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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6861 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BELGIUM

FROM 21 JANUARY TO 01 FEBRUARY 2013

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS ON FOOD SAFETY AND PROCESS HYGIENE CRITERIA (COMMISSION REGULATION (EC) NO 2073/2005)

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 a Food and Veterinary Office (FVO) audit to Belgium which took place from 21 January to 1 February 2013. The objective of the audit was to evaluate the official controls of food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005. *The 11 establishments visited covered different types of food production including ready to eat (RTE) food (dairy, fishery products, egg products, pre-cut fruits and vegetables, sprouted seeds, unpasteurised juices, red meat, poultry meat, meat preparations, minced meat, mechanically separated meat and meat products).*

Competent Authorities (CA)s for the purpose of official controls in relation to the requirements of Regulation (EC) No 2073/2005 have been designated and the system of co-ordination between and within the CAs is largely adequate. Training was mainly organised for the laboratory aspects, while specific training in relation to controls over the provisions of Regulation (EC) No 2073/2005 at establishment level was limited. CA inspectors carried out official controls with the allocated frequency and using the dedicated procedures, according to the plan annually established at central level by the Federal Agency for the Safety of the Food Chain. The system for organising official controls is risk based without taking into account all the provisions of Article 3 (1) of Regulation (EC) No 882/2004. It does not include all the relevant risk factors, any information that might indicate non-compliances and it takes into consideration the history of non-compliance with a delay of two years. In addition it is designed in a way that does not allow an establishment with a validated own control system to receive a high frequency of official controls. The validation of food business operators' (FBOs) own control system is carried out either by the CA or by private certification and inspection bodies. The controls carried out by the private certification and inspection bodies have not been effective in some of the establishments visited by the FVO audit team.

The organisation of official controls at FBO level in relation to Regulation (EC) No 2073/2005 in general and to food safety and process hygiene criteria in particular, varies widely between the different types of commodities in terms of level of detail and frequency which are not adequate for certain commodities. Several pieces of legislation, circulars and service notes aiming at facilitating the implementation of Regulation (EC) No 2073/2005 have been issued. Nevertheless, for most of the commodities the procedures for official control at establishment level included very limited aspects concerning compliance with the different requirements of Regulation (EC) No 2073/2005. Controls over specific requirements of Regulation (EC) No 2073/2005 (eg as regards food safety and process hygiene sampling and testing procedures, shelf-life studies, analyses of trends, sampling and testing of processing areas and equipment) were not adequately documented in most cases. The implementation of these controls was not fully effective in several cases assessed (in particular for meat preparations, fishery products and food of non-animal origin). Numerous shortcomings were not detected by the CA. A lack of CA action for long-standing deficiencies, in particular as regards sampling and testing methods and action in case of non-compliant test results (including for food safety criteria) was noted. Moreover, the sanctions given were not proportionate in the cases reviewed by the FVO audit team in the dairy sector.

A comprehensive official monitoring plan is in place and it takes into consideration the relevant microbiological criteria provided by Regulation (EC) No 2073/2005 in different matrixes and at all levels (production, distribution, retail). A National Reference Laboratory (NRL) has been appointed for the microbiological parameters required by Regulation (EC) No 882/2004. Evidence of a well co-ordinated official laboratory network was presented. The notification of non-compliant test results for food safety criteria from private approved laboratory level to the CCA is not routinely implemented.

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
BELAC	Belgian Organisation for Accreditation
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
E.coli	*Escherichia coli*
EU	European Union
EURL	European Union Reference laboratory
FASFC	Federal Agency for the Safety of the Food Chain *(FAVV-Federaal Agentschap voor de Veiligheid van de Voedselketen AFSCA - Agence fédérale pour la Sécurité de la Chaîne alimentaire FASNK -Föderalagentur für die Sicherheit der Nahrungsmittelkette)*
FBO(s)	Food Business Operator(s)
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Points
Hygiene Package	Set of the following Regulations: Regulations (EC) No 852/2004, No 853/2004, No 854/2004, No 882/2004
ISO	International Standardisation Organisation
L. monocytogenes	*Listeria monocytogenes*
MANCP	Multi-Annual National Control Plan
MD	Ministerial Decree
NRL	National Reference laboratory
PCU	Provincial Control Unit
RASFF	Rapid Alert System for Food and Feed
RD	Royal Decree
RTE	Ready-to-eat
sp	Subspecies
STEC	Shiga Toxin Producing *E. coli*
VTEC	Verocytotoxin Producing *E. coli*

1 Introduction

The audit to evaluate the official controls on food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005) in Belgium formed part of the FVO's planned audit programme. It took place from 21 January to 1 February 2013. It is part of a series of audits to Member States in 2011 (Denmark, Germany and Ireland), 2012 (France, Finland, Hungary, Spain, Czech Republic) and 2013 (Belgium, Cyprus, Italy, Poland). The audit team comprised two auditors from the FVO. The audit team was accompanied during the whole audit by a representative of the central competent authority (CCA), the Federal Agency for the Safety of the Food Chain *(FAVV-AFSCA-FASNK- Federaal Agentschap voor de Veiligheid van de Voedselketen - Agence fédérale pour la Sécurité de la Chaîne alimentaire – Föderalagentur für die Sicherheit der Nahrungsmittelkette)*. An opening meeting was held on 21 January in Brussels with the CCA. At this meeting, the objective of, and the itinerary for the audit were confirmed by the FVO audit team and the control systems were described by the authorities.

2 Objectives and Scope

The objective of the audit was to evaluate the implementation of official controls on food safety and process hygiene criteria, mainly in products of animal origin, including in addition RTE foods, pre-cut RTE fruits and vegetables, and unpasteurised fruit and vegetable juices, in the framework of Regulations (EC) No 178/2002, No 852/2004, 853/2004, 854/2004, 882/2004 and 2073/2005.

The scope of the audit covered the chain involved in the production of the above foodstuffs (from the establishment receiving the primary products to retail). Special emphasis was given to the implementation of the official controls in relation to RTE foods and to the use of shelf-life (durability) studies or other scientific based demonstration of the implementation of the Listeria criteria in RTE foods and the application of the criteria in the absence of such studies.

The table below lists the activities of the establishments visited and meetings held in order to achieve the objective of the audit:

Meetings/Bisits		No	Comments
Competent Authorities	Central	1	
	Province	7	In the Flemish region, in the Walloon region and in Brussels Central region
Laboratories	Reference	1	
	Federal	1	
Food business operators (FBOs)		11	1 bovine slaughterhouse, 1 poultry slaughterhouse also producing meat preparations and mechanically separated meat, 1 establishment producing RTE meat products, 1 fish processing establishments processing smoked products and 1 establishment producing fresh fish RTE products including sashimi, 1 establishment producing RTE pre-cut fruits and vegetables, 2 dairy

		establishments one of which also producing baby-foods, 1 establishment producing sprouted seeds, 1 establishment producing un-pasteurized juices, 1 establishment producing egg products.
FBOs own control laboratories	2	One FBO in-house laboratory and one private laboratory approved for performing also official testing.

3 Legal Basis

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

References to relevant EU legislation are given in Annex I and refer, where applicable, to the last amended version.

In addition to the standards established by the EU legislation against which the evaluation was carried out, account was taken of the relevant international standards, in particular the standards, guidelines and recommendations developed by Codex Alimentarius and the International Organisation for Standardisation (EN/ISO).

4 Background

The Hygiene Package and Regulation (EC) No 2073/2005 provide specific rules on FBO's obligations in relation to food safety and process hygiene criteria and official controls over these criteria. FVO audits to Member States on official controls in relation to food safety and process hygiene criteria have been scheduled in 2011-2013. This is the first audit round in the Member States targeted at official controls solely on this area of activity.

Several FVO audits to Belgium covering different sectors of food and feed production were carried out in 2012. The reports of the individual missions can be found at:

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

In 2011 and 2012, 40 Rapid Alert system for Food and Feed (RASSF) notifications in relation to microbiological hazards in foodstuffs from Belgium have been launched, 19 of them by other Member States and 21 by Belgium. Information related to the recalls carried out can be found on the FASFC website: http://www.favv-afsca.fgov.be/productterugroepingen/default.asp

5 Findings And Conclusions

5.1 National Legislation/criteria and guidelines

Legal requirements

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

Article 7 of Regulation (EC) No 852/2004 stipulates that Member States shall encourage the development of national guides to good practice for hygiene and for the application of Hazard Analysis Critical Control Points (HACCP) in accordance with Article 8 of the Regulation and that Community Guides should be developed in accordance with Article 9 of the Regulation. Article 8.1 of the same Regulation stipulates that national guides to good practice shall be developed and disseminated by food business sectors in consultation with the stakeholders. The guides should have regard to relevant codes of practice of the Codex Alimentarius. The Member States shall forward the national guides to the Commission. According to Article 3.2 of Regulation (EC) No 2073/2005 guidelines for conducting shelf-life studies may be included in the guides to good practice referred to in Article 7 of Regulation (EC) No 852/2004.

Findings

Regulation (EC) No 2073/2005 is directly applicable in Belgium. Several pieces of legislation have been issued in Belgium in relation to the sampling and testing for microbiological parameters of foodstuffs. Some examples are given below:

- The Royal Decree (RD) of 26/4/2009 on microbiological criteria in foodstuffs which lays down process hygiene criteria for minced meat, raw milk, yoghurt and fermented milk and ice-cream, introduces additional requirements to the provisions of Regulation (EC) No 2073/2005.
- The RD of 3 August 2012 on approval of laboratories which carry out tests in relation to food chain safety lays down the requirements for approval by the FASFC of private laboratories to carry out official testing of food samples. It also provides that the NRLs have to be designated by the FASFC.
- The RD of 14 November 2003, regarding the own controls, the compulsory notification and the traceability in the food chain, requires all FBOs and laboratories to notify the FASFC of any suspicion in relation to products which may pose a risk to human health. The Ministerial Decree (MD) of 22 January 2004 establishes the modality of notification to Provincial Control Units (PCUs) in such cases. Procedure LAB P 504 “Notifying test results of FASFC laboratories by means of FoodLims and of external labs by means of ExtLab”, published on the FASFC website, mentions that all non-compliant results have to be notified to the FASFC.
- The RD of 20 September 2012 regarding sampling and testing of samples provides the framework line to be taken for official sampling and testing. It also stipulates that the FBOs have the right to counter analysis and that the decisive test result is the one of the counter-analysis if requested.
- The MD of 24 October 2005, regarding derogations in the modality of application of own controls and traceability in certain food business, sets down the criteria for such derogations.

According to the information provided by the CCA, this MD is currently under review[1].

Forty national guides for the implementation of the FBOs' own control systems have been approved by the CCA and notified to the European Commission. An overview of these guides is available on both the FASFC and the Commission's websites.

Several circulars, instructions, explanatory documents aiming at facilitating the implementation of Regulation (EC) No 2073/2005 have been issued and are published on the FASFC website. Some examples are given below:

- Document on action limits for microbiological contaminants in foodstuffs, last updated in June 2010, which describes the measures to be taken in case the legal limits and action limits for microbiological parameters are exceeded. The action limits (including for cases which are not covered by the Regulation mentioned above) are fixed by the FASFC and approved by the Scientific Committee. [2]The legal basis for taking measures in case of non-conforming analytical results and inspections is the RD of 22 February 2001.
- Explanatory document on notification, last updated in June 2012, which details the instances that require notification as set by the RD of 14 November 2003 and the MD of 22 January 2004 (mentioned above).
- Circular letter of 3 November 2008 concerning microbiological analysis in butcher's shops, which provides for a sample (n=1) of minced meat and meat preparations to be taken each year in butcher shops and retail shops and tested for *Salmonella, Escherichia coli (E. coli)* and *Aerobic colony count*. It also provides the action to be taken in case of non-compliant test results.
- Circular letter of 5 August 2010 concerning sampling frequencies for microbiological checks of minced meat and meat preparations in processing establishments, which provides the criteria to be taken into consideration for allowing reduced sampling frequencies in such establishments and the different frequencies which may be applied.
- Circular letter of 13 March 2010 concerning labeling of minced meat, meat preparations and poultry meat products, which notifies the amendment of Regulation (EC) No 2073/2005 in 2010.
- Circular letter of 22 February 2012 concerning the process hygiene criterion for *Salmonella sp.* in carcasses of broilers and turkeys, the food safety criterion for *Salmonella enteritidis* and *Salmonella typhimurium* in fresh poultry and turkey meat and the sampling frequency in small slaughterhouses and small meat cutting plants. This mentions the changes in the legislation introduced by Regulation (EC) No 1086/2011 and details the approach to be taken by the CA for reducing the sampling frequency in small white meat slaughterhouses and cutting plants.
- Circular letter of 3 July 2012 concerning hygiene measures to be taken during the production of sprouts which also includes sampling and testing criteria.

In relation to the laboratory activity several service notes for the official laboratory network and in some cases for all laboratories in the country are available on the FASFC website and will be mentioned in relevant chapters of the report:

In the context of the *E. coli* O104 outbreak in 2011, Service Note GDP/LABO/684289 of 9 June

1 In their response to the draft report the CA noted that the new MD of 22/03/2013 has been published on 05/04/2013 on the FASFC website.

2 In their response to the draft report the CA noted that the new update of this document has been published on the FASFC website.

2011 informed the FBOs which are the laboratories able to perform the test and recommended by the FASFC (approved laboratories).

National *Salmonella* surveillance programmes in the pigs and poultry population are in place in accordance with the RD and the MD of 27 April 2007 for combating *Salmonella* in the poultry population and on surveillance of *Salmonella* in the pigs population. Specific circular letters for the implementation of these decrees are published on FASFC website.

Observations

- Instruction had not been issued on which terms and conditions exemptions from the sampling frequency of carcasses for the process hygiene criteria in low-throughput red meat slaughterhouses could be granted. The CCA and the representatives of the PCU visited stated that no derogations are applied.
- Although the own control guides also include provisions of Regulation (EC) No 2073/2005, not all relevant aspects per type of commodity are covered (eg: sprouted seeds guide does not include testing for *L. monocytogenes* in the chapter related to testing requirements). In the notification chapter, exceeding the legal limits for *L. monocytogenes* is cited as an example.
- Circular letter of 3 July 2012, concerning hygiene measures to be taken during the production of sprouts does not stipulate that sprouts should be tested for *L. monocytogenes*.

Conclusions

Several pieces of legislation as well as relevant circulars and service notes aiming at facilitating the implementation of Regulation (EC) No 2073/2005 have been issued and they are available to the relevant stakeholders. Industry guides which also include the provisions of this Regulation have been approved by the CCA and notified to the European Commission.

Full coverage of the interpretation of Regulation (EC) No 2073/2005 is not in place (eg. in the case of sprouted seeds requirement).

5.2 COMPETENT AUTHORITIES

5.2.1 Designation of the CAs

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires that the Member States shall designate CAs responsible for the purposes and official controls set out in the Regulation.

Findings

A detailed description of the CAs can be found in the country profile for Belgium which is accessible at:http://ec.europa.eu/food/fvo/ir_search_en.cfm

The FASFC is the CCA for the purpose of official controls on food of animal origin and non-animal origin. Competence for food inspections and monitoring programmes lie within its remit and the 11

PCUs which are responsible for enforcement measures to be taken (with CCA involvement for prosecutions and administrative fines). Approval and registration of establishments is carried out at PCU level. No changes in the designation of CAs occurred since the last update of the country profile.

A working group on food borne infections and intoxications has been set up and it meets every four months. It's members are the different bodies involved in dealing with the FBOs in such cases: the FASFC, the Health Inspectors, the NRL for food pathogens. There is a system in place for for notifications of food borne infections and Rapid Alert System for Food and Feed (RASFF) alerts, for exchanging information and coordination both between the different stakeholders involved in investigating a food borne outbreak (the Federal Public Service for Health, Food Chain Safety and Environment through the Institute of Public Health - section epidemiology and the NRL for food borne outbreaks, the FASFC through its provincial interface - the PCUs - and the regional Health Inspection), as well as within the FASFC. The investigation related to suspected food samples is carried out by the PCUs' representatives according to the procedure for managing such notifications which is issued by the CCA. Samples may be sent by the Health Inspection to the NRL for food pathogens (as described in chapter 5.3.2). Isolates may be sent by the Clinical Microbiological Laboratory (examining human samples) to the National Reference Centre which is in close collaboration with the NRL for food pathogens.

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

Findings

Co-ordination between the CCA and the PCUs is achieved through procedures, technical documents and service notes covering different aspects of the official control activities which are issued by the CCA for implementation by the PCUs. Regular meetings take place between the Heads of each Sector from provincial level and the CCA representative responsible for the specific sector co-ordination. The information received during these meetings is cascaded at PCU level.

Minutes of meetings organised both at PCU and CCA levels where aspects of implementation of Regulation (EC) No 2073/2005 were discussed were made available to the FVO audit team.

The system in place for co-ordination within the CA and with other CAs (see chapter 5.2.1) in the case of food alerts including RASFF was used in the management of the nine RASFF cases and two Belgian food alerts assessed by the FVO audit team.

Observations

- Reporting of official controls takes place at the level of the provincial units. Information is fed into the IT system which is accessible to the central level. The details concerning the level of compliance with Regulation (EC) No 2073/2005 are only available for the aspects covered by questions in the own control inspection check-list (see chapter 5.2.4). According to the annual activity report of the FASFC for 2011, 63,2% compliance level was achieved

in 2011 for implementation of FBOs' own control system.

- In most of the food alert cases assessed by the FVO audit team, the CA followed the procedures in place in terms of communication with the relevant stakeholders, traceability checks, recalls, detainment and destruction.
- In relation to four RASFF alerts on meat products in one establishment the CA did not carry out verification checks to ensure that all possibly affected products (produced under the same conditions) were traced back. In two of these cases the CA's visits on the spot were delayed by 9 and 14 days. The FBO concerned has put in place numerous actions to prevent re-occurrence.
- Notification from the Health Inspection to the PCU of an incident involving sick people hospitalised with food borne infection symptoms was carried out with a delay of two weeks due to a misspelling of the email address used for notification.
- The action taken by the CA in relation to two RASFF alerts in red meat, involving numerous PCUs was difficult to retrieve. The CCA informed the FVO audit team during the final meeting that a new system was put in place at central level to keep track of the different actions taken in relation to RASFF alerts.

5.2.3 Staffing provisions, facilities, qualifications and training

Legal Requirements

Article 4 (2) of Regulation (EC) No 882/2004 requires the CA to ensure that they have access to sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

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

Findings

No evidence of staff shortages was noted by the FVO audit team and facilities and equipment for official use seen were appropriate.

Most of the staff met at the different offices and premises and at the official and private laboratories visited by the FVO audit team were suitably qualified and experienced.

Yearly training on microbiological aspects is delivered by the Belgian Society for Food Microbiology in cooperation with the NRL and the FASFC during the "Food microbiology conference". Only a few of the official control staff met participated in such training.

Clarification on different implementation aspects of Regulation (EC) No 2073/2005 is provided to PCU Heads of Sector during the regular meetings held at CCA level which is consequently cascaded down to the official control staff at PCU level.

During the 2011 *E coli* outbreak in Germany, extensive discussions on the topic took place at all levels of official controls according to the meetings minutes seen. The awareness of all staff was raised in relation to the requirements for sprouted seeds production.

5.2.4 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.

Findings

Controls over FBOs' HACCP based procedures and over compliance with Regulation (EC) No 2073/2005 are carried out as part of controls over FBOs' own control system. General check-lists for such controls are issued by the CCA and are available on the FASFC website. The Foodnet application and intranet make available to PCU official control staff more detailed explanations for the different questions included in the check-list.

The procedures and check-lists for official controls over FBOs' own control system were used by the officials met according to the instructions received from the CCA.

Observations

- The check-lists used in the pre-cut fruits and vegetables establishment and in the dairy product establishment had limited questions ("whether sampling and testing plans to ensure the validity of the own checks system have been established").

- In the fishery establishments, sprouted seeds establishment, cutting plant, meat product establishment, un-pasteurised juices establishment no specific questions for compliance with Regulation (EC) No 2073/2005 were included in the check-list. According to the CCA this check-list is used in establishments for which an industry guide was approved by the CCA. Nevertheless, it is not compulsory for the FBOs to implement those guides. For sectors for which an own control guide has been approved by the CCA, an additional check-list is used for the inspection of the HACCP-plan. This checklist contains three questions which change on a yearly basis. Through this rotation system, specific questions concerning the above mentioned Regulation can be included in the checklist.

- For the mechanically separated meat the check-list includes questions related to the frequency of testing and the use and labeling of product with non-compliant test results. The minced meat and meat preparation check-list includes a question related to the frequency of sampling.

- Instructions for controls over HACCP are included in the technical data-sheets associated with the auto-control check-lists. The technical data-sheet for dairy establishments included relevant questions for parameters to be tested and for action to be taken; it was however not covering *Salmonella* testing in milk powder although RASFF alerts have been issued in recent years for milk powder originating in Belgium. For the other types of establishments visited the technical data-sheets in general do not cover the provisions of Regulation (EC) No 2073/2005.

- A dedicated check-list for relevant provisions of Regulation (EC) No 2073/2005 is available only for slaughterhouses. It includes questions for the different aspects of the sampling method, the tests results and action in case of non-compliant test results. This check-list has not been updated to take into consideration the provisions of Regulation (EC) No 1086/2011.

- In most establishments visited, the reports were only mentioning answers to the questions on the check-lists. Except for slaughterhouses, the reports seen did not include relevant aspects of Regulation (EC) No 2073/2005 (eg sampling and testing methods and action in case of non-compliant test results). Additional comments were seen only in a few cases. The approach taken by the official control staff met was to make additional comments mainly in relation to non-compliance. Some of the officials met perceived the check-lists as closed and not allowing for specific questions to be asked in relation to Regulation (EC) No 2073/2005.

5.2.5 Enforcement requirements

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 Regulation (EC) No 882/2004 states that a Member State shall lay down rules on sanction applicable to infringements of feed and food law and other EU provisions relating to the protection of animal health and welfare and shall take measures necessary to ensure that they are implemented. The sanctions provided must be effective, proportionate and dissuasive.

Findings

The enforcement actions taken by the CA for non-compliances in relation to Regulation (EC) No 2073/2005 were reviewed in the establishments visited. In most of the cases the procedures in place were followed by the CA. Evidence of adequate enforcement measures taken was seen by the FVO audit team in some cases.

Observations

- Although the sprouted seeds establishment visited was involved in a RASFF alert in July 2012, to the date of the FVO audit food safety parameters were not tested. Water testing as required by RD of 14 January 2002 on the quality of water intended for human consumption which transposed Council Directive 98/83/CE was not carried out either in that establishment although the water was recycled. In general compliance with Regulation (EC) No 2073/2005 was not ensured (see chapter 5.5.3-5.5.8). The deadlines given by the CA for some of the identified non-compliances were not complied with and were extended without justification.

- Pooling of samples and testing *Salmonella* in 750g in milk powder was allowed for several years despite negative feedback on the testing method from the NRL available in 2009. Action was taken by the CA only after a RASFF alert in 2012. Despite clear instruction issued in 2012 by the CCA in relation to pooling of samples, no action was taken in the egg product establishment where *Salmonella* testing is used for verification of the pasteurisation process.

- In a large dairy establishment producing infant food, the presence of *Salmonella* in the final product was not communicated to the CA although detected by the FBO. No action was taken by the FBO towards the product which was placed on the market without restrictions. The CA did not identify the problem and started to take action only after a RASFF alert. Moreover, the fine imposed by the FASFC was only 1 250 Euro. A few months later the action taken by the CA in relation to another RASFF alert on product originating in the same establishment included also a fine of 1 500 Euro. According to the RD of 22 February 2001 (as amended by RD of 29 March 2012), the maximum administrative fine for not complying with the Regulations of the EU is 5 000 Euro. This amount is increased according to the provisions of the Penal Code.

- In the establishments visited, most of the FVO audit team's findings have not been previously identified by the CA (see following chapters).

Conclusions

CAs for the purpose of official controls in relation to the requirements of Regulation (EC) No 2073/2005 have been designated. A system of co-ordination between and within the CAs is in place and evidence of adequate co-ordination was noted in most of the cases assessed. Training was mainly organised for the laboratory aspects, while specific training in relation to controls over the provisions of Regulation (EC) No 2073/2005 at establishment level was limited.

A lack of CA action for long-standing deficiencies, in particular as regards sampling and testing methods and action in case of non-compliant test results was noted. Moreover, sanctions imposed in the cases assessed were not proportionate. This is contrary to the provisions of Articles 54 and 55 of Regulation (EC) No 882/2004.

The procedures for official control at establishment level included very limited aspects concerning compliance with the different requirements of Regulation (EC) No 2073/2005, for most of the commodities under review.

In most cases, the reports seen were not documented to have taken into consideration the relevant aspects of Regulation (EC) No 2073/2005.

5.3 Laboratory network

Legal requirements

Article 12 of Regulation (EC) No 882/2004 requires that the CA designates laboratories that may carry out the analyses of samples taken during official controls. Point 2 (c) of Article 4 of Regulation (EC) No 882/2004 stipulates that the CAs must ensure that they have or have access to an adequate laboratory capacity for testing.

Findings

There are five federal laboratories designated for analysis of official food samples in Belgium. Only two of them perform testing for microbiological parameters of food samples.

In addition to the federal laboratories, currently 24 private laboratories are approved according to the provisions of the RD of 3 August 2012 to perform official testing for microbiological parameters of food samples. The list of approved private laboratories and the tests for which they are approved for are published on the FASFC website. In order to be approved, a private laboratory

is required to be accredited according to ISO 17025 (and the scope of accreditation to include the tests which will be performed for the FASFC), not be involved in activities that may give rise to a conflict of interest, to participate in the proficiency tests organised by the FASFC and to communicate their results.

The system remains as described in previous reports: one of the two federal laboratories mentioned above functions as a dispatch center for official samples collected in the southern half of Belgium while the other carries out the same task for official samples collected in the northern half of Belgium.

The system in place (Foodlims) in the two dispatch centers ensures that the samples are attributed to the laboratories accredited and approved to perform the specific tests. Currently the majority of the samples are tested in the two federal laboratories. According to the Service Level Agreement between FASFC and the NRL, 10% of the food samples are dispatched to and analysed by the NRL. Histamine testing takes place in one private approved laboratory and in one federal laboratory, while enterotoxins tests are carried out by the Institute of Public Health (NRL) and the NRL for milk and dairy products. The approved private laboratories may be used for analysing other parameters when the testing capacity of the federal laboratories and the NRL is exceeded. This was the case during the *E coli* outbreak in 2011.

The laboratory network receives scientific and technical support from DG Laboratory and the NRL by means of circulars, training, notifications which are either available on the FASFC website or on the secure application for the use of federal and approved laboratories (Intralab).

Observations:

- The procedure in place in the federal laboratory visited requires that all samples which arrive to the dispatch center have to be analysed. If deficiencies are identified (eg. interruption of the cold chain, broken packaging, size of the sample insufficient, typing errors in the results), they are recorded in the system. The data available for the previous year showed that 139 out of 13 000 samples analysed fall into this category.

- Service Note LB/LABO/669351 of 27 May 2011 on compulsory notification in the framework of own controls reinforces the obligation of the laboratories to supply the FASFC with the result of tests. It also mentions that if the notification is made by the operator, the laboratory shall ensure that the proof of the notification to the FASFC is in its possession.
- In the private approved laboratory visited by the FVO audit team the requirement for notification only started to be implemented. In the absence of a documented procedure it was explained to the FVO audit team that if the FBO does not provide the proof of notification after three days from the date the non-compliant results are available, the laboratory will inform the FASFC. This was not done in the case assessed by the FVO audit team (food safety non-compliant test results were not notified to the CCA according to the described procedure). For the private laboratory staff met it was not always clear if notification is necessary or not. The laboratory staff mentioned that the notifications are not always made due to possible problems with their clients for passing the information to the CCA.

5.3.1 Laboratory accreditation and quality controls

Legal requirements

Point 2 of Article 12 of Regulation (EC) No 882/2004 requires that the designated laboratories have to be accredited in accordance with the following European standards:

(a) EN/ISO/IEC 17025 on "General requirements for the competence of testing and calibrating laboratories".

(b) EN/ISO/IEC 17011 on "General requirements for accreditation bodies accrediting conformity assessment bodies", taking into account criteria for different testing methods laid down in the feed and food law of the EU.

The accreditation and assessment of testing laboratories referred to above may relate to individual tests or groups of tests.

Findings

Accreditation of laboratories according to EN/ISO/IEC 17025 is carried out by the Belgian Organisation for Accreditation (BELAC) managed by the Federal Public Service of Economic Affairs. The accreditation scope of the laboratories is listed on the BELAC website.

According to RD of 3 August 2012, the federal and private laboratories approved for performing official testing have to be accredited. The scope of accreditation of the NRL, the federal and the private approved laboratories visited by the FVO audit team included methods indicated by Regulation (EC) No 2073/2005. Evidence of successful participation of these laboratories in the relevant proficiency testing schemes for food pathogens was available (for example, for *Salmonella, L. monocytogenes, E. coli*). Action was taken in the case of non-compliant test results.

Audits of the federal laboratories are regularly carried out by the CCA. The federal laboratory visited by the FVO audit team was subject to internal audits from the internal audit service (staff attached to the services of the Chief Executive) twice per year and reports were made available to the FVO audit team.

The coordinators of the DG laboratories of the FASFC participate as observers to BELAC audits of the approved laboratories.

Observations

- The reference methods as mentioned in Annex I to the Regulation (EC) No 2073/2005 or alternative methods validated according to EN ISO 16 140 were routinely used for official testing.

- In both federal laboratories a non accredited alternative method (Tempo) is used for testing official samples. According to the CCA, in 2012 the validation of the Tempo method was performed in parallel with the ISO-method. After this validation, the Tempo method was used for testing official samples. Evidence of contradictory results between official tests carried out with this method and FBO own test results was seen in one establishment (five positive test results for Coagulase-positive *staphylococci* using this method were all negative at FBO own testing in an approved private laboratories). The results of the official investigation concluded that the correct results were of the FBO own testing. According to the CCA, from that moment on, both federal laboratories performed the enumeration of the Coagulase-positive *staphylococci* using the ISO-method. Both federal laboratories were at the time of the FVO audit in the course of accreditation of this method.

