

EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6365 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

HUNGARY

FROM 23 TO 27 APRIL 2012

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS OVER INFANT FORMULAE, FOLLOW-ON FORMULAE AND BABY FOODS, INCLUDING THE SUPPLY CHAIN

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

Executive Summary

The report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Hungary from 23 to 27 April 2012. The main objective of the audit was to evaluate the official controls over infant formulae (IF), follow-on formulae (FOF) and baby foods (BFs), including the supply chain and the follow-up actions taken by the competent authorities (CAs) in response to the recommendations made in the report DG(SANCO)/2008-7817 (published under report DG(SANCO)/2009-8346).

Progress in the organisation and implementation of official controls over manufacturing and/or placing on the market of IF, FOF and BFs in Hungary was noted since the previous audit (Ref. DG(SANCO)/2008-7817). The national measures for the implementation of the EU Directives relevant for the scope of this audit have been largely adopted. The competent authorities (CAs) responsible for the official control of IF, FOF and BFs have been designated, official controls in relation to labelling and compositional criteria have been organised, co-operation within the CAs is in general ensured and some training in relation to compositional criteria and labelling was recently organised for representatives of one CA.

However, not all CAs perform the official control activities they are responsible for at all stages of production, processing and distribution taking into account all criteria for risk assessment. Co-ordination within and between the different CAs is not fully adequate. The procedures for the performance of control activities over IF, FOF and BFs are not addressing the specific requirements in relation to pesticides, contaminants, compositional criteria and labelling while the reports following official controls are not fully documented. The risk-based approach taken in deciding the control frequency for the previous years and for 2012 took into consideration only the type of product. Verification of the effectiveness of the official controls in relation to IF, FOF and BFs has not been implemented and training was not provided to the CA with responsibility for food safety.

Recommendations no 5, 11 and 12 of the previous report have been largely addressed in relation to IF, FOF and BFs. However, the controls in place do not include all compositional criteria and the re-labelling activity. Further action is required on the organisation of official testing in relation to the accreditation of the laboratories used for the official control of IF/FOF and BFs, in particular, with regard to the detection limits for some of the relevant pesticides indicated by Commission Directives 2006/125/EC and 2006/141/EC and some of the contaminants indicated in Regulation (EC) No 1881/2006 as well as in relation to the complete list of pesticides, contaminants and composition criteria which require testing in this matrix. Recommendation no 4 of the previous audit is not addressed in relation to official controls over FBOs' Hazard Analysis Critical Control Points (HACCP)-based systems in BFs manufacturing establishments, while no shortcomings were identified in relation to identification marking and microbiological controls in BFs.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation	
BF(s)	Baby food(s)	
CA(s)	Competent Authority(ies)	
CCA(s)	Central Competent Authority(ies)	
COM	European Commission	
CCP(s)	Critical Control Point(s)	
DG(SANCO)	Health & Consumers Directorate General	
EC	European Community	
EU	European Union	
FBO(s)	Food Business Operator(s)	
FOF	Follow-on formulae	
FVO	Food and Veterinary Office	
HACP	Hungarian Authority for Consumer Protection (Fogyasztóvédelmi Felügyelőség)	
НАССР	Hazard Analysis of Critical Control Points	
IF	Infant Formulae	
MRD	Ministry of Rural Development (Vidékfejlesztési Minisztérium)	
MANCP	Multi-Annual National Control Plan	
NFCSO	National Food Chain Safety Office	
NIFNS	National Institute for Food and Nutrition Science (Országos Élelmiszer-és Táplálkozástudományi Intézet)	
NOCMO	National Office of the Chief Medical Officer (Országos Tisztifőorvosi Hivatal)	
NPHMOS	National Public Health and Medical Officers Service (Állami Népegészségügyi és Tisztiorvosi Szolgálat)	
OV(s)	Official Veterinarian(s)	
RASFF	Rapid Alert System for Food and Feed	

1 Introduction

The audit took place in Hungary from 23 to 27 April 2012 as part of the planned audit programme of the FVO. The FVO audit team comprised two auditors from the FVO.

The FVO audit team was accompanied throughout the audit by representatives from the Central Competent Authority (CCA), the National Food Chain Safety Office (NFCSO) under the Ministry of Rural Development (MRD)¹ and for one of the visits by representatives of the National Public Health and Medical Officers Service (NPHMOS) within the Ministry of National Resources.

The opening meeting was held on 23 April 2012 with the representatives of the CCAs (MRD, NFCSO, Hungarian Authority for Consumer Protection (HACP) and NPHMOS) in Budapest. At this meeting the objectives of, and itinerary for the audit were confirmed, and additional information required by the FVO audit team for the satisfactory completion of the audit was requested.

2 OBJECTIVES

The main objective of the audit was to evaluate the official controls over IF, FOF and BFs, including the supply chain and the follow-up actions taken by the CAs in response to the recommendations made in the report DG(SANCO)/2008-7817 (published under report DG(SANCO)/2009-8346-MR Final with regard to:

In particular controls over IF, FOF and other foodstuffs for infants and young children, including the supply chain in the framework of:

- Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EC) No 854/2004, (EC) No 882/2004, (EC) No 2073/2005 and (EC) No 1881/2006,
- Directive 2009/39/EC of the European Parliament and of the Council and Commission Directives 2006/141/EC and 2006/125/EC.

In pursuit of these objectives, the audit itinerary included the following meetings and visits:

COMPETENT AUTHORITIES			Comments
Competent authorities	Central	3	Initial and Final Meeting with the representatives of MRD, NFCSO,
	Regional	2	NPHMOS and HACP. During the visits on the spot, county and district representatives were present and also a visit to a CA district office was
	Local	4	performed.
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
BF producer 2		2	
BFs, IF and FOF storage and distribution to retailers centre		1	
BFs, IF and FOF retail shop 1		1	

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular Article 45

¹ In their response to the draft report the CAs noted that the NFCSO works under the direction of the Ministry of Rural Development but is not part of that Ministry.

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.

Full EU legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.

