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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

ITALY

FROM 06 TO 17 SEPTEMBER 2010

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE  
PRODUCTION AND PLACING ON THE MARKET OF FISHERY 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 specific audit in Italy which took place between 6 to 17 September 2010, as part of the General Audit of Italy carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.*

*The specific audit evaluated the implementation of national measures, aimed at the control of the production of fishery products.*

*Currently the official control system covering fishery products in Italy is implemented across three competent authority levels: central, regional and local.*

*This system presents significant shortcomings concerning the official controls of primary production (i.e. aquaculture farm and fishing vessels) and freezer and factory vessels. In general the official controls of fishery products are well implemented in both regions visited. However, deficiencies were identified in respect of the monitoring arrangements to check residues and contaminants in fishery products.*

*In addition, the effectiveness and comparability of official controls cannot be ascertained by the different levels of competent authorities due to limited or non existing verification procedures.*

*It is therefore concluded that the system of official controls of fishery products implemented by the Italian competent authorities cannot be considered as fully compliant with EU requirements due to the deficiencies observed and in particular the limited or absence of verification procedures.*

*The report makes a number of recommendations to the Italian competent authorities, 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**

<b>Abbreviation</b>	<b>Explanation</b>
AUSL	Local Health Units
CA	Competent Authority
CCA	Central Competent Authority
CP	Country Profile
DG(SANCO)	Health and Consumers Directorate-General
DGFSN	Directorate General for Food Safety and Nutrition
DVPHNFS	Department for Veterinary Public Health, Nutrition and Food Safety
EC	European Community
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Points
IZS	Experimental Zooprohylaxis Institute
MANCP	Single Integrated Multi-Annual National Control Plan
MH	Ministry of Health
MS	Member State
RASFF	Rapid Alert System for Food and Feed
SIAN	Food and Hygiene Service

## 1 INTRODUCTION

The specific audit formed part of the Food and Veterinary Office's (FVO) planned mission programme. It took place from 6 to 17 September 2010 and forms a component of the FVO's general audit to Italy. The audit team comprised two inspectors from the FVO. Representatives from the central competent authority (CCA) accompanied the audit team for the duration of the audit.

An opening meeting was held on 6 September 2010 with the CCA and the competent authorities (CAs) of the regions to be visited, Sicily and Veneto. At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit team. Not all the information requested by the audit team was made available by the regional CA of Sicily.

## 2 OBJECTIVES 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 single integrated multi-annual national control plan (MANCP) prepared by Italy
- evaluate whether the organisation of the CAs and their implementation of national provisions, for the control of fishery products are compliant with EU requirements.

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

- As regards Regulation (EC) No 882/2004, the organisation of official controls (Article 3-7), control and verification procedures and methods (Article 8-10), enforcement (Article 54-55), MANCP (Article 41-42) and registration and approval of establishments (Article 31).
- As regards the specific area under review the following legislation was subject of the audit:
  - Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption;
  - Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs;
  - 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, in particular Annex III, Section VIII;
  - 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;
  - Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;
  - Commission Regulation (EC) No 2074/2005 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 (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.

The table below lists the sites visited and meetings held in order to achieve these objectives:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Initial and final meeting at the headquarters of the CCA (Directorate General for Food Safety and Nutrition, “ <i>Direzione Generale della Sicurezza degli Alimenti e della Nutrizione</i> ” (DGFSN))
	Regional	2	Meetings with the regional CAs of Veneto and Sicily regions
	Local	2	Meetings with the local CAs (Local Health Units, “ <i>Aziende Unità Sanitarie Locali</i> ” (AUSL)) of Mazara del Vallo and Chioggia.
LABORATORIES		2	Laboratory of the Experimental Zooprophyllaxis Institute, “ <i>Istituti Zooprofilattici Sperimentali</i> ” (IZS) of Sicily (headquarters in Palermo) and IZS laboratory of Venice (headquarters in Legnaro-Padua).
FISH FARMS		2	One in each region visited.
ESTABLISHMENTS		8	Four in each region visited.
OTHER SITES		3	Fishing vessels.
		2	Freezer vessels.
		2	Landing sites.

### 3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of EU legislation, and in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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 (MS). The main purpose of such audits is to verify that, overall, official controls take place in MS in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with EU 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 fishery products specific issues.

## **4.2 SUMMARY OF PREVIOUS FVO MISSION RESULTS**

The previous mission concerning fishery products was carried out from 20 September to 1 October 2004 the results of which are described in report DG(SANCO)/7026/2004. This report is accessible at [http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=1299](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1299).

The CCA sent an action plan addressing all the recommendations of this report in a satisfactory way other than the details on how it intended to ensure that the EU legislation applicable at that time was uniformly implemented, controlled and enforced throughout the whole Italian territory.

## **4.3 PRODUCTION AND TRADE INFORMATION**

According to the Italian CCA website, approximately 2,300 food business operators (FBOs) facilities are approved to place fishery products on the market (34 factory vessels and 179 freezer vessels are included).

According to the information provided by the Italian CCA, national production of wild fishery products was 227,000 tonnes in 2008 and national production of aquaculture fishery products was 74,000 tonnes in 2009.

According to Eurostat, in 2009:

- Italy imported over 444,000 tonnes of fishery products from 80 third countries (TCs), mainly from Thailand (13%), Vietnam (8,96%), Ecuador (8,78%), Morocco (7,05%), Argentina (6,44%), India (5,93%) and China (4,97%).
- Italy received 468,000 tonnes of fishery products from other MS, mainly from Spain (38,7%), The Netherlands (10,65%), Greece (10,43%), France (10,15%), Germany (9,81%) and Denmark (9,2%).
- Italy sent 109,000 tonnes of fishery products to other MS, mainly to Spain (49,65%), France (11,18%), Greece (10,43%) and Germany (8,92%).

## **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 MS to designate the CAs responsible for official controls.

#### **Findings**

Designation of the CAs responsible for official controls and their management structure are detailed in the country profile (CP) for Italy, DG(SANCO)/8105/2009 – CP Final, available on the internet at:

[http://ec.europa.eu/food/fvo/country\\_profiles/CP\\_italy.pdf#page=8](http://ec.europa.eu/food/fvo/country_profiles/CP_italy.pdf#page=8).

As described in Italy's CP, Office III of DGFSN within the Department for Veterinary Public Health, Nutrition and Food Safety (DVPHNFS) of Ministry of Health (MH) functions as the CCA responsible for the area covered by this specific audit.

The description, organisation and duties of NAS (a special branch of military police forming part of the *Carabinieri*) can also be found in the Italian CP. During the specific audit the controls carried out by NAS staff were not evaluated by the audit team.

With regard to water the designated CCA is Office IV of the Directorate General for Sanitary Prevention within the Department for Prevention and Communication of MH.

The designated CAs at regional level, the regional Veterinary Services, are also described in the Italian CP.