5.3.2 National reference laboratories

Legal requirements

Article 33 of Regulation (EC) No 882/2004 stipulates that the Member States shall arrange for the designation of one or more national reference laboratories (NRLs) for each EU reference laboratory (EURL) referred to in Article 32. Article 33(5) of the same Regulation requires that Member States that have more than one NRL for a EURL must ensure that these laboratories work closely together, so as to ensure effective co-ordination. The tasks of the NRLs are laid down in Article 33(2).

Findings

The list of NRLs as designated by the FASFC in their Decision of 30/11/2012 for the designation of NRLs following the provisions of RD of 3 August 2012 is published on the FASFC website. The Scientific Institute for Public Health (of the Ministry of Public Health) is the NRL for *Listeria monocytogenes (L. monocytogenes)*, *Salmonella, Coagulase-positive staphylococci*, including *Staphylococccus aureus, Escherichia coli,* including V*erocytotoxin* producing *E. coli* (VTEC), *Campylobacter*, food borne infections, viral and bacteriological contaminations of bivalve molluscs.

Evidence of NRL participation with good results in proficiency rounds organised by the EURL or other proficiency tests by private providers was available, including action in case of non-compliant test results.

The NRL is also organising proficiency tests for the regional and approved laboratories involved in official microbiological tests and follows up on the action taken in case of non-compliance test results.

The NRL participated in meetings organised by the EURL and passed the relevant information received to the federal and approved private laboratories in the network.

Relevant training for testing methods including for the parameters of Regulation (EC) No 2073/2005 is delivered by the NRL during the yearly food microbiology conferences to which representatives of all laboratories in the network and of the PCUs are invited to participate.

The NRL for *E. coli* carried out method development for the VTEC and the Shiga toxin producing *E. coli* (STEC) in co-operation with the EURL.

Analysis of samples in case of complaints and food borne outbreaks is only carried out in the NRL.

Conclusions

A NRL is appointed for all the pathogens in Regulation (EC) No 2073/2005 which have an EURL. It has taken on its duties by organising proficiency tests for the regional and approved laboratories involved in official microbiological tests, passing the relevant information to them and delivering relevant training.

The network of official laboratories is in general well co-ordinated by the CCA with the NRL input. The laboratories involved in testing official samples are able to perform the tests required by Regulation (EC) No 2073/2005, they are accredited for most of the methods used for official testing and they are participating, in general with good results, in proficiency testing for the different pathogens. The notification of non-compliant test results for food safety criteria from private approved laboratory level to the CCA is not routinely implemented.

5.4 METHODS OF SAMPLING AND ANALYSIS

Legal requirements

Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant rules of the EU or, if such rules do not exist, with internationally recognised rules and protocols or those agreed in national legislation. In the absence of above, other methods fit for the intended purpose or developed with a scientific protocol may be used. Whenever possible, the methods of analysis should be characterised by the criteria set out in Annex III to Regulation (EC) No 882/2004.

Article 5 of Regulation (EC) No 2073/2005 stipulates that the analytical methods and sampling plans and methods laid down in Annex I to this Regulation have to be applied as reference methods.

5.4.1 Methods used for official sampling and testing

Findings

Official samples can include monitoring sampling (one sample unit) and regulatory sampling (five sampling units). Regulatory sampling takes place if the initial monitoring sample is positive. On an exceptional basis the exclusive use of regulatory samples takes place in case of alerts or complaints. According to the RD of 20 September 2012 the FBO has the right to have counter samples taken (with five sample units) at the same time of official regulatory sampling and to test them at a later stage. The decisive result is of the FBO counter sampling which can be tested in an approved laboratory.

Service Note BP/LABO/188590 of 19 October 2007 (regarding the microbiological analyses - methods according to Regulation (EC) No 2073/2005) and Service Note BP/LABO/ 143532 of 26 October 2006 (regarding recognised methods in microbiology - Regulation (EC) No 2073/2005), both published on the FASFC website, contain instructions for the methods to be used in the framework of official testing and FBO own checking in line with the above-mentioned Regulation.

The list of approved methods (both reference methods and alternative methods validated against the reference methods using ISO 16 140) is reviewed twice per year by the NRL and published on the FASFC website.

Observations

- If the result of the official sample is positive and the result of the FBO counter sample is negative, no action is taken. According to the procedure in place ("Document on action limits"), the counter sample is kept at -18°C (unless it is possible to keep it at room temperature).

5.4.2 *Methods used in the framework of FBOs' own controls*

Findings

The Service notes addressed to laboratories and the list mentioned in the previous chapter specify the methods that can also be used in the framework of FBOs' own controls. This information is available on the FASFC website.

The FBOs are required to use laboratories which participate in proficiency testing when carrying out own testing. Most of the FBOs visited also provided evidence of accreditation of the laboratory and of the methods used for own testing. In most cases the methods used were either reference methods or alternative validated methods. The own laboratory used by a dairy establishment was not accredited but participated with good results in proficiency tests.

In the red meat slaughterhouse visited sampling for *Enterobacteriaceae* and *Aerobic colony count* was carried out using the swab technique. This procedure for correlation with the destructive sampling technique has been validated by the Belgian Scientific Committee and a 0.5 mean log increase is recommended to be applied to the results when testing carcasses for process hygiene criteria using the swab technique. This principle was followed during the visit on the spot.

Observations

- In the absence of a clear instruction from the CCA level, some of the official control staff met on the spot stated that controls at establishment level verify only if the FBO uses a laboratory which participates in proficiency tests, but not if the method used complies with the requirements of Regulation (EC) No 2073/2005. With few exceptions (eg. slaughterhouses), the reports seen following official controls did not have any records of checks over the sampling and testing method.

- Pooling of samples and testing on 750 g using an alternative method not approved by the NRL was carried out in the powder plants visited (both dairy and egg products) for many years. Sampling five units and testing using the reference method has been introduced in the dairy establishments visited only last year, in connection with a RASFF alert. In the egg establishment sampling five units was introduced and testing on 250g continues. (see chapter 5.2.4).

- Several shortcomings have been identified by the FVO audit team and not by the CA as detailed below:

    - Sampling in the red meat slaughterhouse was carried out in the chiller after slaughter. The official guidance in place allows sampling in the chiller within two-four hours of slaughter.

    - In one of the fishery establishments visited Histamine testing was carried out at a frequency of twice per year by the FBO, one sample each time. The raw fish received by the establishment was tested for Histamine by the provider using an ELISA method. Regulation (EC) No 2073/3005 requires HPLC (High performance liquid chromatography) testing.

    - Reduced sampling units (one sample unit instead of five) for testing both food safety and process hygiene criteria were used at the time of the FVO audit in the sprouted seeds establishment, the unpasteurised juices, both fishery establishments in the absence of documented justification.

    - No evidence was available in relation to the laboratory and the methods used by the

sprouted seeds FBO.

Conclusions

In general, official controls at establishment level over the sampling and testing methods used by the FBOs could not be demonstrated to be routinely carried out. Several shortcomings have been identified by the FVO audit team.

The methods of sampling and testing used by the CA were in general in line with the requirements of Regulation (EC) No 2073/3005.

5.5 Official controls

Legal requirements

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

Article 10(1) of Regulation (EC) No 882/2004 stipulates that tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

Point (2) (d) of Article 10 of Regulation (EC) No 882/2004 requires that official controls on food shall include, inter alia, the assessment of procedures on good manufacturing practices(GMP), good hygiene practices (GHP) and HACCP, taking into account the use of guides drawn up in accordance with EU legislation.

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 FBO compliance with these requirements.

Point 5 (a) of Article 4 of Regulation (EC) No 854/2004 stipulates that the CA's audits of HACCP-based procedures shall determine whether the procedures guarantee, to the extent that it is possible, that products of animal origin comply with microbiological criteria laid down in the legislation of the EU. Point 8 (c) of the same Article requires the CA to take special care to take samples for laboratory analysis when necessary. The second paragraph of Point 5 of Article 4 of the same Regulation stipulates that if the FBO uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit should cover the correct use of these guides.

Preamble (15) of Regulation (EC) No 852/2204 states that HACCP requirements should provide sufficient flexibility to be applicable in all situations, including in small businesses. Point 4(a) of Article 5 of the said Regulation stipulates that the FBO has to provide the CA with evidence of their compliance with the implementation of procedures based on HACCP principles in a manner that the CA requires, taking account of the nature and size of the food business.

Point 1(f) of Article 5 of Regulation (EC) No 854/2004 requires that the inspection tasks of the official veterinarian in a slaughterhouse, game handling establishment and cutting plant placing

fresh meat on the market, should include inspections on laboratory testing.

Point F 1 (a) of Chapter II, Section I of Annex I to Regulation (EC) No 854/2004 requires that the official veterinarian has to ensure that sampling takes place and that samples are appropriately identified and handled and sent to the appropriate laboratory within the framework of the monitoring and control of zoonosis and zoonotic agents.

Article 1 of Regulation (EC) No 2073/2005 requires that the CAs verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005 in accordance with Regulation (EC) No 882/2004.

5.5.1 Organisation of official controls

Findings

Official controls are carried out with a risk based frequency, established annually by the CCA for each FBO using clear criteria and a complex algorithm. The frequency per category of establishment (eg; dairy, fishery) is established in the business plan which is reviewed once every three years and published on the FASFC website. The frequency per individual FBO, within each category of establishment, is set up annually by the CCA taking into consideration the risk profile of each operator.

The risk profile uses a scoring system which takes into consideration the compliance history and whether the establishment has a validated own control system. Reliability of FBO own controls is considered as covered by the question related to the validation of own controls.

The validation of FBOs' own control systems can be carried out by the FASFC or by a private approved certification body. According to the RD of 14 November 2003, the certification and inspection body has to be approved by the CA and accredited by the BELAC according to EN ISO 17020, EN 45011 or ISO/IEC 17021. The list of approved certification and inspection bodies and the CCA procedure for their approval are available on the AFSCA website.

The frequency of inspection was followed in the establishments visited and additional targeted inspections were carried out as well.

In most types of establishment the frequency of checking compliance with Regulation (EC) No 2073/2005 (according to the specific check-lists as described in chapter 5.2.4) varies between every second to every fourth inspection in the plant. For example compliance of FBOs with Regulation (EC) No 2073/2005 and HACCP provisions may be checked once every 4-8 years in a dairy establishment, once every 8-12 years in an establishment producing pre-cut fruits and vegetables, un-pasteurised juices, once every 2 years in egg product establishment. In the meat sector the frequency is higher (eg in slaughterhouses a dedicated check-list for the provisions of Regulation (EC) No 2073/2005 is used once every two months).

Observations

- The target population and size of production are not taken into account for establishing the frequency of inspection. For example a large dairy establishment producing infant food has the same frequency of inspection as a small dairy.

- The history of compliance is taken in consideration with a delay of two years. It does not directly take into account information that might indicate non-compliances originating outside the FASFC system (eg. consumer complaints, food alerts including RASFFs, relevant information received from other Member States). Moreover, the system for adapting the frequency of inspection is designed in a way that does not allow an establishment with a validated own control system to receive a high frequency of official controls. In practice, for establishments producing food subject to RASFF alerts the frequency of inspection has not changed except if the validation of the own control system was suspended. Additional targeted inspections took place in these establishments.

- The CCA considers the controls carried out by the private certification bodies as equivalent to official controls. These control tasks are conferred in accordance with the provisions of Article 10 of RD of 14 November 2003 without making reference to the provisions of Regulation (EC) No 882/2004. The provisions of Article 10 of RD of 14 November 2003 includes most of the requirements of Article 5 of Regulation (EC) No 882/2004. According to the approval procedure, action is taken by these bodies to ensure that identifying non-compliances are remedied by the FBO, including follow-up visits.

- Only food safety breaches ("infraction") are required to be immediately communicated by the private certification bodies to the CA in accordance with the general notification requirement (RD of 14 November 2003). The results of the inspections carried out by these bodies can be made available to the CA. Nevertheless, the CA is not required to routinely take them into consideration when organising own controls. Serious food safety non-compliances with no action taken by the FBO were found in establishments with validated own control systems (eg *Salmonella* positive cases in the final product in the establishments producing meat preparations and dairy products as described in Chapters 5.2.5 and 5.5.4).

Conclusions

The system for organising official controls is risk based without taking into account all the provisions of Article 3 (1) of Regulation (EC) No 882/2004. It does not include all relevant risk factors, any information that might indicate non-compliances and it takes into consideration the history of non-compliance with a delay of two years. In addition it is designed in such a way that establishments with a validated own control system cannot receive a high frequency of official controls. The official controls carried out by the private certification and inspection bodies carrying out validation of FBOs own control systems have not been effective in some of the establishments visited by the FVO audit team. Official inspections are carried out with the scheduled frequency and using the allocated check-lists.

The frequency of official controls over food safety and process hygiene criteria as required by Regulation (EC) No 2073/2005 varies widely between the different commodities concerned and it is not adequate for certain commodities.

5.5.2 Official sampling and testing

The official sampling plans are designed at central level based on the principles laid down in the MANCP and transmitted monthly to the PCUs for implementation. The allocation of the number of samples for the different commodities per PCU, the parameter to be tested and the place of sampling (production, distribution, retail) is decided at central level. The Provincial Units allocate

the specific samples to be taken per FBO.

Technical data-sheets taking into consideration the provisions of Regulation (EC) No 2073/2005 have been developed by the CCA and are available to PCU staff performing the sampling for each type of commodity included in the official sampling plan.

Official sampling and analysis is carried out to monitor FBOs compliance with Regulation (EC) No 2073/2005 and other microbiological criteria. Follow-up regulatory sampling is carried out in case of non-compliant test results at monitoring sampling (see chapter 5.4). Zoonosis monitoring is carried out in accordance with the national programms in place based on Regulation (EC) No 2160/2003.

According to the information provided by the CCA, in 2011, 29 179 official samples have been taken and 61 818 microbiological tests have been carried out with a general level of compliance around 94.5%. The details of the results per type of commodity and pathogen are presented in the FASFC activity report available at http://www.afsca.be/rapportsannuels/_documents/2012-06-26_RA2011Fr_S.pdf

Observations

- The official sampling programmes were generally followed in the cases assessed. The small differences between the planned and the executed sampling were justified. The results seen were in most cases satisfactory and evidence of follow up actions taken in line with the procedures in place was available in the cases of unsatisfactory results

- In all establishments visited by the FVO audit team, official samples had been taken during previous years.

- Additional sampling for *E.coli* and *E. coli* O104:H4 was put in place around the outbreak in Germany in 2011 and continued in 2012 and is planned for 2013. In 2012 additional testing for *E. coli* O157 and VTEC (*E. coli* O26, *E. coli* O103, *E. coli* O111, *E. coli* O145) was carried out and it is scheduled for 2013.

Conclusions

A comprehensive official monitoring plan is in place and it takes into consideration the relevant microbiological criteria provided by Regulation (EC) No 2073/2005 in different matrixes and at all levels (production, distribution, retail). Guidance for official sampling in both the animal products sector and in the vegetable sector is in place.

5.5.3 Controls over HACCP based procedures

Findings

Controls over FBOs' HACCP based procedures are carried out during controls over FBO's own control plan using dedicated check-lists and technical data-sheets (see chapter 5.2.4).

There is as system in place for allowing derogations from compliance with full HACCP requirements by small FBOs (see chapter 5.1) and it was used in the cases assessed.

All establishments visited had implemented HACCP based procedures. In most cases the validation and verification of the HACCP based procedures was carried out by applying microbiological testing for criteria laid down in Regulation (EC) No 2073/2005.

The CAs' controls over HACCP-based procedures were carried out with the planned frequencies and in most cases covered relevant parts of the programmes (for example validation, controls over CCPs, controls limits).

Observations:

- The sprouted seeds establishment's own HACCP based procedures were issued prior to the entry into force of the Hygiene Package and not updated. They were not taking into consideration the requirements of Regulation (EC) No 2073/2005. No sampling plan was in place.

The FVO audit team identified non-compliances which were not noted by the CA:

- In one fishery establishment validation for the hot smoking process was not carried out.
- In most of the establishments the frequencies of sampling performed for food safety and process hygiene criteria were not established in the context of the FBO's procedures based on HACCP principles and good hygiene practices as required by Article 4, point 2 of Regulation (EC) No 2073/2005.
- No sampling plan was in place for the pre-cut fruits production in the establishment visited.
- The procedure for action in case of non-compliant test results was in most of the cases either non-existent, not well documented, not reflecting the reality, not including the root cause analysis or changes in the HACCP based procedures.
- In few cases, food safety non-compliances were not notified to the CA (see chapter 5.2.4 and 5.5.4)
- Environment *L. monocytogenes* positive samples in the meat products establishment visited did not lead to any action over the product by the FBO. The foodstuffs produced during the days when the positive test results in the environment were available were at a later stage the subject of RASFF alerts.

Conclusions

The CAs' controls over HACCP-based procedures were implemented according to the plan and using comprehensive control procedures. They were however unable to identify that the provisions of Regulation (EC) No 2073/2005 in terms of establishing the frequency of testing and taking action in case of non-compliant test results were not integrated in these procedures.

5.5.4 Controls over FBOs' compliance with food safety criteria

Findings

The CA controls over FBOs' compliance with food safety criteria are considered as part of controls over FBO's own control plans (see chapter 5.2.4 and 5.5.1).

In most establishments visited sampling and testing for the relevant food safety criteria was in place. In the official reports seen, evidence of controls over these aspects was in general limited (see Chapter 5.2.4). When food alerts had been issued in relation to products originating in those establishments the reports included more details.

Observations

The FVO audit team identified non-compliances which were not noted by the CA:

- In the sprouted seeds establishment, no testing was carried out for *L.monocytogenes. Salmonella* testing started after a RASFF alert originating in the establishment in July 2012 and it was carried out mainly in water. In the sprouting seeds it only took place once.
- No testing of pre-cut fruits was carried out in the establishment visited.
- In one establishment visited the FBO applied for poultry meat preparations the food safety criteria for fresh poultry meat. The FBO only took action in relation to the product when *Salmonella enteritidis* or S*almonella typhimurium* were identified in the meat preparations. The *Salmonella sp* positive batches of meat preparations produced in that establishment in 2011 and 2012 had been placed on the market.

- The FBOs visited producing RTE food defined as supporting the growth of *L monocytogenes* used the "absence in 25g" criteria for *L. monocytogenes* for microbiological own control of their final products in most cases. In the fishery establishments visited the FBO applied at production level the limit provided by the legislation for products placed on the market.
- Non-compliances in relation to sampling units and methods have been described in chapter 5.4.2.

Conclusions

The official controls over FBOs' compliance with food safety requirements were not adequately documented in most cases. The implementation of these controls was not fully satisfactory as numerous shortcomings in relation to sampling and testing for the relevant food safety criteria were not detected by the CA.

5.5.5 Controls over FBOs' compliance with process hygiene criteria

The controls over FBOs' compliance with process hygiene criteria are considered as part of controls over FBO's own control system (see chapter 5.2.4 and 5.5.1).

In most establishments visited sampling and testing for the relevant process hygiene criteria was in place. In the official reports seen, evidence of controls over these aspects was in general limited (except for slaughterhouses where more details were included in the reports following controls and an establishment producing meat preparations and mechanically separated meat- see chapter 5.2.4).

Observations

The FVO audit team identified the following non-compliances which were not identified by the CA:

- In the mechanically separated meat establishment visited the *E. coli* results were in general unsatisfactory, although the limit applied was 10 times bigger than provided by the Regulation. No other action except for labelling the product as intended for the production of heat treated meat products was taken by the FBO.
- Pre-cut fruits were not tested for the relevant process hygiene criteria.

- In the sprouted seeds establishment visited *E coli* was tested only in the water.

- Non-compliances in relation to sampling units and methods have been described in chapter 5.4.2.

Conclusions

Except for slaughterhouses, the official controls over FBOs' compliance with process hygiene requirements were not adequately documented. The implementation of these controls was not fully satisfactory as numerous shortcomings in relation to sampling and testing for the relevant process hygiene criteria were not detected by the CA.

5.5.6 Controls over sampling and testing of processing areas and equipment (especially for Listeria monocytogenes when manufacturing ready-to-eat foods)

Findings

By Service Note BP/LABO/ 861230 of 10 September 2012 published on the FASFC website, the Guidelines on sampling the food processing area and equipment for the detection of *L. monocytogenes* of the European Union reference laboratory for *L. monocytogenes* are announced and made available to the laboratory network on Intra-lab (the protected web-site of the laboratories' administration).

Observations

- The check-lists for control do not include a specific question in relation to testing of processing areas and equipment (especially for *L. monocytogenes*).
- The official controls over sampling and testing of processing areas and equipment including for *L. monocytogenes* when manufacturing ready-to-eat foods were in most cases not documented.
- The majority of FBOs visited were carrying out testing to verify cleaning and disinfection. Environmental testing for *L. monocytogenes* was carried out in most cases by FBOs manufacturing RTE foods able to support its growth. No such testing was carried out in the sprouted seeds establishment.

Conclusions

The official controls over sampling and testing of processing areas and equipment including for *L. monocytogenes* when manufacturing RTE foods were in most cases not documented. Most of the FBOs manufacturing RTE able to support the growth of *L. monocytogenes* were carrying out environmental testing for this pathogen.

5.5.7 Controls over alternative sampling and testing procedures

Findings

The information regarding the alternative testing methods which are allowed by Regulation (EC) No 2073/2005 and approved by the CA is published on the CCA website (see chapter 5.4).

The FBOs in the sectors evaluated used alternative testing methods for food safety and process hygiene criteria. In most of the cases these were validated methods against the reference methods in Regulation (EC) No 2073/2005 (see chapter 5.4).

Observations

- The check-lists for control do not include a specific question in relation to the use of alternative sampling and testing procedures.
- Controls over alternative sampling and testing procedures at establishment level were not

documented (except for the dairy establishments following RASFF alerts) and according to official control staff on the spot, not carried out (see chapter 5.4).

Conclusion

At establishment level, the controls over alternative sampling and testing procedures were in most cases not documented. Nevertheless FBOs' compliance was ensured in most cases assessed by the FVO audit team.

5.5.8 Controls over shelf-life studies and over analyses of trends

Findings

The approved laboratories performing challenge tests are required to be accredited to perform such tests and to use the "Technical guidance document on shelf-life studies for *L. monocytogenes* in ready-to-eat foods" (November 2008) of the CRL for *L. monocytogenes* (as per Service Note BP/LABO/ 433514 of 16 March 2010 on the accreditation of laboratories for challenge tests). This guidance was made available to all approved laboratories on Intra-lab. Currently there are five approved laboratories accredited to perform challenge tests in Belgium.

In most establishments visited shelf-life studies have been established based on experience, historical data and by checking the sensory and microbiological quality of the products at the end of the shelf- life. None of establishments visited had used predictive modelling as a tool to establish the shelf-life. Challenge studies were seen in two cases.

Analyses over trends were available in the form of graphs or oversights in relation to microbiological verification of cleaning and disinfection results and in relation to food safety and process hygiene criteria in most establishments visited.

Observations

- The check-lists for control do not include a specific question in relation to shelf-life studies and analyses of trends.
- Tests at the end of the shelf-life and the challenge tests presented to the FVO audit team did not take into account the foreseeable conditions of storage and distribution (temperature). This has not been identified by the CA as a non-compliance.
- CA controls with regard to this aspect of Regulation (EC) No 2073/2005 (trend analyses and shelf-life study) were only documented in a few cases, mainly related to food alerts or non-compliant test results at official sampling.
- In one of the two slaughterhouses visited a trend analysis was not available. In the other slaughterhouse no action had been taken in a few cases where a trend towards unsatisfactory results was indicated by the results. One of these instances could be correlated with a commodity involved in a RASFF alert.
- Tests at the end of the shelf-life were carried out only for process hygiene criteria in the un-pasteurised juices establishment and in one dairy establishment.

Conclusions

At establishment level, the controls over shelf-life studies and over analyses of trends were in most cases not documented. CA did not identify that tests at the end of shelf-life and challenge tests did not take into consideration the foreseeable conditions of storage and distribution. Official controls are in place over the performing challenge tests in approved laboratories.

5.5.9 Supervision of in-house and other private laboratories used by the FBOs for microbiological analyses of foodstuffs

Findings

There is a system in place for supervision of approved private laboratories (see chapter 5.3). No supervision system is in place for other private laboratories that FBOs may use for own testing. The requirement for FBOs refers only to the use of approved methods and to participation in proficiency testing.

Observations

Limited documentary evidence was seen of the supervision at establishment level of methods applied by in-house private laboratories or by other private laboratories used by the FBOs for microbiological analysis of foodstuffs.

Conclusions

A supervision system over approved private laboratories which may be used by the FBOs for microbiological analyses of foodstuffs is in place. No such system exists for in-house laboratories.

5.6 Labelling requirements for minced meat, meat preparations and meat products intended to be eaten cooked

Legal requirements

Article 6 of Regulation (EC) No 2073/2005 sets out labelling requirements for batches of minced meat, meat preparations and meat products of all species, intended to be eaten cooked, which fulfil the requirements for *Salmonella* as set down in Annex I. Such batches must be clearly labelled by the manufacturer in order to inform the consumer of the need for thorough cooking prior to consumption.

Findings

Although no longer required by Regulation (EC) No 2073/2005, the white meat establishment visited which was producing *meat preparations and meat products intended to be eaten cooked* was labelling all its products in order to inform the consumer of the need for thorough cooking prior to consumption. This was considered a precautionary measure as the FBO decided not to follow the current limit for *Salmonella sp* in such products, but the fresh poultry meat criteria (see chapter 5.5.4).

The check-list used for performing official controls in minced meat, meat preparations and meat product establishments does not include questions in relation to the labelling requirement set out by Regulation (EC) No 2073/2005.

The poultry mechanically separated meat in the establishment visited was labelled as Bader Meat. An indication was placed on the label in relation to the intended use for the production of heat treated meat products, regardless of the microbiological test results.

Conclusions

The requirements of Article 6 of Regulation (EC) No 2073/2005 regarding labelling of batches of minced meat, meat preparations and meat products of all species, intended to be eaten cooked, which fulfil the requirements for *Salmonella* as set down in Annex I are not included in the official control documented procedure.

6 Overall Conclusion

A system for official controls on the implementation of Regulation (EC) No 2073/2005 is in place. Several pieces of legislation, circulars and service notes aiming at facilitating the implementation of Regulation (EC) No 2073/2005 have been issued. CA inspectors carried out official controls with the allocated frequency and using the dedicated procedures, according to the plan established by the CCA. Although the system for organising official controls is risk based, it does not take into account all the provisions of Article 3 (1) of Regulation (EC) No 882/2004 in such a way as to achieve the objectives of this Regulation.

The organisation of official controls at FBO level in relation to Regulation (EC) No 2073/2005 in general and to food safety and process hygiene criteria in particular, varies widely between the different types of commodities in terms of level of detail and frequency which are not adequate for certain commodities. For most of the commodities under review, the procedures for official control at establishment level included very limited aspects concerning compliance with the different requirements of Regulation (EC) No 2073/2005. The official controls were not adequately documented to have covered all relevant aspects of this piece of legislation in most cases. The implementation of these controls was not fully effective in several cases assessed (in particular for meat preparations, fishery products and food of non-animal origin). Numerous shortcomings were not detected by the CA. A lack of CA action for long-standing deficiencies, in particular as regards sampling and testing methods and action in case of non-compliant test results (including for food safety criteria) was noted. Moreover, the sanctions given were not proportionate in the cases reviewed by the FVO audit team in the dairy sector. The official controls carried out by the private certification and inspection bodies carrying out validation of FBOs' own control systems have not been effective in some of the establishments visited by the FVO audit team.

The official monitoring plan in relation to the microbiological criteria provided by Regulation (EC) No 2073/2005 and the official laboratory network are in general adequate.

7 Closing Meeting

A closing meeting was held on 1 February 2013 with representatives of the CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities provided clarification to some of the issues raised during the presentation

8 Recommendations

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

N°.	Recommendation
1.	To ensure that the risk based system used for determining the frequency of official controls takes into consideration all provisions of Article 3 (1) of Regulation (EC) No 882/2004 in such a way as to achieve the objectives of this Regulation and that controls over food business operators' compliance with Regulation (EC) No 2073/2005 are carried out with an adequate frequency in all types of establishments as required by the same article of Regulation (EC) No 882/2004.
2.	To ensure that appropriate action is taken by the Competent Authorities, as required by Article 54 of Regulation (EC) No 882/2004, when non-compliances are identified in relation to the requirements of Regulation (EC) No 2073/2005, in particular in relation to food safety criteria.
3.	To ensure that sanctions imposed when non-compliances are identified in relation to the requirements of Regulation (EC) No 2073/2005, in particular in relation to food safety criteria are proportionate and dissuasive as required by Article 55 of Regulation (EC) No 882/2004.
4.	To ensure that the documented procedures in place for carrying out official controls (e.g. guidance, circulars, technical sheets, check lists) contain complete information and instructions for staff performing official controls in order to comply with Article 8(1) of Regulation (EC) No 882/2004, in particular the relevant requirements of Regulation (EC) No 2073/2005.
5.	To ensure that when the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators take the appropriate measures as provided by Article 7 of Regulation (EC) No 2073/2005.
6.	To ensure that the storage conditions are taken into account when shelf-life studies are

N°.	Recommendation
	carried out as required by Annex II to Regulation (EC) No 2073/2005.
7.	To ensure that official controls over food business operators' Hazard Analysis Critical Control Points based procedures cover all relevant aspects, including the requirements of Articles 3, 4, 5 and 7 of Regulation (EC) No 2073/2005 in particular in relation to the actions in case of non-compliant test results, trend analysis, shelf-life studies, sampling and testing procedures for both food safety and process hygiene criteria.
8.	To ensure the effectiveness of official controls as required by Article 4 of Regulation (EC) No 882/2004, when such controls are carried out by the private certification and inspection bodies as well as by representatives of the Federal Agency for the Safety of the Food Chain.

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=2013-6861

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. 2160/2003	OJ L 325, 12.12.2003, p. 1-15	Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents
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. 1688/2005	OJ L 271, 15.10.2005, p. 17-28	Commission Regulation (EC) No 1688/2005 of 14 October 2005 implementing Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs
Reg. 669/2009	OJ L 194, 25.7.2009, p. 11-21	Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC
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. 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