4 BACKGROUND

The previous audit concerning the official controls over IF, FOF and BFs in Hungary was carried out from 15 to 25 April 2008, the results of which are described in report DG(SANCO)/2008-7817 (published under the General Report DG(SANCO)/2009-8346) – MR Final (hereafter referred to as the previous audit report . This report is accessible at:

http://ec.europa.eu/food/fvo/index en.cfm

The action plan received from the Hungarian authorities in response to the report's recommendations provided satisfactory guarantees in relation to the four relevant recommendations (No 4, 5, 11 and 12) which were related to IF, FOF and BFs and followed up during this audit.

Recommendation No 4. "To improve official controls in order to ensure that microbiological criteria for foodstuffs is in line with the requirements set out in Annex I to Regulation (EC) No 2073/2005; that HACCP systems comply with the requirements of Art. 5 of Regulation (EC) No 852/2004; and that identification marking complies with the requirements of Art. 5 of Regulation (EC) No 853/2004 and Annex II, Section I of Regulation (EC) No 853/2004".

Recommendation No 5. "To bring the water analyses in line with Directive 98/83/EC".

Recommendation No 11. "To include in the monitoring programmes all the products for all the criteria set in Regulations (EC) No 2073/2005 and (EC) No 1881/2006 and in Directives 2006/125/EC and 2006/141/EC."

Recommendation No 12. "To carry out official controls to ensure that specific requirements for labelling and compositional criteria in BF products comply with the requirements of Directives 2006/141/EC and 2006/125/EC."

5 FINDINGS AND CONCLUSIONS

5.1 National legislation

Article 291.1 of the Treaty on the functioning of the EU requires that Member States adopt all measures of national law necessary to implement legally binding Union acts.

Audit findings

Since the previous audit, the Ministerial Decree 20/2008 has been adopted, transposing the provisions of Commission Directive 2006/141/EC of 22 December 2006 on IF and FOF and amending Commission Directive 1999/21/EC. The Ministerial Decree 36/2004 was also amended to include the transposition of Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses.

Council Directive 92/52/EEC of 18 June 1992 on IF and FOF intended for export to third countries was previously transposed by Ministerial Decree 23/2003 which has been repealed by Ministerial Decree 20/2008. The latter Ministerial Decree does not transpose the provisions of Council Directive 92/52/EEC.

The Ministerial Decree No 35/2004 which transposes the provisions of Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and BFs for infants and young children is still in place.

Except for the transposition acts of the EU Directives, no other national legislation relevant for the scope of this audit field has been adopted.

Conclusion

With the exception of Council Directive 92/52/EC relevant legislation has been transposed into Hungarian legislation.

5.2 Competent Authorities

5.2.1 Designation of Competent Authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs.

On the basis of Article 9 of Commission Directive 2006/141/EC and Article 11 of Directive 2009/39/EC, Member States have to identify the competent authorities to which the placing on the market of IF and of certain foodstuffs intended for a particular nutritional use have to be notified.

Audit findings

A detailed description of the responsibilities and organisation of the MRD, NPHMOS and HACP is provided in the Country Profile for Hungary which is available at http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=HU.

The Governmental Decree 22/2012, which entered into force on 15 March 2012, created the National Food Chain Safety Office (NFCSO) under the MRD, which has taken over the responsibilities of the former Agricultural Office. The NFCSO is the CCA responsible for implementation of official controls in relation to food safety and food quality requirements. The President of the NFCSO acts under the professional guidance of the Chief Veterinary Officer which is the MRD State Secretary for Food Chain Control and Agricultural Administration. The former Hungarian Food Safety Office continues as the Food Safety and Risk Evaluation Directorate within the structure of the NFCSO. The MRD Department of Food Chain Control, Department of Food Processing and Department of Forestry and Game have the legislative responsibility and act under the co-ordination of the Deputy State Secretary for Food Chain Control and Agricultural Administration. The organisation of controls on three levels (central, county and local) has been maintained.

Official controls in relation to the specific requirements for pesticides and contaminants in IF, FOF, and BFs (provided by the EU Commission Directives 2006/141 and 2006/125 and by Regulation (EC) No 1881/2006) are part of the food safety competences of the NFCSO under the MRD. Official controls (on the spot) are carried out by the district offices (DO) of the County Government Offices Directorate for Food Chain Safety and Animal Health (CGO-DFCSAH) under the NFCSO.

Official controls over labelling and compositional criteria in IF, FOF, and BFs (provided in the above- mentioned Directives) can also be performed by the NFCSO representatives as part of the controls in relation to food quality.

The responsibilities for sampling and testing pesticides in BFs was transferred on 28 May 2010 to the Food and Feed Safety Directorate (within NFCSO). Since 1 April 2012 pesticides testing in BFs takes place in the laboratory of the Plant Protection and Soil Conservation Directorate, while sampling is carried out by the Food and Feed Safety Directorate local representatives.

Official controls on the spot are carried out by the local level official control staff (within the District Offices of the County Government Offices Directorate for Food Chain Safety and Animal Health under the professional guidance of NFCSO).

The NPHMOS within the Ministry of National Resources is responsible for nutritional characteristics controls (including labelling and compositional criteria). The NPHMOS through their county and local representatives only carry out controls at retail level, although they have the legal responsibility to act throughout the food chain. Until 2012, in relation to BFs, IF and FOF the NPHMOS have only carried out inspections in the framework of food alerts. For 2012, BFs was indicated as a priority in the themes of inspections and official testing to be implemented at county and local levels.

The National Institute for Food and Nutrition Science is the CA designated to be notified at the first placing on the market of IF and certain foodstuffs intended for a particular nutritional use.

The HACP within the Ministry of National Economy is responsible for official controls in relation to unfair commercial practices including misleading labelling. However, according to the information provided by the CCA, the HACP did not perform any activity in relation to BFs, IF, FOF during 2010 and 2011. The control plan for 2012 does not include such activities either.

5.2.2 Co-operation and co-ordination between and within Competent Authorities

Legal requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination between CAs. Article 4(5) of the Regulation 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.

Audit findings

Co-ordination between the different organisational levels within the same CA is carried out through the pyramidal chain of command from the central to the county and consequently to the local official control structures.

Co-operation between different Directorates of the same CCA was seen in relation to the organisation of testing of BFs for pesticides and contaminants. A protocol signed by two different directorates within the NFCSO allows the testing of BFs in the laboratory under the co-ordination of the Plant Protection, Soil Conservation and Agri-environment Directorate starting 1 April 2012 although the responsibility for such testing is with the Food and Feed Safety Directorate. The purpose of the protocol was to enhance the testing capacity as the laboratories under the co-ordination of Food and Feed Safety Directorate did not have the capacity to test for most of the relevant pesticides mentioned in Commission Directives 2006/141/EC and 2006/125/EC in BFs, IF and FOF and for nitrates (see chapter 5.3).

The Plant Protection and Soil Conservation Directorate representatives have the responsibility for

official control at agricultural producer level in relation to maximum residue limits of pesticides. If such limits are exceeded, the representatives of the same Directorate have the responsibility to take action throughout the food chain and therefore no mechanism of co-ordination is in place with the other CAs responsible for official controls at the level of BF producers. According to the CCA, the details of the lots with exceeding maximum residue limits and the FBO details are published on the MRD and NFCSO websites.

The NFCSO is the national contact point in relation to Rapid Alert System for Food and Feed alerts. When such alerts relate to compositional criteria, the details are passed to the NPHMOS which has the responsibility in this field. The NPHMOS county and local representatives carry out official controls only at retail level and at the headquarters of the involved company². No controls are carried out in the centres of storage and distribution. Also during the visit carried out by the FVO audit team in a retail establishment which was involved in a RASFF alert it was identified that the checks carried out by the local representatives of the CA took place two months after the start of the alert. The CA explained that the information was passed from CCA level to local level with this delay.

Ministerial Decree 36/2004 gives competences to both the NFCSO and the NPHMOS county and local representatives in relation to official controls over food intended for particular nutritional purposes (including IF, FOF and BFs) without mentioning a clear split of responsibilities between the two CAs. During the visit on the spot the FVO audit team identified that both CAs carry out controls at retail level in relation to the hygiene requirements, while labelling and compositional requirements may form part of the controls, without any recording the findings of such controls if they took place. According to the CCA, no co-ordination is ensured between the two CAs at this level. No evidence of co-ordination was seen between the NPHMOS and NFCSO representatives in relation to official controls over IF, FOF and BFs at any of the central, county or local levels.

According to the provisions of Act No CXL from 2004, when a CA identifies non-compliances in the field of responsibility of another CA, they are required to communicate it to the responsible CA. Evidence of such coordination was seen during the visit on the spot when the HACP county representative communicated to the County Food Chain Safety and Animal Health Office the identified non-compliances in relation to expired food products (although not IF, FOF or BFs). However, when a possible misleading labelling aspect was identified by the district Food Chain Safety and Animal Health Office representative (differences between the German and Hungarian label of products) this was not communicated to the HACP representatives (see chapter 5.4.3).

In relation to the laboratories used for official control purposes Ministerial Decree 36/2004 mentions that the National Institute for Food and Nutrition Science (NIFNS) will be used for testing in relation to nutritional characteristics while the NFCSO laboratories for testing in relation to food safety and food quality. In practice, when compositional criteria are tested by the NFCSO representatives as part of the food quality controls they use their own laboratory capacity.

5.2.3 Staff performing official controls

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.

Audit findings

The relevant legislation in relation to IF, FOF and BFs is included in the "Collection of legislation"

² In their response to the draft report, the CAs noted that in Hungarian terminology the retail level is the same as the distribution level.

which is updated monthly and available on the internal and external websites of NFCSO to both CA representatives at county and district levels and FBOs.

Training on the specific requirements in relation to IF/FOF and BFs was not provided to the NFCSO representatives at district or county level and it was not scheduled either at the time of the audit. Participation in the Better Training for Safer Food training initiative organised by the European Commission in relation to BFs in 2012 is envisaged by the central authority representatives of the NFCSO.

In February 2012 the NPHMOS organised specific training for its employees in relation to nutritional characteristics in IF, FOF and BFs. The content of this training is available to the NPHMOS county and district representatives via the intranet.

During the visits on the spot the official staff awareness in relation to the labelling and compositional criteria in BFs was largely satisfactory, while in relation to the specific obligations of the FBOs regarding contaminants and pesticides in BFs, re-labelling of IF, FOF and BFs and CAs' related responsibilities it was not satisfactory in the cases assessed (see chapters 5.4.2 and 5.4.3).

5.2.4 Registration/approval of Food Business establishments

Legal requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Audit findings

The approval of FBOs is carried out by the county representatives of the NFCSO in accordance with a general procedure covering all categories of foodstuffs and no specific guidance is provided for the approval of BF producers. The BF operators visited were approved. The scope of approval was however different in the two cases. In one case the approval letter referred to the "homogenised mixed babyfood" food category only while in the other case it referred to 11 food categories (e.g. "heat treated jar with pork content", "heat treated jar with semi-finished poultry meat", including the "homogenised mixed babyfood" category). The decision on the approval category was taken by the county CA following the approval procedure in place.

5.2.5 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, processing and distribution 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, to introductions from third countries into the EU and to placing on the EU market.

Audit findings

The frequency of controls carried out by the NFCSO representatives during the previous years and in 2012 was established at central level taking into account the type of product and it was transmitted for implementation to the county and district levels. The NFCSO representatives stated during the final meeting that currently a new risk categorisation system is being implemented taking into consideration all the relevant criteria mentioned by Regulation (EC) No 882/2004. The new

system is computerised and the input data is sent fed from the district level.

The BF producers are currently placed in the highest risk category with an annual inspection which was found to be correctly implemented on the spot. In addition to the yearly comprehensive inspection, extra targeted inspections were carried out by the local and county NFCSO representatives (e.g. for official sampling). No official controls are carried out at BF producer level by the other two CAs although they have responsibilities in this regard.

The inspections carried out in retail centres by representatives of both the NFCSO and the NPHMOS with a frequency between once every year to once every three years cover the hygiene requirements and according to the CCA they may include IF, FOF and BFs, but this is not specifically required and the decision is left with the inspector on the spot. The distribution centres are subject to official controls by the NFCSO local representatives under the same conditions. No evidence was seen that the official control activities at distribution level cover the specific requirements for IF, FOF and BFs. The NFCSO official controls at retail level are carried out in relation to IF, FOF and BFs specific requirements only in the framework of the monitoring plan for pesticides, contaminants, microbiological criteria, labelling and compositional criteria (see chapter 5.3).

The NPHMOS only started this year to take on their official control duties in relation to IF, FOF and BFs (see chapters 5.2.1 and 5.2.2).

The official controls carried out at primary agricultural producer level do not concern the specific requirements in relation to the BF ingredients. No official controls in relation to the specific BF requirements are carried out at BF supplier level either.

The labelling controls in place cover the compliance of the Hungarian label with the legislation. No controls are in place over the re-labelling of IF and FOF for the Hungarian market.

The NIFNS is the CA who receives the notifications of the IF and FOF and other food intended for specific nutritional purposes before their first placing on the Hungarian market. This information is available to the public on the NIFNS website and can be used when planning the official monitoring activity. However, according to the information received by the FVO audit team, none of the CCAs uses this information in planning the official monitoring activity. According to the provisions of Article 9 of Commission Directive 2006/141/EC and Article 11 of Directive 2009/39/EC the information notified by the FBOs at the first placing on the market of these products is intended to facilitate the monitoring activity.

According to the CCA, stages 1 and 2 IF and FOF are sold in pharmacies, drugstores and foodstores in Hungary. Pharmacies have been included in the monitoring plan of the NFCSO only starting in 2012.

The organisation of official controls at retail and distribution levels does not differentiate between IF, FOF and BFs that are imported, originating in other Member States or in Hungary. Also, the official controls at BF producer level are applied for both products intended to be exported and products intended for the domestic market.

5.2.6 Procedures for performance 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 Regulation (EC) No 882/2004 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 FBO concerned.

Audit findings

Documented instructions, inspection check-lists and report forms are in place for the official controls carried out by the CAs responsible.

The NFCSO's instructions that are available to official control staff at district and county level mention that compliance with all relevant legislation has to be ascertained during the official control activity without including any related guidance for implementation of controls over these commodities. Examples of instructions received from central and regional levels in relation to IF, FOF and BFs monitoring and inspection programmes were available at district level. The NFCSO inspection instructions do not include the requirements of Commission Directives 2006/125/EC, 2006/141/EC and Regulation (EC) No 1881/2006 in relation to these commodities, while the monitoring instructions do not always indicate the appropriate laboratory for testing a specific parameter. These impacted on the quality of official controls over FBO compliance with the specific requirements. (see chapters 5.3, 5.4.2, 5.4.3).

In the case of the NPHMOS, instructions in relation to official controls over IF, FOF and BFs have only been issued this year by the CCA for the county and local level employees and their implementation is envisaged to start in June 2012.

The representatives of the NPHMOS have access via intranet to the presentations given in February 2012 in the framework of the training organised in relation to nutritional characteristics and labelling of BFs and these presentations are used as a guidance.

The check-lists used by the NFCSO representatives when performing official controls in relation to IF, FOF and BFs are general ones, used for both registered and approved establishments, both in relation to food of animal origin and non-animal origin. They are intended to cover the provisions of the Hygiene Package and do not include any specific requirements on composition, labelling, pesticides and contaminants which would be relevant for the commodities under the scope of this audit nor any reference to the relevant legislation (e.g. the Hungarian transposition acts for Commission Directives 2006/125/EC, 2006/141/EC, Regulation (EC) No 1881/2006) for IF, FOF and BFs.

No harmonised check-list is used by the NPHMOS representatives and according to the CCA it is down to the individual inspectors to create their own.

The reports of the official controls carried out were available in the cases assessed, with the exception of the distribution centre visited where no copy of the official control report could be provided by either the FBO or the CA during the visit on the spot.

The control method, the results and a request for FBO action for the shortcomings identified were mentioned in the reports assessed by the FVO audit team. Copies of reports were made available to the FBO. The action plans provided by the FBO and the results of the CA follow-up visits were also available in separate reports.

The purpose of the official control was included in the report and its wording was either "public health", "complex" or "targeted" without mentioning in most cases the legal requirements the control focussed on. In one case, the legal requirements were mentioned but they referred exclusively to the Hygiene Regulations with no reference to specific BF legislation (the Hungarian transposition acts for Commission Directive 2006/125/EC) or the specific provisions of Regulation (EC) No 1881/2006 applicable to BFs.

5.2.7 Enforcement measures

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. Article 55 of the Regulation requires Member States to lay down the rules on sanctions applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and to take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Audit findings

The provisions which give legal powers to the CAs to take measures or to impose sanctions when deficiencies or infringements are identified and the range of actions which can be taken by the CAs according to the severity of the deficiency or infringement are described in the country profile.

Specific actions in relation to food intended for specific nutritional purposes including coordination provisions between the different stakeholders involved and communication to the European Commission (COM) when food safety is put at risk are laid down in the Ministerial Decree No. 36/2004.

Evidence of CAs using their legal powers was seen on the spot. Also, the CAs' reports on the follow-up visits in order to verify the actions taken by the FBOs in relation to the non-compliances identified were seen. However, no action was taken by the CAs in relation to the long-standing deficiencies identified by the FVO audit team in relation to FBOs procedures based on HACCP (see chapter 5.4.2), nor in relation to the possible misleading labelling (see chapter 5.4.3).

The FBO's procedure in place for dealing with a food safety risk, including informing the CA, withdrawal and recall was evaluated in one case and found to be satisfactory.

5.2.8 Verification and review of official controls and 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 that corrective action is taken when needed and to update documentation concerning information and instructions where needed. Under Article 4 of the Regulation 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.

Audit findings

The procedures in place to verify the effectiveness of official controls and carry out internal audits are described in the country profile.

Verification of the effectiveness of the controls in the BF establishments is carried out from County and District levels (either through joint inspections or separate). Nevertheless, the check-list used for such inspections is the same one used by the OVs, for both registered and approved establishments. This was also identified in the previous report. No mention is required to be made in relation to the effectiveness of the official controls in the supervisory report and none was seen in any of the documentation assessed by the FVO audit team.

The official controls in place did not cover all the specific requirements of IF/FOF and BFs in relation to pesticides, contaminants, composition and labelling (see chapter 5.4.2 and 5.4.3) and this was not identified during the supervisory visits.

The audits carried out to date by the responsible unit (the System Management Unit within the NFCSO) did not include BFs, IF, FOF, nor are any planned on this topic.

Conclusions on Competent Authorities

Progress was noted regarding the organisation of the official controls system in relation to IF, FOF and BFs since the previous audit. The national measures for the implementation of the EU Directives relevant for the scope of this audit have been largely adopted, the CAs responsible for the official control of IF, FOF and BFs have been designated and co-operation within the CAs is in general ensured. The procedures for approval of FBOs and for performance of control activities were found to be largely followed. Some training in relation to compositional criteria and labelling was recently organised for the representatives of one CA.

However, not all CAs perform the official control activities they are responsible for at all stages of production, processing and distribution and coordination within and between the different CAs is not fully adequate. The procedures for performance of control activities in relation to IF, FOF and BFs are not addressing the specific requirements in relation to pesticides, contaminants, compositional criteria and labelling and the official controls are not fully documented. Although the enforcement powers were used when non-compliances were identified by the CA, no action was seen for the shortcomings identified by the FVO audit team. The risk-based approach taken in deciding the control frequency for the previous years and for 2012 took into consideration only the type of activity. Training was not provided to the CA with responsibility for food safety and verification of the effectiveness of the official controls in relation to IF, FOF and BFs has not been implemented.

5.3 OFFICIAL 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 requirement for the laboratories so designated.

With regard to microbiological criteria, Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation. Specific requirements related to residues of pesticides, composition and limits for vitamins, minerals and trace elements are set out in Commission Directive 2006/125/EC for cereal-based foods and BFs and Commission Directive 2006/141/EC for IF and FOF. Commission Regulation (EC) No 1881/2006 contains provisions for maximum levels of certain contaminants in foodstuffs, including IF, FOF, cereal-based foods and BFs.

Audit findings

In their response to Recommendation No 11 of the previous report in relation to testing all types of IF, FOF and BFs and for all criteria the CCA undertook to amend their monitoring programme in relation to IF, FOF and BFs in accordance with the respective recommendation. Comprehensive monitoring plans have been implemented in 2010 and 2011 and are scheduled for 2012 for most

types of BFs. Babydrinks were not mentioned in the 2010 and 2011 plans, but are included in the 2012 plan.

According to the information provided by the CCA, 13 laboratories are used for the official testing of IF, FOF and BFs. Most of these laboratories are accredited by the Hungarian Accreditation Board and the rest are in the course of accreditation. However, the state of accreditation in relation to the different methods for pesticides, contaminants and compositional criteria, with the applicable limits for IF, FOF and BFs in the relevant matrix, varies between the laboratories performing official control testing.

Official sampling is currently carried out in the framework of the monitoring plans developed at central level by the NFCSO and transmitted to county level and consequently to district level representatives which are responsible for their implementation. The plans include the number of tests to be carried out, the type of foodstuffs, the criteria to be tested for and the place of sampling.

Sampling takes place at producer level and at retail/distribution level. The CA stated that the same Hungarian word is used to designate the distribution and the retail levels and the choice is of the district level officials, which in the cases assessed sampled at the retail level.

The laboratories to be used are communicated to the district level by means of a Circular from 2009 which is not detailed to indicate the different laboratories to be used for the each contaminant and compositional criteria. Not all the laboratories used for such testing can test for all the relevant parameters and as a consequence the use of methods within the scope of accreditation of the laboratory cannot be ensured in all cases. In addition, in a few of the cases assessed by the FVO audit team the method was not able to detect the low detection limit required in BFs. The CCA stated that a comprehensive table to address this shortcoming was drafted and will be made available to the district official control staff.

The monitoring plans for 2010, 2011 and 2012 include testing of the contaminants for which specific requirements are laid down in Regulation (EC) No 1881/2006 in relation to the commodities within the scope of this audit. The 2012 plan no longer includes tin as there is no canned IF, FOF and BFs on the market since the CA risk assessment. The detection limits for BFs, IF and FOF were not in a few cases within the accreditation scope of the laboratories used for the relevant matrix or not at all in the laboratory capacity. In 3 of the 17 cases assessed the results of the official sampling in relation to contaminants were expressed in a manner which did not allow the evaluation of the compliance with the legislation (the result for Aflatoxin B1 was expressed as <1 micrograms/kg, while the limit is <0.1 micrograms/kg, for Ochratoxin A as <2 micrograms/kg, while the limit is <0.5 micrograms/kg, for Fumonisin as <500 micrograms/kg, while the limit is <200 micrograms/kg). No action was triggered by either the official laboratory or the CA, which performed the sampling and received the results.

Labelling and compositional criteria controls are included in the monitoring plan of the NFCSO (as part of their food quality checks). A very limited number of official controls over compositional criteria and labelling has been carried out to date in relation to IF, FOF, BFs, but a higher number has been included in the 2012 plan. Official testing for compositional criteria is carried out in different laboratories under the NFCSO co-ordination. None of them has the capacity to test for all relevant criteria in BFs, IF and FOF. During the visits on the spot the only official testing for compositional criteria carried out in one of the BF producers between 2010-2012 was in relation to carbohydrates and protein.

The NIFNS under the co-ordination of the NPHMOS carries out nutritional characteristics testing at the request of the FBOs. Up to now the NPHMOS have not carried out the testing of IF, FOF and BFs as part of their routine official control activities. This was identified as a priority for the 2012 plan and starting in June such testing is envisaged to take place. The NPHMOS local representative

carrying out the on-the-spot check brought the sample into the county laboratory for testing, although the laboratory was not accredited at the time of the FVO audit. However, according to the CCA, it is currently going through the accreditation process.

The laboratory testing capacity of NIFNS included, according to the accreditation certificate provided to the FVO audit team and the test results seen, protein, carbohydrates, thiamine, riboflavin, pyridoxine and niacin. At the time of the FVO audit it was undergoing a re-accreditation process.³

There is no official laboratory capacity in the country to test for all the compositional criteria required for in relation to BFs, IF, FOF.

The monitoring plans for 2011 and 2012 include testing for pesticides in 10 samples of processed cereal based BFs as required by the Multi-annual control Programme of the Union to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin. Only the 2012 plan makes reference to the Union Programme. The 2010 monitoring plan did not include the 10 samples in the framework of the programme.

The Plant Protection and Soil Conservation Directorate Official Laboratory carried out several comprehensive tests of BFs in 2010 until such responsibility has been taken over by the Food and Feed Safety Directorate. Starting in April 2012, the laboratory recommenced carrying out out official testing for pesticides in IF, FOF and BFs. The test results available show compliance with the specific pesticides residue limits in Annexes VI and VII to Commission Directive 2006/141/EC and Annexes VII and IX to Commission Directive 2006/125/EC, with the exception of propineb/propylenethionourea (sum of propineb and propylenethiourea) for which the laboratory does not have testing capacity. The CCA stated that testing for this substance will take place after the re-accreditation exercise in 2013. Also, the accreditation of this laboratory does not include testing for BFs and the specific low limits laid down in the above mentioned Commission Directives.

According to the information provided by the CCA, the Food and Feed Safety Directorate laboratory which was used for official testing of IF, FOF and BFs between March 2010 and April 2012 does not have the laboratory capacity for testing cadusafos, demeton-S methyl/demeton-S-methyl sulfone/oxy-demeton-methyl, ethoprophos, propineb/propylenethiourea, fensulfothion, fentin, haloxyfp, omethoate, terbufos (for which specific requirements are laid down in Commission Directives 2006/141/EC and 2006/125/EC) nor for testing most of the pesticides mentioned in the Multi-annual control Programme of the Union. No results of testing carried out by this laboratory were provided to the FVO audit team even though they had been requested. In the establishments where this aspect was assessed by the FVO audit team, no testing of pesticides took place in 2011 and 2010. The 2012 testing included both BFs, IF and FOF and was carried out in the laboratory of the Plant Protection and Soil Conservation Directorate Official Laboratory with satisfactory results under the limitations mentioned above.

In relation to microbiological contamination, the sampling programmes for 2011 and 2012 are covering the relevant parameters of provided by Regulation (EC) No 2073/2005 except for *Enteriobacteriacea*. IF and FOF are however not produced in the country. The 2010 plan includes only testing for *Salmonella* and *Listeria*.

Testing for melamine is also included in the monitoring programmes. No distinction is made

³ In their response to the draft report, the CAs stated that the accreditation certificate of NIFNS was reissued on 23 May 2012. According to the information provided by the CA following the FVO audit, the current capacity of the NIFNS includes also Vitamin A, Vitamin E, dietary fibre content, fatty acid distribution, zinc, copper, iron and manganese content.

between products which are imported or produced in Hungary or other Member States in relation to sampling and testing.

Conclusions

Recommendation No 11 of the previous report has been largely addressed in relation to testing for pesticides, contaminants and microbiological criteria. However, further action is required in the organisation of official testing in particular in relation to accreditation of the laboratories used for the official control of IF/FOF and BFs and with regard to the detection limits for some of the relevant pesticides (indicated in Annexes VI and VII to Commission Directive 2006/125/EC and Annexes VIII and IX to Commission Directive 2006/141/EC) and for some of the contaminants indicated in Regulation (EC) No 1881/2006 as well as in relation to the complete list of pesticides, contaminants and composition criteria which require testing in this matrix.

Compliance with the requirement of testing 10 BFs samples in the framework of the Multi-annual control Programme for the Union could not be ascertained for previous years, but it is planned for 2012.

5.4 Official controls over Food Business Operators' compliance with the requirements

5.4.1 General and specific hygiene requirements

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establish that the FBO carrying out any stage of production, processing and distribution of food after the stage of primary production and associated operations listed in Annex I shall comply with general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004. These provisions relate, among other issues, to cleaning and maintenance, layout, design, construction, sitting and size of food premises.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the relevant provisions of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses.

Article 4(2) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify the FBO's compliance with these requirements.

Audit findings

Official controls regarding general and specific hygiene requirements were in place and carried out by the CA in the establishments visited.

In one of the BF producers only minor maintenance issues were identified by the FVO audit team. At the other BF producer the product and personnel flow involved crossing the yards. Nevertheless, only wrapped product and personnel wearing yard coats was witnessed crossing the yards. Some of the doors and ceilings required pest proofing. The paint on the ceiling in the heat treatment room for packed product was peeling off. In the storage room, a contaminated broken cereal bag of raw material with potential to contaminate the product inside was noted. The FBO stated that there was a procedure in place to remove contaminated product before processing and an action plan to address the maintenance issues and the fragmentation of the site was in the process of being implemented.

Recommendation No 5 of the previous report requires for water analysis to comply with the requirements of Council Directive 98/83/EC. The water testing procedure and the test results of both the FBO and the CA were assessed in one of the establishments and found to be compliant with the legal requirements. No shortcomings have been identified in relation to microbiological testing either.

Conclusion

The official controls in place ensure that in general the general and specific requirements are met. Some deficiencies were noted in one BF establishment. Recommendation No 5 of the previous report was addressed in relation to BFs.

5.4.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the Hazard Analysis of Critical Control point (HACCP) principles. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures (Article 4 (3)(a) and (5) of Regulation (EC) No 854/2004).

With regard to microbiological criteria, the FBO shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Regulation (EC) No 2073/2005. To this end the FBO shall take measures as part of their procedures based on HACCP principles at each stage of food production, processing and distribution, including retail. Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation. Specific requirements related to residues of pesticides, composition and limits for vitamins, minerals and trace elements are set out in Commission Directive 2006/125/EC for cereal-based foods and BFs and Commission Directive 2006/141/EC for IF and FOF. Regulation (EC) No 1881/2006 contains provisions for maximum levels of certain contaminants in foodstuffs, including IF, FOF, cereal-based foods and BFs.

Audit findings

Recommendation No 4 of the previous report envisaged improvement of official controls in order to ensure that FBO HACCP based systems comply with the requirements of Article 5 of Regulation (EC) No 852/2004.

Controls over the FBO's compliance with the HACCP based procedures is part of the check-list used for official controls in all types of food establishments. The check-list is very general and does not target any specific BF requirements. No other guidelines are available to the official control staff in relation to the specific pesticides, contaminants, microbiological and composition hazards in BFs

In the BF establishments visited only heat treated products in hermetically sealed glass containers were produced. Both BF manufactures visited had HACCP programmes in place. Heat treatment, metal and glass contamination were controlled through CCP monitoring by both BF producers visited. Pesticides and contaminants were controlled through testing of the raw material in both cases. Monitoring testing was carried out in one establishment in both raw material and final product. In one establishment, with the exception of heavy metals, contaminants have not been identified as a hazard, while pesticides, although identified as a hazard, were only tested in raw material of plant origin. Monitoring testing was carried out for some other contaminants either in the raw material or in the final product, but not all contaminants for which Regulation (EC) No

1881/2006 lays down specific provisions in BFs were tested for. Testing of the final product was carried out for monitoring purposes with a frequency which would ensure that all types of products would be tested once within 26 months, but not for all relevant parameters.

In the same establishment, for one CCP, the control limit was expressed as "compliance with the legal requirements" without mentioning which legal requirements should be complied with. In addition, this CCP was designed to address different hazards for which the legal requirements are laid down in different pieces of legislation.

In the other establishment no written procedures could be provided to confirm the procedure to address the identified pesticides and contaminants hazards. In relation to contaminants, the approach taken by the FBO was to test for different contaminants in different raw materials without being able to demonstrate that the system in place would ensure compliance with the legal requirements in relation to all contaminants relevant for BFs as prescribed by Regulation (EC) No 1881/2006. Final products were not tested.

In one of the establishments, some of the composition criteria was tested by one of the FBOs for the placing on the market of a new recipe with no monitoring testing of the final products.

In the other establishment monitoring testing was carried out in their own laboratory, but not for all parameters. Testing before first placing on the market was carried out in the NFNSI.

No official supervision is currently in place over the FBOs' own laboratories.

The CA approach for the verification of FBOs' compliance with the composition criteria was by means of carrying out official testing. The testing capacity of the laboratories used for official testing did not include all the relevant parameters described in Commission Directive 2006/125/EC (see chapter 5.3).

With the exception of the ambiguous expression of the CCP critical limit, the CAs did not identify any of the other non-compliances identified by the FVO audit team in relation to the FBOs' HACCP based procedures.

The CA in one of the counties visited was not aware that checking whether the FBO control plan ensures compliance with the legal requirements is part of the control tasks.

Conclusions

The BF manufactures visited had HACCP programmes in place but they were either only partly designed to take into account the specific risks associated with the production of BFs or no written procedures were available to demonstrate how compliance with the requirements is ensured. Shortcomings were noted with regard to the controls of composition, pesticides and contaminants.

Official controls over HACCP did not ensure that the BFs, IF, FOF specific hazards related to pesticides, contaminants and composition were controlled.

Recommendation no 4 of the previous report is not addressed in relation to official controls over FBOs' HACCP based systems in BF manufacturing establishments,

5.4.3 Identification marking, labelling and compositional criteria

Legal requirements

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 and verification of compliance with these requirements is foreseen by Article 4(6) of Regulation (EC) No 854/2004.

Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be

delivered as such to the ultimate consumer, Article 9 of Directive 2009/39/EC set out conditions under which those particulars shall apply to foodstuffs for particular nutritional uses. Article 8 of Commission Directive 2006/125/EC set out further labelling requirements for processed cereal-based foods and BFs for infants and young children. Article 13 of Directive 2006/141/EC sets out labelling requirements for IF and FOF.

Commission Directives 2006/141/EC and 2006/125/EC specify requirements regarding ingredients, compositional criteria and nutritional substances for IF, FOF, cereal-based foods and BFs.

Audit findings

Identification marking of approved establishments was correctly placed on the final product packaging in the cases assessed by the FVO audit team.

Recommendation no 12 of the previous report refers to the performance of official controls in relation to labelling and compositional criteria as required by Commission Directives 2006/141/EC and 2006/125/EC.

Labelling and compositional criteria checks have been carried out by MRD (currently NFCSO) representatives as part of the monitoring plan for food quality requirements in the previous years and are planned for 2012. The inspection plans includes this check only starting in 2012 and one such check was carried out prior to the FVO visit in the retail establishment visited. Inspection reports including the checks carried out in relation to composition labelling in randomly selected BF products were presented by the NFCSO local representative in one county and the public health local representative visited. The NFCSO composition labelling check was also performed in connection with the official testing results of the products assessed. The NFCSO local representative in another county was not aware on how these checks could be carried out and did not perform any. Both FBO and official test results available include a limited number of criteria. The most comprehensive test result available referred only to protein, carbohydrates, thiamine, riboflavin, pyridoxine and niacin. There is no official laboratory capacity in the country for the complete list of compositional parameters mentioned in Commission Directives 2006/141/EC and 2006/125/EC.

The labelling controls in place concern compliance of the Hungarian label with all the relevant requirements and were largely satisfactory.

No official controls are in place regarding the re-labelling activity in relation to IF, FOF and BFs although the IF and FOF on the Hungarian market is not produced in the country. Differences between the country of origin label and the Hungarian label were noticed by the FVO audit team in two cases. In one case the original label was reading "milk for children" while the translated Hungarian label "FOF". In another case the original label mentioned the presence of choline and carnitine while the Hungarian translation of the label mentioned their average quantity in 100 ml as well. No action had been taken or considered necessary to be taken by the CA in any of these cases.

No official controls have been carried out to date or planned for 2012 by the Hungarian Authority for Consumer Protection in relation to IF, FOF and BFs, although misleading labelling falls within their responsibility.

Conclusions

Recommendation No 12 of the previous report has been largely addressed. However, not all CAs designated for official controls in relation to labelling and compositional criteria have taken up their duties yet, while the controls in place do not include all compositional criteria and the relabelling activity.

No shortcomings have been identified in relation to identification marking.

5.4.4 Traceability

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires that the verification of compliance with traceability requirements takes place in all approved establishments.

Audit findings

Traceability is included in the check-list for inspection used by the CA for the comprehensive checks in both approved and registered establishments.

Both BF producing establishments visited had traceability procedures in place. In one of the establishments the CA demonstrated the evaluation of the FBO traceability system for the individual ingredients in one of the final products intended for export. In the other establishment a full traceability exercise was demonstrated to the FVO audit team for a randomly chosen product in the storage facility. Both exercises were satisfactory.

Conclusions

The traceability systems of the BF producers were were operating adequately, ensuring compliance with Article 18 of Regulation (EC) No 178/2002, in the cases assessed by the FVO audit team.

No shortcomings have been identified in relation to the CA verification of compliance with the traceability requirements in the BF producing establishments.

5.5 EXPORT OF INFANT FORMULAE AND FOLLOW-ON FORMULAE

Council Directive 92/52/EEC lays down specific requirements Member States have to comply with in relation to IF and FOF exported from the EU.

Audit findings

Council Directive 92/52/EC was transposed by Decree 23 of 2003. However, this Decree was repealed by Decree 20 of 2008 which according to the CA does not transpose the requirements of Council Directive 92/52/EC. However, according to the CCA, no IF and FOF is exported from Hungary.

6 OVERALL CONCLUSION

Progress in the organisation and implementation of official controls over manufacturing and/or placing on the market of IF, FOF and BFs in Hungary was noted since the previous audit (Ref. DG(SANCO)/2008-7817). However, full compliance with the specific requirements in relation to these commodities is still not ensured.

Recommendations no 5, 11 and 12 of the previous report have been largely addressed in relation to IF, FOF and BFs. However, the controls in place do not include all compositional criteria and the relabelling activity and further action is required regarding the organisation of official testing in particular in relation to the accreditation of the laboratories used for the official control of IF/FOF and BFs with regard to the detection limits for some of the relevant pesticides indicated by Commission Directives 2006/125/EC and 2006/141/EC and some of the contaminants indicated in Regulation (EC) No 1881/2006 as well as the complete list of pesticides, contaminants and composition criteria which require testing in this matrix. In addition, Recommendation no 4 is not addressed in relation to official controls over FBOs' HACCP based systems in BF manufacturing establishments, while no shortcomings were identified in relation to identification marking and microbiological controls in BFs.

7 CLOSING MEETING

A closing meeting was held on 27 April with the representatives of the CCAs, the MRD, the NFCSO, the HACP and the NPHMOS. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.

The representatives of the CCA acknowledged the findings and conclusions presented by the FVO audit team. In addition, information on action already taken and planned in order to address particular findings in the establishments visited was provided.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	To ensure that the provisions of Council Directive 92/52/EC are transposed into national legislation.
2.	To ensure that Competent Authorities designated to perform official controls in relation to infant formulae, follow-on formulae and baby foods carry out these controls according to their responsibilities and at all stages of production, processing and distribution as required by Article 3 (3)of Regulation (EC) No 882/2004.
3.	To ensure efficient and effective co-ordination between the different Competent Authorities responsible for carrying out official controls in the field of infant formulae, follow-on formulae and babyfood as required by Article 4(3) of Regulation (EC) No 882/2004.
4.	To ensure that official controls are carried out regularly, on a risk basis, taking into account all of the points mentioned under 1 (a) -1 (d) of Article 3 (1) of Regulation

N°.	Recommendation
	(EC) No 882/2004.
5.	To ensure that appropriate training is provided to official control staff as required by Article 6 of Regulation (EC) No 882/2004.
6.	To ensure that official controls over infant formulae, follow-on formulae and babyfood are carried out in accordance with documented procedures containing the relevant information and instructions in relation to such controls, as required by Article 8 of Regulation (EC) No 882/2004.
7.	To ensure that verification of the effectiveness of official controls is implemented as required by Article 8 of Regulation (EC) No 882/2004.
8.	To ensure access of competent Authorities to adequate laboratory capacity as required by Article 4 of Regulation (EC) No 882/2004.
9.	To ensure that all laboratories involved in analysis of official samples of infant formulae, follow-on formulae and babyfood are accredited as required by Article 11 of Regulation (EC) No 882/2004, that the methods used for testing infant formulae, follow-on formulae and baby foods are within the scope of accreditation for the relevant parameters and that the methods used for the detection of pesticides, contaminants are characterised by the appropriate detection limits provided by Regulation (EC) No 1881/2006 and Commission Directives No 2006/125/EC and 2006/141/EC in infant formulae, follow-on formulae and babyfood.
10.	To ensure that all pesticides mentioned by Commission Directives 2006/125/EC and 2006/141/EC are tested for in infant formulae, follow-on formulae and babyfood and compliance with the Multi-annual control Programme of the Union to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin is ensured.
11.	To ensure that official controls in relation to labelling and compositional criteria ensure compliance with all relevant requirements of Commission Directives 2006/125/EC and 2006/141/EC.
12.	To improve official controls in order to ensure that food business operators' Hazard Analysis Critical Control Points based systems comply with the requirements of Article 5 of Regulation (EC) No 852/2004.

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

 $\underline{http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6365}$

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	p. 1, Corrected and	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	p. 55, Corrected and	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	p. 206, Corrected and	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004		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. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Legal Reference	Official Journal	Title
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10–12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council
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
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 97/78/EC	OJ L 24, 30.1.1998, p. 9-30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Dir. 2006/141/EC	OJ L 401, 30.12.2006, p. 1-33	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC

Legal Reference	Official Journal	Title
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of \(\beta\)-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Dir. 2002/99/EC	OJ L 18, 23.1.2003, p. 11-20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Dir. 2006/125/EC	OJ L 339, 6.12.2006, p. 16-35	Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version)
Dir. 2009/39/EC	OJ L 124, 20.5.2009, p. 21-29	Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (recast)
Dir. 1999/21/EC	OJ L 91, 7.4.1999, p. 29–36	Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes
Dir. 92/52/EEC	OJ L 179, 1.7.1992, p. 129-130	Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries
Dir. 90/496/EEC	OJ L 276, 6.10.1990, p. 40-44	Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs