



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

DG(SANCO)/ 2008-7930 - MR - FINAL

FINAL REPORT OF A MISSION
CARRIED OUT IN
ITALY
FROM 13 MAY TO 23 MAY 2008
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 AND MILK

*Please note that factual errors in the draft report have been corrected in response to comments by the
Competent Authority.*

Executive Summary

The Italian Central Competent Authority (CCA) replied to the recommendations of the previous mission report. At desk analysis, the response was found to be satisfactory. The mission team found on the spot that improvements have been made at central and regional levels. However, at local level, the action taken in response to some recommendations was not always sufficient, in particular in relation to the efficiency of official controls and enforcement of the hygiene rules by the food business operators (FBOs), as the action taken has produced little results.

The official controls are carried out on a regular basis and their frequency is often higher than that foreseen by the rules of the risk basis classification of establishments. In most cases they are also documented. However, in a number of cases, the reports do not reflect what is happening in the establishments. Significant or major non-compliances noted by the mission team had not been identified by the Competent Authorities (CA). There was seldom any documented follow-up for deficiencies noted by the CA (written notification to the FBO, deadlines, re-checks).

General hygiene requirements were found to be satisfactory, with only minor remarks, or deficiencies limited to single rooms in 6 of the 12 establishments visited. In the remaining 6 establishments major deficiencies were noted in relation to the structure, maintenance and general hygiene requirements of Regulation (EC) No 852/2004. Three out of 4 slaughterhouses (SH) visited, one situated in each region, did not comply with the specific hygiene requirements in Regulation (EC) No 853/2004. Only one SH, very recently built, was found to be satisfactory. Another point of concern was poor or the non implementation of Hazard Analysis Critical Control Points (HACCP) in most of the establishments visited.

After the mission team visit, the 2 Regional Competent Authorities (RCA) suspended SHs found to be unsatisfactory in their regions and at the final meeting the third declared their intention to do the same.

Audits carried out by the CA at central and regional (Lazio) levels are mostly audits of FBOs and not audits of official controls as laid down in Art. 4.6 of Regulation (EC) No 882/2004. They have no proper follow-up and to date have not contributed to an improvement in the situation.

Satisfactory staffing situation at local and district level was noted in the regions visited. In Lazio, the Regional Authority indicated a shortage of staff to carry out audits and inspections. Sicily does not carry out audits and inspections at regional level as there is only one official available who is responsible for food safety and 2 000 food establishments.

In relation to approvals, concern is raised about a large number of very small approved establishments, mostly dairy (some 850 in Sicily only). These establishments mostly produce for direct sale or for their own municipality. The Sicilian Regional Authority started a review of their approvals, in order to withdraw approvals and register, on the basis of national SCR agreements, two-thirds of them. The national measures to allow derogations in SHs have been adopted but to date have not been used in the provinces

visited.

In cases examined by the mission team, training provided to the FBO staff or to the official veterinarian (OV) was found to have no impact on their performance because it was inefficient or its use was not enforced.

TABLE OF CONTENTS

1	INTRODUCTION.....	1
2	OBJECTIVES OF THE MISSION.....	3
3	LEGAL BASIS FOR THE MISSION.....	3
4	BACKGROUND.....	3
5	MAIN FINDINGS.....	4
5.1	Competent Authorities.....	4
5.1.1	<i>Designation of competent authorities and operational criteria.....</i>	<i>4</i>
5.1.2	<i>Staff performing official controls.....</i>	<i>7</i>
5.1.3	<i>General obligations with regard to the organisation of official controls</i>	<i>8</i>
5.1.4	<i>Control and verification procedures.....</i>	<i>8</i>
5.2	Official certification.....	8
5.3	Registration and approval of establishments.....	9
5.3.1	<i>Registration and approval of establishments.....</i>	<i>9</i>
5.3.2	<i>National measures and derogations.....</i>	<i>9</i>
5.4	Application of Hygiene Rules at establishment level and official controls.....	10
5.4.1	<i>Food business operators' obligations.....</i>	<i>10</i>
5.4.2	<i>Official controls at establishments for verification of food business operators' compliance.....</i>	<i>14</i>
5.4.3	<i>Official inspection tasks in establishments.....</i>	<i>14</i>
5.4.4	<i>Action in case of non-compliance.....</i>	<i>16</i>
6	CONCLUSIONS.....	16
6.1	Follow-up of previous FVO missions.....	17
6.2	Competent authorities	17
6.3	Registration and approval of establishments.....	17
6.4	Application of hygiene rules at establishment level and official controls.....	18
6.5	Overall conclusion.....	18
7	CLOSING MEETING.....	18
8	RECOMMENDATIONS.....	19

ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
AUSL	Local Health Units (<i>Aziende Unità Sanitarie Locali</i>)
CA	Competent Authority
CCP	Critical Control Points
Central Authority	Central Competent Authority - Department for Veterinary Public Health, Nutrition and Food Safety (<i>Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti</i>) furthermore called Central Authority
DG(SANCO)	Health & Consumers Directorate General (EC)
EC	European Commission
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis & Critical Control Points
OV	Official Veterinarian
Regional Authority(ies)	Regional Competent Authority - Regional Public Health Services (<i>Servizi di Sanità Pubblica delle Regioni</i>) furthermore called Regional Authority or Regional Authorities
RHM	"regional health ministries" - <i>Assessorati Regionali alla Sanita</i>
SCR	Standing Conference for Relations between the State, the Regions and Autonomous Provinces of Trento and Bolzano
SH	Slaughterhouse

1 INTRODUCTION

The mission took place in Italy from 13 to 23 May 2008, as part of the planned mission programme of the Food and Veterinary Office (FVO). The mission team comprised 2 FVO inspectors and was accompanied during the whole mission by 2 representatives from the Central Authority - Department for Veterinary Public Health, Nutrition and Food Safety (*Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti*) under the Ministry of Health (*Ministero della Salute*).

At the opening meeting, the objectives, itinerary and reporting procedures were confirmed and information complementary to that which was received in the course of the preparation of the mission was requested by the mission team.

The mission itinerary in pursuit of the mission's objectives included the following:

Competent authorities			Comments
Competent authorities	Central	1	CCA for the opening and closing meeting
	Regional	3	Autonomous Region of Sicily, Region of Lazio, Autonomous Province of Bolzano / Bozen
	Local		RVA and OV in establishments visited
Food production/processing / distribution - Activities			
Slaughterhouses		4	Sicily (not operating), Bolzano and Lazio (2)
Cutting plants		6	3 integrated with slaughterhouses
Meat products		2	Bolzano / Bozen and Lazio
Meat preparations plants		0	Sicily (meat preparations plant integrated with cutting plant)
Milk processing plants		4	Sicily, Lazio, and Bolzano /Bozen

Establishments to be visited were selected in co-operation with the Central and Regional Authorities, and the final itinerary was agreed at the initial meeting, with the participation of the representatives of the Regions and the Autonomous province of Bolzano / Bozen. During the visit to a SH and cutting plant in Sicily it was found, that this plant, previously agreed with the CA, was not in operation.

The Regional Authority explained to the mission team that it was a planning mistake as this establishment did not work every day and they then arranged for a visit to a meat plant in the immediate vicinity.

In the Region of Lazio, at the request of the mission team, an additional visit at very short notice was arranged (establishment selected by the regional authorities).

2 OBJECTIVES OF THE MISSION

The main objective of the mission was to follow-up the previous FVO mission DG(SANCO)2007-7435 on official controls related to food safety of food of animal origin, in particular meat and milk. The main scope of the mission was an evaluation of the level of the implementation and enforcement of the action plan submitted by the Central Authority following that mission. In particular, controls over meat, milk and their products in the framework of Regulations (EC) No 178/2002, No 882/2004, No 852/2004, No 853/2004 and No 854/2004 of the European Parliament and of the Council were subject to the evaluation. References to Community Acts relevant to this mission are listed in the Annex to this report.

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.

4 BACKGROUND

The previous FVO mission in the evaluated sectors was carried out from 4 to 15 June 2007 (ref. number DG(SANCO) 2007-7435) and the following recommendations were made:

- (1) To review the action plan based on the recommendations of report DG(SANCO)/8145/2006 and bring it into line with these recommendations.
- (2) To establish a system of appropriate and effective coordination between the regional authorities and between the regional and central authorities.
- (3) To ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of the Regulation (EC) No 882/2004 as required by Article 3.
- (4) To adapt the national legislation, and finalise the updating of instructions and guidelines, in line with the requirements of the new EU hygiene legislation.
- (5) To review the present audit system in such a way that the competent authorities are aware of the results and in position to take appropriate measures and corrections.
- (6) To ensure that FBOs comply with the general and specific hygiene requirements laid down in Regulations (EC) No 852/2004 and No 853/2004 respectively.
- (7) To improve the official controls at establishment level to assure FBOs' compliance with the general and specific hygiene requirements of Regulations (EC) No 852/2004 and 853/2004 and ensure that corrective action is taken when needed as required by Article 8 of Regulation (EC) No 882/2004.
- (8) To ensure that the post-mortem inspections are carried out and that they comply

with Regulation (EC) No 854/2004.

(9) To ensure as a matter of urgency that in all regions all staff receives appropriate training in their area of competence as required by Regulation (EC) No 882/2004, Article 6.

(10) To carry out a full review of the lists of approved establishments to ensure that inaccuracies are removed and to ascertain the reasons for establishments remaining under provisional approvals for periods of years.

(11) To take the necessary measures to bring the controls and identification of animal by-products into compliance with Regulation (EC) No 1774/2002.

The CCA responded on 2 October 2007 to the recommendations with an action plan prepared by the Central and Regional authorities. At desk analysis, the response of the CCA was found to be satisfactory. On the occasion of the current visit, the CCA requested, and received from the Regions, an updated version of their response to some of the previous mission recommendations.

However the mission team found on the spot that action taken in response to some of the recommendations was not always efficient, in particular in relation to the efficiency of official controls and implementation of the hygiene rules by the FBO.

5 MAIN FINDINGS

5.1 COMPETENT AUTHORITIES

5.1.1 Designation of competent authorities and operational criteria

As described in the previous mission report, health in general, and with it animal health, food and feed safety and animal welfare, are matters of shared responsibility between the Central Authority and the Regional Authorities. Except for those matters explicitly reserved for the Central Authorities, such as import controls and matters of international prophylaxis, all administrative tasks and competences to carry out official controls in these areas on the regional level have been conferred to the Regional Authorities.

The Central Authority also drafts the legislation in the area of its responsibilities at state level.

The Regional Authorities in 19 regions and 2 autonomous provinces have responsibility for planning, co-ordination, guidance, authorisation and verification of controls with a high degree of independence.

The operational implementation of controls is handled at local level by Local Health Units (*Aziende Unità Sanitarie Locali* - AUSL). These are public enterprises responsible for the organisation and management of all public health services. The AUSLs have a high degree of managerial, administrative, financial and technical autonomy.

Observations

- There are no changes in the organisation of the CAs as described in the FVO report DG(SANCO)/8145/2006, except for the fact, that the new Italian government has reorganised the Ministries in order to bring down their number to eleven. The Ministry of Public Health was included in a new “superministry” called the Ministry of Welfare, together with Social Affairs and Labour. This, however, did not provoke any changes within the Ministry itself.
- Regarding recommendation No.1 of the report DG(SANCO)/8145/2006 the Central Authority presented to the mission team the *Decreto Legislativo 6 novembre 2007* transposing Directive 2004/41/EC of the European Parliament and of the Council. This is considered to be the key legal act for the implementation of the Hygiene Package in Italy.
 - o Art. 3 repeals the old national legislation based on repealed Directives and also introduces sanctions in accordance with Art. 55 of Regulation (EC) No 882/2004.
 - o Art. 4 lays down the details for the health mark and identification mark to use for emergency slaughter outside the slaughterhouse.
 - o Art. 6 lays down the provisions for applying sanctions for not respecting the requirements of the Hygiene Package. Depending on the level of non conformities, fines of up to €150 000 are foreseen. The Central Authority has provided data to the mission team concerning the application of the sanctions in 10 Regions (Abruzzo, Bolzano, Sardegna, Friuli-Venezia Giulia, Liguria, Lombardia, Piemonte, Toscana, Valle d’Aosta and Veneto), with most of the sanctions also applied in Lombardia, Piemonte, and Veneto.
 - o Art. 7 indicates that all existing approvals of establishments remain in force and thus, it will be a re-assessment of approvals.
 - o Art. 9 lays down that the national rule applies temporarily until a specific regional rule is available (*clausola di cedevolezza*). It was explained to the mission team that in practice the purpose of regional guidelines is to facilitate implementation and provide clarification.

In addition, the CCA provided a list of 16 national measures and guidelines, developed to address the recommendation 1 of the report DG(SANCO)/8145/2006.

5.1.1.1 Co-ordination of competent authorities

As indicated in the previous missions report, the coordination of the Regional Authorities and between the Central Authorities and the Regional Authorities is established via the Standing Conference for Relations between the State, the Regions and Autonomous Provinces of Trento and Bolzano (SCR) horizontally or vertically from the Central Authority to the Regional Authorities via the "regional health ministries" - *Assessorati Regionali alla Sanita*, in the autonomous province of Trento via the *Provincia Autonoma Di Trento* and in the autonomous province of Bolzano via the *Assessorato all'agricoltura della Provincia autonoma di Bolzano* (RHM).

Observations

Guidelines regarding Regulations (EC) No 852/2004 and No 853/2004 have

been prepared and distributed by the Regional Authorities of the Regions visited.

5.1.1.2 Audits of the competent authorities

As indicated in the previous mission report, an audit system in the areas of food safety and animal health from central level (Office IX) to regional level was introduced in 2003. Following the previous mission recommendation no 5 (to review the present audit system...., see section 4 Background) the Central Authority has initiated a process to review and agree with the regions and autonomous provinces the rules and criteria for audits with the aim of finalising the framework by the end of 2008. In the meantime, the audit activities will continue as planned.

A system for the reporting of audit activities carried out by the regions was established in February 2007 and has been implemented.

Observations

An inspection plan for the second part of 2007 and the beginning of 2008 has been prepared by Office III of the Central Authority (*Igiene degli Alimenti di origine animale* – DG SAN). According to this plan, a series of inspections of food businesses has been carried out from October 2007 to March 2008 in 9 regions (Friuli-Venezia Giulia, Campania, Sardegna, Calabria, Toscana, Lombardia, Sicilia, Abruzzo and Molise). In selecting the regions priority was given to the regions visited by the FVO in 2006 and 2007. It was explained to the mission team that the delay in the performance of the plan and its limited scope were due to the lack of funds at central level. In total, up to 7 ordinary officials (not specialised auditors) at central level were available for carrying out inspections, operating in teams of 2-3 and visiting 5 to 10 establishments per region over five days. In total, 70 establishments were visited, including 10 low capacity SHs. Specific check lists for different sectors were used. It was explained to the mission team that the purpose of this series of inspections was to explain to the FBO their obligations. The regional officials were present during the inspections or the auditors' observations were forwarded to them. Furthermore, a general report per region was produced, in the form of a one page letter, and forwarded by the under-secretary to the Ministers of Health in the regions visited. No deadlines were mentioned in these letters, and the responsibility to take action lies with the Regional Authorities.

The findings of the Central Authority's auditors were quite similar in all the regions visited and included:

1. a. deficiencies concerning hygiene requirements, due to poor structure and maintenance and total lack of understanding of requirements in force for a large number of FBOs,
- b. serious deficiencies in the plans for auto-controls,
- c. an insufficient presence and efficiency of the regional and local (ASL) veterinary services.

The mission team was not provided with any evidence of action taken by the Regional Authorities of the regions concerned in response to the inspections reports.

The Auditors of Office III plan to visit 119 establishments during the second half of 2008.

In the regions visited, the Lazio Region has set up an audit plan for 2008 and is completing an audit team consisting of up to 5 officials. The Region of Sicily has not set up any regional audit plan as there is only one official available at regional level who is responsible for food safety issues including 2 000 establishments.

Moreover all these inspections were related to FBO activity and no evidence of specific audits of the CA as laid down in Art. 4.6 of Regulation (EC) No 882/2004 was provided.

The CCA indicated, that the audits of the CA are carried out by Office IX, on which web site more information about audit activities can be found:

<http://www.ministerosalute.it/alimenti/attivita/sezAttivita.jsp?lang=italiano&label=aud&id=435>

5.1.2 Staff performing official controls

There are no changes in the staff performing official controls as described in the FVO report DG(SANCO)/8145/2006. All the controls are performed by the official veterinarians (OV).

Observations

- In general the staff met were highly motivated, in particular at regional level, and properly trained, although there were some exceptions.
- Evidence of training for the staff, already performed or planned, was provided in all regions visited. As an example, in the Region of Sicily, a six day training course related to quality, auditing and control systems for food safety was planned in May/June 2008 for 30 participants (OV and auxiliaries) with trainers from the Central Authority and also representatives from other regions.
- In one SH, showing serious deficiencies, the OV from the ASL demonstrated a very limited understanding for the rules in force, behaving as if he was a representative of the FBO, denying obvious findings of the mission team and, after the visit, contradicting the decision of the regional authorities to suspend the establishment.
- In another SH with very serious deficiencies, the OV was not familiar with the rules for post-mortem inspection and for general hygiene supervision. When asked if he received appropriate training for the performance of his task, he confirmed this fact.
- In another SH with serious deficiencies, the OV admitted he did not see them, as he has been present in this establishment for a very long time.
- No shortages of staff were noted at local (ASL) level in the provinces visited.
- Serious problems were noted at regional level in the Region of Sicily with only one official available for food safety issues. The mission team was informed at regional level of staff shortages making it difficult to complete a regional audit team. For this purpose, one official from the regional laboratory had to be used part time as an auditor for the Regional Authority.

5.1.3 General obligations with regard to the organisation of official controls

In reply to the previous missions recommendation no 3 (“To ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency....”, see section 4) the Central Authority has issued guidelines in a Circular dated 31 May 2007. On the basis of these guidelines, the Regional Authorities were requested to implement a risk-based system for official controls.

Observations

- All the regions visited have responded to the guidelines of the Central Authority (Circular of 31 May 2007) to develop a risk based system of official controls.
- For this purpose, all the approved establishments have been assessed taking into consideration the following parameters: date of construction and last significant alteration, general maintenance level, production volume, destination / distribution of the products, type of products (to be cooked, transformed, etc.), co-operation with – and level of training of the FBO, system of own checks and previous non-conformities. On the basis of these parameters, the score for each establishment was calculated, dividing them into low risk (under 30 points), medium risk (between 30 and 42 points) and high risk (over 42 points). It was noted that the classification was very much fixed on the age of the premises, structures aged over 20 years adding automatically 30 points, i.e. in practice high risk.
- The frequency of official controls is supposed to be based on the score received: for low risk every 6 months, for medium risk every 2 months and for high risk every month. However, in almost all of the establishments visited, the frequency of official controls was higher than requested. For example, in a large meat product establishment, classified as medium risk, the declared frequency of official controls was once a week; in another meat plant, classified as low risk, the frequency of controls was also once a week. Despite this fact, the controls failed to identify serious non conformities found by the mission team (see section 5.4.2.1).
- In the Autonomous Province of Bolzano/Bozen, the mission team was informed that the frequency of official controls based on risk classification will be applied from 2009 and is now only in an experimental phase.

5.1.4 Control and verification procedures

Observations

- Documented procedures on official controls in line with Art. 8(1) of the Regulation (EC) No 882/2004 were seen only in the Region of Lazio and Province of Bolzano/Bozen.

5.2 OFFICIAL CERTIFICATION

Observations

Some establishments visited were approved for export to third countries but had not exported in 2007 or 2008.

5.3 REGISTRATION AND APPROVAL OF ESTABLISHMENTS

5.3.1 Registration and approval of establishments

There were no change in the registration and approval of establishments as described in the FVO report DG(SANCO)/8145/2006. The power of approval is given by the Central Authority to the Regional Authorities, who carry out the controls, deliver the approval and complete the procedure in the Sintesi database system.

Observations

- All establishments visited were approved, having a valid approval decision based on the old legislation. However, the approval did not always cover all the activities of the establishment. For example, one SH traded with carcasses from the outside, without being approved as a cold store.
- In the region of Palermo, one very small milk establishment did not fulfil the conditions of approval (no checks on the incoming raw milk, no own checks documentation available or no HACCP implemented). This establishment has been approved without any derogation, which was possible under the old Community legislation (Commission Decision 95/165/EC). The Regional Authority explained to the mission team, that this was the reality under the old national legislation and that there are some 800 similar or even smaller dairy establishments in Sicily, placing their products on the local market only. The Regional Authority have started to review their status. For some 300 the approval has already been withdrawn and replaced by registration according to Art. 4 § 1 of Regulation (EC) No 853/2004. The mission team was informed, that this procedure is based on the agreements within the SCR on national derogations for local producers. No information was provided on whether it is in accordance with national law or if it is to be considered as marginal, localised and restricted activity, as laid down in Art. 1 § 5 (b) (ii) of Regulation (EC) No 853/2004. The registered establishments are allowed to place their product on the market in the province or in the surrounding provinces.
- In the Autonomous Province of Bolzano, the Provincial Authority expressed concern about the future of some 60 very small slaughterhouses situated in the mountains, in light of their ability to fulfil the requirements of the Hygiene Package prior to approval by the end of 2009. The intention of the authorities is to evaluate the situation for each of these establishments and to inform the FBO by the end of 2008, in order to give them time to adapt to the requirements before the end of 2009. To date, no such establishments have been approved under the provisions of the national derogations, see section 5.3.2.

5.3.2 National measures and derogations

Observations

The mission team has received a document (*Conferenza permanente per I rapporti tra lo stato, le regioni e le province autonome di Trento e Bolzano*) *Provvedimento 31 maggio 2007* introducing national rules for SHs of ungulates, in line with Art. 10 of Regulation (EC) No 853/2004, with permanent derogations for the presence of lairages (only water requested), facilities for washing of trucks and transport of meat not fully chilled. The animals for slaughter have to come from the same province or surrounding provinces (including another Member State if adjacent). Pending approval, temporary derogations apply. The production for slaughterhouses is limited to 20 units per week, 1 000 units per year and, for cutting plants, 5 tonnes per week of ungulate meat or 3 tonnes per week of poultry meat. The health mark applied is not to be confused with what is described in Art. 5 § 1 of Regulation (EC) No 853/2004. The meat has to be placed on the national market only.

The FBO has to apply for approval by 31 December 2009 at the latest. The lists of derogated SH and cutting plants are to be kept by the Regional Authorities. The Central Authority have notified these national measures to the European Commission and the Member States, as required by Art. 10 § 5 of Regulation (EC) No 853/2004. The mission team were informed that to date no establishments were approved under the provisions of these derogations.

5.4 APPLICATION OF HYGIENE RULES AT ESTABLISHMENT LEVEL AND OFFICIAL CONTROLS

5.4.1 Food business operators' obligations

In reply to the previous mission recommendation no 6 (“To ensure that FBO comply the general and specific hygiene requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004...”, see section 4), the Italian Authorities have taken a number of measures, including the introduction of penalties for the FBOs who do not respect the rules and on-the-spot inspections by the Central Authority of the FBOs in various regions, see section 5.1.1.2.

5.4.1.1 General hygiene requirements

Observations

- In 3 of the 4 SHs visited, general hygiene requirements, such as the cleanliness of premises and equipment and the general level of maintenance were found to be unsatisfactory.
- Crossing of flows of raw material, intermediate products, final products and crates with possible cross contamination were noted in one large cutting- and meat product establishment and in one medium sized cutting and meat preparation establishment, and , for the crates only, in one dairy establishment.
- Maintenance problems, such as rust, flaking paint, exposed insulation, leaking cold units were identified in 6 of the 9 meat and meat product establishments visited and in one milk-processing establishment. In particular, condensation problems,

sometimes serious, were present in several establishments, including this milk establishment.

- In the same milk processing establishment, in the cold store of final products, some of them exposed, the crates for the products were not properly cleaned, with visible mould stains on some of them. In the same establishment, the mixers coated with Teflon were flaking, with a risk of contamination of intermediate product. Only one of 3 mixers, recently re-coated, had a smooth surface.
- In 6 of the 9 meat and meat products establishments visited, equipment was insufficiently cleaned and some of the equipment was corroded.
- In 3 of the 4 slaughterhouses visited, pest control was unsatisfactory, with establishments operating with open doors and gaps under doors. In one SH numerous birds were present inside the building.
- In a number of cases, drains from cold units and hand washbasins were not properly ducted to floor drains in areas where unprotected products or meat was stored or processed. The Provincial Authority stopped production for the day in one establishment during the mission team visit due to leakage from the cold unit over the cutting table.
- In 2 of the 3 slaughterhouses seen in operation, floors, equipment, carcasses or their parts were hosed down causing splashing and a risk of general contamination of meat.
- Most of the establishments had facilities for the proper separation of working and street clothes. However, in a number of cases, they were not respected, with working and street clothes mixed up, dirty working clothes present in the lockers and a lack of a satisfactory system for the collection of dirty clothes.

5.4.1.2 Specific requirements

Many of the establishments visited did not comply with the specific hygiene requirements in Regulation (EC) No 853/2004.

Observations

- In a SH in the Region of Lazio the slaughter hygiene was unsatisfactory, with faecal contamination and hair on carcasses caused by improper slaughter procedures, contamination with the stomach content, due to deficiently tying-up the oesophagus, no sterilisation of the knives, one single sterilizer operating at prescribed temperature, and no sterilizers at the positions for carcass splitting and opening of the breast cavity. Cleanliness of the slaughter room, adjacent cold store and equipment were unsatisfactory.
- The cutting room adjacent to this SH, not in operation during the visit, was found to be acceptable from the point of view of structure, cleanliness and maintenance (with the exception of rust on the rail).
- In a SH in the Autonomous Province of Bolzano, the slaughter hygiene was unsatisfactory, with faecal contamination of carcasses, contamination with the

stomach content, due to deficiently tying-up the oesophagus, unacceptable de-hiding technique (hosing down of dirty carcasses prior to de-hiding and cutting across wet skin and under it without changing, rinsing and sterilising the knife). Only one out of 6 sterilisers checked operated at the prescribed temperature.

- In all (3 out of 3) cutting plants and meat product establishments receiving carcasses as raw material, there was no proper control at arrival. Contamination of incoming carcasses with grease from the rail, other black spots or even faecal contamination were noted. This problem was generally not understood by the FBOs who, when asked about incoming carcass controls and a fitted place for trimming them, answered, that they “do not receive dirty carcasses”.
- In one cutting plant, the operator did not change or sterilise the knife having cut a carcass with faecal contamination. The steriliser was not functioning.

In response to this situation, the CA took the following action:

- Operations in the SH in the Region of Sicily where the mission team had detected serious non-compliance were stopped from the next working day by the Regional Authority.
- The same action was taken the day after the visit of the mission team in a SH in Lazio.
- The Authority of the Autonomous Province of Bolzano announced at the final meeting that similar action was taken in a SH.
- Operations in one establishment in the Autonomous Province of Bolzano were stopped on the day of the FVO mission team visit because of contamination of the meat with condensation water. The CA assessed this problem as accidental (broken cold unit pipe). In the opinion of the mission team, this problem was systematic, due to very severe condensation in the whole cold store for carcasses prior to cutting, because of poor ventilation.

5.4.1.3 HACCP based systems

Observations

- The establishments visited had the documented HACCP plans in place. These were mostly established in co-operation with external consultants.
- HACCP based systems were at different degrees of development, from very few implemented to some only drafted on paper or not following the HACCP principles, for example Critical Control Points (CCPs) not properly designed, the principle of CCP not understood, no monitoring or corrective action described and lack of documentation.
- In the Region of Sicily, only one out of 5 establishments visited had a working HACCP based system. Other establishments presented systems with CCPs not following the HACCP principles, with no records or monitoring.
- In the Region of Lazio, in two SHs, in which auto control was run by the same consultant, the HACCP based system was satisfactory in one establishment but was

not following the HACCP principles in the other. This also includes the performance of bacteriological examination of carcasses as laid down in Regulation (EC) No 2073/2005.

- In the Autonomous Province of Bolzano, in the SH where the HACCP based system was checked there was no monitoring of CCP in place and some CCPs set should be considered as CP only (for example, vacuum packing) in the re-packing centre. For other CCPs the corrective action described did not reflect the reality and monitoring of one CCP was not performed.

The following observations were made regarding own check controls:

- Parameters and frequency of sampling and examination of bovine carcasses in the SHs visited were not respected in 3 of the 4 SHs visited.
- Pest control procedures were established in most establishments visited, but these were insufficiently controlled by the FBOs and insufficient measures were taken to prevent the presence of rodents, insects and birds. This was due to gaps under the doors, absence of nets on the windows and the obvious practice in the SHs of keeping the doors to the outside open.

5.4.1.4 Identification marking

Observations

- In two approved meat product establishments, the shape of the identification mark was not as requested by Art. 5 § 1 of Regulation (EC) No 853/2004.
- Unidentified meat in small quantities was found in one cutting plant. The systematic presence of some unidentified meat, intermediate and final products was noted in a large meat product plant, see below.

5.4.1.5 Traceability and labelling

Observations regarding traceability

- In one large cutting and meat product establishment, some intermediate products but also final products were present in chilling rooms without any identification or traceability information. The FBO defended this system, referring to documentation kept elsewhere. However, the correlation between documents and products could not be demonstrated in a satisfactory way. In the same establishment, crates containing raw material, said to originate in establishment X, had old labels from different establishments, but not establishment X.
- In one medium sized cutting and meat preparation plant, one batch was the production day. The mission team confirmed that the system allowed tracing back to a batch of pigs slaughtered in the supplying SH during one day.

Observations regarding identification of animal by-products

- Not all the containers used for the collection of animal by-products were properly identified in 3 of the 4 SHs visited. In one of them non-coloured specified risk

material was placed in plastic bags without any labelling in the cold store.

5.4.1.6 Control at arrival of animals at the slaughterhouses

Observation

- The controls at arrival were satisfactory in the SHs visited.

5.4.2 Official controls at establishments for verification of food business operators' compliance

Observations

- As indicated in section 5.1.3, official controls were performed in all the establishments visited, often with much higher frequency than requested by the requirements of the risk based classification system. It was explained to the mission team in one establishment visited that these visits were not to be considered as “official controls” but “periodical routine controls”. The controls were documented in the reports (*Verbale di sopralluogo*). However, in a number of cases, documentation of controls were not available. The OV in one establishment told the mission team that if there were no particular findings only oral communication took place.
- In a number of cases when the reports were available they contained no remarks or findings, and, in most cases, they did not reflect the situation in the establishments as seen by the mission team.
- Check lists were used for official controls. For milk establishments in Sicily, the checks lists differed from one province to another.

5.4.2.1 Audits of good hygiene practices

Observations

No documented evidence of the audits of good hygiene practice was found in the SHs visited.

5.4.2.2 Audits of HACCP-based procedures

Observations

- - o A deficient HACCP based programme was validated by the OV in one case.
 - o A HACCP based programme which did not exist in practice was described in the OV report as implemented in another case.
 - o The CA noted the deficiencies in identifying the CCPs in a very few cases.

5.4.3 Official inspection tasks in establishments

5.4.3.1 *Ante-mortem inspection*

Observations

- Ante-mortem inspections were always carried out by an OV. Ante-mortem records were generally available as was the health declaration accompanying the animals.
- The records for ante- and post-mortem inspection in one SH in the Region of Lazio did not contain any remarks for months. The status for ante-mortem was always indicated as "favourable" even in the case of emergency slaughter.

5.4.3.2 *Post-mortem inspection*

Observations

- Post-mortem inspections were always carried out by veterinarians and records of post-mortem inspections were available.
- The OV was not familiar with the performance of post-mortem inspection in the same SH in the Region of Lazio. The following deficiencies were noted by the mission team:
 - bovine hearts not opened as prescribed, or hearts not opened at all,
 - no inspection of bovine heads,
 - no inspection of white offal.
- In the previously mentioned SH in the Autonomous Province of Bolzano bovine heads were not post-mortem inspected, as they were removed prior to inspection, with only mandibula remaining on the hook.

5.4.3.3 *Health marking*

Observations

- Health marking was generally found to be acceptable but in some cases marks were difficult to read.
- In one SH 2 highly emaciated carcasses, which in the opinion of the mission team were unfit for human consumption, were found wearing health marks. It was explained to the mission team that they were destined for the zoo, but no documentation was presented to confirm this fact.

5.4.3.4 *Animal welfare at the time of slaughter or killing*

Observations

- Stunning performance and equipment were satisfactory in 2 of the 3 SHs seen in operation.
- In the third SH, in which 2 animals were slaughtered during the visit, one of them was shot twice. The construction of the stunning box allowed animals to move their heads, which made the stunning difficult.

- In the fourth SH, not in operation, the stunning position was not fitted with the volt- and ampere- meter. The FBO demonstrated that they have one set of indicators for 2 lines, and switched it between the sheep and pig lines according to need.

5.4.3.5 *Health requirements and criteria for raw milk*

A check on the incoming raw milk were carried out in one dairy establishment visited only. In the other establishment no raw milk was used for the production of milk products. In the third (non industrial) no checks on the incoming raw milk were carried out, with no evidence of action taken by the CA.

Observations

The system for check of incoming raw material was examined in one industrial dairy establishment in the Autonomous Province of Bolzano. If a supplier exceeds the limits for 2 months for TBC / 3 months for SCC, the FBO suspends the supplies for 5 days. After 5 days, the supplier is allowed to start again. If the same supplier exceeds the limits again, next time he will be suspended for 10 days. The system described was said to be in conformity with the instructions provided by the Provincial Authority. However, in the instruction for the performance of official controls in dairy establishments, issued by the Central Authority (Office III) via the SCR, suspension of suppliers for 5 respective 10 day periods is not mentioned.

5.4.4 *Action in case of non-compliance*

Observations

- - o In general, deadlines and follow up of controls were not documented.
 - o An establishment in Sicily, in which the mission team found very serious deficiencies in relation to cleanliness, maintenance, and own checks system, was previously suspended for 3 months by the ASL. However, the ASL failed to explain in a satisfactory way why the suspension was lifted, as no official control took place to check the compliance prior to lifting the restrictions. It was explained to the mission team, that the ASL took the decision by phone after a talk with a private consultant in charge of own checks system.
 - o In the region of Lazio, where 2 SHs were visited, of similar size, under the supervision of the same ASL, one was found to be satisfactory and one unsatisfactory. In addition, documentation was provided that the same ASL took efficient action in relation to a third similar SH in the same district (not visited by the mission team). When serious deficiencies were found in this SH in Autumn 2007, it was suspended, and the suspension was lifted only when the deficiencies were addressed.

6 CONCLUSIONS

6.1 FOLLOW-UP OF PREVIOUS FVO MISSIONS

The Central Authority replied to the recommendations of the previous mission report. At desk analysis, the response of the Central Authority was found to be satisfactory. On the spot, the mission team found that improvements had been made at central and regional levels. However, at local level, the action taken in response to some recommendations was not always sufficient, in particular, in relation to the efficiency of official controls and the enforcement of the hygiene rules by the FBOs as action has produced little results. Many of the observations about the establishments during the previous missions by the FVO (DG(SANCO)/8145/2006) in November 2006 and (DG(SANCO)2007-7435) in June 2007 were noted again during this mission.

6.2 COMPETENT AUTHORITIES

The Italian Ministries have recently been reorganized under the new government, however, no changes have been made in relation to the structure and organization of the Central Authority, and it has not influenced its relationship with the Regional Authorities.

The National legislation has been updated by the publication of *Decreto Legislativo 6 novembre 2007* completing the implementation of the Hygiene Package in the national legislation. The Central Authority provided the mission team with the first data concerning sanctions applied under this Law for non respect of the Hygiene Package requirements in 6 Regions.

The mission team did not identify coordination problems between the Central Authority and the Regional Authorities. The representatives of the regions met were well aware of the requirements of the current EU and national legislation, and they were committed to implementing it in their regions. They have produced and distributed updated guidelines and instructions for their services. They have implemented the instruction of the Central Authority of 31 May 2007 in relation to the classification of establishments on a risk basis. However, despite this coherent approach at regional level, their ability to enforce the rules was limited, in particular, in the Region of Sicily, and the official controls were not always efficient. At local level, there were significant differences between the regions visited. In more than half (7 out of 13) of the establishments visited, significant or major non-compliances, including for official controls, were found by the mission team. This is due to the non-implementation of the rules on the spot, including the performance of the OV because of poor enforcement by the higher (district) level.

Audits carried out by the CA at central and regional (Lazio) levels are mostly audits of FBOs and not audits of official controls as laid down in Art. 4.6 of Regulation (EC) No 882/2004. They have no proper follow-up and to date have not contributed to an improvement in the situation.

While satisfactory staffing was noted at local and district levels, staff shortages to carry out audits and inspections were observed at regional levels in Lazio and Sicily.

6.3 REGISTRATION AND APPROVAL OF ESTABLISHMENTS

All the approved establishments have been assessed for classification on a risk basis. The

establishments visited, with a few exceptions, had correct approvals. In the Region of Sicily, numerous small milk establishments are being reassessed in order to replace current approval by registration based on the agreement within the SCR on derogations for local producers. The national rules introduce derogations foreseen by Art.10 of Regulation (EC) No 853/2004 for slaughterhouses in the Autonomous Region Trento and Bolzano.

6.4 APPLICATION OF HYGIENE RULES AT ESTABLISHMENT LEVEL AND OFFICIAL CONTROLS

Little improvements were noticed since the previous mission regarding the application of hygiene rules at establishment level and official controls. Many deficiencies in the application by FBOs of their obligations were found during the previous FVO mission and were again identified by this mission team.

The general hygiene requirements were found to be satisfactory with only minor remarks or deficiencies limited to single rooms in 6 of the 13 establishments visited.

Major deficiencies were noted in relation to the structure, maintenance and general hygiene requirements of Regulation (EC) No 852/2004 in the remaining 7 establishments. Three out of 4 SHs visited, one situated in each region, did not comply with the specific hygiene requirements in Regulation (EC) No 853/2004. Only one very recently built SH was found to be satisfactory.

Implementation of HACCP-based systems, mostly developed and run by external consultants, were generally not satisfactory. A number of major deficiencies found by the mission team in different establishments, in particular in relation to lay-out, were not identified during the OVs' official controls.

Deficiencies were found in the performance of bacteriological examinations required by Regulation (EC) No 2073/2005.

Problems still exist in the performance of post-mortem inspection.

6.5 OVERALL CONCLUSION

A significant effort was undertaken at Central and Regional levels since the last mission to implement the Hygiene Package in a coherent way, however, the results at local and establishment levels were limited due in a number of cases to unsatisfactory enforcement. In particular, SHs had a poor performance with a lack of respect for essential rules. The audit systems by the Central and Regional Authorities are at a very early stage of implementation and to date have not been efficient.

7 CLOSING MEETING

A closing meeting was held on 23 May 2007 with the representatives of the Central Authority and of the Regional Authorities of the regions visited, during which the mission team presented its initial findings and conclusions of which the Italian

Authorities took note. They also provided clarification and additional information, in particular in relation to corrective action taken (see section 5.4.1.2).

8 RECOMMENDATIONS

The Central Authority is invited to provide, within twenty five working days of receipt of the report, an action plan containing details of the actions taken and planned, including deadlines for their completion, to address the following recommendations:

No.	Recommendation
1	To ensure adequate staffing and adequate prioritisation of food safety issues in all competent authorities involved, in particular at regional level in order to comply with Art. 4.2 of Regulation (EC) No 882/2004.
2	To extend action already initiated in order to fully implement the system of audits of competent authorities at all levels.
3	To take action in order to improve the system of official controls in Italy, to comply with all other requirements of Article 4 of Regulation (EC) No 882/2004.
4	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.
5	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 Art. 54 Regulation (EC) No 882/2004.
6	To ensure that post-mortem inspection in all slaughterhouses is carried out in compliance with the requirements of Regulation (EC) No 854/2004.
7	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 Commission Regulation (EC) No 2073/2005 and as laid down in Art. 10.2 of Regulation (EC) No 882/2004.

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

http://ec.europa.eu/food/fvo/ap/ap_italy_7930_2008.pdf

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Directive 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
Directive 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
Directive 98/83/EC	OJ L 330, 5.12.1998, p. 32–54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Directive 2004/41/EC	OJ L 157, 30.04.2004, p.33 corrected and re-published in OJ L 195, 02.06.2004, p. 12	Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation	OJ L 338,	Commission Regulation (EC) No 2075/2005 of 5

Reference	OJ Ref.	Detail
(EC) No 2075/2005	22.12.2005, p. 60–82	December 2005 laying down specific rules on official controls for Trichinella in meat
Regulation (EC) No 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
Regulation (EC) No 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 by-products not intended for human consumption
Regulation (EC) No 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 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
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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

Reference	OJ Ref.	Detail
Regulation (EC) No 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