The audit team noted that in Sicily the designated regional CA is the Food Hygiene Service within the Department for the Sanitary Activity and Epidemiological Observatory of Sicilian Health Councillorship (*Assessorato della Salute*) and in the Veneto region the designated CA is the Food Hygiene, Nutrition and Water Service within the Animal Health and Food Hygiene Department (*Unità di Progetto sanità animale e igiene alimentare*) of the Health Regional Secretariat.

The Italian CP also describes the designated CAs at local level, the AUSLs (*Aziende Unità Sanitaria Locale*). Within these AUSLs the public health responsibilities are shared between two separate services: the Food and Hygiene Service (SIAN) (dealing with water potability) and the Local Veterinary services, which are divided in three different areas (A, B and C).

The audit team noted that the designation of the AUSLs recently become ASP (*Aziende Sanitaria Provinciale*) in Sicily and AULSS (*Aziende Unità Locale Socio Sanitaria*) in Veneto.

The audit team noted that each level of CA (central, regional and local) has a high degree of independence from the other levels. The responsibilities of each CA level is mentioned in Italy's CP.

### 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**

The co-operation between CCA and regional CAs is ensured through monthly meetings of the Permanent Inter-Regional Committee on Food Safety which is assisted by different working groups, e.g. "Fishery Products Technical Working Group". The decisions and documents agreed in the above Committee are then sent to the Standing Conference State-Regions for political approval and further sent to the regions to be transposed into the regional legal framework.

Eight regions take part on a voluntary basis in the Fishery Products Technical Working Group: Campania, Emilia Romagna, Lazio, Liguria, Puglia, Sardinia, Sicily and Veneto. This working



group has dedicated the last two years to the development of working documents related to the application of Regulations (EC) Nos 852/2004, 853/2004 and 854/2004 to Live Bivalve Molluscs. More recently it has been working on four specific topics, *i.e.*

1. official controls of the landing sites and transport to the first FBO;
2. visual checks for parasites;
3. Hazard Analysis of Critical Control Points (HACCP) for fishery products to be consumed raw and;
4. official controls of fishing vessels.

The Fishery Products Technical Working Group is also currently revising fishery products Guidelines issued in November 2006 and is expected to submit a revised version to the Standing Conference State-Regions by the end of 2011.

Between the regional CAs and the AUSLs co-operation is ensured by several meetings and exchanges of information.

With regard to the co-ordination role of the regional CA over the AUSLs in Sicily the audit team noted that that this co-ordination role is restricted to the reception of information from the AUSLs to be sent to the CCA and the diffusion of CCA guidance documents to the AUSLs. The regional CA does not co-ordinate the interpretation and the implementation of the CCA guidelines nor the official inspection plans. The audit team noted that the interpretation of the CCA guidelines by different AUSL staff in charge of official controls was different and had a negative impact on the performance of the official controls.

#### *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**

Within each of the CAs co-operation is ensured, as necessary, through technical meetings and exchanges of information (reports on official controls carried out, guidance documents) and also through training sessions. In one AUSL visited by the audit team areas A and C were merged to improve co-ordination and co-operation.

#### *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**

There is no delegation of official tasks to control bodies.

### *5.1.5 Contingency planning*

## **Legal Requirements**

Article 4 of Regulation (EC) No 882/2004 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 MS 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**

Under a MH Decree of 7 March 2008 a crisis unit was established within the CCA to deal with outbreaks regarding foodstuffs. Facilities, equipment, chain of command, responsibilities and list of contact points were identified and made available to the different CAs. This crisis unit was then replicated at regional and local levels.

The CCA contingency plan was tested in May 2010 with all regions and the outcome was satisfactory. Another test involving the FBOs is planned.

In Sicily a formal plan was also drafted and distributed to the relevant services. In Veneto arrangements to follow the crisis unit established at CCA level were defined but no written procedure has yet been drafted.

## **Conclusions on Competent Authorities**

Competent authorities were designated in accordance with EU requirements and with regards to fishery products there are three levels of CA, *i.e.* CCA, regional CAs and local CAs.

Co-operation and co-ordination between and within the CAs visited is ensured by different mechanisms. Nevertheless, the regional CA of Sicily does not ensure efficient and effective co-ordination of the AUSLs in charge of carrying out the official controls.

No official tasks are delegated to other control bodies.

A contingency plan and/or arrangements are in place in accordance with EU requirements.

## **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 CAs have the necessary powers of access to food business premises and documentation.

## **Findings**

The powers of official staff to carry out official controls are set down in national legislation, in particular Law No 689/1981. This legislation assigns the powers to CA staff to enter establishments, have access to documentation, take official samples, implement enforcement and put in place necessary decisions and orders. CA staff, under the terms of Article 3 of Law 283/1962, may also request police assistance where and when necessary. The FBOs are obliged to allow their premises to undergo inspection by the CAs.

The powers to inspect in the context of regular/routine official controls are attributed only to the veterinary inspectors of the local CAs and do not include staff from regional CA or CCA. This issue was raised by the regions which question the legal basis for the CCA to carry out such inspections in establishments based on Italian constitutional arrangements. The audit team was informed by the CCA that this issue had been clarified and that inspections to premises can be performed by the CCA officials, but only in the context of audits.

During the specific audit the audit team noted that, in general, official inspectors have access to the establishments and the relevant documentation without restriction. Inspection reports were available in the premises visited and none of them cited any problem concerning access to premises or documents.

Nevertheless, in Sicily and on two separate occasions during the specific audit the audit team was unable to perform the assessment of the FBOs. In one case, one local CA informed that the requested unannounced visit could not take place because it was not possible to find or contact the FBO and the establishment was closed. In another case, vessels were available for inspection but no FBO was present, as a consequence the audit team did not have access; on the following day FBOs of two vessels were present but in one of the vessels no documentation was available for assessment.

### *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**

Staff numbers of the different CAs involved in the official controls are indicated in Italy's CP.

The audit team noted that the CCA has one official appointed for the fishery products sector and another official to perform on the spot inspections to establishments. This fishery products CCA appointee depends upon the cooperation of other staff within the DGFSN and DVPHNFS for specific horizontal issues, e.g. additives, environmental contaminants, training and laboratories.

The regional CAs of Sicily and Veneto stated that the human resources available for the execution of the tasks assigned to them were not sufficient. In addition the Sicilian CA stated that a re-organisation of the services was carried out during 2009 adding potable water quality supervision to the competence of the service.

The audit team confirmed that in Sicily the regional CA had not drafted annual inspections plans, nor coordinated the activities of the AUSLs (including the issuance of guidance documents and written procedures) and had not ensured the verification of the official controls performed by the AUSLs. The audit team also noted that the duties of information transmission between the CCA and the AUSLs were ensured, nevertheless, deficiencies were noted (see sections 5.3.2 and 5.3.3). After the services reorganisation and the recruitment of a new staff member in December 2009, the Sicilian CA prepared official control plans covering different sectors but fishery products were not included, e.g. Genetically Modified Organisms, Phytosanitary Residues, Phytosanitary Products, Acrylamide, Mycotoxins, Allergens, Solid Impurities in foodstuffs and RASFF.

In Veneto the audit team was informed that due to the non-replacement of one staff member the 2010 regional audit programme to the AUSLs was not carried out. Despite the shortage of staff stated by Veneto CA, the audit team noted that written procedures (which include guidance documents), annual inspections and sampling plans and communication mechanisms between the CCA and the AUSLs were created and are in place.

In the AUSLs visited the audit team found that staff carrying out fishery products official controls are also in charge of official controls and sampling of other premises producing, handling or selling foodstuffs (including temporary premises and retail), which could mean that an official could be responsible over one year for from 9 to 30 approved establishments and up to 500 registered premises. The audit team noted that the planned official control frequencies were not respected by AUSLs staff (see section 5.3.2).

The audit team visited one local office and found that staff carrying out official controls had access to adequate and properly maintained facilities and to proper equipment, e.g. telephone, computers, hard copies of files, procedures and legislation, electronic copies of files, procedures and legislation and measuring equipment. Some of the establishments visited also had a locked office for the official inspectors.

According to the information provided by the CCA and CAs the independence and prevention of conflict of interest of official staff are dealt with in the Ministerial Decree of 28 November (Code of conduct for civil servants) and also in the *Professional Code* for veterinarians.

### 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**

Staff performing official controls must possess a specific qualification such as a university degree in veterinary medicine and also a specialist diploma in the field of food hygiene.

Permanent training is given to all staff under the national programme for continuous education in medicine (ECM). The ECM covers the training given by the AUSLs, scientific or professional companies, IZS and other bodies specifically involved in health training.

The CAs also informed the audit team that specific training was also provided to regional and local staff, in particular with regard to audits and auditing techniques to be used in the framework of official controls.

### **Conclusions on Resources for Performance of Controls**

The CAs have the necessary legal powers to perform their official control tasks.

At regional level not all the assigned tasks are carried out and at local level the frequencies of controls are not respected. Both regional CAs visited signalled a shortage of staff.

Staff qualification and training were found to be adequate.

## **5.3 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS**

### *5.3.1 Registration / approval of food business operators establishments*

#### **Legal Requirements**

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

#### **Findings**

Fish farms should be registered at the AUSLs (Area A). However, because of the different types of procedures and information storage software used by the different CAs a common national procedure has been developed by the CCA and is ready to be implemented by Office II of Directorate General for Animal Health and Veterinary Medicine within DVPHNFS.

Fishing vessels are registered by the port authorities (under the Ministry of Agriculture and the Ministry of Transport) for non-sanitary requirements. With the entry into force of Regulations (EC) Nos 852/2004 and 853/2004 a “Declaration of Commencement of Activities” (DIA – *Dichiarazione Inizio Attività*) was introduced under national legislation in all regions. In Sicily this DIA is submitted by the FBO to the municipal authority following which the FBO must register with the AUSL for sanitary purposes. In Veneto the FBO must submit the DIA directly to the AUSL.

The AUSLs and Port Authorities exchange information in order to identify all primary production fishing vessels and to require them to undergo sanitary controls. However, the audit team noted that not all primary production fishing vessels are under the sanitary supervision of the AUSLs.

There is a procedure in place for establishment approval which is implemented at regional level. The regional CA under a proposal from the respective AUSL approves an establishment after an on-the-spot visit. Initially a conditional approval for up to three months can be granted. If within the

three months the results of inspection visits are not satisfactory conditional approval may be extended up to a maximum period of six months. Once approval has been granted by the regional CA, the information is then entered in the national database for approved establishments, SINTESI.

Regarding the approval procedures the audit team noted that all the establishments visited were approved in accordance with EU requirements, with the exception of:

- One establishment in Sicily where provisional approval was extended for longer than the maximum allowed period of six months;
- The documentation of a factory vessel provided by the CA to the audit team showed that a provisional approval was issued in 1996 and a final approval was never granted;
- A freezer vessel operating since 2001 was approved in 2008. In relation to this finding both the regional CA and the CCA stated that in, “Guidelines for Fishery Products and the New Community Legislation”, of 16 November 2006 and published in *Gazzeta Ufficiale* N. 68 of 22 March 2007, the deadline for the approval of freezer vessels was 31 December 2009 and as such the audit team finding was not a noncompliance under Italian legislation;
- In a wholesale market in Veneto, a single approval was granted covering the main building and the 58 surrounding units. However each of the 59 premises are under the responsibility of different FBOs and have their own HACCP plans.

### 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 should be carried out at any stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls should be applied with the same care to exports from the EU, imports into the EU and to product placed on the EU market.

## **Findings**

The CCA issued, on 31 May 2007, guidelines (reference DGSAN/3/6238/P, referred to hereafter as CCA Guidelines) for the official controls foreseen in Regulations (EC) Nos 854/2004 and 882/2004 where a risk based approach for the categorisation of food processing establishments was proposed. These guidelines were sent to all regions in order to establish minimum standards and criteria for the risk categorisation to allow the regional CAs to draft the annual official control plans and the setting up of adequate frequencies for the different types of control activities, methods and techniques.

The audit team noted that in Veneto Decree No 292 of 23/05/07 and annexes were drafted and adopted by the regional CA even before the issuance of the CCA Guidelines. This Decree is in line with the CCA Guidelines, covers at least the same requirements and adapts the risk categorisation to the characteristics of the region. The audit team noted that this Decree also determines the frequency for official controls to be carried out based on the risk categorisation of each premises.

Conversely, in Sicily the audit team noted that the CA forwarded, with a two months delay, the CCA

Guidelines to the AUSLs without establishing frequencies for the official controls to be carried out. After the reception of the CCA Guidelines each AUSL established their own official control programme with individually defined frequencies. Three of the four AUSLs visited provided their official control programmes, together with forms, check-lists and written procedures for those controls. The audit team noted that although the three AUSLs used the same guidelines for risk categorisation with three risk classes (high, medium and low) the frequencies defined for each risk class were different, *e.g.*:

- for the low risk class the frequency foreseen ranged from once a year to three times a year;
- for the medium risk class the frequency foreseen ranged from one visit every three or six months to a bimonthly visit;
- for the high risk class the frequency foreseen ranged from a bimonthly visit to a monthly visit.

Furthermore, the audit team was informed by an AUSL staff member during a visit to one establishment that no instructions were available to define the frequency of controls based on the risk categorisation and that when the establishments were categorized as high risk the local CA together with the FBO would take the necessary measures to reduce the risk in order to allow the establishment to be graded as either medium or low risk.

The audit team noted that the establishments risk categorisation was being implemented in both regions since 2007. The first risk categorisation of an establishment is carried out following an on-the-spot visit and then every year a new risk evaluation is performed based on a desk study. In all the establishments visited by the audit team a risk categorisation was performed. In one case, the assessment of the risk factors was not properly executed and as consequence an establishment that should have been categorised as high risk was categorised as medium risk.

### *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**

The CCA Guidelines specify the control activities, methods and techniques that should be used by the CAs in the performance of official control visits to establishments. The audit team found this to be compliant with EU requirements. This document clearly describes the instruments available, when they should be used, what should be checked and recorded, how to record the results of those checks. Finally, it also defines how and when to communicate the annual official control activities to the CCA.

As mentioned in section 5.3.2, the Veneto CA drafted and adopted the Decree No 292 where the control activities, methods and techniques that must be used for the performance of the official control visits to the establishments are defined. It also specifies the different frequencies for the different visit types (*e.g.* verifications, inspections and audits).

In Sicily the situation concerning guidelines and frequencies of visits is as described in section 5.3.2. Each AUSLs visited provided their own documentation describing the different control activities, methods and techniques that must be used for the performance of the official control visits to the establishments. This documentation consisted, among others, in written procedures, forms, check-list, official notifications to FBOs and sampling forms.

In general, the audit team found the control activities methods and techniques applied in both regions to be compliant with EU requirements.

#### *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**

The official laboratories network is described in the CP for Italy.

Official samples are taken by AUSL staff in accordance with defined procedures. All the samples are sealed when collected and an accompanying form is filled out.

#### *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 CCA Guidelines provide guidance concerning the use of documented procedures containing information and instructions for staff performing controls. These guidelines should be the basis for regional CAs to develop their own documented procedures. In certain cases and in particular as a response to a previous FVO mission the CCA drafted a specific check-list to be used for HACCP evaluation. That check-list was sent to all regions on 30 March 2009.

The audit team found that the Veneto CA adopted written procedures for the performance of the official controls, which are included in Decree No 292 and respective annexes. This document gives precise instructions concerning, among others, the requirements to be evaluated in each visit, the check-lists to be used (where and when necessary), the records to be produced in case of non-compliances detection and how and when to communicate the annual official control activities to



the regional CA.

In Sicily the audit team found that no written procedures were drafted at regional level. The CA forwarded the CCA Guidelines to the AUSLs (see section 5.3.2). During the specific audit the different AUSLs audited showed and/or supplied the audit team with the written procedures to be used during official controls. This documentation consisted of, among others, written procedures, forms, check-lists, official notifications to FBOs and sampling forms. As described already each AUSL had their own individual document templates. The audit team found that the written procedures were at different stages of development and implementation, some of them were drafted just recently and they had not, at the time of the audit, been implemented, others were implemented and finally some are currently being revised. In one specific case the check-list for the HACCP evaluation issued by the CCA on 30 March 2009 was sent to an AUSL six months later, on 29 September 2009. It then took the AUSL one and half months to send it to the official veterinarian in charge of official controls.

### *5.3.6 Transparency and confidentiality*

#### **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**

Audit reports, annual reports on the official control activities in the framework of the MANCP and rapid alerts notices are published on the web site of the CCA. For confidentiality reasons reports of sectoral audits carried by the CCA on the establishments (see section 5.5.1) are not published, but only made available to the CAs.

#### **Conclusions on Organisation and Implementation of Official Controls**

A system for registration and approval of FBOs is implemented and is based on documented procedures. However, gaps or deficiencies concerning the registration of primary production fishing vessels and the approval of factory vessels and freezer vessels do not ensure that all facilities involved in the production and distribution of fishery products are under sanitary supervision. Deficiencies were also noted concerning the period for conditional approval.

In Sicily the delay of the regional CA in transmitting/adapting and implementing CCA guidelines concerning the official controls had a negative impact on the fishery products official control system.

Prioritisation of official controls is performed based on procedures defined at different CA levels which does not ensure a consistent and uniform approach throughout Italy and as a consequence does not ensure the same level of food safety across similar activities.

The control activities, methods and techniques used for the performance of official controls and the laboratory capacity available are compliant with EU requirements.

## 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

According to the information provided by the CCA and CAs there are different types of measures that can be applied by the different CAs involved to ensure that non-compliances detected are corrected by the FBOs:

- Issuance of non-compliance note with deadlines for the correction;
- Seizure of product and if necessary its destruction;
- Suspension of one or all of the activities of the FBO concerned;
- Withdrawal of approval.

These measures are in general applied/proposed by the AUSLs and if needed applied by the regional CA, e.g. approval withdrawal, but in case of serious or special circumstances those measures can be imposed directly by the regional CA or even the CCA in the most extreme cases.

In case of repeated non-compliance a sanction can be applied (see Section 5.4.2 below).

The CCA informed the audit team that following CCA inspections carried out from 12 to 16 October 2009 to four fishery products establishments in Sicily in one of them activity was suspended and the withdrawal of approval proposed. The notice of withdrawal of approval was provided.

### 5.4.2 Sanctions

#### Legal Requirements

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

#### Findings

Sanctions to be applied to FBOs in case of infringements of food law are described in:

- Legislative Decree No 193 of 6 November 2007, which foresees fines up to €30,000 for infringements to Regulations (EC) Nos 852/2004, 853/2004 and 2073/2005 and to measures (e.g. - suspension of activity/ies and approval withdrawal) taken in cases of repeated non-compliances;
- Legislative Decree No 190 of 5 April 2005, which foresees fines up to €12,000 for infringements to Articles 18 to 20 of Regulation (EC) No 178/2002.

Moreover, the Legislative Decree No 194 of 19 November 2008, which prescribes that additional

cost for reinforced or additional official controls (in application of Article 28 of Regulation (EC) No 882/2004) must be charged to the FBO concerned, is used as an additional sanction.

There is an obligation to refer the case to the public prosecutor for investigation in case of suspicions of criminality, even in situations where administrative sanctions are imposed.

### **Conclusions on Enforcement Measures**

The actions foreseen in Article 54 of Regulation (EC) No 882/2004 are applied by the different CAs involved in accordance with that Article.

Rules on sanctions applicable to infringements of food law were adopted and are in accordance with 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**

Currently supervisory arrangements over the tasks performed by the local and regional CAs are not implemented. Until 2009 supervisory inspections were carried out in the regions by the CCA (Office III of DGFSN). Twenty fishery products establishments were inspected in five regions (i.e. Calabria, Liguria, Puglia, Sardinia and Sicily). The reports of these inspections visits carried out to the Sicilian establishments were provided to the audit team who noted that the deficiencies detected during those earlier inspections were similar to the ones detected during this specific audit (see section 6.1). Furthermore, the activities of one establishment were suspended and the approval withdrawn following the CCA inspection (see section 5.4.1).

The regional CAs of Veneto and Sicily informed the audit team that supervision is carried out or foreseen to be carried out during regional audits of the AUSLs (see section 5.5.2).

### *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**

Currently no audits are carried out by Office IX of Directorate General for Animal Health and Veterinary Medicine within DVPHNFS (the service within the CCA designated to perform audits) over the regional CAs. It was foreseen to start to perform audits of the regions in the beginning of 2010 but the procedure was delayed and is expected to begin in October 2010.

In Sicily the regional authorities are in the initial stages of audit training and drafting of procedures. It is expected to be implemented at some later date.

In Veneto a system of audits of the AUSLs was implemented in 2009 and three audits were carried out by the regional CA. The CA drafted the audit reports indicating the non-compliances detected and an action plan to correct those deficiencies was requested from the AUSLs concerned. However, the requested action plans were not delivered by the AUSLs. External audits of the CCA are not foreseen.

### **Conclusions on Verification Procedures and Audit**

Currently procedures for the verification of the effectiveness and appropriateness of the official controls are either implemented in an inconsistent way or are absent.

Currently audits as required by Article 4 of Regulation (EC) No 882/2004 are not carried out by the CCA or other external body.

## **5.6 MULTI ANNUAL NATIONAL CONTROL PLAN**

### **Legal Requirements**

Article 41 of Regulation (EC) No 882/2004 requires that each MS 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 MS concerned are provided.

### **Findings**

The audit team noted that the current available MANCP covering the years 2007-2010 and divided into three sections includes the identity and description of all control authorities responsible for official controls of food and feed safety, animal health, animal welfare and plant health. Section 1, on control systems, gives a general description of the official controls system applicable to food of animal origin, which includes fishery products, though no specific operational information with regard to fishery products is provided. It was noted that the plan has not been updated, although the annual MANCP reports contain a section describing updates on implementation that were performed in that year and the updates proposed for the following year.

Reports on the implementation of the MANCP are published annually on the CCA website, with the latest available covering the year 2009. All regions are required to supply the CCA with the relevant data concerning the implementation of their respective control programmes. The CAs of both regions showed to the audit team the reports which had been sent to the CCA with the information concerning the implementation of the fishery products official control plans.

The MANCP defines the head of the CCA as the National Contact Point. The National Contact

Point is responsible for preparing the MANCP, for producing the annual reports, and for coordinating any activities necessary on foot of the evaluation of the annual reports.

## **Conclusions on Multi-Annual National Control Plan**

The Italian CCA prepared a MANCP for 2007-2010 in accordance with Article 42 of Regulation (EC) No 882/2004, which is, in general, implemented in the regions visited.

### **6 SECTOR SPECIFIC FINDINGS AND CONCLUSIONS**

#### **6.1 OFFICIAL CONTROLS OF PRODUCTION AND PLACING THE MARKET**

##### *6.1.1 Primary production (aquaculture farms, fishing vessels)*

#### **Legal Requirements**

Point 4, Section VIII of Annex III to Regulation (EC) No 853/2004 states that, in relation to fishery products, primary production covers farming, fishing and the collection of live fish with a view to their being placed on the market.

Part A of Annex I to Regulation (EC) No 852/2004 lays down the general hygiene provisions for primary production and associated operations.

Point 2 of Article 4, of Regulation (EC) No 854/2004 requires that the CA should carry out official controls to verify FBOs' compliance with the requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004.

Point 1 (b) of Chapter I, of Annex III to Regulation (EC) No 854/2004 requires that official controls on the production and placing on the market of fishery products are to include, in particular, inspections at regular intervals of vessels and establishments on land, to check, in particular, whether the fishery products are handled correctly, for compliance with hygiene and temperature requirements, and the cleanliness of vessels, their facilities and equipment, and staff hygiene; and checks on storage and transport conditions.

Chapters I and III, of Section VIII, of the Annex III to Regulation (EC) No 853/2004 lays down the requirements that should be followed by FBOs responsible for vessels.

#### **Findings**

Currently, official control visits to aquaculture farms intended to verify compliance with Regulation (EC) No 852/2004 are not carried out.

Fish farms are visited by AUSL staff (Area A) to check animal health requirements, traceability and for sampling under the National Residues Monitoring Plan.

The audit team visited one fish farm in each region (Sicily and Veneto) and noted that:

- No records of CA visits (Area A) were available for the farm in Sicily;
- Regular visits to the farm in Veneto were performed by AUSL staff to check compliance

with EU requirements (mainly animal health and residues) and records of those checks were available. NB: these checks included verification of compliance with the requirements of Regulation (EC) No 852/2004 even if those requirements were not included in the legal basis for the visit, but no conclusion concerning compliance of fish farms is produced;

- The farms visited can be considered generally as compliant with EU requirements.

Fishing vessels which are registered as primary producers are also subject to inspections carried out by AUSL staff. The inspection reports provided by the CA showed that the check-lists used in Sicily did not cover all the applicable EU requirements. In the CAs procedures and inspection plans, it is foreseen that primary production facilities should be inspected once a year. However, the inspection of primary production fishing vessels started recently. Furthermore, as a consequence of the fact that not all fishing vessels are currently under sanitary supervision (see section 5.3.1), not all vessels are inspected.

The audit team visited three fishing vessels and apart from minor structural, equipment and hygiene deficiencies they can be considered as compliant with EU requirements.

### **Conclusions**

An official control system to check compliance of aquaculture farms to EU requirements, in particular with the requirements of Regulations (EC) Nos 852/2004 and 853/2004, is not currently implemented in Italy. Nevertheless and despite this absence, in Veneto, fish farms are checked for those requirements during the visits performed to evaluate animal health and residue requirements.

Currently the official controls of fishing vessels are not performed in accordance with EU requirements. They are not regular and they are not performed to all primary production fishing vessels.

#### *6.1.2 Landing sites and first sales site*

### **Legal Requirements**

Point 2 of Article 4, of Regulation (EC) No 854/2004 requires that the Competent Authority (CA) shall carry out official controls to verify FBOs compliance with the requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004.

Points 1 (a) and (b) of Chapter I, of Annex III to Regulation (EC) No 854/2004 require that official controls on the production and placing on the market of fishery products are to include, in particular, regular checks on the hygiene conditions of landing and first sale sites, and hygiene of establishments on land, including fish auctions and wholesale markets in order to check the approval conditions, hygiene of handling and temperature of the products.

Chapter II, of Section VIII, of Annex III to Regulation (EC) No 853/2004 lays down the structural, equipment, and hygiene requirements that should be followed by FBOs responsible for these premises.

### **Findings**

Regular checks on the hygiene conditions of landing of fishery products are performed by the

AUSLs in both regions. In Sicily the landing sites are independent from processing establishments and are located in fish harbours. In Veneto, usually the landing sites are annexed to wholesale markets and controlled at the time of the official control of those markets.

The audit team visited one landing site in each region and noted that:

- The landing site in Sicily consisted of a quay where the fishing vessels can moor and unload fishery products directly to transport vehicles. This landing site had no unloading equipment on land nor a water supply. At the time of the audit team visit the landing site was not in operation (no landing of fishery products was foreseen due to bad weather conditions);
- Monthly inspections were performed to that landing site by AUSL staff from January to August 2009. However, all inspection reports stated that “no activity was being carried out at the time of the visit and no other findings were observed”;
- For 2010 it was planned to carry out weekly inspections (50 over the year) to that landing site. However, the inspections started in March 2010. For every inspection carried out a check-list was used and a report produced. The inspection reports cover the hygiene of landing operations, workers, vessels and transport vehicles.
- The landing site in Veneto was annexed to a wholesale market and was in operation at the time of the visit. The landing operations observed were compliant with EU requirements.

## **Conclusions**

Currently the official controls on the hygiene conditions of landing sites are carried out by the CAs and are compliant with EU requirements.

### *6.1.3 Facilities handling fishery products: freezer and factory vessels*

## **Legal Requirements**

Point 1 (b) of Chapter I, of Annex III to Regulation (EC) No 854/2004 requires that official controls on the production and placing on the market of fishery products are to include, in particular, inspections at regular intervals of vessels, to check, in particular, whether the conditions for approval are still fulfilled and the fishery products are handled correctly, for compliance with hygiene and temperature requirements, and the cleanliness of vessels, their facilities and equipment, and staff hygiene; and checks on storage and transport conditions.

Article 54 of Regulation (EC) No 882/2004 requires the CA to take action when non-compliances have been identified to ensure that the FBO remedies the situation. When deciding which action to take, the CA shall take into account the nature of the non-compliance and the FBO's past record with regard to non-compliances.

Chapters I and III, of Section VIII, of the Annex III to Regulation (EC) No 853/2004 lays down the requirements that should be followed by FBOs responsible for vessels.

Point 2 of Article 4, of Regulation (EC) No 854/2004 requires that the CA shall carry out official controls to verify FBOs' compliance with the requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004.

Point 3 of Article 4, of Regulation (EC) No 854/2004 requires that official controls shall include audits of good hygiene practices and HACCP based procedures.

Points 4 and 5, of Article 4, of Regulation (EC) No 854/2004 lay down the requirements that the CA should verify during the audits of good hygiene practices and HACCP based procedures.

### **Findings**

The majority of Italian freezer vessels (90%) are based in Sicily. According to the procedures and annual inspection programmes defined by the CAs freezer vessels should be inspected by the CA officials at least twice a year. Nevertheless the audit team noted that some freezer vessels have not been inspected and others were not inspected with the foreseen frequency, e.g. the CAs informed the audit team that from the 140 vessels based in one AUSL, 59 were inspected during 2008, other 23 during 2009 (plus nine new approval inspections) and other 32 from January to July 2010 (plus five new approval inspections). Due to difficulties in the official control of these vessels the CCA issued a note (reference 0024122-P-29/07/2010) informing the regions that from 10 July 2010 onwards the official controls and the approval of factory vessels and freezer vessels would be the responsibility of Office III of DGFSN.

The audit team visited two freezer vessels. One of them was in operation since 2001 but had been approved in 2008 (see section 5.3.1). This freezer vessel was inspected once, on 08/03/2010, since its approval and at the time of the inspection it was not in operation. During that inspection the CA assessed the documentation related to HACCP and good hygiene practices and required the presentation of the vessel's HACCP manual by the FBO at CA headquarters.

Some deficiencies identified by the audit team had not been detected by the CAs, e.g. the temperature recording device was broken since February 2010, rusted surfaces and reception deck with surfaces that can enter into contact with fishery products and do not avoid contamination (wood), formal errors in the HACCP plan, limits of CCP refer to legislation but values or legislation not available on board, the results of the analysis on additives (sulphites) performed in 2010 presented a level above the limit fixed in EU legislation for the category of shrimp concerned (170 mg instead of 150 mg).

With regard to the other freezer vessel the necessary documentation for the assessment was not available at the time of visit. The documentation had been requested by the audit team but until the final meeting was not provided (last inspection report, own check samples test results). The audit team noted several deficiencies, e.g. flaking paint, rust, packaging material insufficiently protected against contamination and absence of procedures or instruction for the sulphite treatment of the shrimps.

The CAs informed the audit team that factory vessels approved in the past were not subjected to an official control visit after their approval.

During the visit of the port authority premises on a landing site in Sicily the file of a factory vessel currently fishing in African waters was presented by the CA. The audit team found out that this vessel has not been inspected since its approval in 1995 (conditional approval, see section 3.5.1).

### **Conclusions**

Currently the official controls of factory and freezer vessels cannot be considered as compliant with



the EU requirements because inspection visits to check compliance with EU requirements are not carried out and when carried out they are not regular. As a consequence it is not possible for the CAs to ascertain if the vessels still fulfil the conditions of approval and if they are in compliance with EU requirements (hygiene, equipment, temperature and HACCP requirements).

#### *6.1.4 Facilities handling fishery products: land based establishments*

### **Legal Requirements**

Point 1 (b) of Chapter I, of Annex III to Regulation (EC) No 854/2004 requires that official controls on the production and placing on the market of fishery products are to include, in particular, inspections at regular intervals of establishments on land, to check, in particular, whether the conditions for approval are still fulfilled and the fishery products are handled correctly, for compliance with hygiene and temperature requirements, and the cleanliness of establishments, their facilities and equipment, and staff hygiene; and checks on storage and transport conditions.

Article 54 of Regulation (EC) No 882/2004 requires the CA to take action when non-compliances have been identified to ensure that the FBO remedies the situation. When deciding which action to take, the CA shall take into account the nature of the non-compliance and the FBO's past record with regard to non-compliances.

Chapter III, of Section VIII, of the Annex III to Regulation (EC) No 853/2004 lays down the requirements that should be followed by FBOs responsible for establishments on land.

Point 2 of Article 4, of Regulation (EC) No 854/2004 requires that the CA shall carry out official controls to verify FBOs' compliance with the requirements laid down in Regulations (EC) Nos 852/2004 and 853/2004.

Point 3 of Article 4, of Regulation (EC) No 854/2004 requires that official controls shall include audits of good hygiene practices and HACCP based procedures.

Points 4 and 5, of Article 4, of Regulation (EC) No 854/2004 lay down the requirements that the CA shall verify during the audits of good hygiene practices and HACCP based procedures.

### **Findings**

According to the procedures and annual inspection programmes defined by the CAs, staff of AUSL should perform official controls of the land based establishments through verifications, inspections and audits with a defined frequency. Written procedures for those official controls and documents to be used have been drafted and adopted at the different CA levels (see sections 5.3.2. and 5.3.3).

The audit team visited four land based establishments in each region and noted that:

- The frequencies foreseen for inspections and audits were not followed by the AUSLs and the visits occurred on a non-regular basis;
- The prescribed procedures for the official controls sometimes were not followed, *i.e.* check-lists were not used to perform the assessment of the level of compliance of the establishment;

- In one case the risk assessment of the establishment was incorrectly performed (see section 5.3.2);
- Establishment approval procedures were not followed, *e.g.* lack of use of supporting documents to assess the establishment (check-lists), inspection report without mentioning the specific legal requirements that were checked, time intervals between conditional and final approval non-compliant with EU requirements;
- Deficiencies noted by the audit team had previously not been identified during the official controls;
- In the eight establishments visited minor deficiencies were identified by the audit team in different establishments, *e.g.*:
  - Structural and equipment deficiencies, *i.e.*: surfaces which can be in contact with fishery products not smooth, easy to clean and disinfect; presence of rust on metal equipment, wooden materials and cutting boards; pooling of water; windows and doors not pest-proof; receptacles used for fresh fishery products not allowing drainage of the melting ice; storage of frozen fishery products in cold stores not ensuring the maintenance of the cold chain (heavily packed);
  - Hygiene deficiencies, *i.e.*: cutting boards not cleaned; staff changing rooms not clean; stacking of fillets touching the upper part of a hatch between two production rooms; salt with dirt; ice with dirt; hoses for cleaning laid directly on the floor; and fishery products inside chilling rooms not protected from water condensation;
  - Own-checks and HACCP deficiencies, *i.e.*: use of different and non-validated testing method for histamine testing (own-checks), HACCP principles not followed – no hazard analysis; absence of a logical approach for the definition of critical control points (CCP); hazards not identified even if relevant (tin in canned food, heavy metals in specific fish species, histamine in fish species with a high content of histidine, *Listeria monocytogenes* in ready to eat products and Polycyclic Aromatic Hydrocarbons (PAH) and dioxins in smoked/cooked fishery products);
- In two different establishments significant deficiencies (without impact of the safety of the products) were observed, *i.e.*: products received from other establishments (in Italy or from another MS) without the identification mark; use of an identification mark belonging to another establishment; no identification mark on the fishery products produced.

## Conclusions

The official controls on the production and placing on the market of fishery products include inspections of land based establishments to check compliance with EU requirements, which are performed by the local CAs, but the foreseen frequency is not respected and they are not regular. The establishments visited were found, in general, to be compliant EU requirements.

### 6.1.5 Follow up of RASFF notifications

The follow up and measures taken for two RASFF notifications were assessed by the audit team and found to be adequate.

## 6.2 OFFICIAL CONTROLS OF FISHERY PRODUCTS

### Legal Requirements

Chapter II of Annex III to Regulation (EC) No 854/2004 requires that official controls of fishery products are to include, at least:

- a) random organoleptic checks at all stages of production, processing and distribution;
- b) freshness indicators (i.e. Total Volatile Basic Nitrogen (TVB-N), and Trimethylamine Nitrogen (TMA-N), when the organoleptic examination reveals any doubt as to the freshness of the fishery products);
- c) random histamine testing;
- d) monitoring of residues and contaminants;
- e) where necessary, microbiological checks;
- f) random parasites testing;
- g) checks to ensure that poisonous fishery products are not placed on the market.

Annex I of Regulation (EC) No 2406/96 lays down the common marketing standards, including the freshness categories and ratings for certain fishery products.

Chapter I, Section II of Annex II of Regulation (EC) No 2074/2005 lays down the TVB-N limit values for certain categories of fishery products and analysis methods to be used by CA.

Chapter 1 of Annex I of Regulation (EC) No 2073/2005 lays down the food safety microbiological criteria (*e.g.* histamine), including the applicable sampling plans with the respective number of units comprising the samples, and the number of sample units giving values over or between the established limits.

Regulation (EC) No 333/2007 lays down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, and benzo(a)pyrene in foodstuffs.

### Findings

- Random organoleptic checks and freshness indicators:

The CAs informed the audit team that random organoleptic checks on fishery products are carried out at landing sites, wholesale markets and processing establishments. However, in Sicily no written evidence was provided concerning the checks performed at the landing sites.

When organoleptic checks reveal any doubt as to the freshness of the fishery products freshness indicators testing is foreseen (i.e. Total Volatile Basic Nitrogen (TVB-N) and Trimethylamine (TMA-N)).

- Random histamine testing:

Sampling of fishery products for random histamine testing is performed by AUSL staff. In Veneto this sampling is part of a regional sampling plan for microbiological testing of fishery products. In general all the results observed complied with EU

requirements. In one case where fishery products products tested had a histamine level above the EU maximum the regional CA produced a RASFF notification and took the appropriate measures.

Histamine testing of fishery products caught by the factory vessels (operating far offshore) is never performed by any CA.

- Monitoring arrangements for residues and contaminants:

A national control programme for residues and contaminants for farmed fishery products is in place. Official samples are taken in farms and processing establishments. Currently there are no monitoring arrangements defined at national level for contaminants in wild fishery products. The Sicilian CA also does not have in place a monitoring arrangement for contaminants in wild fishery products. Conversely, the Veneto CA has developed and implemented an official control programme with sampling of wild fishery products for heavy metals testing (i.e. Lead (Pb), mercury (Hg) and cadmium (Cd)). However, this programme does not include fishery products testing for PAH, tin in canned food or dioxins (despite the production of fishery products which could be contaminated *i.e.* smoked products and canned fish).

- Microbiological checks:

Both visited regions carry out official fishery products testing for microbiological checks.

In Sicily the programme for microbiological checking is developed and implemented by the AUSLs.

In Veneto the regional CA has defined a sampling programme that includes microbiological checks for fishery products. The audit team saw that samples were taken by AUSL staff at the processing establishments and the relevant analyses were carried out in the regional IZS laboratory network. The audit team noted that the results and subsequent measures adopted by Veneto CA (concerning *Listeria monocytogenes*) were in accordance with EU requirements.

- Random parasites testing:

Visual testing for the detection of parasites is carried out during official visits to establishments.

- Poisonous fishery products:

Checks to ensure that poisonous fishery products are not placed on the market are carried out by AUSL staff at processing establishments and landing sites.

- Water testing:

Official water testing is carried out by the local CA, SIAN which is responsible for checking water potability. In general the frequencies foreseen and the parameters

checked follow the requirements of Council Directive 98/83/EC.

Before establishment approval a water potability check must be performed by SIAN which then issues a declaration that is provided to the AUSL in charge of establishment approval. In spite of a request, the audit team was not provided with test results used to support the water potability attestation. This attestation was issued by SIAN but no reference regarding the parameters checked was found. As a consequence it was not possible for the audit team to determine if all the relevant parameters had been checked.

## **Conclusions**

In general official controls carried out on fishery products were found to be compliant with EU requirements. However, monitoring arrangements to control the levels of contaminants in wild fishery products are not defined at national level. The monitoring programme of one region visited included heavy metals (i.e. Pb, Hg and Cd) but did not cover PAH, tin in canned food or dioxins. The other visited region had no monitoring arrangements to control the levels of contaminants in wild fishery products.

### **6.3 LABORATORIES**

#### **Legal Requirements**

Article 12 (1) of Regulation (EC) No 882/2004 states that CA shall designate laboratories that may carry out the analysis of samples taken during official controls.

Article 12 (2) of Regulation (EC) No 882/2004 requires CAs to only designate official laboratories that operate and are assessed and accredited in accordance with several standard (e.g. EN ISO/IEC 17025), taking into account criteria for different testing methods laid down in EU legislation.

Article 12 (3) of Regulation (EC) No 882/2004 states that the accreditation and assessment of testing laboratories referred to in Article 12 (2) may relate to individual tests or groups of tests, and

Article 12 (4) of Regulation (EC) No 882/2004 states that the CA may cancel the designation referred to in Article 12 (1) when the conditions referred to in Article 12 (2) are no longer fulfilled.

Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods, used in the context of official controls, comply with relevant EU rules or with internationally recognised rules or protocols or, in the absence of these, with other methods fit for the intended purpose or developed in accordance with scientific protocols).

Chapter 1 of Annex I of Regulation (EC) No 2073/2005 lays down the food safety microbiological criteria (e.g. histamine), including the applicable sampling plans with the respective number of units comprising the samples, and the number of sample units giving values over or between the established limits.

Regulation (EC) No 333/2007 lays down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, and benzo(a)pyrene in foodstuffs.

## **Findings**

The official laboratories designated by the CA, IZS network, are accredited by ACCREDIA to ISO 17025.

The audit team visited two laboratories and found that:

- The scope of accreditation encompasses the appropriate methods to be used in fishery products and water testing;
- A quality manual and standard operational procedures were developed and are in place;
- They have highly qualified and trained staff and well equipped premises;
- Proficiency tests are regularly performed;

Nevertheless, deficiencies were noted regarding:

- the performance criteria (insufficient limit of detection (LOD) and limit of quantification (LOQ)) of the methods used by one of the laboratories for testing fishery products for Pb and Cd;
- one laboratory did not perform proficiency tests for Pb, it had inconclusive proficiency test results for Cd for the last two years and the proficiency test for histamine was unsatisfactory;
- in the other laboratory the routine method used for determination of histamine levels in fishery products was an ELISA (Enzyme Linked Immunoassay) method but the file on the method's validation against the EU reference method (HPLC) was insufficient;
- significant delays in some cases were noted in the provision of test results, in particular in the testing for histamine on a batch of fresh fish for which the results (three results out of nine showing a level of histamine above the permitted levels (levels of 383 ppm, 443 ppm and 766 ppm, when the maximum admitted levels is m equal 100 ppm, M equal to 200 ppm, and C equal to two, for n equal to nine) were faxed to the CA 14 days after analysis commenced.

## **Conclusions**

The laboratories visited by the audit team performing analyses for the official controls of fishery products can not be considered in full compliance with EU requirements. The deficiencies found by the audit team concerns the technical aspects of the methods and the procedures for the communication of analyses results which can have a negative impact on the system of fishery products official controls.

## **7 OVERALL CONCLUSION**

Currently the official control system covering fishery products in Italy is implemented across three CA levels: central, regional and local.

This system presents significant shortcomings concerning the official controls of primary production (i.e. aquaculture farm and fishing vessels) and freezer and factory vessels.

In general the official controls of fishery products are well implemented in both regions visited. However, deficiencies were identified in respect of the monitoring arrangements to check residues and contaminants in fishery products.

In addition, the effectiveness and comparability of official controls cannot be ascertained by the different levels of CAs due to limited or absence of verification procedures.

In summary a system of official controls of fishery products is implemented by the Italian CAs but it cannot be considered as fully compliant with EU requirements due to the deficiencies observed and in particular the limited or non existing verification procedures.

## 8 CLOSING MEETING

A closing meeting was held on 17 September 2010 with representatives of the CCA and of the regional CAs concerned. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement, presented some additional clarifications and stated that they would take whatever actions were deemed necessary in order to correct the deficiencies presented.

## 9 RECOMMENDATIONS

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

N°.	Recommendation
1.	Efficient and effective coordination between all the CAs performing official controls in the fishery products sector should be ensured (see Article 4(3) of Regulation (EC) No 882/2004).
2.	The CAs should have in place procedures to verify the effectiveness of official controls carried out (see Article 8(3) of Regulation (EC) No 882/2004).
3.	The CAs should carry out internal audits or may have external audits carried out (see Article 4(5) of Regulation (EC) No 882/2004).
4.	The CAs should ensure that lists of registered fishery products food business operators are drawn up and kept up to date or that they have access to up to date lists (see Article 31(1) of Regulation (EC) No 882/2004).
5.	The CAs should ensure that all fishing vessels involved in primary production are registered by the relevant CAs on the basis of sanitary criteria (see Article 6(2) of Regulation (EC) N0 852/2004 and Article 4(1) of Regulation (EC) No 853/2004) and regularly inspected (see Article 7 and Annex III, Chapter I, 1 (b) of Regulation (EC)

N°.	Recommendation
	No 854/2004).
6.	The CAs should ensure that the procedures and deadlines for establishments approval are respected and appropriately implemented (see Article 31(2) of Regulation (EC) No 882/2004) and in particular that for each FBO establishment one approval is granted.
7.	The CAs should ensure that only registered and regularly inspected fishing vessels are allowed to operate as part of the fishery products chain (see Article 7 and Annex III, Chapter I, 1 (b) of Regulation (EC) No 854/2004) and those fishing vessels comply with the requirements of Regulations (EC) Nos 852/2004 and 853/2004 (see Article 4(2) of Regulation (EC) No 854/2004).
8.	The CAs should ensure that only fish farms compliant with the requirements of Regulations (EC) No 852/2004 are allowed to operate as part of the fishery products chain (see Article 4(2) of Regulation (EC) No 854/2004).
9.	The CAs should ensure that only freezer and factory vessels compliant with the requirements of Regulations (EC) Nos 852/2004 and 853/2004 are allowed to operate as part of the fishery products chain (see Article 4(2) and Annex III, Chapter I, 1 (b) of Regulation (EC) No 854/2004).
10.	The CAs should ensure that official controls on the production and placing on the market of fishery products are implemented in accordance with the requirements of Regulation (EC) No 854/2004, in particular to include inspection at regular intervals of vessels and establishments on land (see Article 4(2) and point 1 (b) of Chapter I of Annex III to Regulation (EC) No 854/2004).
11.	The CAs should set up monitoring arrangements for fishery products chemical contaminants as required in Annex III, Chapter II, D, of Regulation (EC) No 854/2004.
12.	The CAs should ensure that testing methods for histamine follow the references contained in Regulation (EC) No 2073/2005, or have been validated against these methods.
13.	The CAs should ensure that testing methods for heavy metals follow the reference methods contained in Regulation (EC) No 333/2007.
14.	The CA should ensure that the National Reference Laboratory, particularly for environmental contaminants, coordinates the activities of official laboratories (see Article 33 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\\_it\\_2010-8525.pdf](http://ec.europa.eu/food/fvo/ap/ap_it_2010-8525.pdf)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Reg. 2406/96	OJ L 334, 23.12.1996, p. 1-15	Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
		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. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives