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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

ITALY

FROM 26 APRIL TO 07 MAY 2010

IN ORDER TO EVALUATE THE FOLLOW-UP ACTION TAKEN BY THE COMPETENT AUTHORITIES WITH REGARD TO OFFICIAL CONTROLS RELATED TO THE SAFETY OF FOOD OF ANIMAL ORIGIN, IN PARTICULAR MEAT, MILK AND THEIR PRODUCTS

IN THE CONTEXT OF A GENERAL AUDIT

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

This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Italy, which took place from 26 April to 7 May 2010, as part of the general audit of Italy carried out under the provisions of Regulation (EC) No 88de 2/2004 on official food and feed controls. This specific audit evaluated the follow-up action taken by the competent authorities (CAs) with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products.

No significant changes occurred in the structure of the CAs since the last FVO mission. Co-ordination and co-operation exist within as well as between, the CAs. The structure and organisations of all CAs should allow the application of the relevant requirements of Regulation (EC) No 882/2004.

O fficial controls are carried out regularly on a risk basis and with defined frequencies and control activities, methods and techniques are in use. However delays remain in the implementation of the action plan to improve the quality and consistency of official controls.

Significant effort was undertaken at central and some regional levels (with the exception of Sardinia) to address some of the recommendations made in the mission report DG(SANCO)/2008-7930, and to implement the Hygiene Package (HP) in a coherent way. A system of internal audits by the Central Competent Authority (CCA) in accordance with Article 4 of Regulation (EC) No 882/2004 is only partially in place as no sectoral audits referring to meat and milk are in place at central level. Instead the CCA is carrying out inspections in establishments. In 2009, the CCA identified during their inspections major noncompliances in 30% of the establishments and action was taken. No guarantees were provided that the 2010 inspection programme will be implemented by the CCA as planned. Audit programmes are in the initial stage of planning in some Regions, whilst in others a lack of staff seriously undermines the audit capability of regional services. The inspections by the CCA that were carried out in 2009, already showed some impact in some Regions. However, the planning for inspections in 2010 has not yet started as the Regions question the legal basis for the CCA to carry out inspections in the establishments based on the constitutional arrangements in Italy.

However, in a large number of establishments visited by the FVO these efforts did not result in compliance with European Union (EU) requirements. A very large number of recurring deficiencies already highlighted during previous FVO missions still remain, mainly because of non satisfactory enforcement. Three out of 10 establishments visited were not compliant with the general and specific hygiene requirements and in four others significant deficiencies in structure, installation and equipment, maintenance and cleaning, operational practices, slaughter hygiene, implementation of microbiological sampling and testing, Hazard Analysis Critical Control Points (HACCP) based systems were noted. In particular the situation in slaughterhouses and dairy establishments (in particular in Sardinia) indicated a poor performance of the CAs. The guarantees received concerning training were not consistently implemented and training already provided often had no practical impact on the performance of official veterinarians (OVs) in the field.

Identification marking and labelling and traceability systems were in general, with some exceptions, in line with the legal requirements. The Food Chain Information (FCI) is in place for all species. Deficiencies in relation to post-mortem examinations, the application of the health mark and animal welfare requirements were seen.

Testing of raw milk and the monitoring by the CA of the checks carried out by the food business operators (FBOs) is done correctly in two Regions visited. However in Sardinia the quality of the raw sheep and goat milk and the monitoring by the CA is not in compliance with the relevant Community requirements. The nature of the non-compliances and their incidence, identified by the CCA during their audits in the Regions, are largely in line with the findings of the FVO team during this mission. It is therefore concluded that the implementation of the HP is not guaranteed in all establishments in Italy in a coherent way.

The report makes a number of recommendations to the Italian CAs, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation		
ABP	Animal By-products		
ASL	Local Veterinary Units (Servizi Veterinari delle Aziende Sanitarie Locali)		
AUSL	Local Health Units (Azienda Unità Sanitarie Locale)		
CA	Competent Authority		
ССР	Critical Control Point		
CCA	Central Competent Authority – Department of Veterinary Public Health, Nutrition and Food Safety (Dipartimento par la Sanita Pubblica Veterinaria, la Nutrizione e la Sigurezza degli Alimenti)		
CSR	Standing Conference between State and Regions (Conferenza Stato/Regioni)		
DG(SANCO)	Health and Consumers Directorate-General		
DGSA	General-Directorate for Animal Health and Veterinary Drugs (<i>Direzione Generale Sanità Animale e Farmaco Veterinario</i>)		
DGSAN	General-Directorate for Food Safety and Nutrition (Direzione Generale Sicurezza Alimenti e Nutrizione – DGSAN)		
DSPVNSA	Department of Veterinary Public Health, Nutrition and Food Safety (Dipartimento della Sanita Pubblica Veterinaria, la Nutrizione e la Sigurezza degli Alimenti)		
EC	European Community		
EU	European Union		
FBO	Food Business Operator		
FCI	Food Chain Information		
FVO	Food and Veterinary Office		
HACCP	Hazard Analysis Critical Control Points		
HP	Hygiene Package		
ICQRF	Central Inspectorate for Quality Controls and Antifraud of Foodstuffs and Agricultural Products		
IZS	Network of Official laboratories (Instituti Zooprofilattici Sperimentali)		
MANCP	Single Integrated Multi-Annual National Control Plan		
NAS	special body of the Army with sanitary inspectors (Carabinieri N uclei A ntisofisticazioni e S anità)		
RASFF	Rapid Alert System for Food and Feed		
Regional Authorities	Regional Competent Authorities – Regional Public Health Services (Servizi di Sanità Pu lica delle Regioni)		

SCC	Somatic Cell Count
TPC	Total Plate Count

1 Introduction

The Specific Audit formed part of the FVO's planned mission programme. It took place in Italy from 26 April to 7 May 2010. The audit team comprised two inspectors from the FVO. Representatives from the CCA, the Department of Veterinary Public Health, Nutrition and Food Safety (*Dipartimento della Sanita Pubblica Veterinaria*, *la Nutrizione e la Sigurezza degli Alimenti* (DSPVNSA)) accompanied the FVO team for the duration of the audit. An opening meeting was held on 26 April 2010 with the CCA. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit team and the control systems were described by the authorities.

2 ORIECTIVES OF THE MISSION

The **objectives** of the Specific Audit were to:

- verify that official controls are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by Italy
- evaluate the follow-up action taken by the CA in response to the recommendations made in the report DG(SANCO)/2008-7930 with regard to
 - CA organisation and operation,
 - official controls over FBOs' compliance with general and specific rules on the hygiene of food of animal origin.

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

- Regulation (EC) No 882/2004, the organisation of official controls (Articles 3-7,) control and verification procedures and methods (Articles 8-10), enforcement (Articles 54-55), and MANCP (Articles 41-42); and registration and approval of establishments (Article 31).
- the specific area under review and in the framework of Regulations (EC) No 178/2002, No 852/2004, No 853/2004 and No 854/2004, the controls over meat of domestic ungulates, minced meat, meat preparations, meat products, raw milk and dairy products.

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

MEETINGS/VISITS		n	COMMENTS
COMPETENT	Central	1	Initial and final meeting
AUTHORITIES	Regional	3	Official at regional and local level (Calabria, Liguria and Sardinia) were met in the establishments visited.
SLAUGHTERHOU	SES	3	
MEAT ESTABLISHMENT	PRODUCTS S	1	
CUTTING PLANTS	8	2	
MINCED PREPARATIONS	MEAT:MEAT	1	

MEETINGS/VISITS	n	COMMENTS
DAIRY ESTABLISHMENTS	4	One collection centre and 3 dairy establishments

3 Legal Basis for the Mission

The mission was carried out under the general provisions of Community legislation, and in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

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

4 BACKGROUND

4.1 CONTRIBUTION TO THE GENERAL AUDIT

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in Member States. The main purpose of such audits is to verify that, overall, official controls take place in Member States in accordance with the MANCPs referred to in Article 41 and in compliance with Community law.

This Specific Audit was carried out as a component of a General Audit to Italy. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

4.2 Summary of Previous FVO mission results

The previous missions concerning the safety of food of animal origin in Italy were carried out from 4 to 15 June 2007 and 13 to 23 May 2008, the results of which are described in reports DG (SANCO)2007-7435 –MR Final and DG(SANCO)2008-7930 – MR Final (hereafter referred to as report 2008-7930). These reports are accessible at:

http://ec.europa.eu/food/fvo/ir search en.cfm

The action plan received from the Italian CCA in response to the recommendations of report 2008-7930 provided unsatisfactory responses to all except one of the seven recommendations made.

The seven recommendations pertained to the lack of staff, the extension of audits of CAs at all levels, quality and consistency of official controls, identification and correction of deficiencies in establishments, post-mortem inspection, and HACCP based systems. The recommendations and a short summary of the CA response can be found under the relevant heading in this report.

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/country profiles en.cfm

5 Findings And Conclusions related to implementation of Regulation (EC) no 882/2004

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for official controls.

Findings

The CCA responsible for the areas covered by this FVO audit, is the DSPVNSA under the Ministry of Health (*Ministero della Salute*). Under the DSPVNSA, both Directorates-General are in charge of matters in the areas covered by this audit:

- General-Directorate for Animal Health and Veterinary Drugs (*Direzione Generale Sanità Animale e Farmaco Veterinario* DGSA)
 - Ufficio II Animal Health and Animal Identification
 - Ufficio VI Animal Welfare
 - Ufficio IX Audit responsible for the implementation of the general audit programme and to carry out systematic audits over the general organisation of the regional and local CAs
- General-Directorate for Food Safety and Nutrition (*Direzione Generale Sicurezza Alimenti e Nutrizione* DGSAN)
 - Ufficio III Hygiene of Products of Animal Origin responsible for official controls over the production of meat, milk, fishery products and animal by-products (ABP)
 - Ufficio VIII Food Chain Control and Alert System responsible for MANCP, contingency plans for food and feed and annual reporting.
- The Regional Public Health Services (*Assessorati alla Sanità*) include the Veterinary Services at regional level (19 Regions and 2 Autonomous Provinces) and are responsible for the management of animal and public health through the local level (*Servizi Veterinari delle Aziende Sanitarie Locali* ASL). This latter is organised into three areas: A-animal health, B-public health and C-hygiene of farming (with competence on milk processing establishments).
- A special section of the Army (*Carabinieri Nuclei Antisofisticazioni e Sanità* NAS) functionally depending on the Ministry of Health, has 1 096 specialised staff with the powers of sanitary inspectors, distributed between three Inter-regional groups and 38 nuclei with competence at regional or inter-provincial levels.
- According to Legislative Decree No 123/1993, analyses on official samples shall be performed by the laboratories of the ASL, of the Experimental Zooprophylaxis Institutes (*Istituti Zooprofilattici Sperimentali* - IZS) and other public laboratories.

5.1.2 Co-operation between Competent Authorities

Legal Requirements

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

Findings

Co-operation between the CCA and the regional services is carried out by meetings within the Inter-Regional Committee for Food Safety, which meets once a month to discuss technical topics; once approved, documents are forwarded to the *Conferenza Stato/Regioni* (CSR) for the political approval and are furthermore transposed into the regional law. Between 2006 and 2009 several documents concerning the hygiene package have been adopted by this procedure, e.g. guidelines on traceability, HACCP-based procedures, hygiene rules based on Regulations (EC) No 852/2004 and No 853/2004, official controls for *Trichinella* and the adoption of the MANCP 2007-2010. The results and reports of FVO missions were also discussed.

Concerning the implementation of the CCA's programme of audits/inspections over the Regions, the discussion on the competence on food safety (shared between the CCA and regional CAs according to the Law No 833/1978 and Legislative Decree No 502/1992) has delayed the implementation of the audit/inspection programme for 2010 (see 5.5.2). Regional representatives consider the sectoral audits as inspections of establishments processing food of animal origin (the exclusive competence of the regional services), while only verification of compliance with the national and Community legislation by means of audits on the control systems should be carried out by the CCA.

Every year, the Regions must send the CCA the report of the annual control activities and their results; this information is used to draft the annual report on the implementation of the MANCP.

In addition, Regions must send the report of their audit activities by 28 February of each year to Office IX; however, three Regions (Basilicata, Sicilia and Puglia) have not yet sent the requested data to the CCA.

Evidence of letters exchanged between the CCA and the Ministry of Agricultural, Food and Forestry Policies was seen with regard to the recent case of mozzarella cheese adulteration. Samples were taken by the Central Inspectorate for Quality Controls and Antifraud of Foodstuffs and Agricultural Products (ICQRF) showing adulteration by the addition of cow raw milk to the buffalo milk; no risk for human health was identified.

At CCA level extensive technical training has been provided to the NAS staff.

5.1.3 Co-operation within Competent Authorities

Legal Requirements

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

Findings

At CCA level extensive technical training has been provided to the NAS staff.

In Calabria and Sardinia, meetings were held by the Regional Veterinary Service with staff of the ASL in order to harmonise controls and to discuss organisational issues.

Some Regional Veterinary Services (e.g. Piemonte) have well built websites in which legislation, guidelines, press releases and other useful information can be consulted.

Within the Veterinary Service of the ASL, different staff (areas "A", "B" and "C") are responsible for controls on animal and public health. During visits in the milk processing establishments, the mission team saw that OVs in charge of supervision could get information on the health status of the dairy holding by consulting the national database for animal identification (in which data about the tests are uploaded by the relevant Veterinary Services of Area A), or were authorised to access on line the database of the Inter-professional laboratories in charge of the controls of raw milk criteria, or have been authorised by the farmers supplying raw milk to receive the certificate of the health status of the herd directly from the Veterinary Services of Area A.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

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

Findings

No official tasks have been delegated to any control bodies in the area covered by this FVO audit.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that CAs have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

Drafting of the National Contingency Plan is the responsibility of Office VIII of DGSAN. The Act 6/CSR of 24 January 2008 was adopted by the Standing Conference between State and Regions (*Conferenza Stato/Regioni (CSR)*) to implement the contingency plan for food and feed; on 15 May 2009 a Crisis Unit was set up, physically located at CCA headquarters (room AK 48) and supplied with an e-mail address. The CCA stated that similar Crisis Units are also set up at regional and local levels. A database with the contact points at regional and local levels is currently under construction at CCA level.

A working group was created on 29 April 2010 to draft specific emergency programmes based on the updating of the existing ones.

A three days training on "Food safety emergency: procedures and management" for 100 participants is planned for May, including a simulation exercise.

