EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6335 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 16 TO 25 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 Spain from 16 to 25 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)/2008-7816.

Comprehensive official controls were carried out in relation to hygiene requirements, usually at a frequency of once per year or every 18 months. Official controls in relation to the specific requirements such as composition, pesticides and contaminants were however not fully documented and resulted in some cases in the lack of detection of non-compliances. National surveys of pesticides in the specified foods were carried out. Official controls over compositional criteria and for contamination with pesticides and contaminants at the Autonomous Community (AC) level varied between the three ACs visited. The 2009-2011 pesticide residue monitoring programmes for IF, FOF and BFs were not adequate in one AC (only testing raw materials of plant origin). In the other two ACs only minor shortcomings with regard to the application of correct detection limits for pesticides were noted. Monitoring for contaminants varied from largely adequate to inadequate between the three ACs. Official verification of the sampling of IF, FOF and BFs at the processing level for contamination with pesticides was not carried out. Adequate surveys of microbiological contamination in IF, FOF and BFs were organised in all three ACs visited and official sampling and testing at local level takes place. Action in the case of non-compliance was not fully satisfactory in a case of IF contaminated with Salmonella where the official control of the recall procedure did not detect the use of a non-validated testing method used previously.

Five Food Businesses operating in the evaluated sector were visited. The CAs in the different ACs authorised the use of raw milk that did not comply with the raw milk criteria. Apart from some maintenance issues detected in two establishments visited, no major shortcomings with regard to hygiene of operations were noted at the manufacturers. All establishments visited had Hazard Analysis Critical Control Point (HACCP) programmes in place but in some cases (two out of five establishments) they did not integrate adequately the specific requirements regarding pesticides. Shortcomings were noted with regard to the controls of composition, pesticides and contaminants and the use of microbiological testing methods in line with Regulation (EC) No 2073/2005. All traceability systems were operational and when tested by the FVO audit team were operating adequately. The labelling and presentation were generally in compliance with the legislation.

Exports of IF, FOF and BFs to third countries were controlled with the same intensity as products for the EU market.

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
AC	Autonomous Community
AESAN	Spanish Food Safety Agency (*Agencia Espanola de Seguridad Alementaria y Nutricion)*
BF(s)	Baby food(s)
CA(s)	Competent Authority(ies)
CAG-AC	Ministry of Agriculture and Livestock
CCA(s)	Central Competent Authority(ies)
CCP(s)	Critical Control Point(s)
COM	European Commission
CS-AC	Ministry of Health of the AC
DFSMP	Dietary Foods for Special Medical Purposes
DG(SANCO)	Health & Consumers Directorate General
EU	European Union
FBO(s)	Food Business Operator(s)
FOF	Follow-on formulae
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
Hygiene Package	Regulations (EC) No 852/2004, No 853/2004 and No 854/2004
IF	Infant Formulae
MAGRAMA	Ministry of Agriculture, Food and Environment *(Ministerio de Agricultura, Alimentación y Medio Ambiente)*
MANCP	Multi-Annual National Control Plan
MSSSI	Ministry of Health, Social Services and Equality *(Ministerio de Sanidad, Servicios, Sociales e Igualdad)*
NRL	National Reference Laboratory
RD	Royal Decree

1 Introduction

The audit took place in Spain from 16 to 25 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 Spanish Food Safety Agency (AESAN - *Agencia Espanola de Seguridad Alementaria y Nutricion*) and the CAs of the ACs.

The opening meeting was held on 16 April 2012 with the CCA in Madrid. At this meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required 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)/2008-7816 – MR Final with regard to:

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	2	Establishments in ACs of Madrid, Asturias and Catalunya visited. The CA of the ACs of Asturias and Catalunya visited. Territorial authorities, where the establishments visited were located.
	Regional	3	
	Local		
FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES			
Processing establishments		5	Processing IF/FOF and/or BFs
Retail shops			One retail shop and one pharmacy

3 Legal Basis

The audit was carried out under the general provisions of European Union (EU) 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.

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 Spain was carried out from 24 November to 5 December 2008, the results of which are described in report DG(SANCO)/2008-7816 – MR Final (hereafter referred to as report 2008-7816). This report is accessible at:

http://ec.europa.eu/food/fvo/index_en.cfm

The action plan received from the Spanish authorities in response to the report's recommendations provided satisfactory guarantees in relation to the 7 (recommendations Nos 1,2,4-6,7,14 of report 2008-7816) relevant recommendations for this audit out of 15 recommendations made.

According to the CCA currently IF, FOF and BFs are produced in Spain, traded and to a large extent exported to third countries. The establishments chosen for the audit were amongst the main producers and exporters in Spain.

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

Commission Directives 2006/125/EC and 2006/141/EC have been transposed as also has Council Directive 92/52/EEC.

A new legislative act has been adopted in order to adapt the Spanish situation to the European legislation and facilitate their compliance. Other aspects envisaged in this Law include an article on the exchange of information between the ACs and the CCA.

Guidelines have been issued covering energy and nutrient requirements in DFSMP, labelling of nucleotides in IF and quantitative declarations of ingredients in BFs.

Conclusion

Relevant legislation has been transposed into Spanish 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 CAs 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

The AESAN is the CCA within the scope of this audit and it is an Autonomous Body attached to the Ministry of Health, Social Services and Equality *(Ministerio de Sanidad, Servicios, Sociales e Igualdad)* – (MSSSI)). It has central responsibility for food safety. The CCA for raw milk production is the Ministry of Agriculture, Food and the Environment *(Ministerio de Agricultura, Alimentación y Medio Ambiente)* – (MAGRAMA). The implementation of official controls falls within the remit of the 17 ACs and their respective territorial units and some municipalities (the latter not for primary production). Although the organisation may vary between the ACs, the responsible CA for public health aspects is the Ministry of Health of the AC, the CS-AC whereas the responsible CA for primary production of raw milk was the Ministry of Agriculture and Livestock of the AC, the CAG-AC.

The CCA for co-ordinating labelling controls in order to prevent fraud at the retail level is the National Consumer Institute under the MSSSI. At the level of the processing establishments it is the CS-ACs (the sanitary public health directorates under the Ministry of Health of the ACs). The National Consumer Institute carries out national control campaigns in co-operation with the respective bodies within the ACs.

The organisation of the Spanish CA is described more detailed in the Country Profile which can be found at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

Conclusion

The designation of the CAs for the official control of IF/FOF and BFs covers all aspects of the official control in line with the requirements of Article 4 of Regulation (EC) No 882/2004.

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

A number of co-ordinating bodies are in place at central level in order to co-ordinate the activities of the ACs.

Co-ordination at the level of the ACs is based on a clear delineation of responsibilities that is described in legislation and regular coordination meetings are held at different levels, inter-territorial , both at state- and autonomous level.

Observations

- Reporting of official controls takes place at the level of the territorial units. Information is forwarded to the central level of the CS-ACs and details concerning the level of compliance with Commission Directives 2006/152/EC and 2006/141/EC are available at the CS-AC level.
- A general reporting of official controls from the ACs to the AESAN takes place on a yearly basis within the context of the compilation of the annual control report. Nevertheless, no details on the levels of compliance with Commission Directives 2006/125/EC and

2006/141/EC were reported. This kind of documented compliance is only kept at the level of Territorial Units in each of the ACs. A similar situation as regards sampling activities was noted that documentation in which context samples have been taken is only kept at the same level.

- In the AC of Catalunya a Food Safety Agency functions as the primary co-ordinating body. In the ACs of Madrid the co-ordination is managed by Technical Committees and the Network Group. In Asturias the co-ordinating body is the Food Security Co-ordinating Body (*Mesa de Coordinación de la Seguridad Alimentaria)*.
- Co-ordination did not ensure that controls were carried out consistently across the ACs visited in relation to:
    - In one case reviewed the lack of direct forwarding of some relevant information (from one AC to another) during a recall procedure of a potentially contaminated IF due to the lack of a procedure for such cases under the Rapid Alert System implemented in Spain (for more details see 5.2.7).

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

Sufficient staff resources for the official control were in place. The facilities visited for official controls were adequate and no conflicts of interests were noted.

Observations

- Several training events in the food hygiene aspects had taken place for the staff involved. However, no specific training had been provided on the specific requirements of the production and marketing of IF/FOF and BFs.
- The awareness of the specific requirements for the official controls of IF/FOF and BFs varied between the officials met from good to inadequate. For instance, in one establishment detailed knowledge was not demonstrated concerning the Commission Directives 2006/125/EC and 2006/141/EC (in particular concerning pesticide requirements), Regulation (EC) No 1886/2006 (in particular its specific application in the evaluated sector) and Regulation (EC) No 2073/2005 (in particular concerning the use of laboratory methods) whereas a partly adequate knowledge was encountered in two establishments visited. In the remaining two establishments visited an adequate level of knowledge was demonstrated.

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

In their response to the Recommendations Nos 1 and 2 of report 2008-7816 regarding registration and approval of the food establishments in compliance with Regulations (EC) No 852/2004 and

853/2004 and to take measures in order to ensure that the procedures foreseen in Article 31 of Regulation (EC) No 882/2004 are complied with and to take measures in order to ensure that the published lists of approved establishments are up-to-date as foreseen in Article 31 of Regulation (EC) No 882/2004 the CCA undertook to issue a new Royal Decree (RD) 191/2011 on approval of establishments fully in line with Article 31 of Regulation (EC) No 882/2004.

The RD 191/2011 addresses the main issues of Article 31 of Regulation (EC) No 882/2004.

A new IT application has been developed which retains all relevant information and ensures update of published lists.

According to the system the approval number includes a sector specific part (which also covers IF/FOF and BFs), the specific establishment number and two acronyms corresponding to the province in which it is located.

Observations

- All establishments visited were listed correctly for the activities performed with regard to the production of IF/FOF and BFs.
- The available approval and registration documents did not specifically refer to Regulation (EC) No 853/2004 or (EC) No 852/2004. Nevertheless, this information was referred to by the Spanish legal reference in the documents**.**

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

Criteria to be taken into account when determining the frequency of official controls have been laid down in the Multi-Annual National Control Plan (MANCP). The CA stated that the evaluation of individual establishments to determine the frequency of official controls is done at the level of the AC.

Observations

- There is no specific model or guidelines agreed at national level on how to determine the control frequency. The frequency of official controls may vary for an establishment of the same type and presenting the same risk depending on which AC they are located in.
- The models used to determine the risk classification of individual establishments included all relevant criteria foreseen in the legislation in all three ACs. In two ACs (the AC of Madrid and Asturias) the sensitivity of the target population was included as a specific criteria. This had resulted in a higher control frequency in one AC**.**
- The ACs visited have or are developing specific software tools where data collected during inspections as well as other data/results are entered. The CA stated that these tools will help in determining the risk classification concerning individual establishments.
- The controls, including all relevant aspects of food safety in general were covered in the ACs visited. However, concerning the specific requirements as regards composition,

labelling, pesticides and contaminants for the production of the specified foods there was a lack of some specific procedures and/or check-lists in one AC (the AC of Catalunya) whereas in the AC of Asturias such documentation has been developed, but not applied yet. In the AC of Madrid check-lists are being applied for all requirements except those referring to contaminants and pesticides. Consequently there was a lack of official controls on some aspects of production and marketing of the specified foods and therefore a lack of detection of some deficiencies was noted. (For more details see Chapter 5.2.7).

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 business operator concerned.

Audit findings

Provisions are in place in the MANCP to provide in general for procedures and check-lists. Moreover, IF, FOF and BFs are now included in the MANCP within sector 12, on food and feed supplements**.**

Observations

- Documented procedures and inspection forms are in place for the majority of the controls to be carried out of animal products. Nevertheless, procedures and specific inspection forms are in place for the control of the specific requirements regarding IF, FOF and BFs were only partly implemented: The AC of Madrid is applying general procedures for inspection, audit and sampling, which are supplemented with sector guides for the requirements of labelling, processing and microbiological criteria. However, there are no guides for contaminant and pesticides requirements. Only recently, procedures and check-lists for IF, FOF and BFs have been put in place in the AC Asturias, but they are not yet applied. In the AC of Catalunya procedures and check-lists for the specified foods have not yet been adopted (for more details see point 5.4.2).
- Reports were normally drawn up after official controls and a copy provided to the FBO. However, in some cases the reports were not detailed enough to provide adequate information on the deficiencies identified and therefore did not provide a sufficient basis for evaluating corrective measures and follow up.

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

In their response to the Recommendation No 5 of report 2008-7816 on ensuring that the follow-up and the actions taken in case of breaches of the legislation in all ACs are sufficient to ensure that the FBO remedies the situation, as required by Art. 54 of Regulation (EC) No 882/2004 the CCA undertook to make sure that procedures for follow-up were available in all the ACs.

A database ALCON has been created at national level to compile official control data from all ACs in order to prepare the annual report.

Observations

- Concerning follow-up a mixed picture was noted. In some cases follow up controls were properly documented in others not. In particular, due to the lack of documented procedures and check-lists, the control of some areas was not documented or controlled leading to a lack of an indication of the non-compliances and consequently no documented follow-up.
- In the AC of Catalunya procedures were developed in 2011 in case non-compliances are detected including seizure, preventive closure, suspension of operation, withdrawal of approval. However, these procedures have not yet been adopted .[1] In the ACs of Madrid and Asturias the procedures for audits and follow-up of controls on HACCP and hygiene measures have been adopted.
- Adequate recall procedures as an integral part of the HACCP programmes were in place at all FBOs visited. In general very limited evidence of follow-up actions was noted due to a low detection rate of non-compliances by the CA. However, in one case of an IF contaminated with *Salmonella* actions were taken that were not fully effective due to the use of a non-compliant method for microbiological testing of the contaminated product by the FBO of destination. This was not detected by the CA. Moreover, relevant information was not passed to the AC responsible for the control of the FBO of the origin of the product. In another case during the follow-up to verify that a banned ingredient to be used in IF was not used (cotton oil), an unacceptably long deadline for the follow-up was set (six months). In some cases minor shortcomings (although detected and documented) concerning non-compliance with general hygiene requirements could persist for a long time without any deadlines set for their rectification.
    - In the three ACs visited no sanctions have been taken in the sector evaluated for the last three years.[2]

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.

1 In their comments to the draft report the CA of Catalunya noted that Law 18/2009 on public health in Catalunya already establishes a set of precautionary measures that can be applied when necessary.

2 In their comments to the draft report the AC of Madrid noted that the establishment was in operation for only one year, and no major issues had been detected requiring sanctions to be applied.

Audit findings

Some activities have been implemented to verify compliance of the FBO with the Hygiene Package legislation and specific requirements of Commission Directives 2006/125/EC, 2006/141/EC and Regulation (EC) No 1881/2006.

Observations

- In general products for export were controlled with the same intensity as products destined for the EU market. In case of products to be exported deviating from EU requirements on composition and labelling for which the importing country requested different requirements, there was no evidence of verification of compliance with those requirements.
- Evidence on the verification of the effectiveness of the controls of the specified foods as required by Article 8 (3) of Regulation (EC) No 882/2004 was not noted.
- Audit systems in the CS-AC within the scope of the audit were being developed. However, full audits of the evaluated sector have not been carried out.
- Some elements of audit were in place in all ACs visited. For example, in one case reviewed concerning contaminated IF placed on the market as documented in two of ACs visited (Asturias and Catalunya).
- In general no documentation was in place for the verification of the effectiveness of the official controls by the CS-AC.[3]

Conclusions on Competent Authorities

Recommendation No 1 of report 2008-7816 has been addressed.

Recommendation No 2 and No 5 of report 2008-7816 have not been addressed.

The lack of detailed information from all ACs on the levels of compliance with Commission Directives 2006/125/EC and 2006/141/EC at the level of the individual CS-AC limits the possibility of carrying out a proper risk assessment as required by Article 3 (1) of Regulation (EC) No 882/2004. However, detailed information is availabe at the level of the Territorial Units. Moreover, the ACs visited have or are developing specific software tools where data collected during official controls as well as other data/results are entered. It is the plan that these tools will be used in determining the risk classification concerning individual establishments**.**

Staff resources and facilities were adequate whereas specific training on the official controls of IF/FOF and BFs is inadequate which is contrary to the requirements of Article 6 of Regulation (EC) No 882/2004.

The system of listing of establishments allows the identification of processing establishments of the specified foods, the system is in line with Articles 31 (1 (a) and 2 (f)) of Regulation (EC) No 882/2004.

Despite the introduction of special provisions in the MANCP for the official control of IF/FOF and BFs, procedures and check-lists for the official controls of IF/FOF and BFs have not been adopted and implemented in all ACs contrary to the requirements of Article 8 of Regulation (EC) No 882/2004. The reports of official controls were not always in line with the requirements of Article 9 of Regulation (EC) No 882/2004 with regard to indicating non-compliances and documented follow-up.

3 In their comments to the draft report the CCA noted that the ACs have a supervisory programme for official controls, although the establishments visited had not received such supervision.

Although enforcement measures have been adopted in case non-compliances are detected, they were not in all cases adequately applied to ensure compliance with Article 54 of Regulation (EC) No 882/2004.

Verification of the effectiveness of the official controls as required by Article 8 (3) of Regulation (EC) No 882/2004 of 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 7 of report 2008-7816 to include in the monitoring programmes for IF, FOF and BFs for the criteria as set out in Regulations (EC) No 2073/2005 and No 1881/2006 and in Commission Directives 2006/125/EC and 2006/141/EC the CCA undertook to have monitoring programmes including IF/FOF and BFs.

Official laboratories

All laboratories for official control of IF/FOF and BFs are designated and approved by the CA of the ACs. The National Reference Laboratory (NRL) for contaminants and microbiological contamination (*Salmonella*, *Listeria*, *E.coli, Campylobacter*, coagulase positive *staphylococcus*) is the National Food Centre. For pesticides this activity is shared with the Food and Agriculture Arbitration Laboratory (Laboratorio Arbitral Agroalimentario).

All three ACs visited had accredited laboratories according to ISO 17 025 for contaminants and microbiological contamination. As regards pesticides such laboratories were available in two of the ACs visited

Observations

- The state of accreditation of all relevant methods for pesticides and contaminants at the NRL could not be evaluated based on the documentation provided. Accredited methods for microbiological contamination for *Enterobacteriaceae, Chronobacter spp (E. sakazakii)* and *B.cereus* were not available. Moreover, the method for detection of *Chronobacter spp (E. sakazakii)* was not accredited in the official laboratory in the AC of Asturias. In the AC of Catlunya the accredited method was used in one official laboratory. In the AC of Madrid the method was not accredited in all official laboratories.

- Prescribed methods or alternative methods validated against the reference methods were used in most cases in accordance with the requirements of Regulation (EC) No 2073/2005.
- The AC of Asturias was outsourcing its laboratory examinations for pesticides to accredited laboratories in other ACs.
- The range of detection of contaminants did not cover all relevant substances as indicated in Regulation (EC) No 1881/2006 in two out of the three ACs visited (Madrid and Asturias).

Organisation of the sampling programmes

The CS-ACs are planning the official sampling programmes.

Such programmes are organised according to hazards and not to commodities. The specified foods have been included in the programme for control of biological hazards and for the control of contaminants.

According to the AC of Catalunya, the implementation of the programme is monitored by reviewing the sampling programmes for both pesticides, contaminants and microbiological contamination covering the relevant parts of Regulation (EC) No 2073/2005.

In the AC of Madrid monitoring sampling for contaminants and pesticides have been in place since 2004 for the specified foods. The microbiological monitoring have been implemented including the specified foods since 2010. In 2011 an evaluation was carried out on pesticide residues in foodstuffs in general and on nitrate in BFs.

In the AC of Asturias in general very limited monitoring takes place for pesticides, contaminants and microbiological contamination. Nevertheless, verification sampling for compliance with Regulation (EC) No 2073/2005 is organised during the official control of producers of the specified foods

When official sampling was organised it covered the whole chain of processing, distribution and retail.

Implementation of the sampling programmes 2009 – 2011

Pesticides

National surveys of pesticides in the specified foods were carried out since the previous mission in 2008.

The 2009-2011 pesticide residue monitoring programmes for IF/FOF and BFs were largely adequate in two of the three ACs visited (Madrid and Catalunya) with only minor shortcomings concerning the testing of all relevant substances or the correct application of some of the prescribed detection levels as laid down in Annexes VI and VII to Commission Directive 2006/125/EC and Annexes VIII and IX to Commission Directive 2006/141/EC.

In Asturias no pesticides residue monitoring programme for the specified foods was implemented in the above period.[4]

4 In their comment to the draft report the AC of Asturias noted that a pesticide residue programme is in place for raw (plant) materials.

Contaminants

Monitoring programmes covering parameters in Regulation (EC) No 1881/2006 were implemented in the three ACs visited: In two of them (Catalunya and Madrid) some parameters were covered and some sampling activity took place, whereas in the third one (Asturias) very limited sampling took place including very few parameters.

Microbiological contamination

Adequate monitoring programmes of microbiological contamination in IF/FOF and BFs were implemented in all three ACs visited. In the AC of Asturias only one processing IF/FOF establishment was sampled (one sample in 2010 and two samples in 2011). Nevertheless, official verification, sampling and testing at local level takes place in all three ACs visited.

Composition

Official sampling for composition was in general limited and only applied in case of a special control campaign on labelling and composition of BFs for infants and young children implemented by ICN in 2010.[5]

Conclusions

Recommendation No 7 of report 2008-7816 has not been addressed.

The laboratory network for the official control of IF/FOF and BFs is inadequate with regard to the detection limits for some relevant pesticides as indicated in Annex VI and VII to Commission Directive 2006/125/EC and Annex VIII and IX to Commission Directive 2006/141/EC and as regards the availability of some accredited methods for the detection of contaminants in line with Regulation (EC) No 1881/2006 which is contrary to the requirements of Article 12 of Regulation (EC) No 882/2004.

Official sampling activity of the specified foods for pesticides, contaminants and microbiological contamination varied according to the analytic group and between ACs visited. For pesticides adequate programmes were seen in only two of the three ACs visited. For contaminants only partly adequate programmes were seen in two of the three ACs visited. Regarding official sampling in order to verify compliance of composition requirements very limited sampling took place. As regards microbiological contamination adequate programmes were seen in all three ACs visited.

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

5 In their comments to the draft report the CCA stated that composition controls are carried out during labelling controls.

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

In their response to the Recommendation No 4 of report 2008-7816 on improving the official controls at establishment level in order to assure FBOs' compliance with the general and specific hygiene requirements of Regulations (EC) No 852/2004 and No 853/2004 the CS-AC undertook in relation to food establishments, with the aim of improving official controls ensuring that the general and specific hygiene requirements of Regulations (EC) Nos 882/2004 and 853/2004 are fulfilled, technical instructions, documented procedures and questionnaires for use during inspections have been developed. These procedures contain official document templates that are used as reports to be provided to the operator, for each one of the official controls conducted and also taking samples. Audits are also conducted of the food industries own-checks, which enable the quality of official controls to be improved.

In their response to the Recommendation No 14 of report 2008-7816 regarding measures in order to ensure that the official services are monitoring the checks of the criteria for raw milk as foreseen in Annex IV, Chapter II of Regulation (EC) No 854/2004 and take the appropriate measures and urgently to ensure that raw milk not meeting the criteria as regards plate count and somatic cell count is only used in accordance with the provisions of Article 10(8b) of Regulation (EC) No 853/2004, the AC stated that they would establish control plans for raw milk. The DG-SG should carry out random controls of the milk supplying farms. All FBO controls are introduced in the database Q. In case of non-compliances, the CA is notified. In the establishments in case of reception of non-compliant milk a check is made to verify that the milk originates from an authorised farm and that the milk is treated in line with Article 10 (8 (b) of Regulation EC No 853/2004.

In general adequate verification controls with regard to the general and specific hygiene requirements were in place. Nevertheless, official verification controls covering the specific requirements of IF/FOF and BFs, in particular concerning pesticides, contaminants, composition and labelling were not adequate in order to verify compliance (see also points 5.3, and 5.4.2).

Verification of the eligibility of raw materials of animal origin took place in all establishments visited whereas such controls for ingredients of non-animal origin only took place in two establishments.

Observations:

General hygiene requirements

The FVO audit team visited five establishments processing IF, FOF and/or BFs and evaluated the cleaning and maintenance, layout, design and construction of the premises. The following was noted:

- In three establishments the maintenance and cleanliness was satisfactory and procedures for pest control were in place.
- In the other two establishments a lack of maintenance (leaking pipes, rust, flaking paint) and gaps under the doors were noted. Moreover, in one of them, a highly sensitive processing area (adding of additives and mixing), the overhead structures was not easy to clean due to rust on the overhead construction and due to wall and floor damages.

Most of these shortcomings noted by the FVO audit team were not detected by the CA during the official controls.

When the FVO audit team checked water testing carried out in the establishments it was compliant with the EU requirements.

Specific hygiene requirements

Own-check procedures for raw milk criteria were as described in the action plan. Nevertheless, the basis for the authorisation of the treatment necessary to protect public health or the general instruction on the use of raw milk, as provided for in Annex IV to Regulation (EC) No 854/2004, not complying with the raw milk quality criteria as laid down in Section IX, Annex III to Regulation (EC) No 853/2004 to be used for the production of IF/FOF, was not based on a risk assessment or other scientific evidence. In particular, no regard was given to the specific health sensitivities of the specific categories of infants. Moreover, in the AC of Asturias a deadline for ensuring compliance and suspension of production was not laid down, whereas in the AC of Catalunya nine months was set as the deadline for the suspension of delivery.[6]

In general the FBOs had monitoring programmes in place to ensure compliance with Regulation (EC) No 2073/2005 which were adequate to verify compliance. In one case, it was not documented if the method for the detection of *L. monotytogenes* had been validated against the reference method and moreover the laboratory protocol had been changed without validation against ISO 16 140.

In another case, the method for *Salmonella* detection was only validated recently (November 2011) against the EU reference method. In that establishment a non-validated method had been in use when Salmonella contaminated IF had caused an outbreak amongst infants in Spain in August 2010. This had not been detected by the CA (for more details see point 5.2.7).

In the establishments visited the procedures for contaminated products excluded the re-use of IF/FOF and BFs after reprocessing.

Conclusions

Recommendation No 4 of report 2008-7816 has been addressed.

The elements of recommendation No. 14 of report 2008-7816 concerning the use of non-compliant raw milk have not been addressed.

The official control as laid down in Article 4 (2) of Regulation (EC) No 854/2004 to ensure compliance of the FBO with the raw milk criteria as laid down in Section IX, Annex III to Regulation (EC) No 853/2004 for the production of IF/FOF were not adequate due to the lack of an assessment of the public health risk of the specific categories of infants for the authorisation of non-compliant milk and a lack of definition of the use and necessary treatment in order to protect public health for this particular sensitive population.

The official control of the FBOs' compliance with the requirements of Regulation (EC) No 2073/2005 was not fully adequate.

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

6 In their comments to the draft report the AC of Asturias noted that after 3 months notice of ensuring compliance with raw milk criteria a sanction may be imposed and the sale of milk prohibited.

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. 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 6 report 2008-7816 regarding the taking of measures in order to ensure that sampling for microbiological analysis by the FBOs is carried out in accordance with Regulation (EC) No 2073/2005 the AC undertook to take specific measures when non-compliances are detected. There is an overall control programme for verification of FBOs' own-checks and a control programme for biological risks.

In all five establishments visited the FBOs had implemented and maintained procedures based on the HACCP principles.

With some exceptions HACCP plans were developed according to sector specific guides and were adapted to the establishments in particular for the production of IF, FOF and BFs.

In all establishments visited the HACCP programmes integrated the requirements regarding pesticides and contaminants as required by Commission Directives 2006/125/EC, 2006/141/EC and Regulation (EC) No 1881/2006 and Regulation (EC) No 2073/2005.

Observations

- The FBOs' systems for supplier controls (owners' declarations and audits) were set up in all establishments visited. In general they included controls on pesticides, contaminants and microbiological contamination when relevant. Nevertheless, in two establishments, the products' specifications did not include all specific requirements concerning pesticides as laid down in Commission Directive 2006/141/EC.
- In one establishment raw material control was carried out by laboratory examinations and some pesticides and contaminants were not analysed for.
- In three of the establishments visited neither the list for pesticide substances nor the application of the detection limits was in compliance with the requirements of Commission Directives 2006/125/EC and 2006/141/EC.
- In only one of the five establishments visited had a complete monitoring programme been implemented covering all the relevant contaminants listed in the Annex to Regulation (EC) No 1881/2006.
- FBOs' composition controls were in place to ensure compliance with the requirements of Commission Directive 2006/125/EC and Annex I to Commission Directives 2006/125/EC and 141/2006/EC. Nevertheless, only limited verification sampling took place and this was mostly for the presence of allergens in BFs for infants under six months of age.

- Procedures for official control on HACCP and check-lists were in place based on the requirements of Regulation (EC) No 852/2004 and (EC) No 853/2004 in all three ACs visited. However, procedures on the specific requirements of Commission Directives 2006/125/EC, and 2006/141/EC and of Regulation (EC) No 1881/2006 covering specifically the controls on composition, labelling, pesticides and contaminants were only implemented in two of the ACs visited and specific check-lists covering the specific requirements had only been adopted recently in one AC and were not applied yet. Moreover, the capability of detection of non-compliances regarding the specific requirements was in some cases not adequate. In addition, the knowledge of the officials controlling on-the-spot about the specific requirements relevant for this audit based on interviews was deemed to be adequate in only three out of five establishments (see also 5.2.3).
- HACCP based procedures were in all cases subject to official controls but deficiencies mentioned above were not detected by the CA.
- FBO sampling programmes in line with Regulation (EC) No 2073/2005 were in place in all establishments visited. However, in a few cases alternative methods were used that had not been validated against the reference methods.
- In all three ACs the controls on microbiological sampling and testing are covered in inspection protocols and in all establishments visited the FBO controls in line with Regulation (EC) No 2073/2005 were verified by the CA. However, the above shortcomings had not been detected.

Conclusions

Recommendation No 6 of report 2008-7816 has not been addressed.

HACCP based procedures were put in place and implemented. Nevertheless in three out of the five establishments visited HACCP plans did not integrate adequately the specific provisions of paragraph 3 of Article 7 of Commission Directive 2006/125/EC and paragraph 2 of Article 10 of Commission Directive 2006/141/EC and of Regulation (EC) No 1881/2006 and therefore were not complying with Article 5 (2) of Regulation (EC) No 852/2004.

The official control over the FBOs' compliance with Regulation (EC) No 2073/2005 was inadequate with regard to FBOs' proper use of laboratory methods.

The official control of HACCP programmes was inadequate, due to the lack of specific check-lists and in some cases lack of specific procedures and check-lists to control the specific requirements of Commission Directives 2006/125/EC and 2006/141/EC.

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 Commission 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 baby foods."

Audit findings

In general identification marking was correctly applied.

Product labelling control is the responsibility of the CS-AC. Centrally, the CA are the National Consumer Institute (composition and fraud) and the AESAN (food safety labelling). The Agency exercises its duties through national campaigns, local thematic projects and consumer complaints.

The CS-ACs are responsible for requesting the necessary corrective actions to be taken. The AESAN is informed if non-compliances are detected where there is a possible impact on the health of consumers.

In 2010 a national campaign was organised in Spain regarding the labelling of IF, FOF and BFs identifying general problems in relation to labelling and composition.

Another national campaign focusing specifically on the gluten content in foodstuffs and also including the IF/FOF and BFs has just been completed.

The general and specific labelling presentation requirements were complied with during the FVO audit of labels on products of IF/FOF and BFs and of the presentation of IF/FOF.

Conclusion

The general and specific labelling requirements were in compliance with the general and specific labelling requirements in accordance with Directive 2000/13/EC and Commission Directive 2006/141EC**.**

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 systems were in place in all establishments visited and no shortcomings were noted during the exercises carried out by the FVO audit team.

In two establishments a special software tool was used for the recording of incoming raw materials and outgoing products and the verification of the traceability was very fast and effective.

Conclusion

Adequate traceability systems were in place in all the establishments visited complying with the requirements of Article 18 of Regulation (EC) No 178/2002.

5.5 Export of infant formulae and follow-on formulae

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

Audit findings

Verification of compliance with Council Directive 92/52/EEC by the FBO was in place in three of the five establishments visited, where this requirement was applicable.

In general products for export were controlled with the same intensity as products destined for the EU market. There were official procedures in place to ensure compliance with EU standards. Nevertheless, they were in some aspects inadequately applied as regards controls on pesticides, contaminants and composition (see also points 5.3 and 5.4.1). Moreover, there was no evidence of controls or procedures in place for verification of compliance with Third Country requirements in case the Third Country requirements are different from EU requirements as regards composition (for more details see Chapter 5.2.8).

Conclusion

In general, exports of IF, FOF and BFs to third countries were controlled with the same intensity as products for the EU market and were largely adequate.

6 Overall Conclusion

Some progress was noted since the previous audit in 2008. However, official controls over manufacturing and placing on the market of IF, FOF and BFs in Spain ensure only partly that the specific legislative requirements are complied with. Official controls on IF/FOF and BFs are not fully adequate and varied between the five establishments visited and did not cover all aspects of the relevant specific legislation which is contrary to the requirements of Article 3 (3) of Regulation (EC) No 882/2004. In particular, official controls on the specific requirements, laid down in Commission Directives 2006/125/EC and 2006/141/EC were in some cases inadequately applied and documented. The general and specific hygiene requirements were covered but were in some cases not always adequately applied.

The recommendations concerning approval of compliant establishments and of the official controls over general and specific hygiene requirements of the specified foods have been satisfactorily addressed.

7 Closing Meeting

A closing meeting was held on 25 April 2012 with the central and regional competent authorities**.** At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the central and regional competent authorities of the relevant time limits for production of the report and their response.

The representatives of the CCA provided comments during the closing meeting to the labelling controls and approval and registration of establishments. The AC of Asturias provided documentation of actions already taken concerning amendments to procedures and check-lists.

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 develop appropriate documented procedures for the official controls of the implementation of Commission Directives 2006/125/EC and 2006/141/EC and Regulation (EC) No 1881/2006 as required by Article 8 of Regulation (EC) No 882/2004.
2.	To provide adequate training on the official controls on the production and marketing of infant formuale, follow-on formulae and baby foods as required by Article 6 of Regulation (EC) No 882/2004.
3.	To ensure that the organisation of the official control of infant formuale, follow-on formulae and baby foods covers all relevant aspects as required by Article 3 (3) of Regulation (EC) No 882/2004.
4.	To ensure an adequate official laboratory network for the official control of infant formuale, follow-on formulae and baby foods as required by Article 12 of Regulation (EC) No 882/2004, in particular by ensuring the detection of all relevant contaminants by relevant accredited methods as required by Regulation (EC) No 1881/2006 and for pesticides the provision of all relevant accredited methods and the application of the required detection limits as indicated in Commission Directives 2006/125/EC and 2006/141/EC.
5.	To ensure that adequate enforcement measures are applied against non-compliances detected with regard to applicable EU legislation for the production and marketing of infant formuale, follow-on formulae and baby foods as required by Article 54 of Regulation (EC) No 882/2004.
6.	To implement procedures for the verification of the effectiveness of official controls of the production and marketing of infant formulae, follow-on formulae and baby foods as required by Article 8 (3) of Regulation (EC) No 882/2004.
7.	To ensure that when raw milk not meeting the criteria laid down in Section 9, Annex III to Regulation (EC) No 853/2004 as regards Total Plate Count and Somatic Cell Count is authorised for the production of infant formulae and follow-on formulae on the basis of Chapter II, Annex IV to Regulation (EC) No 854/2004, it is ensured that the use and treatment required will guarantee protection of the public health of the targeted population, in order to comply with the said provision of Annex IV to Regulation (EC) No 854/2004.
8.	To ensure that that the Food Business Operators in the sector evaluated comply with

N°.	Recommendation
	Article 5 of Regulation (EC) No 852/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6335

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	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
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
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 ß-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)
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. 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

Legal Reference	Official Journal	Title
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