM in the field of food of animal origin (FAO) in the context of this mission. Since November 2009, Food Safety and Quality Directorate (FSQD) has been renamed to Animal Health and Food Safety Directorate (AHFSD) however, there is no change in terms of its responsibilities. The implementation of these official Regional Veterinary Services (RVS).

The CCAs informed the mission team that a new future strategy on food safety is being planned. It is envisaged that food inspectors from the Public Health Directorate (PHD), the NVS, the National

Service for Plant Protection (NSPP) and part of the National Grain and Feed Service (NGFS) will be operating under the aegis of the Food Safety Agency (FSA). The NGFS will be split into two sections; Feed and Grain. The feed sector will be part of the FSA. The proposal has been approved by the Council of Ministers and is about to be discussed in Parliament. The FSA is expected to be operational in 2011.

### *5.1.2 Co-operation between Competent Authorities*

**Legal Requirements**

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between CAs.

**Findings**

Two bodies have been set up to ensure co-operation between the CAs; the National Council for Food Safety (NCFS) and the National Council for Co-Ordination of Controls (NCCC). Co-ordination and co-operation between CAs at the operational level takes place via joint control programmes (e.g. the registration of establishments and joint inspections in response to consumer complaints.)

Co-operation between the MoH and MAF is prescribed in the Food Law. The mission team was informed that there are a number of activities being performed jointly by the two ministries; the registration of establishments and joint inspections in response to consumer complaints. In the two RIPHPC visited where RVS representatives were also present joint inspections have taken place in 2010 in relation to registration. In addition, in Plovdiv RIPHPC further joint inspections with RVS relating to official control of FA users is envisaged for the second half of 2010. This co-operation started in 2010.

A written agreement on co-operation between the MoH and the Customs Department has been signed in order to control FNAO and other products with public health significance at import. FCM falls under the latter. Currently, no FCM are controlled at the point of import however importers are in the process of being registered and inspected.

### *5.1.3 Co-operation within Competent Authorities*

**Legal Requirements**

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

**Findings**

The PHD draws up a framework control plan in collaboration with the 28 RIPHPCs, which in turn develop their own detailed regional annual plan. Each year, a national conference where all 28 RIPHPCs participate is organised in-order to have input for the following years work programme. In addition, there are working groups established between the PHD and RIPHPCS as required (e.g. In response to new legislation and SOPs for FCM).

The NVS draws up a framework control plan in collaboration with the 28 RVS which in turn develop their own detailed regional annual plan. Since 2009, an annual national conference where all 28 RVSs participate is organised in-order to have input for the following years work programme. In addition there are regular meetings with the Directors of RVS and NVS. There are also working groups established between the NVS and RVS (e.g. Instructions for the implementation of MANCP).

### *5.1.4 Delegation of specific tasks related to official controls*

**Legal Requirements**

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

**Findings**

The CCAs stated that no tasks relating to official controls within the scope of this audit are delegated.

### *5.1.5 Contingency planning*

**Legal Requirements**

Article 4 of Regulation (EC) No 882/2004 also requires that CA 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 MS 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**

As described in the MANCP, a general crisis management plan, in the context of general food safety has been developed by MoH where the roles, responsibilities and procedures are defined.

**Conclusions on Competent Authorities**

There are two CAs in the scope of this audit which have been designated as required by Article 4.1 of Regulation (EC) No 882/2004.

There is adequate co-ordination and co-operation between the two CAs.

There is adequate co-ordination and co-operation within each CA.

There is no delegation of specific tasks related to official controls to any control bodies in the context of this audit.

The contingency plan in the form of a general crisis management plan, in the context of general food safety has been developed by MoH as required by Article 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 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**

In the context of this mission, the Food Law (SG No 102 / 2003) as amended and Veterinary Activity Law (SG No 87/2005) as amended lays down the legal powers to carry out official controls and allows the CA staff to have the necessary powers of entry to establishments and access to Food Business Operators' (FBO) documentation as far as both Ministries are concerned.

### *5.2.2 Staffing provision and facilities*

**Legal Requirements**

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

**Findings**

The PHD of MoH stated that there are currently five staff dealing with co-ordination of official controls at central level. In the 28 regions there are 420 inspectors in total, excluding laboratory staff. The CA stated that there are adequate facilities and sufficient equipment.

For the NVS, there are four staff dealing with food of animal origin including one person for FCM. There are 580 RVS inspectors. The CA stated that there are adequate facilities and sufficient equipment.

The Law on conflict of interest and Law on civil service which applies to all CAs, lays down provisions to avoid any conflict of interest. Staff performing official controls are legally obliged to declare annually that they are not in conflict of interest and to disclose their assets.

### *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 minimum recruitment qualifications are specified for technical and professional staff in the two CAs.

In the MoH staff qualifications are mainly medical doctors, food technologists and health inspectors. The MoH 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. In the context of this mission, a two-day training course was organised at central level in May 2009 for FCM in which 19 inspectors participated from different regions. Regarding FA, a two-day training course was organised also at central level in April 2009 where 10 inspectors participated. Two staff members, one from PHD and one from RIPHPC, participated in DG SANCO Better Training for Safer Food (BTSF) in May 2010.

In Plovdiv RIPHPC, two training sessions took place in 2009 -2010 on food control, FCM and registration of FCM operators. In Sofia region there was a training session on FA based on a desk study regarding colours in which 30 inspectors participated. Another session took place in 2009 regarding legislation on FA (Ordinance No 8) and checklists provided by the central level. Two training sessions took place in 2010 regarding EU FCM legislation and registration of FCM operators including checklists in which 55 staff participated. An additional training session on the labelling of FA took place in June 2010 in which 55 inspectors participated.

Within the MAF five staff of the National Reference Centre of Food Safety participated in an external training session on a variety of food safety issues including FA. These participants provided four further training session to regional laboratory staff. No FA training has been carried out at national level however, in Plovdiv RVS three training sessions took place in 2008-2010 and another three training sessions on FA in Sofia RVS. In addition, there was another training session on FCM in March 2010. RVS inspectors responsible for performing HACCP audits have been trained in this matter.

Some inspectors met by the audit team failed to adequately assess some of the requirements of the Declaration of Compliance (DoC) and procedures based on HACCP (see Section 6.2.1 and 6.2.2).

**Conclusions on Resources for Performance of Controls**

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

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

There is a training system established in all CAs in the scope of this audit. Although specific training on FCM and FA has been undertaken, inadequate assessment of HACCP and DoC by the inspectors have been observed during on-site inspections. (Section 6.2.1 and 6.2.2).

## 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 MS 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**

Producers of FA and production, processing, storage and packaging of FNAO are registered under the RIPHPC following the requirements of the Food Law. An amendment to the Public Health Act, which entered into force in June 2009, requires all FCM manufacturers and traders to be registered in the RIPHPCs. However, the implementation of this requirement has only commenced since April 2010. The MoH stated that it took some time to set up the resources and gather the necessary information.

Establishments producing, processing, storing and packaging of FAO are registered / approved under the RVS following the requirements of the Food Law. When appropriate, joint inspections are undertaken by the RIPHPC and RVS ( e.g supermarkets) for registration.

The information on registration of all FBOs and Business Organisations is publicly available on the websites of both ministries. The database is structured according to food groups and it is updated every three months.

### *5.3.2 Prioritisation of official controls*

**Legal Requirements**

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

**Findings:**

In the MoH, the controls on the FA and FCM are executed on a risk basis and the methods of controls are according to the requirements of Regulation (EC) 882/2004 on official control. All official controls are carried out without prior warning, except in the case of audits which are carried out with prior warning. All food production units, including FCM, are considered high risk and are subject to four inspections per year. Controls on FCM manufacturers and traders only started in April 2010.

Each year, the MoH provides guidelines for official controls which identify the types of product and number of samples to be taken. This can consist of thematic controls (such as FA and FCM) and specific campaigns by means of direct instruction from the central level; (e.g. the use of palm oil in margarine manufacture in relation to Sudan dyes). The sampling plan is developed on the basis of results of previous inspections, RASFF notifications from the previous year, requirements of

legislation and specific food types. In addition there are thematic controls from time to time.

There are no FA producers as such in Bulgaria, however there are FBOs blending different FA.

For the NVS, prioritisation of inspections is based on 13 criteria for determining the frequency of inspection. In relation to FA, all FAs listed in the technical documents are subject to control by NVS. This includes checking for unauthorised use of FA, ensuring correct concentrations of FAs are used, and FAs are correctly identified on the label. There are three levels of risk associated with inspection frequency of veterinary establishments; high risk giving rise to weekly inspections, medium risk which are inspected every two weeks and low risk which are inspected once a month. The RVS undertakes thematic inspection which are drawn up by the NVS and emailed to the RVS (e.g. labelling on milk and dairy products).

### *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**

Tasks related to official controls are in general carried out using appropriate control methods and techniques such as monitoring, verification, audits, inspection, sampling and analysis. National Operational Procedures which provide instructions to inspectors have been issued by the MoH to cover food production, food trade, food distribution and storage and trading establishments. Similar National Operational Procedures for FCM producers and traders were also issued in April 2010, and the MoH have only commenced inspection activities in FCM establishments two months ago.

Official controls have included the examination of written material and other records. However, this assessment has not always been adequately carried out. (see section 6.2.1 & 6.2.2).

### *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**

Within the MoH, there are 28 RIPHPC laboratories, six of which are designated for official control in the context of this mission. Each of the 6 laboratories has been accredited to ISO 17025 and in 2010 an extension of the scope of accreditation was requested to include FCM and FA.

The laboratory at Plovdiv has been designated as the NRL for FCMs since the start of 2009 but the designation as NRL for FCMs will probably change to the RIPHPC laboratory located in Veliko Tarnovo from July 2010. The reason given for this change is staffing issues. A representative from the laboratory in Veliko Tarnovo began attending the EURL network meetings in April 2010.

Within the MAF there is a National Reference Centre for Food Safety in addition to 16 Regional Veterinary Laboratories responsible for testing nitrite. These 16 laboratories are accredited and the scope of accreditation includes nitrites. With the exception of phosphates no other FA are being tested. In 2009, there were 547 finished products (meat products with short shelf life) tested for residual nitrite levels, of which there were 6 non compliances found. However, the requirement for quantifying the residual nitrite levels has been repealed by Directive 2006/52/ EC which came into force in Februray 2008. The CAs stated that the non-compliances were followed up by taking additional samples and checking the technical documentation. No non-compliances were found in the follow-up.

### *5.3.5 Procedures for performance and reporting of control activities*

**Legal Requirements**

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

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

**Findings**

The two CAs operate on the basis of documented procedures containing information and instructions for staff performing official controls. National Operational Procedures are issued by the MoH to all inspectors (see Section 5.3.3) as well as checklists for inspection duties.

In the context of this mission reports are drawn up after each official control by the two CAs and a copy of the report is given to FBOs. Evidence of this was seen by the audit team and they were considered complete and satisfactory.

### *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 MoH publishes the results of controls and legislation on the RIPHPC website. In the Plovdiv region the RIPHPC has regular meetings with the media to provide information to the public on the activities of the CAs.

The MAF publishes the MANCP, the annual report and audit information on its website.

The NVS has a press centre at central level. All information from the RVS is directed through this

centre which liases with the media. The NVS has its own website where the names of establishments which have been closed are displayed.

**Conclusions on Organisation and Implementation of Official Controls**

There are adequate procedures for registration of FBOs and FCM manufacturer and traders.

Official controls by both CAs in the scope of this audit are carried out at predefined regular intervals and on a risk basis.

Tasks related to official controls are generally carried out using appropriate methods and techniques. However, controls on FCM operators started as of May 2010 and assessment of written material and records was in some cases inadequate contrary to Article 10(2)(e) of Regulation (EC) No 882/2004.

There are instructions available to inspectors on the official controls of FA and FCM.

The range of FCM analysis in the accredited laboratories is very limited.

The NRL in the scope of this audit has been designated as required by Article 33 of Regulation (EC) No 882/2004.

All CAs draw up reports on the official controls that they have carried out and a copy is provided to the FBO concerned as required by Article 9 of Regulation (EC) No 882/2004.

Information on the control activities of the CAs are publicly available and adequate steps have been taken to ensure that members of their staff have no conflict of interest.

## 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**

A number of measures are in place by the two CAs when a non-compliance is identified such as prohibition of the placing the product on the market, closure of establishment and recall from the market of defective food. The audit team reviewed one file from 2008 relating to unauthorised colours in foodstuffs. The analyses of samples were found to be non compliant and in that case the FBO was informed in writing about the decision concerning the action to be taken together with the reason for the decision and the information on rights of appeal against such a decision. The FBO challenged the findings and samples were sent to the National Centre for the Protection of Health for retesting, which confirmed the presence of allure red and a product recall was initiated.

#### *5.4.2 Sanctions*

**Legal Requirements**

Article 55 of Regulation (EC) No 882/2004 states that MS 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**

Legal basis for imposition of administrative sanctions by the CAs arises from the framework legislative acts. The framework legislation in the context of this mission is Food Law as amended and the Sanction and Infringement Administrative Act 92/1963.

Article 9 of the Food Law provides the range of fines that can be imposed. A first offence can result in fines from 500-1000 lv (€250-500). A second offence ranges from 1000-3000 lv (€500-1,500). Evidence of sanctions imposed by the CAs was given to the mission team.

**Conclusions on Enforcement Measures**

The measures put in place by the CAs in the case of non-compliance follow the requirements of Article 54 of Regulation (EC) No 882/2004.

All CAs have the power to impose sanctions which are effective, proportionate and dissuasive as required by Article 55.1 of Regulation (EC) No 882/2004.

### 5.5 Verification and review of official controls and procedures

#### *5.5.1 Verification procedures*

**Legal Requirements**

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

**Findings**

In the MoH verification of effectiveness of official control is carried out mainly at regional level. There are standard operating procedures (SOPs) at regional level dealing with verification. In the two RIPHPC visited verification was carried out by the Head of the Department. Verification consisted of documentary check of inspection files, interview with the inspector concerned and an on the spot observation of an inspection.

In the NVS verification is also carried out a regional level, three times per year. The verification is undertaken once per year by the Head of Department and twice a year by the Head of Sector. Verification consisted of documentary check of inspection files, interview with the inspector concerned and an on the spot observation of an inspection. The mission team was informed that due to the removal of the Head of Sector posts this level of verification would disappear in 2011.

In both CAs reports are made with conclusions and recommendations and forwarded to the regional Director.

#### *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**

Several types of audit arrangements to meet the requirements of Regulation (EC) No 882/2004 are carried out in Bulgaria and are based on the principles set out in the Commission Guideline 2006/677/EC. The summary of reports from such audits is available to the public through the relevant websites in the case of the MAF and the PHDof the MoH.

Within the MAF the AHFSD is responsible for establishing and implementing the audit programme. The team of 14 auditors has been reduced to six auditors by Ministerial Order No PDO9-920 dated the 27th November 2009. These auditors have been trained to ISO 19011 and ISO 9001 standards in May 2009. There is a five-year cycle audit plan in which all RVS and other central services has to be audited. The audit programme, which is available on the MAF website started in 2007. In 2009, some 13 audits were planned and 12 were completed. The remaining audit that was not undertaken forms part of the 2010 audit plan which consists of a total of 13 audits. The scope of the audits consists of a documentary check, interview with inspector concerned and if required an on the spot observation of an inspection.

The MoH has developed an audit manual since 2008 and undertook three audits during that year on RASFF, Import Controls and Contaminants. Five audits were planned for 2009, however only one was completed due to financial and staff constraints. The trigger to undertake an audit were based on findings of past FVO missions and preparation for future FVO mission as well as inspectors performance. Audits were always undertaken by two auditors, one from the CCA and the other from a regional directorate, different to the region being audited. The auditors in the MoH have no formal training in audit techniques such as ISO 19011. In addition, the evaluation of activities undertaken by regional Directors is assessed every three years. This assessment (based on a detailed questionnaire); includes amongst other things, the level of implementation of the annual plan, the knowledge of staff and level of implementation of training programmes. The last assessment was carried out in 2009 on the Regional Director of Sofia. This completed the full cycle.

**Conclusions on Verification Procedures**

There are procedures in place for verification in both CAs.

Audits within the meaning of Article 4.6 of Regulation (EC) 882/2004 are undertaken by both CAs.

### 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 have been received by the Commission from the Bulgarian authorities. The control systems applied to FA and FCM are not described.

**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**

The drafting of legislation in relation to food safety is undertaken by the MoH and drafts are distributed to all other ministries for their input. The MoH is responsible for the transposition of EU legislation in the area of food safety. Once officially approved all new legislation is available on the web site of the MoH.

Regarding FA, the MoH stated that all EC FA Legislation has been transposed by Ordinance No 8 of 2002 on the requirements for use of additives in foodstuffs (SG No 44 of 29/04/2002) as amended and Ordinance No 21 of 15 October 2002 on the specific criteria, and requirements for purity of additives intended for use in foodstuffs (SG 104/6 of 06/11/2002) as amended.

In relation to FCM, the MoH also stated that EC legislation has been transposed by Ordinance No 2 of 2002 related to plastic materials and articles intended to come into contact with foodstuffs (SG No 13 of 8 February 2008) as amended and Ordinance of 2007 on specific requirements for materials and plastics intended to come into contact with foodstuffs (SG No 51 of 26 June 2007) as amended are the relevant national legislation for official control of FCM.

There is additional legislation in place for FCM in the form of an amendment in 2009 to Article 34 of the Public Health Law which requires FCM producers and traders to be registered (see Section 5.3.1).

**Conclusions**

Responsibilities for drafting and transposing legislation in the scope of this audit are clearly defined.

Legislation is well disseminated and publicly available.

The EC Directives relevant to this audit have been transposed into Bulgarian law.

## 6.2 Requirements along the food chain for food additives and food contact materials

### *6.2.1 Declaration of Compliance*

**Legal Requirements**

Article 16 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food requires that FCM shall be accompanied by a written declaration stating that they comply with the rules applicable to them.

Article 9 of Commission Directive 2002/72/EC as amended relating to plastic materials and articles intended to come into contact with foodstuffs requires that at the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles, shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

Article 2(a) of Council Directive 84/500/EEC as amended relating to ceramic articles intended to come into contact with foodstuffs requires that at the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

**Findings**

The audit team visited two FCM plastic manufacturers, an FCM user in a meat processing establishment, an FCM importer and an FA producer that used FCM. In four of the five companies visited, the RIPHPC was the CA responsible for the assessment of official controls relating to FCM, including the DoC. In the meat processing establishment the RVS was the responsible CA.

The assessment of the DoC at the meat processing establishment by the RVS inspector had some shortcomings as she was not aware of the requirements of Annex VI of Commission Directive 2002/72/EC and had little previous experience of evaluating DoCs.

At the importer of FCM, the inspector detected the absence of DoC which should have accompanied imports of FCM from Turkey and China. The FCM concerned were quarantined until the relevant paper work was provided.

For the inspection of the plastic manufacturer in Plovdiv the inspector followed a check list and demonstrated a good knowledge of the requirements for the DoC to be in compliance.

The visit to a second plastic FCM manufacturer in Sofia was undertaken by a relatively new RIPHPC inspector with one year work experience. The inspector reviewed the DoC but failed to detect a number of non compliances e.g. (i) the absence of a statement that the raw material was suitable for manufacture of FCM and (ii) the presence of monomers and additives in the raw material which are subject to some restrictions.

The control of the DoC at the FCM user was not complete as the inspector did not check if the plastic containers used for product storage were of food grade and accompanied by a DoC.

**Conclusions**

Assessment of DoC in the companies visited did not always follow the requirements of Annex VIa of Commission Directive 2002/72/EC.

### *6.2.2 Controls at visited premises including traceability and hazard analysis and critical control points (HACCP)*

**Legal Requirements**

Article 10 of Regulation (EC) No 882/2004 lays down that official controls shall, in general, be carried out using appropriate control methods and techniques.

Article 5(1) of Regulation (EC) No 852/2004 requires that FBO shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

Article 5(2)(g) of Regulation (EC) No 852/2004 requires that the HACCP principles shall consist, among other things, of establishing documents and records commensurate with the nature and size of the food business.

Article 5(5) of Regulation (EC) No 852/2004 allows the adoption of arrangements to facilitate the implementation of the HACCP requirement by certain FBO. These include the use of guides for the application of HACCP principles.

Article 18 of Regulation (EC) No 178/2002 establishes traceability requirements in food and feed.

Article 17 of Regulation (EC) No 1935/2004 establishes traceability requirements in FCM.

**Findings**

In the meat processing establishment the inspector was the official veterinarian responsible for this establishment and had undertaken the most recent inspection on 21 June 2010. The establishment was categorised as a medium risk and was inspected every two weeks. Previous inspections did not focus on controlling FCM and were limited to ensuring that any plastic packaging used was suitable for food use. The inspector focussed on controlling the labelling requirements of the finished product, the HACCP plan relating to the use of FA and traceability. The inspector adequately assessed the above issues, including the testing of added amounts of nitrites. Following RVS instructions, in 2009, the inspector took a number of samples to assess the residual amount of nitrites in finished products.

The importer of FCM was registered on 11 June 2010 and the first official control was being undertaken during the FVO visit. Regarding traceability the assessment of FCM products was adequately undertaken.

For the inspection of the plastic manufacturer in Plovdiv the inspector followed a check list which covered aspects of GMP, labeling, traceability and storage of finished products. The inspector demonstrated good knowledge on GMP and traceability. The company was never inspected prior to registration as a FCM manufacturer in May 2010.

The visit to a second plastic FCM manufacturer in Sofia was undertaken by a RIPHPC inspector

The company was first registered on 1 June 2010. The same inspector was involved in the registration process which included an on-site visit during which samples for laboratory analysis were taken. All samples were found to be compliant. The first official control was being undertaken during the FVO visit. Although the inspector had a check list, it was not used during the inspection. In addition, the inspector failed to check documentation adequately (following links between the different pieces of documentation of a chosen finished product from raw materials through production to storage of finished product).

The inspection of the FA blender was carried out by a RIPHPC inspector. The company, as a production site is classified as a high risk and is subject to four inspections per year. However, in 2009, only three inspections were carried out. This was partially due to the site not being in operation full time. In the previous inspection on 27 May 2010 a non compliance, the lack of appropriate HACCP related record keeping had been detected and an order to rectify the situation was given to this FBO. The inspection observed by the audit team covered traceability, labeling of raw materials and finished products as well as the HACCP plan. During the inspection the inspector identified a number of shortcomings regarding labeling of FA in the finished product and raw materials, failure to implement own instructions on HACCP plan and lack of appropriate record keeping. However, there was no link between the information on the certificates of analysis and the finished product and the inspector failed to detect this. The certificates stated that the product complied with certain specifications however the inspector failed to notice that there was no evidence of any laboratory tests being undertaken.

The visit to another FA producer was carried out by a RIPHPC inspector. The inspection was well structured and focused on raw materials, labeling requirements, HACCP plan, traceability and finished products. However, some shortcomings were identified regarding the examination of written materials (e.g. no checks on instructions and records of calibration of scales as it was considered a CCP, no check on the certificate provided by the TC regarding purity)

**Conclusions**

Examination of written documentation including the requirements on purity criteria of FA was not adequately assessed in all sites visited as required by Article 10.2(e) of Regulation (EC) No 882/2004.

There was an incomplete assessment of the procedures on HACCP which is contrary to Article 10.2(d) of Regulation (EC) No 882/2004.

### 6.3 Good manufacturing practice for FCM

**Legal Requirements**

Article 3 of Regulation (EC) No 1935/2004 requires that FCM shall be manufactured in compliance with good manufacturing practice (GMP).

Commission Regulation (EC) No 2023/2006 on GMP for materials and articles intended to come into contact with food.

**Findings**

As stated in point 5.3.1 the registration and inspection of business establishments manufacturing

and trading FCM has only commenced in April 2010. At the time of the FVO audit data on the total number of FCM manufacturers in Bulgaria. Once the process of registration is completed in each region the level of GMP implementation will be available.

**Conclusions**

No information on the level of GMP implementation is currently available.

### 6.4 Monitoring systems for the consumption and use of additives

**Legal Requirements**

Article 27 of Regulation (EC) No 1333/2008/EC requires MS shall maintain systems to monitor the consumption and use of FA on a risk-based approach and report their findings with appropriate frequency to the Commission.

**Findings**

T he MoH is responsible for the monitoring of use and consumption of FA in Bulgaria. Currently, there is no monitoring of consumption of FA. However, the National Center for Public Health Protection, under the MoH is currently compiling existing food consumption data.

There is a monitoring system for the use of FA in FNAO. However, there is no such system in the field of FAO.

**Conclusions**

There is no monitoring system for the consumption of FA and the monitoring system for the use of FA does not cover FAO contrary to the requirements of Article 27 of Regulation (EC) No 1333/2008.

### 6.5 Laboratories carrying out official control analysis

**Legal Requirements**

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

Article 12 of Regulation (EC) No 882/2004 requires CAs 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 NRL for each Community reference laboratory (CRL) referred to in Article 32. The NRL shall collaborate with the CRL, coordinate activities, organise comparative tests, ensure dissemination of information, and provide scientific and technical assistance.

Article 24 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food requires the CRL for FCM and NRL established as laid down in Regulation (EC) No 882/2004 to assist MS with a high quality and uniformity of analytical results.

**Findings**

The mission team visited two laboratories, namely the RIPHPC laboratory in Plovdiv which undertakes official controls for FA and FCM and also includes the NRL for FCM, and the RIPHPC laboratory in the Sofia. The two laboratories visited were adequately staffed and were well equipped. Training records in both laboratories visited were in order. None of the designated official control laboratories in Bulgaria participate either in Proficiency Tests (PT) or in any interlaboratory comparative studies in the context of this mission.

In the Plovdiv laboratory there is a total of 44 staff in the whole laboratory. For FCM and FA there are three chemists and five technicians. There is a Quality Manager for the laboratory. The ratio of official control samples/ private samples is approximately 80:20. Accreditation is according to 17025, certificate dated 3-12-2009. Some 99 methods are accredited including sweeteners (aspartame, saccharin, and acesulphame K in food) but none are for FCM or colours. In April 2010, a request for an extension to the scope of accreditation for specific migration of lead and cadmium in ceramics, overall migration in plastics, and vinyl chloride in plastics and sweeteners and preservatives in non-alcoholic beverages was submitted.

In 2008, there were no FA samples in the plan for this laboratory. In 2009, 130 non alcoholic carbonated drink samples were planned (119 actually analysed) for colours, preservatives and sweeteners. There were 37 non-conformances for cyclamate and saccharin. In addition, 84 samples of bread were planned (76 analysed) for FAs. There was one non-conformance (tartrazine). In 2010, 130 samples of non-alcoholic carbonated drinks are planned. To-date, 28 samples of local drinks have been analysed for sweeteners and preservatives and two ketchup, two vinegar, and two tomato concentrate have also been analysed.

In 2008, the number of samples analysed for FCMs were seven plastics and five ceramics for lead and cadmium. No non-conformances were found. In 2009 a total of 59 samples (50 plastics and nine ceramics) with two non-compliances for lead in ceramics. The team enquired about the follow-up of one of these non-conformances with the company by the CA and were informed that the company destroyed the non-conforming articles. In 2010, 55 samples of plastic are planned.

The validation data for the method for colours in FA was examined by the audit team together with the method for specific migration of lead and cadmium in ceramics. The method for overall migration from plastics was also briefly discussed with the responsible chemist. Validation reports and SOP for both the methods were checked. The LOD, LOQ, and measurement of uncertainty data were calculated for both methods. Although quality control checks are performed as a matter of course no trending of the data is performed. The data for the specific migration of lead and cadmium from one sample was examined by the audit team. The results for the sample were satisfactory. However, only one specimen (dish) was taken at the sampling stage. This means that, the method used does not follow the requirements of Council Directive 84/500/EC since the additional three dishes were not available for the repeat analysis.

In the laboratory in Sofia, there is 89 staff in the laboratory as a whole with 37 concerned directly for food safety (25 chemistry and 12 microbiology). Of the chemistry staff 10 are chemists and 15 technicians, of which two chemists and two technicians are devoted full time to FA and one chemist and one technician to FCM. The laboratory is accredited to 17025 with certificate granted in 07-01-2010. There is a Quality Manager for the laboratory. A variety of tests are performed including FA and FCM.

The scope of accreditation for FA consists of sweeteners (aspartame, acesulphame K and saccharin), preservatives (benzoic acid and sorbic acid) and colours (ten of the most common colours). A different analytical method for the Sudan colours and Para red is also accredited. For FCM the scope of accreditation is limited to overall migration in plastics and specific migration from

ceramics (lead and cadmium). The residual amount of nitrite in FAO is generally analysed by the RVS laboratories.

The number of samples analysed in 2008 for FAs were preservatives (156), sweeteners (113), and colours (148). There were 29 non-conformances (25 for saccharin in non-alcoholic drinks, two for benzoic acid and two for both benzoic acid and sorbic acid). In 2009 no FA samples were analysed at this laboratory-the analysis was done by other laboratories (including Plovdiv). In 2010, a total of 57 FA samples have been analysed to date, preservatives (3), sweeteners (22), and colours (32). There have been no non-conformances in 2010 to date.

The number of samples analysed in 2008 for FCM were 21, 12 plastics for overall migration and 9 for lead and cadmium in ceramics. There were no non-conformances. In 2009, no FCM samples were analysed at this laboratory-the analysis was done at Plovdiv. In 2010, ten samples have been analysed for FCM, six for overall migration from plastics (including two from China) and four for lead and cadmium in ceramics. There were no non-conformances.

Validation data for two methods were examined by the audit team, one from the FA group (sorbic acid and benzoic acid) and one from the FCM group (specific migration for lead and cadmium from ceramics). In both cases data for LOD, LOQ, uncertainty and recovery data had been determined and documented in individual reports. However, regarding ceramics tests results are incorrect as an average of four specimens is given.

For routine analysis of samples a SOP is available and the analysis is carried out according to this procedure. Similarly an SOP is available for the preservatives (benzoic acid and sorbic acid). System suitability limits have been set and are recorded but are not graphed for trend analysis.

**Conclusions**

All laboratories visited were adequately equipped and appropriately staffed.

None of the designated official control laboratories in Bulgaria have participated in any PT schemes in the context of this mission (point 5.9 of ISO 17025:2005 and Article 12 of Regulation (EC) No 882/2004.

The range of accredited methods for FCM and FA is very limited.

The method used for testing ceramics does not fully meet the requirements of EC Directive 84/500/EC.

### 6.6 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, this information shall be immediately notified to the Commission under the rapid alert system.

Article 19.3 of Regulation (EC) No 882/2004.When 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**

In the Republic of Bulgaria, the RASFF system is in operation since January 2007. The AHFSD within the MAF is the National Contact Point for RASFF. The CAs illustrated to the mission team how an FCM and FA RASFF notification were followed up in Bulgaria.

**Conclusions**

An adequate communication network has been established to transfer information to and from the RASFF contact point in the MAF.

## 7 Overall Conclusion

The official control of FA and FCM is undertaken as part of the broader official control of foodstuffs. The system for FA is mainly carried out following the relevant EC legislation. However, the shortcomings identified regarding assessment of documentation and the limited scope of laboratory analysis might reduce the efficiency of the system.

The official control system for FCM is newly set up and requires legal registration of FCM manufacturers and traders. However, a number of shortcomings have been identified in relation to the very limited scope of analysis, accreditation status and the incomplete assessment of the DoC, which may lead to ineffective controls.

## 8 Closing Meeting

A closing meeting was held on 29 June 2010 with representatives of the CCAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The Bulgarian authorities did not express disagreement and accepted the observations and initial conclusions presented during that meeting with some general comments.

## 9 Recommendations

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

| N°. | Recommendation |
|---|---|
| 1. | Ensure that staff performing official controls receive appropriate training in the area of FA and FCM as required in Article 6 and Annex II to Regulation (EC) No 882/2004. |
| 2. | Consider broadening the scope of analytical tests on FCM (Article 24(1) of Regulation (EC) No 1935/2004 and Article 3(3) of Regulation (EC) No 882/2004. |
| 3. | Ensure that laboratories involved in official controls participate in proficiency testing |

| N°. | Recommendation |
|---|---|
| | programs as required by ISO/IEC 17025 (Article 12 of Regulation (EC) No 882/2004). |
| 4. | Ensure that official controls include the examination of written material as required by Article 10.2(e) of Regulations (EC) No 882/2004. |
| 5. | Ensure that official controls include the assessment of procedures of HACCP as required by Article 10(2)(d) of Regulation (EC) No 882/2004. |
| 6. | Ensure that the MANCP contains all the information required in Article 42(2)(e) of Regulation (EC) No 882/2004. |
| 7. | Ensure that official inspectors are aware of the requirements of the declaration of compliance prescribed by Annex VIa of Commission Directive 2002/72/EC and ensuretheir correct implementation. |
| 8. | Ensure that FCM manufacturers implement GMP as required by Commission Regulation (EC) No 2023/2006. |
| 9. | Ensure the implementation of the monitoring system for the consumption of FA as required by Article 27 of Regulation (EC) No 1333/2008. |
| 10. | Ensure the method used for testing ceramics follow the requirements of EC Directives 84/500/EEC. |

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2010-8584.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. 1935/2004 | OJ L 338, 13.11.2004, p. 4-17 | Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC |
| Reg. 2023/2006 | OJ L 384, 29.12.2006, p. 7578 | Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food |
| Reg. 282/2008 | OJ L 86, 28.3.2008, p. 9-18 | Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006 |
| Dir. 84/500/EEC | OJ L 277, 20.10.1984, p. 12-16 | Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs |
| Dir. 2002/72/EC | OJ L 220, 15.8.2002, | Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles |

| Legal Reference | Official Journal | Title |
|---|---|---|
| | p. 18-58 | intended to come into contact with foodstuffs |
| Reg. 372/2007 | OJ L 92, 3.4.2007, p. 9-12 | Commission Regulation (EC) No 372/2007 of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods |
| Dir. 82/711/EEC | OJ L 297, 23.10.1982, p. 26-30 | Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs |
| Dir. 85/572/EEC | OJ L 372, 31.12.1985, p. 14-21 | Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs |
| Dir. 78/142/EEC | OJ L 44, 15.2.1978, p. 15-17 | Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs |
| Dir. 80/766/EEC | OJ L 213, 16.8.1980, p. 42-46 | Commission Directive 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs |
| Dir. 81/432/EEC | OJ L 167, 24.6.1981, p. 6-11 | Commission Directive 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs |
| Dir. 93/11/EEC | OJ L 93, 17.4.1993, p. 37-38 | Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers |
| Reg. 1895/2005 | OJ L 302, 19.11.2005, p. 28-32 | Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended |

| Legal Reference | Official Journal | Title |
|---|---|---|
| | | to come into contact with food |
| Reg. 450/2009 | OJ L 135, 30.5.2009, p. 3–11 | Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food |
| Reg. 1333/2008 | OJ L 354, 31.12.2008, p. 16-33 | Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives |
| Dir. 94/35/EC | OJ L 237, 10.9.1994, p. 3-12 | European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs |
| Dir. 94/36/EC | OJ L 237, 10.9.1994, p. 13-29 | European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs |
| Dir. 95/2/EC | OJ L 61, 18.3.1995, p. 1-40 | European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners |
| Dir. 2008/84/EC | OJ L 253, 20.9.2008, p. 1-175 | Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners |
| Dir. 2008/128/EC | OJ L 6, 10.1.2009, p. 20-63 | Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs |
| Dir. 2008/60/EC | OJ L 158, 18.6.2008, p. 17-40 | Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs (Codified version) |
| Dir. 2006/52/EC | OJ L 204, 26.7.2006, p. 10-22 | Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs 94/35/EC on sweeteners for use in foodstuffs |