Conclusions on Competent Authorities

No significant changes occurred in the structure of the CAs. Co-ordination and co-operation exists within as well as between the CAs. All responsibilities for official controls in establishments are delegated to the local level of the CAs. There are no control bodies in the area covered by this FVO audit. The National Contingency Plan for Food and Feed needs to be updated.

The organisations of all CAs should allow the application of the relevant requirements of Regulation (EC) No 882/2004.

5.2 Resources for Performance of Controls

5.2.1 Legal basis for controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on FBOs to undergo inspection by the CAs. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

Findings

There is an obligation on FBOs to undergo inspection by the CAs.

The national legislation assigns the powers for CAs to enter establishments, access documentation, implement enforcement measures and put in place necessary decisions and orders.

The Regions question the legal basis for the CCA to carry out inspections in the establishments based on the constitutional arrangements in Italy. (See also 5.5.2)

5.2.2 Staffing provision and facilities

Legal Requirements

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

Findings

Recommendation No 1 of the report 2008-7930 was to ensure adequate staffing in all CAs involved, in particular at regional level in order to comply with Article 4.2 of Regulation (EC) No 882/2004.

In their response the CA indicated that "...in order to guarantee adequate human resources an assessment of workloads will be made during 2008. All the necessary measures will be taken to overcome the legal and budget constraints that are currently hampering staff hiring. Moreover, all efforts will be made to solve the problem of the regional staff's legal and economical status within the National Health System. The present inequality has led to a gradual shift of human resources

from the regional services to the ASL". In February 2009 the CCA further clarified that "the resolution of the issue is to the attention of central and regional political authorities. Undersecretary of State discussed this issue in a meeting with the Regional Councillors of Health".

At CCA level an increase in staff was noted in all Offices; in particular, Office III now has six veterinary staff, all trained as auditors.

At regional level the staff situation had a negative effect on the official controls and was noticed in all Regions but one (Calabria). The inequalities in salaries still exist, leading to a continued shift of staff from the regional level to the ASL.

- In Calabria 13 staff are currently employed at the Regional Veterinary Service. In addition, following the entry in force of *Ordinanza Ministeriale* 14 November 2006, which foresees reinforced controls for tuberculosis, leucosis and brucellosis in Calabria, Sicily, Campania and Puglia Regions, 219 private practitioners have been contracted to perform diagnostic tests on all flocks in the regional territory, with the view of reaching the official free status for those diseases.
- In Sardinia only one veterinarian is in charge of the Public Health sector at the Regional Veterinary Service; this person moved to the ASL on 7 May 2010 and no replacement has been foreseen. Two officials are in charge of the Animal Health sector.
- In Liguria, one person is in charge of the recently created (2009) Regional Veterinary Service, while one veterinarian from one ASL is designated to assist the regional level. Three ASLs of the Region are currently recruiting a total of six veterinarians, allowing them in the future to reinforce the regional service on a temporary basis with one or two extra staff.

5.2.3 Staff qualifications and training

Legal Requirements

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

Findings

Recommendation No 6 of the report 2008-7930 was to ensure that post-mortem inspection in all slaughterhouses is carried out in compliance with the requirements of Regulation (EC) No 854/2004.

In their response the CA indicated that "the CCA will ask the regional authorities to organise specific trainings on ante- and post-mortem inspection in slaughterhouses for OVs. The Regions will adopt during 2009 a supervisory plan to verify the proper implementation of official controls in slaughterhouses, specifically focused on post-mortem inspection".

Evidence of some general training was provided in all Regions visited.

- In Calabria Region an ASL has been designated as "chef de file" for organising all regional trainings. Specific training on ante - and post-mortem i nspection was only provided in 2007 to 70 OVs.
- In the Liguria Region, the 2010 training on audit and inspection techniques attended by some staff of the ASL, has included ante- and post-mortem inspection in the programme.

• The Sardinia Region received financial resources for a training on ante- and post-mortem inspection in December 2009, however has not yet defined the training programme.

The FVO team found that training provided was often not reflected in the satisfactory performance in the field, especially with regard to animal welfare at slaughterhouses, evaluation of HACCP-based programmes and post-mortem inspection. (see also points 6.5.3 and 6.5.5)

At CCA level extensive technical training has been provided to NAS staff.

Conclusions on Resources for Performance of Controls

The CAs have the necessary legal powers to access food business premises and carry out official controls. Recruitment of additional staff is ongoing, however, in Liguria and Sardinia posts at regional level remain vacant.

The guarantees concerning training were not consistently implemented and training already provided had often no practical impact on the performance of OVs in the field.

5.3 Organisation and implementation of official controls

5.3.1 Registration / approval of food business establishments

Legal Requirements

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

Findings

The CA stated that all establishments (e.g. low capacity slaughterhouses) which needed an approval before the end of 2009 had been closed or approved (possibly granting to them derogations on certain structural requirements according to Act 115/CSR of 2007 – see 6.1) by this date. The FVO team visited one of these establishments (a former low capacity slaughterhouse) and found that not all requirements laid down in the Community legislation were fulfilled when approval was granted. In this case the CAs had not granted any particular derogations.

In the lists of establishments as published on the website of the CCA in some cases obsolete activities were still listed.

A computerised system (S.INTE.S.I. – Sistema INTE grato per Scambi e Importazioni) is accessible since 2000 at central and regional levels, supporting activities related to approval of national establishments. However, mistakes and delays in entering updated data are making it of limited use for planning control activities. The CCA transferred the competencies for approval of establishments to the Regions in 2001 and in 2007 requested officially to have S.INTE.S.I. updated within a short delay. In the Calabria Region this was done in 2009, with staff especially hired for this purpose, whilst in the Sardinia Region the process is currently on-going.

Approval files were available in all establishments visited, but major deficiencies were noted in individual establishments:

- In the Sardinia Region an establishment was approved as a milk collection centre only, although pasteurisation of raw milk was also carried out; the CA did not identify this activity during the approval visit or during subsequent routine supervisory visits.
- In one meat processing establishment of the Calabria Region parts of the premises already in use were not yet included in the approval.
 - 5.3.2 Prioritisation of official controls

Legal Requirements

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

Findings:

Recommendation No 1 of the report 2008-7930 was to ensure adequate prioritisation of food safety issues in all CAs involved, in particular at regional level in order to comply with Regulation (EC) No 882/2004.

In their response the CA did not address the recommendation, but indicated that "the CCA was preparing an inspection programme over the Regional CAs".

Categorisation of food processing establishments according to general criteria of risk assessment and setting of appropriate control frequencies were carried out in all Regions visited. The first evaluation was carried out between 2007 and 2009, with one establishment in Sardinia being categorised for the first time in April 2010. The assessment is updated yearly and documented evidence of such activity was seen in the establishments visited. Some mistakes in the evaluation of risk criteria might, in certain cases seen, undermine the reliability of the assessment.

Control programmes drafted at regional level included a check-list, report templates and models for notification of non-compliances and their follow-up. The set frequencies were generally followed and follow-up carried out when necessary by the AUSL.

5.3.3 Control activities, methods and techniques

Legal Requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

Guidelines on criteria set to identify non-compliances in food processing establishments (meat and milk sectors) and to verify the appropriateness of corrective actions put in place by the FBOs are currently in draft stage at CCA level, and not yet approved by the CSR. They include all possible examples of non-compliances to the HP and related applicable sanctions. In the response to recommendation No 4 it was announced that the guidelines would be ready by December 2009 and that from 2010 all CAs should consider these common criteria when revising registration

documents and procedures adopted.

5.3.4 Sampling and Laboratory analysis

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires CAs to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the CA to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Findings

Analyses on official samples are mainly carried out by the network of the official laboratories, IZS, with laboratory branches located in each Province; the CCA stated that all laboratories are accredited.

In the Calabria Region the CA stated that the *Trichinella* laboratories of some large pig slaughterhouses are in the process of being accredited by the national accreditation body ACCREDIA, and around another 20 medium sized slaughterhouses have investigated this option; currently the OVs are in charge of carrying out *Trichinella* examination, but it is foreseen that in the future this will be the task of the FBO, under official supervision. The Regional Veterinary Service had negotiated a preferential price per analysis with the three regional IZS for the remaining small slaughterhouses in activity in the Region.

5.3.5 Procedures for performance and reporting of control activities

Legal Requirements

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

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

Findings

The CAs have in general written instructions and check-lists covering the areas to be controlled, however, not yet based on the draft guidelines mentioned in point 5.3.3.

In all Regions visited specific check-lists were used for risk categorisation and audit/inspections. In addition, specific check-lists were implemented in the Liguria Region following an audit carried out by the CCA in March 2010, in order to audit animal welfare at slaughterhouses and post-mortem inspection.

A register containing a specific control plan was also available at establishment level in some Regions (Sardinia and Calabria). It contains a list of items to be controlled in this particular

establishment and eventually refers to a specific non-compliance form when deficiencies are identified allowing a follow-up of the corrective action and the closing-out of the non-compliance.

The FVO team noted that in most cases the documentation seen did not reflect the situation as seen in the establishments visited. In several cases, the CA did not identify or report significant non-conformities seen by the CCA and the FVO team during their respective audits.

The CAs stated that formal and detailed reports were produced only in cases of major non-compliances.

5.3.6 Transparency and confidentially

Legal Requirements

Article 7 of Regulation (EC) No 882/2004 requires that CAs carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

General audit reports, annual reports on control activities in the framework of the MANCP and rapid alerts notices are published on the website of the CCA. For confidentiality reasons reports of sectoral audits carried out by the CCA on the establishments are not published, but only made available to the CAs.

Conclusions on Organisation and Implementation of Official Controls

Some errors were identified in relation to the lists of approved establishments published on the CCA website. In addition, the computerised system in use is not fully updated on time by the CAs.

Official controls are carried out regularly on a risk basis and with defined frequencies in accordance with Article 3 of Regulation (EC) No 882/2004. The control activities, methods and techniques listed in Article 10 of Regulation (EC) No 882/2004 are in use. Official controls are mostly carried out in accordance with documented procedures as required by Article 8 of Regulation (EC) No 882/2004. However delays remain in the implementation of the action plan to address recommendation No 4 with regard to the quality and consistency of official controls and their reporting did not reflect in most cases the situation as seen in the establishments visited.

Trichinella testing is carried out in laboratories accredited or for which the accreditation process is on-going.

No clear procedure is in place to grant certain derogations to the FBOs on hygiene requirements.

The requirements of Article 7 of Regulation (EC) No 882/2004 regarding transparency and confidentiality are generally complied with.

5.4 Enforcement Measures

5.4.1 Measures in the case of non-compliance

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Findings

OVs and CAs have the power to impose measures to correct non-compliances and procedures and forms for the follow-up were available in most cases.

In case of suspected illegal activities, or when there is an immediate risk for human or animal health, the action taken can include assistance from the NAS or other Police bodies, and must be reported to the Attorney.

In several cases non-compliances were not identified in the establishments visited and subsequently the appropriate action was not taken by the CA and the FBO to remedy the situation.

During this audit, when non-compliances have been detected in the establishments visited by the FVO team, immediate action has been initiated by the regional and local CAs.

5.4.2 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

The legal framework for the administrative sanctions applicable for infringements of the requirements of the HP has recently been updated and it includes the following legal instruments:

- Legislative Decree 5 April 2006, No 190, which foresees sanctions of up to 12 000 € for infringements to Articles 18, 19 and 20 of Regulation (EC) No 178/2002;
- Legislative Decree 25 July 2007, No 151, which foresees fines of up to 20 000 € for infringements to Regulation (EC) No 1/2005 in the field of animal welfare during transport and loading/unloading;
- Legislative Decree 6 November 2007, No 193, which foresees fines up to 150 000 € (and in some cases also penal detention up to six months) for infringements to Regulations (EC) No 852/2004, 853/2004 and 854/2004;
- Legislative Decree 19 November 2008, No 194, which prescribes that additional costs for reinforced or additional official controls, in applications of Articles 14, 15 and 28 of Regulation (EC) No 882/2004, must be charged to the FBO concerned.

Evidence was seen that financial sanctions have been given in certain cases where major non-conformities have been detected.

It should be noted, however, that the CAs did not always take account of the nature of the non-compliance and the operator's past record with regard to non-compliance, as foreseen by Article 54 of Regulation (EC) No 882/2004. Thus, sanctions applied are often not graduated, proportionate or dissuasive as foreseen by Art. 55 of Regulation (EC) No 882/2004.

Conclusions on Enforcement Measures

The CA have the necessary powers to take appropriate action when non-compliances are identified. National legislation providing detailed rules on sanctions is in place in line with the requirements laid down in Article 55 of the Regulation. However, in several cases, the CA did not act appropriately when significant non-conformities were present. The sanctions applied were often not effective, proportionate or dissuasive as required by Article 55 of Regulation (EC) No 882/2004.

5.5 Verification and review of official controls and procedures

5.5.1 Verification procedures

Legal Requirements

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

Findings

With the exception of the audit/inspection system implemented by the CCA in 2009 and, partially, by the regional CAs, very limited verification on the performance of the OVs was seen and documented. In addition, these verifications failed to identify many of the existing deficiencies in the quality and effectiveness of the official controls.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 CAs are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

Recommendation No 2 of the report 2008-7930 was to extend action already initiated in order to fully implement the system of audits of CAs at all levels (as required by Article 4(6) of Regulation

(EC) No 882/2004).

In their response the CA indicated that the "CCA has already prepared an action plan in order to re-organise the Italian audit system on the Regional CAs, defining performance indicators, identifying available auditors at central level and planning all control activities of the CCA for 2009". In February 2009 the CCA further clarified that "the audit system in force is being re-organised to strengthen auditing activities. Sectoral audits will be carried out only by staff from the specific sector Office and specific training is being provided for staff of those different Offices".

During this audit the following observations were made in relation to audits:

• General audit system . 69 officials (including the six officials of Office III) of the different Offices of the CCA have been trained between April and May 2009 on auditing techniques, ISO norms and control procedures as specified in Annex II to Regulation (EC) No 882/2004. A specific chapter in the budget for 2010 has also been allocated in order to provide financial resources to the 2010 audit programme. Systematic audits are carried out on the general functioning of the regional CAs by Office IX, whilst no sectoral audits only inspections are performed by the Office responsible for the sector (Office III for the milk and meat sectors). It is planned to complete a first round of sectoral inspections on all Regions during a two year inpection cycle. regional CAs have to provide the CCA with a written follow-up until all the requested corrective measures have been taken.

• Implementation of the 2009 audit programme

- Office IX has carried out Systematic audits on the general functioning of one regional CA out of the four planned due to the lack of financial resources.
- Office III has not carried out audits but sectoral inspections in the field of red meat and milk processing in eight different Regions; out of 75 inspected establishments, the regional CAs were requested to suspend approval of 19 plants and withdrawal of another two. Moreover, a number of corrective measures were requested for some of the remaining establishments visited, and evidence of follow-up documentation was presented to the FVO team. Inspections of the rabbit meat sector was not, however, included in the programme.
- <u>Implementation of the 2010 sectoral programme</u>. The CCA stated that the implementation of the programme for 2010 (which foresees inspections in the red meat and milk sectors on 12 Regions) has not yet started as the Regions based on the constitutional arrangements in Italy question the legal power of the CCA to carry out inspections in the establishments.
- Organisation of the audit system by the regional CAs. Since 2007 the CCA collects data on audit activities carried out by the Regions on the local CAs (ASL) according to Article 4.6 of Regulation (EC) No 882/2004. During 2009, 11 Regions have implemented a system of audit, six are currently planning audit activities, and one is carrying out joint inspections with staff of the ASL.
 - The <u>Calabria Region</u> has planned 10 audits on the ASL in 2010, which will include eight sectoral audits in food hygiene and five in animal welfare. Training for 50 staff for the ASL on "Audit of systems for food safety management" is planned in 2010. The FVO team visited one establishment which was previously audited by the regional audit team in relation to "controls over suppliers and internal traceability". The audit findings in the regional report were favourable, and in line with those of the FVO team.
 - In the <u>Liguria Region</u> a team of experienced veterinarians of the ASL completed training in March 2010 on audit techniques and official controls and have also participated in

audits in the Toscana Region, in the framework of an exchange programme. The first audits are planned for the last quarter of 2010.

The <u>Sardinia Region</u> had performed three audits during 2009, which were focussed on traceability and certification in the framework of protection measures against African swine fever foreseen by Commission Decision 2005/363/EC. No other audits on topics covered by the scope of this mission were carried out. The CA stated that no audits are foreseen in 2010 due to lack of staff.

Conclusions on Verification Procedures

A system of internal audits by the CCA in accordance with Article 4 of Regulation (EC) No 882/2004 is only partially in place as no sectoral audits referring to meat and milk are in place at central level. Instead the CCA is carrying out inspections in establishments. In 2009, in 30% of establishments included in the inspections major non-compliances were found and action was taken. No guarantees were provided that the 2010 inspection programme will be implemented by the CCA as planned. Audit programmes are at an initial stage of planning in some Regions, whilst in others a lack of staff seriously undermine the audit capability of regional services.

5.6 Multi Annual National Control Plan

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated MANCP. According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

Findings

The current 2007-2010 MANCP includes 3 sections identifying all control authorities responsible for food and feed safety, animal health, animal welfare and plant health controls, is not up to date; the CCA considers the structure of the MANCP not to be fully appropriate for the purpose, and too static, and some amendments are necessary. The plan is essentially descriptive and does not provide any significant operational information. However, the MANCP was approved by the CSR (Act No 133/CSR of 14 June 2007), and the same long procedure is required for amending it.

The national contact point for the Italian MANCP is the Head of the CCA.

The MANCP 2011-2014 is currently in an advanced stage of drafting by Office VIII of the DGSAN, and will be made available on the intranet of the CCA; it includes seven chapters and a regional part (sudiveded into 21 sections (one for each region and Autonomous Province) and can easily be modified without amending the MANCP itself.

Annual reports on the implementation of the MANCP are published on the Internet, with the latest available covering the year 2008. Regions are requested to supply the CCA with the relevant data concerning the implementation of the control programmes.

Conclusions on Multi-Annual National Control Plan

The MANCP for 2007 / 2010 MANCP is in place but not up to date and the 2011-2014 MANCP is currently drafted and being updated as required by Articles 41 and 42 of Regulation (EC) No 882/2004.

6 SECTOR SPECIFIC FINDINGS AND CONCLUSIONS

6.1 National measures and derogations

Legal Requirements

According to Article 10 of Regulation (EC) No 853/2004 Member States may, without compromising the achievement of the objectives of Regulation (EC) No 853/2004, adopt national measures adapting the requirements laid down in Annex III. The national measures refer to continued use of traditional methods and regions subject to geographical constraints and are subject to notification to the Commission and other Member States. National rules may be maintained or established for placing on the market of raw milk or raw cream for direct human consumption and to permit the use of raw milk not meeting the criteria for plate count and somatic cell count (SCC). Article 7 of Regulation (EC) No 2074/2005 allows Member States to grant establishments manufacturing foods with traditional characteristics derogations from certain requirements set out in Regulation (EC) No 852/2004.

Findings

- A number of national measures and derogations have been introduced by the Italian CAs by acts adopt ed by the CSR and transposed into regional legislation. They have all been notified to the Commission services and include:
 - 1. Derogations to waiting pens, facilities for washing trucks used for transport of live animals and chilling of carcases before dispatch, for slaughterhouses previously operating under the requirements laid down in Article 4 of Regulation (EC) No 2076/2005 (Act 115/CSR of 31 May 2007);
 - 2. Derogations for the partial evisceration of lagomorphs and poultry (Act 257/CSR of 25 November 2007), and of kids, lambs and piglets (Act 232/CSR of 20 November 2008), where viscera others than stomach and intestines can remain in an anatomical connection with the carcass provided they have undergone post-mortem inspection and, in the case of lagomorphs and poultry of at least 5% of the slaughtered animals;
 - 3. Derogations for the production of cheeses using raw milk not in compliance with the requirements of Annex III, Section IX, of Regulation (EC) No 853/2004 as regard total plate count (TPC) and SCC, provided that such cheeses are ripened for at least 60 days as foreseen in Article 10.8 of the same Regulation. Derogations are applicable in the case of raw cow milk (Act 6/CSR of 25th January 2007), as well as in the case of goat and sheep raw milk (Act 2673/CSR of 16 November 2006). However this Act 2673 authorises, the production of dairy products made with sheep and goat raw milk without calculation of the geometric average for TPC when the most recent test prior mountain grazing is favourable;
 - 4. Derogations enabling the continued use of traditional methods at any of the stages of

production and processing, as foreseen in Article 10.4.a).i) of Regulation (EC) No 853/2004 and Article 13.4.a).i) of Regulation (EC) No 852/2004. Derogations are applicable to maturation/ageing rooms, and material for tools and equipment, and are granted by the local CAs taking into account specific HACCP-based procedures established by the FBO. The list of traditional foodstuffs is updated periodically by Ministerial Decree in application of the Legislative Decree No 350/1999.

- By Act 103/CSR of 20 th March 2008, guidelines have been agreed on the implementation of official controls over the direct sale of raw milk at farm level or by means of automatic dispensers, and of milk-based products to the final consumers or retailers. In this case FBOs must be registered according to Article 4 of Regulation (EC) No 853/2004, as falling under the exclusion of Article 1.2 of Regulation (EC) No 852/2004. Marginal activity is defined as "should not prevail in terms of volumes" without mentioning maximum quantities.
- The CCA stated that no derogations have been granted in order to accommodate the needs of food businesses situated in regions that are subject to special geographic constraints.

Conclusions on national measures and derogations

The Italian authorities have notified the Commission and other Member States the derogations granted to FBOs, in accordance with Article 10 (5) of Regulation (EC) No 853/2004 and Article 7 of Regulation (EC) No 2074/2005. The derogation for the calculation of rolling geometric average of TPC in sheep and goat milk goes beyond the provisions of Regulation (EC) No 853/2004. No detailed definition of marginal activity has been provided in order to have harmonised application of the Community legislation for registered FBOs supplying other retailers.

