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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 27 MAY TO 07 JUNE 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 Italy which took place from 27 May to 7 June 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 nine establishments visited covered different types of food production including ready to eat (RTE) food (dairy, fishery, egg products, pre-cut fruits and vegetables, sprouted seeds, unpasteurised juices, red meat, poultry meat, meat preparations, minced meat, mechanically separated meat (MSM) and meat products).

In the five Regions visited there is an official control system in place for checking food business operators' (FBOs) compliance with the requirements of Regulation (EC) No 2073/2005 (hereafter referred to as "the Regulation". Official controls were carried out in all (but one) cases assessed with the risk based frequency, established annually by the local competent authority (CA) for each FBO. One local service in Tuscany failed to ensure their control responsibilities in the establishment producing sprouting seeds. The frequency was not defined until prior to the FVO AT visit when the first visit on the spot took place. The guidelines issued by the central competent authority (CCA) for establishing the frequency of inspection gives little weight to the history of non-compliance and reliability of FBOs' own checks, resulting in no change in the frequency of inspection in the case of serious non-compliances.

The available official control guides, both at national and regional level and the guides for FBO own controls approved by the CCA do not fully integrate the provisions of the Regulation for the different types of commodities and, in particular, in the food of non-animal origin (FNAO) sector.

The system for official controls over food safety and process hygiene criteria as required by the Regulation varies between the different Regions/local units and between the different types of commodities in terms of level of detail of the control procedures. In most cases, the reports seen were not documented to have taken into consideration all of the relevant aspects of the Regulation. The implementation of the provisions of the Regulation as regards testing for the relevant parameters was mainly satisfactory in most of the establishments visited. The action taken in connection to Rapid Alert for the Safety of Food and Feed (RASFF) alerts was largely satisfactory although not adequately documented in some cases. Official controls over FBOs' sampling and testing procedures were not carried out in all cases and some related non-compliances have been identified by the FVO AT. The FBOs' Hazard Analysis Critical Control Points (HACCP) based procedures in general did not fully integrate the provisions of the Regulation as regards the frequency of testing, raw material controls and taking action in the case of non-compliant test results. Significant non compliances were identified as regards testing for inhibitors, plate counts and somatic cells and official control of raw milk quality in Tuscany and Abruzzo.

Official monitoring and verification plans in relation to the relevant microbiological criteria of the Regulation are designed either at regional or at local level and, in all cases, implemented by local level official control staff. In the cases assessed by the FVO AT the plans considered mainly the food safety criteria and to a higher extent in food of animal origin (FAO) matrixes. Testing in FNAO and RTE prepared dishes in the official laboratory responsible for such testing in Lazio was extremely limited. In all the establishments visited official sampling activities were carried out during recent years and were scheduled for 2013.

The official laboratory network for food microbiology testing comprises a large number of accredited laboratories belonging to three different networks (IZS-Experimental Zoophylaxis Institutes, ARPA- Regional Agencies for Environment Protection and LSP- Public Health Laboratories). The FVO AT visited one laboratory from each network. Each of them were participating with good results in proficiency tests for the different relevant parameters. Within the IZS network a system aimed at ensuring co-ordination from central level is under development, while no such system is in place in the other two networks. National Reference Laboratories (NRLs) have been appointed in the IZS network for each of the pathogens in the Regulation which have an European Union Reference Laboratory (EURL). The designated NRLs have taken on their duties to different degrees but mainly in relation to laboratories within the IZS network. There is no system in place for NRL co-ordination of the laboratories in the other two networks, nor within the ARPA and LSP networks in this regard.

The report includes a number of recommendations addressed to the CA of Italy, aimed at rectifying the shortcomings and deficiencies identified and enhancing the implementation of the official control system in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ARPA	Regional Agencies for Environment Protection (<i>Aziende Regionali per la Protezione Ambientale</i>)
AUSL	Local Health Units (<i>Aziende Unità Sanitarie Locali</i>)
AT	Audit team
CA(s)	Competent Authority(ies)
CCA(s)	Central Competent Authority(ies)
EURL	European Union Reference laboratory
DG(SANCO)	Health and Consumers Directorate-General
<i>E.coli</i>	<i>Escherichia coli</i>
EC	European Community
EU	European Union
FBO(s)	Food Business Operator(s)
FAO	Food of animal origin
FNAO	Food of non-animal origin
FVO	Food and Veterinary Office
GMP	Good manufacturing practices
GHP	Good hygiene practices
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
ISS	National Health Institute (<i>Istituto Superiore di Sanità</i>)
IZS	Experimental Zooprophyllaxis Institutes (<i>Istituti Zooprofilattici Sperimentali</i>)
LSP	Public Health Laboratories
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
NRL	National Reference laboratory
OV	Official veterinarian
RTE	Ready-to-eat
TBC	Total Bacteria Count
VTEC	Vero Toxin Producing <i>E. coli</i>

1 INTRODUCTION

The audit to evaluate the official controls on food safety and process hygiene criteria (Commission Regulation (EC) No 2073/2005) in Italy formed part of the FVO's planned audit programme. It took place from 27 May to 7 June 2012. It is part of a series of audits to Member States in 2011 (Denmark, Germany and Ireland), 2012 (France, Finland, Hungary, Czech Republic, Spain) and 2013 (Belgium, Cyprus, Italy, Poland). The audit team (AT) comprised two auditors from the FVO. The FVO AT was accompanied during the whole audit by a representative of the CCA, the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection within the Ministry of Health. An opening meeting was held on 27 May 2013 in Rome with the CCA. At this meeting, the objectives of, and itinerary for the audit were confirmed by the FVO AT 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. (As Regulation (EC) No 2073/2005 is the principal legal basis cited in this report, it is, hereinafter, referred to as „The Regulation“).

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 objectives of the audit:

Meetings/Visits		No	Comments
Competent authorities	Central	1	
	Regional	5	Veneto, Emilia Romagna, Tuscany, Abruzzo, Lazio
	Local	10	
Laboratories	Reference	2	The NRL for <i>Escherichia coli</i> (<i>E. coli</i>) which is also the EURL for <i>E.coli</i> , the NRL for <i>L.monocytogenes</i>
	Local/Regional	2	One laboratory in the ARPA network and one LSP laboratory
Food business operators (FBOs)		9	One bovine slaughterhouse also producing minced meat, meat preparations and meat products, one poultry slaughterhouse also

		producing meat products and MSM, one fishery establishment producing RTE smoked fish, one sushi producing establishment, one establishment producing RTE pre-cut fruits and vegetables and un-pasteurised juices, two dairy establishments, one establishment producing sprouted seeds, one establishment producing egg products.
FBOs own control laboratories	1	

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 FBOs' 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 and carried out from 2011 to 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 Italy covering different sectors of food and feed production were carried out between 2010 and 2012 (Reference Numbers: DG(SANCO)2010-8502, DG(SANCO)/2010-8525, DG(SANCO)2010-8741, DG(SANCO)/2012-6333 and DG(SANCO)2012-6359. Some of the recommendations issued following these audits are relevant for the scope of this audit. The reports of the individual missions can be found at:

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

In 2011, 2012 and the first four months of 2013, 41 RASFF alert notifications in relation to microbiological hazards in foodstuffs from Italy have been launched, 22 of them by other Member States and 19 by Italy.

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

Several pieces of legislation issued by the Italian CA in relation to testing for microbiological parameters of foodstuffs prior to the entry into force of the Regulation are currently in place and applicable only to food produced in Italy. The “Agreement of 10 May 2007 between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano on Guidelines for the application of Regulation (EC) No. 2073/2005”, adopted by all regions visited by the FVO AT, clarifies which of the national acts remain valid (the ones which do not contradict but only supplement the provisions of the Regulation).

The above mentioned Agreement contains also detailed sampling procedures for process hygiene criteria in red meat slaughterhouses and criteria for flexibility in relation to sampling and testing frequency in the meat sector. In the Regions visited by the FVO AT no additional flexibility rules were adopted.

Other national official control guidelines (eg. for risk identification, for identification of non-compliances, for taking corrective actions) are applicable also for controls over FBOs' compliance with the Regulation. According to the CCA these guidelines contain provisions mainly for the FAO sector and more detailed for the meat and dairy sectors.

National guides for the implementation of the FBOs' own control systems in different types of establishments, both in the FAO and in the non-animal origin sectors, have been approved by the CCA. An overview of these guides is available on the Ministry of Health website.

In the Regions visited by the FVO AT no additional guidelines for the implementation of the Regulation were issued. Section 5.2.4 below provides additional detail on the scope and implementation of procedures at regional level.

Observations

- According to the information provided by the CCA, the guidelines concerning FBO own control and the official controls refer to provisions of the Regulation only for the meat and dairy sectors.

- During the initial meeting the CCA informed the FVO AT that several national guidelines relevant for the scope of this audit are under review as they have not been updated to take account of changes to legislation. No deadline was determined for the completion of the revision.
 - The *Salmonella* testing guidance, currently does not include the changes introduced by Regulation (EC) No 1086/2011.
 - The guideline for official controls in the fishery sector aims also to include the provisions of the Regulation.
 - The Guidelines for official control in accordance with Regulations (EC) No 882/2004 and (EC) No 854/2004 aims to review the criteria for risk categorisation and establish subsequent correlation with the frequency of control, including criteria for the FNAO sector and guidance to perform official controls on laboratories.
- With regard to *Salmonella*, a national programme for poultry is in place with relevance for the zoonosis legislation.

Conclusions

The available official control guides, both at national and regional level and the guides for FBO own controls approved by the CCA do not fully integrate the provisions of the Regulation for the different types of commodities and, in particular, in the FNAO sector.

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 Italy which is accessible at: http://ec.europa.eu/food/fvo/ir_search_en.cfm.

Decree No 193 of 6 November 2007 defines the general responsibilities of the three levels of controls (central, regional and local).

The Ministry of Health is the CCA responsible for food safety for FAO and non-animal origin. It issues guidelines for the Regions, carries out audits of the regional control systems and controls on import and export requirements. The microbiological criteria are considered a common issue to be evaluated during different sectoral audits on hygiene of foodstuff production. No changes occurred in the organisation of the Ministry of Health since the last update of the country profile.

The 19 Regions and 2 autonomous Provinces have responsibility, within their territories, for planning, co-ordination and guidance including on official controls of microbiological criteria. The 146 Local Health Units (AUSLs) which are responsible for the operational implementation of controls are autonomous from an organisational and economic point of view.

5.2.2 *Co-ordination and co-operation within and between 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

The system of co-ordination between the central and regional levels and within the Regions as explained in the Country profile was implemented in the regions visited by the FVO AT. Regional CAs issued legislation for adopting the national guidelines relevant for the scope of this audit, related work instruction and circulars and carried out verification audits on the AUSL.

The relevant guidelines and circulars issued by the CCA, the legislation, procedures, joint projects, sampling plans issued by the regional CA, inspection procedures and sampling plans issued by local CA were available to the official control staff at establishment level.

The action taken by the CA in relation to five RASFF alerts was assessed by the FVO AT. In all cases the action taken was prompt, both for notification of identified non-compliances and for carrying out visits on the spot in connection with notifications and ensuring rapid communication with the relevant levels of controls. In all cases assessed traceability exercises were carried out, and recall, detainment and destruction, when necessary, took place.

In the Region of Emilia Romagna a joint research project between the IZS and the official controls staff aiming at analysing the food microbiology status in the Region and making a connection between the scientific level and its application for the protection of public health using predictive microbiology is running since 2010. This project involved training of official control staff in most AUSLs and helped at improving the official control staff's knowledge and capacity of evaluating the production processes, the shelf-life studies, the validation of FBOs own controls systems.

Observations

- The CCA does not have complete knowledge of the registered establishments in the pre-cut fruits and vegetables, unpasteurised juices and sprouted seeds sectors at national level. Moreover, the query made by the CCA, to this regard, before the FVO audit, was not replied to by all Regional CAs. The current categories for registration and control of FBOs in the Regions visited by the FVO AT do not distinguish between pasteurised or un-pasteurised juices establishments and do not specifically include sprouted seeds establishments.
- The working groups for co-ordination between central and regional levels are in the process of re-classifying the production categories for the FNAO sector. It aims at agreeing on uniform national categories for registration of establishments, establishing the associated risks and frequencies of controls. The CCA notified the Regions by circular letters of the change in the sprouted seeds legislation and of the approval requirement for these establishments. The Regional CAs in Veneto, Emilia Romagna and Tuscany were aware of the existence of such establishments and were in the process of amending the procedures for approval of establishments to include the sprouting seeds activity.
- The system of coordination of the official laboratories is not fully adequate (see chapter 5.3)

- The annual activity report published on the Ministry of Health website compiles the data received from the AUSLs, the IZS and the ARPA networks with a two year delay. The overview of the 2011 official control activity, including official sampling activity and results are available at <http://www.salute.gov.it/relazioneAnnuale2011/paginaAttivitaRA2011.jsp?sezione=capitolo2&capitolo=alimenti2¶grafo=sicurezzaalimentazione2&id=1142> and indicate an approx 1% level of non-compliance for microbiological criteria in the official samples.

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 receive appropriate training, and are kept up-to-date in their competencies.

Findings

In most cases assessed, no evidence of staff shortages was noted by the FVO AT and facilities and equipment for official use seen were appropriate. The staff met at the different offices and premises and at the official and private laboratories were suitably qualified.

Numerous training sessions on microbiological aspects including for controls related to the provisions of the Regulation have been organised by different Regions and IZS laboratories.

Observations

In the Regions visited (except for Abruzzo) relevant training on the provisions of the Regulation was organised. In the region of Abruzzo, although the training organised by the regional CA focussed on other aspects of official control, the official control staff may participate in training sessions organised by external training providers including on the provisions of the Regulation.

5.2.4 Procedures for performance of control activities and documentation of official controls

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

All Regions visited had procedures and legislation in place for the organisation of controls on a risk basis both in the FAO and non-animal origin sectors.

In all regions visited (except Abruzzo) the general checklists issued by the regional CA for controls

over FBO's own control system include the requirements of Article 5 of Regulation (EC) No 852/2004 and references to certain provisions of the Regulation. In Emilia Romagna a Manual of control giving more detailed information and referring to the relevant articles of the legislation to be considered for each item in the checklist is available.

The regional CA in the Regions of Tuscany and Lazio also issued additional checklists targeted on provisions of the Regulation. In Tuscany it includes questions related to the sampling method, the tests results and action in case of non-compliant test results.

In Abruzzo the development of checklists and related procedures for controls was left to the local units and they were available in the AUSLs visited.

Observations

Generally the reports seen by the FVO AT and issued by the CA following controls over FBOs own control system and compliance with the Regulation were composed only of answers to the questions in the checklists. Reference to the Regulation in the checklists used in different regions varies significantly between the regions and in Abruzzo also between the AUSLs visited:

- In Emilia Romagna, with few exceptions, most of the relevant provisions of the Regulation are taken into consideration while in Veneto solely in relation to shelf-life studies and controls of FBO's records for own controls).
- The FBO obligations in relation to analysis of trends of the final products test results, labelling of minced meat, MSM, meat preparations (from red meat) as final products was generally not considered in the documented control procedures and reports. Checks over sampling and testing methods were not mentioned in four out of five regions visited. Shelf-life studies were not mentioned either in two of the regions.
- The check-list for microbiological criteria used by the AUSL in charge of controls over the poultry establishment visited in Abruzzo was very limited, general for all types of establishments and did not take into consideration the amendments introduced by Regulation (EC) No 1086/2011 and numerous other relevant aspects of the Regulation.
- The targeted procedure developed by the AUSL visited (in Abruzzo) for controls over the fishery establishment did not include requirements for RTE products, in particular, in relation to *L. monocytogenes*.
- Controls over sampling and testing of processing areas and equipment are provided in the control procedures in Tuscany and Emilia Romagna, while in the procedures seen in Veneto, and in the AUSLs visited in Abruzzo such controls are not included.

In general, where the obligation to carry out specific controls was not included in the relevant procedures/check-lists, these controls were insufficiently implemented (see also section 5.5).

In Tuscany and Abruzzo in the reports following the visits on the spot in connection with the RASFF alerts in the establishments visited there was no mention of the action required by the CA from the FBOs. In the dairy establishment in Tuscany, of 24 visits on the spot during 2012 only in four instances was a report issued by the CA.

In the dairy establishment in Abruzzo, the comprehensive inspection report for 2011 indicated a level of 55% compliance with the HACCP based procedures and 75% compliance with the requirements of the Regulation without mentioning what the identified non-compliances were. The report following the visit in 2012 was not available.

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 sanctions 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 implementation of the Regulation as regards testing for the relevant parameters was mainly satisfactory in most of the establishments visited. In a few cases, documented evidence was available in the official control reports that the CA identified non-compliances, carried out the follow-up and took adequate enforcement measures.

Observations

In the establishments visited most of the FVO AT's findings have either not been previously identified by the CA or only recently identified, prior to the FVO's visit.

- In Tuscany, the local AUSL did not carry out any controls in the sprouted seeds establishment under their supervision until prior to the FVO audit. During this control the CA failed to identify the indication of illegal activity and the non-compliances related to the FBO own control plan (see chapter 5.5). Nevertheless the CA suspended the activity of the establishment.
- The non-compliances related to FBO's HACCP based procedures and the Regulation mentioned in chapters 5.5.2 to 5.5.7, the lack of compliance with the raw milk criteria in the dairy establishments visited were not identified by the local AUSLs in charge of controls in the different Regions (see chapter 5.5.2).
- In Tuscany in the dairy plant visited the lack of a procedure for taking action in case of non-compliant test results was only identified during a recent CA visit prior to the FVO AT's visit.

Conclusions

CAs for the purpose of official controls in relation to the requirements of the Regulation have been designated. A system of co-ordination within and between the CAs is in place and evidence of co-ordination was noted in most of the cases assessed, except for the official laboratories networks coordination and the collection of regional data in some cases. Training in relation to the requirements of this Regulation was in general organised, except for one Region (Abruzzo).

Procedures for performance and documentation of controls have been developed and are, generally, well implemented. However, there is considerable variation in the scope of these procedures between regions and between AUSLs for the different types of commodities controlled. Where specific controls are not included in the procedures, these are, in general, not well implemented.

Reports to the FBOs, as required by Article 9 of Regulation (EC) No 882/2004, were not always issued following official controls where non-compliances were detected. In particular, in a number of cases,

reports did not specify the action to be taken by the FBO.

In some cases when non-compliances were identified by the CA (Regional and AUSLs), they took adequate enforcement action. Nevertheless the controls by the AUSLs, in particular, in the cases assessed by the FVO AT in Tuscany and Abruzzo were not effective as numerous non-compliances, some of which were significant, had not been identified.

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 access to an adequate laboratory capacity for testing.

Findings

A description of the organisation of the laboratory network, can be found in the Country profile available at http://ec.europa.eu/food/fvo/ir_search_en.cfm. The system remains as described in the country profile. The IZS laboratories carry out testing of both FAO and FNAO. The ARPA and the LSP laboratories test mainly FNAO and composite RTE prepared dishes.

The decision on the laboratories to be used for official testing is taken at regional level. In Veneto and Lazio the IZS laboratories are used for testing of FAO while the ARPA laboratories are used for testing FNAO and prepared RTE dishes. In Emilia Romagna all food testing for microbiological criteria is carried out by IZS laboratories.

The IZS laboratories are part of the Ministry of Health's organisational structure with control and co-ordination at regional levels and also a recent co-ordination project from central level. There is a structure within the Ministry of Health responsible for carrying out mainly the financial co-ordination. Currently this unit is in the process of data gathering on a three year project at the end of which the necessary action to be taken will be decided.

The ARPA laboratories performing food microbiology testing are part of the Environmental Protection Agency, but financed for this task from Regional Sanitary Funds. They are co-ordinated by the ISPRA for tasks other than microbiological testing of food.

The LSP's laboratories exist only in a few Regions and according to the CA they are in all cases part of the local AUSLs' structure.

The National Health Institute (ISS) functions described in the country profile remain as described. It however carries out second instance analysis only for non-perishable foodstuffs (42 such tests were carried out in the past 3 years) while for perishable foods the second instance analysis is carried out by the same IZS laboratory that carried out the first instance testing.

Observations

There is no system of co-ordination in place between the IZS, ARPA and LSP networks. The NRLs designated in the IZS network do not coordinate the activity of the laboratories in the ARPA and

LSP networks. No NRLs or other national coordination bodies are designated within the ARPA and LSP networks for food microbiology testing. There is no inter-regional coordination within and between the laboratories in the ARPA and LSP networks (only intra-regional co-ordination and related to the multi-site accreditation system).

5.3.1 Laboratory accreditation and quality controls

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 ISO/IEC 17025 is carried out by the ACCREDIA which under the Inter-Ministerial Decree of 22 December 2009 is designated as the Single National Body authorised to perform accreditation activities in Italy. The accreditation scope of the laboratories and methods are included in the accreditation certificates published on the ACCREDIA website at http://www.accredia.it/accredia_labsearch.jsp?ID_LINK=293&area=7.

All laboratories visited by the FVO AT were accredited. Most test results presented during the visits at establishment level (except in the sprouting establishment) indicated they were performed in accredited laboratories with methods included in the accreditation scope.

The scope of accreditation of all the official laboratories visited by the FVO AT included most methods indicated by the Regulation. This was not the case in a few cases (e.g. for the new method for sprouted seeds testing in IZS Venezie, histamine in ARPA Lazio). Evidence of successful participation of these laboratories in the relevant proficiency testing schemes for food pathogens and of the action taken in the case of non-compliant test results was available.

The official laboratories visited in the IZS, ARPA and LSP networks had multi-site accreditation systems in place. The IZS laboratory visited co-ordinated the activity of seven other testing sites covered by the same multi-site accreditation certificate. Only one of them was performing testing for food microbiology for the respective Region. There are 10 IZS laboratories and co-ordination centres, each with its own multi-site accreditation certificate and according to the information on the CCA website, there are 76 testing sites.

Observations

In order to address Recommendation no 1 following audit DG(SANCO)/2010-8741 (for the CA to arrange for the accreditation of all laboratories involved in official controls and to ensure availability of access to accredited methods and proficiency tests in accordance with Articles 11 and 12 of Regulation (EC) No 882/2004) the CCA issued in 2011 and 2012 circulars to ACCREDIA (asking for verification that all laboratories involved in testing official samples are using accredited

methods for this purpose) and in 2012 to the Regions and IZS laboratories (asking them to ensure that when a laboratory is not accredited for performing a test, the sample has to be sent for testing to a laboratory which is accredited for that purpose). Systems to ensure compliance with the above-mentioned requirements were in place in all cases assessed by the FVO AT. All official test results seen by the FVO AT indicated that testing was carried out with an accredited 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

A NRL is appointed for each criteria in the Regulation which has an EURL. The ISS is the EURL for *E. coli* and NRL for verotoxigenic *E. coli*. The IZS of Umbria and Marche (Ancona) is the NRL for *E. coli* as food safety criteria in bivalve molluscs. The IZS of Abruzzo and Molise (Teramo) is the NRL for *L. monocytogenes*. The IZS of Venice (Padova) is the NRL for *Salmonella*, IZS of Piemonte, Liguria, Valle D'Aosta (Torino) is the NRL for Coagulase-positive staphylococci.

Generally the NRLs participated in proficiency tests organised by EURLs and other privately organised schemes, organised proficiency tests for other laboratories, participated in meetings organised by the EURLs', delivered training and scientific advice to other laboratories and the CCA.

In the NRL visited by the FVO AT random examples for each of the tasks above were assessed, including documentation of the follow-up action taken in the case of non-compliant test results and found to be with few exceptions largely satisfactory. Examples of comprehensive scientific advice given to the CCA and studies carried out upon request from the CCA were available.

The EURL and NRL *E. coli* VTEC regularly organises proficiency tests both for the NRLs from other Member States and for national laboratories involved in official microbiological tests. It follows up on non-compliant test results by organising training for the respective laboratories' staff. It provides scientific advice to the CCA at their request and to laboratories from all national networks.

Observations

The relevant information received from the EURL is passed by the NRLs mainly to laboratories in the IZS network. The NRL for *Listeria* only started to deliver such information in a formal way in 2012 during a yearly conference.

The follow-up done by the NRL *E. coli* on the action taken by the non-compliant laboratories was not documented.

The follow-up done by the NRL *E. coli* on the action taken by the non-compliant laboratories was not not documented.

The IZS, ARPA and LSP laboratory visited participated with good results to numerous comparative tests, most of them privately organised. The NRL for *L. monocytogenes* had not yet organised a

proficiency test for the ISO method provided by the Regulation (only for the US method). It is currently in the process of preparing such a test and aims at organising it in October 2013.

According to the information submitted, the NRL for *Salmonella* organised yearly proficiency tests for detection and sero-typing of *Salmonella*. Nevertheless, detection of *Salmonella* proficiency tests were organised only from faeces since 2010.

The participating laboratories in the proficiency test organised by the NRLs are mainly IZS laboratories and only sporadically a few ARPA laboratories.

Conclusions

The evaluated NRLs have largely carried out their duties (organising proficiency tests, passing the relevant information to other laboratories involved in official testing, delivering relevant training), but mainly for official laboratories in the IZS network. Proficiency tests for *Salmonella* in food matrixes and using the ISO method for *Listeria* were not organised.

The official laboratories networks are not co-ordinated by the CCA (financial co-ordination is currently under development). Nevertheless all the laboratories visited which are involved in testing official samples are able to perform most tests required by the Regulation. They are accredited and participate, in general with good results, in proficiency testing for the different pathogens.

Recommendation no.1 following audit DG(SANCO)/2010-8741, was addressed in relation to the accreditation of methods used for microbiological testing of foodstuffs in the Regions visited. As regards availability of access to proficiency tests, although the laboratories visited were participating in numerous proficiency testing, they were mainly privately organised schemes.

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 in the Regions visited include prospective/monitoring sampling (one sample unit) and regulatory/verification sampling (five sampling units). The reference methods as mentioned in Annex I to the the Regulation and alternative methods validated according to EN ISO 16 140 were in the accreditation scope of the official laboratories where this aspects was assessed by the FVO AT. Detailed guidelines for official sampling issued at regional level were available in Emilia Romagna and Lazio.

Observations

In response to Recommendation no 12 following audit DG(SANCO)/2010-8525 (for the CAs to

ensure that testing methods for histamine follow the references contained in the Regulation, or have been validated against these methods) the CCA took steps in addressing it. The ISS has defined minimum performance parameters for the alternative methods used by the official laboratories for histamine testing. According to the ISS representative, all IZS laboratories use accredited methods based on the HPLC technique. This information is not available on the Accredia website (in the annex to the accreditation certificate) in all cases.

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

Findings

Most of the FBOs visited provided evidence of accreditation of the laboratory and of the methods used for own testing. With few exceptions (eg. the dairy establishments, sprouted seeds establishment), the methods indicated in the test results were either ISO or alternatively validated ones.

Both slaughterhouses visited had a sampling procedure in place. In the red meat slaughterhouse both the written procedure for carcass sampling and the practical demonstration of it largely followed the ISO 17604.

Observations

No guideline is in place for correlation of the results obtained with the destructive sampling technique with regard to the process hygiene criteria in red meat slaughterhouses compared with the results obtained when using the non-destructive technique. In the red meat slaughterhouse visited sampling for *Enterobacteriaceae* and Aerobic colony count was carried out using the excision technique.

The official control staff in Abruzzo (in one of the AUSLs) met on the spot mentioned that controls at establishment level verify only if the FBO uses an accredited laboratory, not if the method complies with the requirements of the Regulation.

The reports seen following official controls did not include checks over the FBO sampling. Official controls in relation to testing methods were documented only in a few cases (see chapter 5.24). No evidence was available in relation to the testing methods in the sprouting seeds FBO (in Tuscany).

Reduced sampling units (n=1 instead of n=5) for testing both food safety and process hygiene criteria were used at the time of the FVO audit in one of the dairy establishments (in Tuscany) in the absence of documented justification. Only recently the FBO started to sample five units and to the date of the FVO AT visit only in one type of cheese. In the other dairy establishments the test results indicated only one test result per sampling session instead of five.

The sampling procedure in the white meat slaughterhouse did not take into consideration the *Salmonella* status in the flock of origin as required by the Regulation.

The test methods for *Listeria* and *Salmonella* in the dairy establishment in Abruzzo could not be demonstrated to be those required by the Regulation (the test results in the accreditation certificate made reference only to the internal Standard Operating Procedure of the laboratory).

Conclusions

Official controls over compliance with the Regulation's requirements for the sampling and testing

methods used by the FBOs were in most cases either not carried out at establishment level (Abruzzo), not documented to have been carried out (eg Veneto, Emilia Romagna) or did not identify non-compliances (eg. Tuscany).

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 852/2004 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.

Article 8.3 of Regulation (EC) No 882/2004 requires that CAs have procedures in place to verify the effectiveness of official controls. Article 4.6 of this Regulation requires the CA to carry out internal audits or to have external audits carried out.

Findings

Official controls in all Regions visited are carried out with a risk based frequency (except in the sprouted seeds plant), established annually by the AUSL for each FBO, taking into consideration the risk profile of each operator. The risk profile of each operator is established using the criteria defined in the regional legislation. The frequency of inspection decided at AUSL level was followed in the establishments visited (except for the sprouted seeds establishment where the frequency was not defined until prior to the FVO AT visit - see observations) and additional targeted inspections were also carried out.

Controls over FBOs' compliance with the Regulation are carried out by AUSL official control staff and site-based official veterinarians (OVs) as part of controls over FBOs' own control system and/or as targeted controls on the provisions of the Regulation. The procedures and checklists for the control over FBOs' HACCP based procedures and the compliance with the Regulation were in most cases used with the frequency established in the control plan.

The determined frequency of inspection in the cases assessed varied between the different types of commodities, regions and AUSLs. In Emilia Romagna the defined frequency in one AUSL was once every two or three years (and not for all aspects of the checklist) in registered establishments evaluated as posing a low risk, once per year in another AUSL for a registered RTE unpasteurised juices establishment. In the egg product establishment in Veneto and in the slaughterhouses visited in Emilia Romagna and in Abruzzo daily presence of OVs was ensured and annual AUSL audits were carried out. In the dairy establishment in Tuscany and Abruzzo the decided frequency was once per year. In Tuscany additional targeted inspections were carried out as well (24 such visits were carried out in the establishment visited in 2012). In the fishery establishment the OV presence was monthly for targeted control activities while the audit frequency was not decided. In most cases compliance with different elements of Regulation (EC) No 2073/2005 was scheduled to be checked from a few times a month to once or a few times per year in establishments producing FAO, once a year or once every few years in establishments producing FNAO, in accordance with the determined risk. These determined frequencies were in general in line with the regional guidance.

Audits were carried out by the AUSL at establishment level with a yearly frequency in Veneto, Emilia Romagna, one of the AUSLs visited in Tuscany and Lazio. In Abruzzo the AUSL are required to perform a minimum of 10 audits per year in the FAO sector and 5 per year in the food of non-animal sector.

Verification audits (provided for by Article 4, paragraph 6 of Regulation (EC) No 882/2004) of the general performance of the AUSLs were carried out by the regional level in Veneto, Emilia Romagna and in Abruzzo where this aspect was assessed. Examples of both system audits and sectoral audits carried out by the regional level were seen in Emilia Romagna and in Abruzzo. A targeted series of audits (provided for by Article 4 of Regulation (EC) No 854/2004) carried out between 2009 to 2011 in slaughterhouses in Emilia Romagna also included verification of compliance with the requirements of Regulation (EC) No 2073/2005.

The provisions of the Regulation are part of the scope of the audits carried out by central level in

the Regions . An overview on such audits carried out in recent years by the central level was presented to the FVO AT.

Observations

One of the AUSLs in Tuscany failed to ensure their control responsibilities in the establishment producing sprouting seeds. The local CA carried out the first and only control in the establishment a few days prior to the FVO visit and suspended the production. The establishment was registered since 2010 and during the FVO visit, indication of illegal production of other types of food were present. Many of the requirements of Regulations (EC) No 852/2004, (EC) No 2073/2005 were not fulfilled. The regional CA took note of the concerns of the FVO AT and drafted a procedure for the registration of establishments to be followed in similar cases when no access to the establishment had been possible.

In one of the AUSLs in Abruzzo the verification audits carried out by the AUSL did not include the evaluation of the OV performance in the plants. In the other AUSL in Abruzzo, audits (provided for by Article 4 of Regulation (EC) No 854/2004) only started to be carried out in 2012 and up to the time of the FVO audit not all establishments under the specific AUSL supervision had been audited, nor was an audit frequency defined. In Lazio, although the regional form for verification over the OV compliance, includes the effectiveness of controls, in the AUSL visited, the form was shortened and this aspect removed.

In three of the Regions (Tuscany, Abruzzo, Lazio) the regional procedures for the organisation of controls consisted of the guidelines issued by the CCA. In these cases the weight given to the reliability of FBOs' own checks and history of compliance does not change the frequency of inspection for large establishments with good compliance history when severe non-compliances are identified.

Conclusions

The system for organising official controls largely takes into account Article 3 (1) of Regulation (EC) No 882/2004, but gives little weight to relevant risk factors, resulting in potentially not achieving the objectives of Regulation (EC) No 882/2004. Official inspections are carried out with the scheduled frequency and using the allocated checklists.

The system for official controls over food safety and process hygiene criteria as required by the Regulation varies between the different Regions and also within the Region between the commodities concerned in terms of level of detail and effectiveness. Compliance with the Regulations was not always ensured.

The controls carried out on raw milk criteria compliance in the dairy establishments visited in Abruzzo and Tuscany were not in line with the requirements of Regulation (EC) No 854/2004. The organisation of controls in the sprouted seeds sector in Tuscany was not satisfactory.

Systems for audit provided for by Article 4 of Regulation (EC) No 854/2004 and for the verification of effectiveness of official controls are in place but are not fully implemented.

5.5.1 Official sampling and testing

Findings

Official monitoring and verification plans in relation to the relevant microbiological criteria of the Regulation and other microbiological parameters are designed either at regional level (for FNAO, in all Regions visited by the FVO AT, for FAO in four of the five regions visited) or at local level

(for FAO in Abruzzo). According to the CCA, in other Regions not visited by the FVO AT the sampling programs are decided at local level as well. In all Regions implementation is carried out by local level official control staff.

When the plans are designed at regional level, the allocation of a number of samples for the different commodities per AUSL, the parameter to be tested and the place of sampling (production and distribution) is decided at regional level. The AUSLs allocate the specific samples to be taken for each FBO.

In all Regions the plans considered mainly the food safety criteria and to a higher extent, FAO matrixes. While in Veneto only foodstuffs produced in the Region were included in the sampling plan, the equivalent of this plan in Abruzzo included also foodstuffs not produced in the Region.

In all but one of the establishments visited official sampling activities have been carried out during recent years and were scheduled for 2013. In Veneto the level of implementation of the plan indicated that additional samples have been taken outside the plan in the FAO sector, while less samples were taken of pre-cut fruits and vegetables sector. According to the CCA sampling in the existing sprouting seeds establishment in the Region took place in recent years outside the sampling plan (not initially scheduled, but carried out). In Emilia Romagna numerous additional samples outside the plan have been taken both in FAO and non-animal origin. In the same Region, although not considered in previous years, sprouted seeds were included in the sampling plan for 2013. Only a small number of non-compliant test results were identified in each of the cases assessed.

The number of samples scheduled to be taken and tested for microbiological criteria varied between the Regions from thousands each year (eg 2 992 samples taken in Veneto in 2012, 3 449 in Emilia Romagna for the years 2010 to 2011 and 2 117 scheduled for the years 2012 to 2013, 2164 planned for 2013 in Tuscany) to hundreds in Lazio for FAO (388 per year scheduled for 2011-2014) to dozens for FNAO in Abruzzo (56 scheduled in 2013).

There are no national monitoring or verification plans in Italy as this is considered a regional task.

Observations

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.

Despite the 2011 outbreak in Germany no official sampling was carried out in the sprouted seeds establishment visited.

Conclusions

Official microbiological verification and monitoring plans are in place in all the Regions visited. They include mainly the food safety parameters of the above mentioned Regulation and to higher extent FAO. Evidence of official sampling was available to the FVO AT in most establishments visited.

5.5.2 Controls over HACCP based procedures

Findings

Controls over FBOs' HACCP based procedures are planned to be carried out by AUSL official control staff and plant based official control staff during controls over the FBO's own control plan in accordance with an annually established frequency (in most cases once per year) and using

dedicated check-lists and procedures.

All establishments visited had implemented HACCP based procedures. These procedures included in most cases the validation and verification of the HACCP based procedures with the application of the microbiological criteria set out in the Regulation and additional ones. This was the case also in the establishment producing un-pasteurised juices using the high hydrostatic pressure technology.

Observations

In the establishments visited the CAs' controls over HACCP-based procedures were carried out with the planned inspection frequencies and in most cases covered relevant aspects, but in general only to a small extent compliance with specific provisions for the Regulation. In one dairy establishment, no evidence was seen in recent reports that during the controls the OV covered the HACCP-based procedures.

The FVO AT identified the following non-compliances not previously identified by the CA:

- In a few cases inaccuracies in the written procedures were noted on the limits of some parameters (eg milk pasteurisation at 66°C). The monitoring of certain control points and critical control points was not carried out or not sufficiently documented: (eg. functioning of by-pass valve at 80°C in the egg products establishment, temperature records). In a dairy establishment it was stated that the control of pH was carried out on the arrival of each truck but it was not recorded and no written procedure was not laid down for this purpose. In the smoked fish establishment the documented procedures indicated “presence in 25 g at production level” for *L. monocytogenes* as the action limit. In reality, such results during the slicing step (in the fish trimmings) did not trigger any action for the rest of the production, unless the count was higher than 10cfu/g, or an analysis of HACCP based procedures.
- In most of the establishments for which the frequencies of sampling and testing are not defined by the Regulation, the frequencies were not established in the context of the FBO's procedures based on HACCP principles.
- The HACCP based procedures in the sprouted seeds establishment were not adapted to the specificity of the establishment and not implemented correctly. In addition, these procedures did not take into consideration the requirements of the Regulation. No sampling plan was in place.
- Product specifications for the incoming fresh, cooked and frozen ingredients were not determined in the sushi producing establishment although these incoming products became RTE final products without treatment.
- In the smoked fish establishment the salting time was not considered as a parameter to be controlled to ensure that sufficient treatment was achieved to manage the evaluated risk in the CCP. For certain steps in the production of the smoked fish, process validation was not carried out. The time the product is kept frozen after smoking (according to the FBO would be in general approximately 12 months, depending on the availability of the customers), before slicing and packing was not defined nor was its impact on the shelf-life of the product analysed.
- The procedure for action in case of non-compliant test results was in most of the cases either not documented, not reflecting the reality, not differentiating between food safety and process hygiene non-compliances, not including the root cause analysis or changes in the HACCP based procedures.
- In both dairy establishments, visited by the FVO AT in Tuscany and Abruzzo, which were

producing both fresh and matured cheeses, the FBO could not demonstrate that procedures were in place to ensure that the raw milk used was in compliance with the criteria required by Annex III, Section IX, Chapter I, Part III of Regulation (EC) No 853/2004. Testing for the presence of antibiotics was not carried out at arrival and not included in the HACCP based procedures. In one of these establishments it was considered sufficient to carry out testing for inhibitors once per year as part of FBO's monitoring plan. In the other establishment the official residue monitoring plan was considered by the CA as sufficient. The latest evidence of controls in relation to raw milk criteria in the latter establishment was in 2010 although official control staff were present on average twice per month in the establishment.

- According to the information provided by the CA, an inter-professional laboratory was testing the milk from the affiliated farms twice per month and made the results available on their on-line database to the FBO and the AUSL. However, if the rolling geometrical averages of total bacteria counts (TBCs) and somatic cells are higher than the limits established by Regulation (EC) No 853/2004 there was no procedure in place to actively inform the farmer, the FBO or the CA. The CA could not provide evidence of a procedure for action to be taken and no evidence was seen of action taken in such situations. The FVO AT received and evaluated the results for three bovine dairy farms where the plate count and somatic cell counts were regularly high above the limits. Although the calculated rolling geometrical averages of plate counts and somatic cell counts were above the limits for several months (up to 18 months) no evidence was provided, although requested, of any action taken by the CA, nor that the delivery of such milk was suspended or that other action was taken to protect public health.
- The OV in charge of the official control in one dairy was not aware of the values of the requirements for raw milk and no evidence was seen of controls on this issue. It was considered that if the farmers declare the milk as compliant (self-certification) this has a legal value and at establishment level verification testing once per year is adequate.
- Following the audit DG(SANCO)2010-8502 a recommendation was issued to *ensure that the CA monitors the check on raw milk carried out in accordance with Annex III, Section IX, Chapter I, Part III of Regulation (EC) No 853/2004 as required in Annex IV, Chapter II of Regulation (EC) No 854/2004,*” (Recommendation No 11) which according to the findings above cannot be considered to have been addressed in Tuscany and Abruzzo.¹

During the final meeting the CCA stated that the non-compliance related to raw milk criteria in Abruzzo was identified by a recent audit performed by the CCA (report currently being drafted).

Conclusions

Although all FBOs visited had HACCP based procedures in place and were mostly testing for the relevant parameters of the Regulation, their HACCP based procedures in general did not fully integrate the provisions of the Regulation in terms of establishing the frequency of testing and taking action in case of non-compliant test results.

Significant deficiencies were identified in the controls of the dairy sector (compliance with raw milk criteria in Regulation (EC) No 853/2004 could not be demonstrated to be ensured) in Tuscany

¹ In their response to the draft report the Regional CA of Abruzzo noted that for the direct sale of raw milk, the control channel is followed (authorisation, own control and microbiological control). The non-compliance identified by the FVO AT refers to the official control over raw milk intended for processing establishments. An official control report with the action taken by the CA in July 2013 in the dairy establishment visited by the FVO AT was received from the Regional CA in Tuscany.

and Abruzzo and the monitoring by the CA of the checks carried out by the FBOs was not carried out as required by Annex IV to Regulation (EC) No 854/2004. The related official controls were not adequately documented in most cases - in particular in relation to the raw milk criteria non-compliances which had not been detected by the CA

5.5.3 Controls over FBOs' compliance with food safety criteria

Findings

The controls over FBOs' compliance with food safety criteria are considered part of controls over FBO's own control plan for microbiological testing.

In most establishments visited by the FVO AT sampling and testing plans for the relevant food safety criteria were in place and largely satisfactory with regard to the parameters and limits applied. The test results seen were in most cases satisfactory.

Observations

The reports following official controls seen by the FVO AT in most establishments visited included reference to the adequate FBO's own control records or sampling plans. Nevertheless most reports seen did not clearly specify that FBO's compliance with the food safety criteria was checked to the detail required by the Regulation.

The FVO AT noted the following non-compliances which have not been identified by the CA:

- In the sprouted seeds establishment, no testing was carried out for food safety criteria.
- In the dairy establishment in Abruzzo, two cheese categories were not tested. Testing of these products was only planned for 2013. In the same establishment producing both fresh and ripened cheeses no procedure was in place to test for enterotoxins when the Coagulase-positive staphylococci level exceeded 10^5 cfu/g.
- 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. Nevertheless, in the fishery establishment a limit of less than 10 cfu/g was used at production level although not demonstrated that the 100cfu/g limit will not be exceeded in the final product by the end of the shelf-life (see chapters 5.5.2 and 5.5.7).
- Non-compliances in relation to sampling units and methods have been described in chapter 5.4, in relation to design of the sampling plan and action for non-compliant test results in Chapter 5.5.2.

Conclusions

The control system in place for checking FBO's compliance with food safety requirements in the Regions visited was implemented largely satisfactory in most cases assessed in terms of tested parameters and acceptability limits. The documentation of controls could not demonstrate that all the relevant details required by the Regulation are checked. Most FBOs visited tested for the relevant food safety criteria. In a few cases non-compliances related to lack of sampling, testing methods and procedures for taking action in case of non-compliant test results were not detected by the CA.

5.5.4 Controls over FBOs' compliance with process hygiene criteria

Findings

The controls over FBOs' compliance with process hygiene criteria are considered part of controls over FBO's own control plan for microbiological testing.

In most establishments visited by the FVO AT sampling and testing plans for the relevant process hygiene criteria were in place and largely satisfactory with regard to the parameters and limits applied. The test results seen were in most cases satisfactory.

Observations

The reports following official controls seen by the FVO AT in most establishments visited in general documented checks over FBO's own control records or sampling plans, although not clearly specified that FBO's compliance with process hygiene criteria was checked or ensured to the detail required by the Regulation. No mention was made of controls over the sampling carried out by the FBOs, not even in the slaughterhouses.

The FVO AT noted the following non-compliances which have not been identified by the CA:

- In one of the dairy establishments some of the cheese categories were not tested for Coagulase-positive staphylococcus, while two cheese categories were not tested at all. In the other dairy establishment no testing for coagulase-positive staphylococcus was carried out, only for enterotoxins.
- Non-compliances in relation to sampling units and methods have been described in chapter 5.4 and in relation to action for non-compliant test results in chapter 5.5.2

Conclusions

The control system in place for checking FBO's compliance with process hygiene criteria in the Regions visited was implemented largely satisfactory in most cases assessed in terms of tested parameters and acceptability limits. The documentation of controls could not demonstrate that all the relevant details required by the Regulation are checked. Most FBOs' visited tested for the relevant parameters. In a few cases non-compliances related to lack of sampling, testing methods and procedures for taking action in case of non-compliant test results were not detected by the CA.

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

Findings

The majority of FBOs visited were carrying out testing to verify cleaning and disinfection. Also environmental testing for *L. monocytogenes* was carried out in most cases by FBOs manufacturing RTE foods able to support its growth.

Observations

The reports following official controls seen by the FVO AT in most establishments visited did not clearly specify that controls over sampling and testing of processing areas and equipment (especially for *L. monocytogenes* when manufacturing ready-to-eat foods) were carried out. No such testing was carried out in the establishment producing sprouted seeds with a six day shelf-life.

In the dairy establishment in Abruzzo verification of efficiency of cleaning and disinfection by sampling and testing was carried out only once a year.

Observations in relation to control procedures for sampling and testing of processing areas and equipment and documentation of controls have been described in chapter 5.2.4.

Conclusions

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

5.5.6 Controls over alternative sampling and testing procedures

Findings

The FBOs in the sectors evaluated used alternative testing methods for food safety and process hygiene criteria. In most of the cases these were demonstrated to be validated methods against the reference methods in the Regulation (see chapter 5.4).

Observations

Official controls over the alternative sampling and testing methods used by the FBOs were in most cases either not carried out at establishment level (Abruzzo), or not documented (eg Veneto, Emilia Romagna) or did not identify non-compliances (Tuscany) - see chapter 5.4.

In general, the official control staff met considered that if the method used for FBO own testing was accredited, compliance with the Regulation was ensured. The test results seen in the dairy establishments and the relevant accreditation certificates did not allow this conclusion to be drawn.

Conclusion

There is no system in place to control the use of alternative sampling and testing procedures at establishment level. In practice such controls were in most cases either not carried out or not documented. Nevertheless, FBO compliance was ensured in most cases assessed by the FVO AT.

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

Findings

In most establishments visited by the FVO AT the shelf-life of the products was established based on experience, historical data and by checking the sensory and microbiological quality of the products at the end of the shelf-life after storing the product at higher temperatures than were indicated on the label, aiming at taking into consideration the foreseeable storage and distribution conditions of the product. None of the establishments visited had used challenge studies as a tool to establish the shelf-life. Predictive modelling was seen in two cases.

Analyses over trends were available either in the form of graphs or as oversights in relation to process hygiene criteria in the establishments where this aspect was checked by the FVO AT.

Observations

CA controls with regard to FBOs' shelf-life studies were documented in most cases while this was not the case for controls over analyses of trends.

No tests at the end of the shelf-life were carried out in the sprouted seeds establishment which allocated the six days shelf-life based on organoleptical observations made after keeping the final

product refrigerated.

In the fishery establishment visited by the FVO AT, producing RTE smoked fish supporting the growth of *L. monocytogenes* (high aw and pH in the final product), the shelf-life-study available did not demonstrate that the limit of 100cfu/g will not be exceeded throughout the shelf-life when less than 10cfu/g is found at production level (which was the limit applied in practice). The 45 days shelf-life defined in FBO procedures was extended for up to 60 days, according to customers' demands. The 60 days shelf-life was not supported by the existing study which concluded that 'it was reasonable to state that the food safety criteria are respected throughout the shelf-life in respect of storage at 0-4C and consumed before the end of the 45 day shelf-life'. In the shelf-life study the storage temperatures were not clearly indicated in order to demonstrate that the foreseeable conditions for storage and distribution were taken into consideration. The CA considered the shelf-life study was satisfactory.

Conclusion

The system of official controls over the FBO's compliance with the shelf-life studies requirements was with few exceptions largely satisfactory while in relation to trend analyses in most cases it could not be demonstrated such controls were carried out. Most of the FBOs visited did not use all the tools stipulated in the Regulation to establish the shelf-life of the products and, in one case, the existing study did not support the practice taken by the FBO in relation to the shelf-life of the its products.

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

Findings

According to the information provided by the CCA, in Italy, the private laboratories performing analysis on behalf of the FBOs (except for in-house laboratories performing testing only for own plant) must be accredited as required by the Agreement between the State, Regions and the Autonomous Provinces pursuant to Article 40, paragraph 3 of Law No 88 of 7 July 2009.

According to the information provided by the CCA some regional CAs carry out audits on private laboratories, other Regions are starting to develop verification plans. This was not the case in the Regions visited by the FVO AT. In the Emilia Romagna Region a new check-list was recently drafted for checks in relation to the laboratories used by the FBO, including those in-house.

The regional CAs visited maintained a list of accredited laboratories and made it available to the AUSLs. This information is also available on Accredia website. The laboratories used by the FBOs visited by the FVO AT were in most cases accredited (see chapter 5.3.1).

Observations

No requirements are in place for in-house private laboratories performing testing only for own plant. The reports of official controls at establishment level in general did not include the supervision of in-house laboratories.

The official controls system in relation to the methods used by the laboratories is not fully adequate (see chapter 5.4).

Conclusion

The official controls on the laboratories used by the FBOs were largely adequate except for controls related to the methods. In-house non-accredited FBOs' own laboratories are not subject to controls.

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

The red meat establishment visited which was also producing minced meat, meat preparations and meat products intended to be eaten cooked was labelling its products in order to inform the consumer of the need for thorough cooking prior to consumption.

The procedures and check-lists used for performing official controls in such establishments do not include checks for compliance with the labelling requirement in the Regulation in the Regions of Veneto, Emilia Romagna, Abruzzo and Tuscany where this aspect was assessed. Such controls were not documented to have been carried out in the establishment visited.

Conclusion

Although the labelling requirements of Article 6 of the Regulation were complied with at establishment level, the CAs could not demonstrate that official controls had been carried out over FBOs' compliance with these requirements due to the absence of relevant documentation.

6 OVERALL CONCLUSION

The official controls system in relation to the implementation of the Regulation (EC) No 2073/2005 at FBO level varies between the different Regions, local units and types of commodities in terms of level of detail, documentation of controls and effectiveness. The implementation of this Regulation as regards testing for the relevant parameters was mainly satisfactory in most of the establishments visited. A few deficiencies have been identified in relation to the official control activity over sampling and testing procedures and FBOs' own controls plans.

Significant deficiencies were identified in the controls of the dairy sector (compliance with raw milk criteria could not be demonstrated to be ensured) in Tuscany and Abruzzo. In Tuscany the overall organisation of controls was found to be unsatisfactory in relation to sprouted seeds.

The designated NRLs have taken on their duties to different degrees and mainly in relation to laboratories within the IZS network. No system of NRL coordination of the laboratories in the other two networks is in place, nor within the ARPA and LSP networks to this regard. The official monitoring or verification plans in relation to the relevant microbiological criteria in the framework of Regulation (EC) No 2073/2005 are either regional or local. The plans assessed by the FVO audit team take into consideration mainly the food safety criteria provided by this piece of legislation and to a higher extent in food of animal origin matrixes.

7 CLOSING MEETING

A closing meeting was held on 7 June 2013 with representatives of the CCA. At this meeting, the FVO audit team presented the main findings and preliminary conclusions of the audit. The authorities provided clarification on 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 25 working days of receipt of this specific audit report.

N°.	Recommendation
1.	To complete the review of guidance documents in place in order to ensure that guidance is updated to include current legislative requirements of Regulation (EC) No 2073/2005.
2.	To ensure that documented procedures for the performance of official controls contain complete information and instructions for staff performing official controls in order to comply with Article 8(1) and Annex II, Chapter II of Regulation (EC) No 882/2004, in particular as regards the relevant requirements of Regulation (EC) No 2073/2005.
3.	To ensure that the relative significance of all provisions of Article 3(1) of Regulation (EC) No 882/2004 is taken into account when determining the risk-based frequency of official controls, so as to achieve the objectives of this Regulation.
4.	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, shelf-life studies, sampling frequency and sampling units for both food safety and process hygiene criteria.
5.	To ensure that reports following official controls over food business operators' compliance with Regulation (EC) No 2073/2005 are adequately documented and indicate the action which the operator is to take, as required by Article 9 of Regulation (EC) No 882/2004.
6.	To ensure that raw milk supplied to dairy establishments fulfils the requirements of

N°.	Recommendation
	Annex III, Section IX, Chapter I, Part III of Regulation (EC) No 853/2004 and that official controls on raw milk are carried out in conformity with Annex IV of Regulation (EC) No 854/2004.
7.	To implement procedures for audit and the verification of effectiveness of official controls in accordance with the requirements of Articles 4 of Regulation (EC) No 854/2004 and 8.3 of Regulation (EC) No 882/2004.
8.	To ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, in line with Article 3 (1) of Regulation (EC) No 882/2004 in the sprouted seeds sector, in all regions and in particular in the region where the sprouted seeds establishment visited during the audit is located.
9.	To ensure that all designated NRLs perform their co-ordination duties as required by Article 33, point (2) letters b) and c) of Regulation (EC) No 882/2004.

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=2013-6875

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
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

Legal Reference	Official Journal	Title
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