6.2 FOOD BUSINESS OPERATORS' OBLIGATIONS AND OFFICIAL CONTROLS

Recommendation No 4 of report 2008-7930 was to ensure that non-compliances in structure, layout, maintenance and, in general, hygiene requirements, as provided by Regulations (EC) No 852/2004 and No 853/2004, are properly identified in all establishments.

Recommendation No 5 of report 2008-7930 was to ensure that, when non-compliances to hygiene requirements are identified, appropriate action is taken to have the FBOs remedy the situation in accordance with Article 54 Regulation (EC) No 882/2004.

In their response the CCA indicated that " a working group between the Ministry, Regional and Autonomous Provinces will be set up to collect all the Guidelines and set criteria and principles established at the national level for the development and adoption of registration documents and operating procedures and non-compliances repertory. Beginning from 2010 all competent authorities must consider these common criteria when revising registration documents and procedures adopted."

6.2.1 General and specific hygiene requirement

Legal Requirements

Article 4(2) of Regulation (EC) No 852/2004 establishes that FBOs carrying out any stage of production, processing and distribution of food after the stage of primary production/associated

operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises. 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 FBOs' compliance with these requirements.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBOs shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analyses. Details on microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005 and 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 FBOs compliance with these requirements. These cover a range of items with regard to requirements for slaughterhouses, cutting plants, emergency slaughter, game handling, raw milk and dairy products and other products of animal origin.

Findings

Three out of 10 establishments visited were found to be mainly compliant with the general and specific hygiene requirements. In one big establishment producing meat cuts and minced meat, the deficiencies identified during an audit visit by the CCA and subsequent investigations done by the OV were correctly addressed. In four other establishments (two in Sardinia, one in Liguria and one in Calabria) deficiencies related to structure, maintenance and operational practices were noted, mainly not identified by the CA.

In three establishments, significant deficiencies were noted and the FVO team requested immediate action:

- In Calabria one meat product plant was found to be unacceptable (deficiencies such as parts of the establishment not included in approval, storage of ingredients and packing materials outside, the presence of spoiled products/best before date passed since 2007, own-checks and HACCP, poor cleaning was identified).
- In Sardinia one milk collection centre and one slaughterhouse were found to be unacceptable:
 - In the slaughterhouse: extremely poor stunning and bleeding, insufficient height of rail and dragging of head in blood and on floor, none of the sterilisers at 82°C. The post mortem examination not correct, un-hygienic slaughter procedures.
 - In the milk collection centre: carrying out pasteurisation without appropriate controls of pasteuriser; open to exterior, poor cleaning, all raw milk accepted without action when 50% of supply exceeded the limits for TPC.

The following additional deficiencies not previously noted by the CA were identified by the FVO team during the visits in one or more of the establishments:

- Structural and lay-out deficiencies:
 - Almost all establishments visited were not sufficiently protected against the entry of pests.
 - Some rooms were missing or too small for the purpose and leading to unhygienic

housekeeping: In a meat product plant diverse materials were stored with packaging materials and equipment, crates, barrels with casings stored outsides. In a cheese factory there was a lack of space for packing material and storage of salt outside; In another cheese factory: storage of intermediate products for 48 hours inside production area.

- Crossings of flows of fresh unprotected meat and carton packed meat with possible cross contaminations were noted in a cutting plant.
- In two slaughterhouses insufficient height to allow hygienic slaughter; eg: heads of big animals dragging on or very close to floor, rodding difficult to perform with risk of rupturing the stomach.
- Waste water outlets not connected to drains with potential cross-contamination by splashing.
- Carcasses touching stands with cross-contamination in places.
- Maintenance problems, such as rust, flaking paint, exposed insulation, leaking refrigeration
 units, infiltration with mould formation close to exposed products, damaged walls and
 floors, were identified in several establishments.
- Operational practices with a negative impact on hygiene were noticed:
 - In three establishments products with an expired date were stored (for example meat products expired since 2007 and 2008).
 - Presence of wood with unprotected products and rough wood in production room of cheese.
 - Condensation droplets on the ceiling or under refrigeration equipment over exposed products was seen in specific areas in two establishments.
 - Extensive use of hand operable hoses in one slaughterhouse.
 - Carcasses touching before post-mortem inspection.
 - Massive visual faecal contamination of bovine carcasses was seen in two of the three slaughterhouses visited (Calabria and Sardinia) and in one cutting plant (in Sardinia). In the latter the presence of sheep carcasses with wool and faecal contamination.

In the Calabria and Sardinia Regions in applying Point 3, Chapter VII, Section I, Annex III to Regulation (EC) No 853/2004 meat which had not attained the prescribed temperature of 7°C was dispatched from the slaughterhouse; however, this derogation was not individually granted by the CAs, as prescribed by Act 115/CSR of 31 May 2007.

6.2.2 HACCP-based systems and own checks

Legal Requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. In Section II of Annex II to Regulation (EC) No 853/2004 the specific requirements for HACCP-based procedures in slaughterhouses are specified. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based procedures (Article 4(5) of Regulation (EC) No 854/2004).

Findings

Recommendation No 7 of report 2008-7930 was to audit the HACCP-based systems in all food businesses, to assess the results of the own checks and, in particular, of bacteriological analysis in accordance with Regulation (EC) No 2073/2005 and as laid down under Article 10.2 of Regulation (EC) No 852/2004.

The CCA response was the same as for Recommendations No 4 and No 5 (see point 6.3).

- All establishments visited had a HACCP based system in place but with varying quality. Generally the HACCP based systems in bigger plants were well developed.
- In smaller establishments generic HACCP plans were frequently used but in most cases they had not been sufficiently adapted to the individual establishments (eg: no risk evaluation included, documentation was not up to date, contained irrelevant information).
- In two establishments (in Calabria) the responsible staff were not very familiar with the content. In the meat product establishment, the cleaning programme (description, procedure and verification of the efficiency) was insufficient and a lack of knowledge of the Quality Assurance Manager concerning own-checks and HACCP was noticed. Confusion arose by the microbiological limits used by the laboratory for contact surfaces, (eg: up to 10 000 TVC/cm2 for walls in chillers was considered as acceptable). In the slaughterhouse, the hazard identified (microbiological growth on carcasses) was controlled by verifying if the temperature of the sterilisers was above 82°C.
- In one collection centre for milk, pasteurisation took place without an approved/evaluated HACCP plan. The pasteurizer was not controlled or calibrated.
- In two bigger dairy establishments (Calabria and Sardinia), the control of the pasteurisation of the milk was limited to one parameter (temperature) although the control requirement indicated time/temperature values.
- In two dairy establishments (Sardinia and Liguria), the description of the procedure for the reception of the milk was not detailed enough and did not reflect actual practice.
- In one establishment (Sardinia), the analysis of the potable water did not include the testing for *enterococci*, and the laboratory used a non-accredited method for the quantification of *streptococci*.
- Analyses within the HACCP-based procedures of the FBOs are carried out by private laboratories.
- The (own-checks) HACCP based systems are cross-checked regularly by official sampling during the official controls. However most of the findings detected by the FVO team had not been detected or acted upon by the CA.
- In one cutting plant in Sardinia, although described in the FBOs' Standard Operating Procedures, the control of the incoming meat was not acceptable: carcasses contaminated due to bad slaughter hygiene (faecal contamination on bovine, sheep and goat carcasses; hair and wool remaining) and contaminated with grease during transport, edible offal on which post-mortem inspection had not been performed completely and pig heads without health marks or identification marks had been accepted.
- With regard to microbiological criteria for certain micro-organisms as laid down in Regulation (EC) No 2073/2005, the CAs in the Calabria Region have granted to certain FBOs the possibility of reducing the sampling frequency following favourable trends, and in accordance with the national guidelines approved by Act 93/CSR of 10 May 2007; however, this derogation was not individually granted in writing, the frequencies were not in line with

Regulation (EC) No 2073/2005 and specific procedures were not described in the own-check manuals, as prescribed in the guidelines.

- The sampling for microbiological examination of carcasses prescribed by Regulation (EC) No 2073/2005 was not in line with the Regulation:
 - In one slaughterhouse visited, the swabs were taken on the cleanest parts of the animal although visual faecal contamination was present in the perineal area of almost all bovine carcasses.
 - In another small slaughterhouse (in Sardinia), no microbiological examination of carcasses took place since last year. The CA had not assessed the individual establishment if a lower frequency of sampling could be considered and no formal derogation was issued as is foreseen in Article 5.3 of Regulation (EC) No 2073/2005.

6.2.3 Identification marking and labelling

Legal requirements

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

Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer. Regulations (EC) No 1760/2000 and No 1825/2000 set out specific labelling requirements for beef meat.

Findings

- In one cutting plant (in Sardinia), labels with redundant approval numbers were present and used. In the same establishment a new identification mark from this Italian establishment was placed on top of the original identification mark/label on the closed original carton boxes with Brazilian horse meat.
- In one meat product plant (Calabria), some barrels and smaller plastic containers with casings did not contain any identification. In one cutting plant (in Sardinia) pigs' heads without identification marks were present in a reception chiller.
- No evidence was seen that the labelling is checked during official controls.

6.2.4 Traceability

Legal requirements

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

Findings

Traceability systems were in place in all of the establishments visited and were found mainly to be in compliance with the legal requirements. A traceability exercise carried out by the FVO team in a cutting plant was successful.

Traceability is occasionally checked during the official controls. In Sardinia, one AUSL had carried out a specific control on traceability.

Conclusions on food business operators' obligations and official controls

Three establishments out of 10 visited were not compliant with the general and specific hygiene requirements and in four significant deficiencies in structure, installation and equipment, maintenance and cleaning, operational practices, slaughter hygiene, implementation of microbiological sampling and testing, HACCP based systems were noted. The officials had in many cases not detected or reported the deficiencies noted by the FVO team.

Identification marking and labelling were in general, with some exceptions, in line with the legal requirements.

Traceability systems were in place in the establishments visited and found to be acceptable.

These findings are very consistent with those (more than 30% of establishments with significant non-compliances) reported by the CCA during their audits of the Regions.

6.3 OFFICIAL INSPECTION TASKS IN ESTABLISHMENTS

6.3.1 Food chain information

Legal requirements

According to Article 3 of Regulation (EC) No 853/2004, the FBOs shall comply with the relevant provisions of Annexes II and III to this Regulation. In particular the FBOs operating slaughterhouses must as appropriate, request, receive, check and act upon FCI in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse. According to Article 5(1) of Regulation (EC) No 854/2004 the OV shall carry out inspection tasks in slaughterhouses also as regards FCI.

Findings

- A system for FCI for all animals is in place in Italy. All animals when sent to the slaughterhouse have to be accompanied by a transport document (*modello 4*) containing the relevant information. In all cases verified, the documents were available and filled-in correctly.
- In one case, horses were presented in the slaughterhouse with the " modello 4 ". The individual identification of each horse was only mentioned in the Annex but there was no cross-reference between both documents.
- The FVO team was informed that it had been very difficult to obtain the FCI for bovine animals coming from an assembly centre in France. The document provided contained a statement "nothing to declare" signed by the OV responsible for the bovine assembly

centre.

6.3.2 Ante mortem inspection

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including ante-mortem inspection of all animals before slaughter in accordance with the general requirements of Section I, Chapter II of Annex I of Regulation (EC) No 854/2004.

Findings

The ante-mortem examinations were carried out by OVs and documented as foreseen in the legislation.

6.3.3 Post mortem inspection

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including post-mortem inspection in accordance with the general requirements of Section I, Chapter II of Annex I and the specific requirements of Section IV.

Findings

The response to recommendation No 6 has been described in point 5.2.3 of this report.

- Training for post-mortem inspection had not been provided in all Regions, contrary to what was announced in the answer to the recommendations of the previous FVO report.
- However deficiencies in post-mortem examination were still encountered:
 - Installations were not always adequate to perform the post-mortem inspection such as insufficient light, green offal belt too high, no stand to inspect hind quarters and kidneys, heads too close to floor.
 - Unsatisfactory performance of the post-mortem examination was seen in several places: mm. masseter not or partially incised or not closely looked at, the green offal and the carcasses were not closely visually inspected, trachea not opened when lungs were destined for human consumption.
 - Evidence was seen that in several slaughterhouses, in Calabria, Sardinia, Sicily, Veneto carcasses contaminated with faecal material, remaining skin, hairs and wool passed post -mortem examination without further trimming required.
 - Neither the ASL nor the regional service had identified deficiencies regarding carcass contamination nor post-mortem and health marking during their supervisory activities over the OV in charge in the establishments.

6.3.4 Health Marking

Legal requirements

Article 5(2) of Regulation (EC) No 854/2004 requires that health marking shall be carried out in slaughterhouses and game-handling establishments by, or under the responsibility of, the official

veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

Audit findings

In one cutting plant it was noted that many health marks on carcasses from several Italian slaughterhouses were not readable.

6.3.5 Animal welfare at the time of slaughter or killing

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal welfare. Council Directive 93/119/EC sets out Community rules with regard to the protection of animals at the time of slaughter or killing.

Audit findings

- In two slaughterhouses (in Calabria and Sardinia) the restraining boxes used in conjunction with a pneumatic captive bolt was not fitted with a device that restricts both the lateral and vertical movement of the head of the animal. Three out of four animals had to be shot twice.
- In the slaughterhouse in Sardinia the situation was particularly poor:
 - stunning equipment not well maintained in good functioning order;
 - bleeding too long: only venae carotidae cut;
 - during five minutes, the bovine animal continued gasping and breathing.
- No evidence was seen that official controls were carried out to ensure that animal welfare conditions are complied with or that non-compliances had been identified, reported and corrective action requested.
 - 6.3.6 Criteria for raw milk

Legal requirements

Article 8 of Regulation (EC) No 854/2004 requires that Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV to Regulation (EC) 854/2004. Annex IV establishes that the CA has to carry out official controls to verify that health requirements and hygiene requirements for raw milk and colostrum are complied with and to monitor the checks carried out for plate count, SCC and residues of antibiotic substances.

Audit findings

- In all three Regions visited, controls are carried out to detect the presence of inhibitors and antibiotics. A procedure to take action is in place and appropriate action and follow-up action is taken when required.
- In two Regions visited (Calabria and Liguria), systems are in place to control raw milk at farm level, and the farmer, the dairy operator and the CA are informed, directly or indirectly regarding holdings exceeding the two or three months rolling geometrical averages. Examples were seen in the two establishments visited that the procedure was followed in

accordance with the Regulation: it could be demonstrated that some farmers had received warning letters, the CA informed, milk collection suspended when required, and evidence of official monitoring of these parameters could be seen with copies of the lifting of the suspension on file.

- In Sardinia however this is not the case for the control of sheep and goats milk:
 - Although all farms are tested twice per month by an inter-professional laboratory which makes the results available on their on-line database to the FBO and the ASL, the two months rolling geometrical averages of TBCs are not calculated and there is no procedure for action laid down and no action is taken. The ASL informed the FVO team that they consulted the database with the test results on a random basis, at least once per month. The averages are not calculated and an occasional visit takes place to a farm. No evidence was seen of action taken (investigations, warning letters, and suspension in accordance with the Regulation). The CA claimed that in the past they had tried it but had to give it up due to a lack of collaboration, results and resources. Many farmers were said to be de-motivated, negligent and would even switch off the cooling equipment for the milk to avoid costs.
 - 50% of the sheep and goat milk collected is above the limit of 1.5 million microbacterial counts and many above the detection limit of 17 million/ml.
 - In one dairy, the results are evaluated on a yearly basis and the farmers performing worst are eliminated as a supplier and some bonuses is given to the ones with good results.
 - In the collection centre visited, the microbiological results were available and were mostly not in compliance but in any case action was taken by the FBO or the FBO informed the ASL.
 - The CCA of Sardinia has not yet considered the giving of derogations for higher microbiological content of raw milk in the case of the production of certain cheeses matured for more than 60 days.

6.3.7 Animal by-products

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the OV carries out inspection tasks, including animal by-products (ABP). Annex II to Regulation (EC) No 1774/2002 sets out the requirements for the collection and transport of ABP, including requirements for identification, records and the use of commercial documents.

Audit findings

- In general containers used were appropriately identified or colour coded and contracts as well as records were seen regarding the removal of ABP.
- In one slaughterhouse in Sardinia, not all spinal cords were removed from animals older than 12 months. This had been identified during a previous audit by the CCA and a reminder about this requirement had sent to all Regions.
- In another slaughterhouse in Liguria, the tray to collect the waste from the carcass splitting saw was not connected to the mains

Conclusions on official inspection tasks in establishments for verification of food business

operators' compliance

The FCI is in place for all species and ante-mortem examinations were always carried out by OVs.

The post-mortem examinations were often not carried out as foreseen in the legislation and the application of the health mark was generally not acceptable as many were not readable or applied on contaminated carcasses.

The animal welfare requirements were not complied with in two out of the three slaughterhouses visited.

The testing of raw milk and the monitoring by the CA of the checks carried out by the FBOs is done as required by Annex IV of Regulation (EC) No 854/2004 in two Regions visited (Calabria and Liguria). In Sardinia the quality of the raw sheep and goat milk is not in compliance with Chapter I, Section IX, Annex III of Regulation (EC) No 853/2004 and the testing of raw milk and the monitoring by the CA of the checks carried out by the FBOs is not done as required by Annex IV of Regulation (EC) No 854/2004.

In general, compliance with ABP legislation with the exception of the removal of the spinal cord in one slaughterhouse, was noted.

7 Overall Conclusion

A significant effort was undertaken at central and some regional levels (with the exception of Sardinia) to address some of the recommendations made in the mission report 2008-7930, and to implement the HP in a coherent way. However, in a large number of establishments visited these efforts did not result in compliance with EU requirements. A very large number of recurring deficiencies already highlighted during previous FVO missions still remain, mainly because of non satisfactory enforcement. In particular the situation in slaughterhouses and dairy establishments (in particular in Sardinia) indicated a poor performance of the CAs. The inspections carried out by the CCA in 2009 already showed some impact in some Regions. However, the planning for inspections in 2010 has not yet started as the Regions question the legal basis for the CCA to carry out inspections in the establishments based on the constitutional arrangements in Italy.

The nature of the non-compliances and their incidence, identified by the CCA during their inspections in the Regions, are largely in line with the findings of the FVO team during this mission.

8 CLOSING MEETING

A closing meeting was held on 7 May 2010 with representatives of the CCA. At this meeting, the FVO team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement and stated that they would take whatever actions were necessary in order to suspend temporarily the activities in the three establishments concerned.

Following the final meeting guarantees were received concerning the temporary suspension of the three establishments.

9 RECOMMENDATIONS

The competent authorities are invited to provide within 25 working days of receipt of the draft report, an action plan containing details of the actions taken and planned, including deadlines for their completion, to address the following recommendations:

N°.	Recommendation
1.	To ensure that contingency plans are drawn up in line with Articles 4 and 13 of Regulation (EC) No 882/2004.
2.	To review the lists of approved establishments as to their accuracy and ensure that they correctly reflect the activities of the approved establishment in line with Article 31 of Regulation (EC) No 882/2004.
3.	To ensure that official controls are effective as foreseen in Article 4(2) of Regulation (EC) 882/2004 and to ensure the verification of the effectiveness of official controls as foreseen in Article 8(3) of Regulation.(EC) 882/2004.
4.	To resume as soon as possible the implementation of the audit plans and extend the action already initiated in the Regions and of competent authorities at all levels as required by Regulation (EC) No 882/2004. Special attention should be given to the situation in Sardinia.
5.	To ensure that a sufficient number of suitably qualified staff is available, in particular, at regional level for controls under the scope of this mission in order to comply with Article 4 of Regulation (EC) No 882/2004.
6.	To ensure that official controls are carried out in accordance with Article 4(2) of Regulation(EC) 854/2004 and that when non-compliances regarding structure, layout, maintenance and, in general, hygiene requirements, as provided by Regulations (EC) No 852/2004 and No 853/2004, are identified, corrective action is taken as required by Article 54 of Regulation (EC) No 882/2004.
7.	To take measures in order to ensure that the HACCP-based systems are in line with Article 5 of Regulation (EC) No 852/2004.
8.	To ensure that microbiological sampling of products and carcasses by the food business operators is carried out in full compliance with Regulation (EC) No 2073/2005.
9.	To ensure that post-mortem inspection in all slaughterhouses is carried out in compliance with the requirements of Regulation (EC) No 854/2004.

N°.	Recommendation
10.	To ensure that the protection of animals at the time of slaughter or killing is in compliance with Council Directive 93/119/EC of 22 December 1993.
11.	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.

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

http://ec.europa.eu/food/fvo/ap/ap_it_2010-8502.pdf

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Reg. 1760/2000	OJ L 204, 11.8.2000, p. 1-10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Reg. 1825/2000	OJ L 216, 26.8.2000, p. 8-12	Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
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. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal byproducts not intended for human consumption
Reg. 852/2004		Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on

Legal Reference	Official Journal	Title
	226, 25.6.2004, p. 3	the hygiene of foodstuffs
Reg. 853/2004	p. 55, Corrected and	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004		Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004		Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 2075/2005	OJ L 338, 22.12.2005, p. 60-82	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat
Reg. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of

Legal Reference	Official Journal	Title
		Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 1/2005	OJ L 3, 5.1.2005, p. 1-44	Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
Dec. 2005/363/EC	OJ L 118, 5.5.2005, p. 39-46	2005/363/EC: Commission Decision of 2 May 2005 concerning animal health protection measures against African swine fever in Sardinia, Italy