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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SPAIN

FROM 20 TO 31 MAY 2013

IN ORDER TO EVALUATE THE FOOD SAFETY CONTROL SYSTEMS IN PLACE  
GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF FISHERY  
PRODUCTS

*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 audit in Spain carried out from 20 to 31 May 2013, as part of its programme of audits in member states.*

*The objectives of the audit were to verify that overall, official controls take place in compliance with EU Law, to evaluate whether the control system in place for the production and placing on the market of fishery products is in compliance with EU requirements and to verify the corrective actions submitted to the Commission services in response to the recommendations of the previous Food and Veterinary Office audit report of 2008.*

*The report concludes that improvements have been made since the last audit and in principle, the current organisation of the competent authorities visited, the standards set and their documented operational procedures, could provide an acceptable system of official controls of fishery products.*

*The deficiencies noted in relation to the supervision and audit of official controls and the shortcomings found in their implementation (related to the approval of establishments and vessels, the controls over the primary production sector, the evaluation of HACCP plans and the monitoring arrangements for certain contaminants), weaken the ability of the competent authorities to guarantee fully that all fishery products comply and were produced in accordance with EU legislation.*

*The report addresses to the Spanish competent authorities a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.*

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**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
AC	Autonomous Community
AESAN	Spanish Food Safety and Nutrition Agency
ASPCAT	Catalonia Public Health Agency
CA	Competent Authority
Cd	Cadmium
CVED	Common Veterinary Entry Document
DG MARE	Maritime Affairs and Fisheries Directorate-General of the European Commission
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EN	European Norm
ENAC	Spanish Accreditation Body
EU	European Union
EUROSTAT	Statistical Services of the European Union
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
Hg	Mercury
ISO	International Organisation for Standardisation
MAGRAMA	Ministry of Agriculture, Food and Environment
MANCP	Multi-Annual National Control Plan
MSSSI	Ministry of Health, Social Services and Equality
NRL	National Reference Laboratory
PAH	Polycyclic Aromatic Hydrocarbons
Pb	Lead
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
RGSEAA	General Health Registration of Food and Food Establishments
SGCI	Sub-directorate General of Control and Inspection of MAGRAMA
SGEH	Sub-directorate General for External Health of MSSSI

## 1 INTRODUCTION

The audit took place in Spain from 20 to 31 May 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme.

The audit team comprised three auditors from the FVO, one national expert from a European Union (EU) Member State and one inspector from the Maritime Affairs and Fisheries Directorate-General (DG MARE).

An opening meeting was held in Madrid on 20 May 2013 with the Competent Authorities (CAs). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit. Representatives from the CAs accompanied the audit team during the whole audit.

## 2 OBJECTIVES AND SCOPE OF THE AUDIT

The objectives of the audit were:

- To verify that official controls of fishery products are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- To evaluate whether the control system in place for the production and placing on the market of fishery products is in compliance with EU requirements.
- To evaluate whether the CAs' organisation and the implementation of national provisions against which the CAs control the terms under which the fishing vessels of third countries may land directly and market their catches at EU ports are compliant with EU requirements.
- To evaluate whether the CAs' organisation and the implementation of national provisions ensure that all fishery products originated in third countries not complying with requirements of Regulation (EC) No 1005/2008 are subjected to import controls laid down in Directive 97/78/EC.
- To verify the extent to which the guarantees and the corrective actions submitted to the Commission services in response to the recommendations of the previous FVO audit report of 2008 and which were assessed as "in progress" in the 2011 General Follow-Up Audit, have been implemented and enforced by the CAs.

The objective of DG MARE's audit was to assess the reliability of the system in place to ensure the traceability of fishery products as required by Article 58 of the Council Regulation (EC) No 1224/2009, establishing a Community control system for ensuring compliance with the rules of the common fisheries policy. DG MARE's findings and conclusions will not be included in this report.

In terms of scope the audit focused on the organisation and performance of the CAs and on the official control systems in place covering production, processing and distribution chains applicable to fishery products placed on the EU market. Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as technical basis for the audit.

In pursuit of these objectives the following sites were visited:

COMPETENT AUTHORITY		
Central level	1	Spanish Food Safety and Nutrition Agency (AESAN)
Autonomous Communities level	4	Catalonia, Galicia, Basque Country, Canary Islands

Local level	1	Technical Unit of the municipality of Madrid
<b>LABORATORY</b>		
Fishery products	5	National Food Centre (CNA) - National Reference Laboratory Laboratory of "Barcelona Public Health Agency" Public health laboratory of Bilbao Public health laboratory of Pontevedra Public health laboratory of Grand Canary
<b>PRIMARY PRODUCTION</b>		
Aquaculture farms	1	Catalonia
Fishing vessels	5	Two in Catalonia, one in Galicia and two in the Basque Country
<b>LANDING AND FIRST SALE SITES</b>		
Auction halls	6	One in Catalonia, three in Galicia, one in the Canary Islands and one in the Basque Country
<b>FACILITIES HANDLING FISHERY PRODUCTS</b>		
Freezer vessels	1	Galicia
Wholesale markets	2	Madrid and Basque Country
Processing plants	10	Three in Catalonia, two in Galicia, three in the Canary Islands and two in the Basque Country

### 3 LEGAL BASIS FOR THE AUDIT

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

Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

### 4 BACKGROUND

#### 4.1 GENERAL BACKGROUND

A previous audit took place in 2008 (ref. DG(SANCO)/2008-7642) and was part of the General Audit carried in that year (ref. DG(SANCO)/2008-8347).

The audit highlighted deficiencies in relation to the repetition of the problems found during previous FVO fishery products audits (in particular those related to histamine testing), the absence of official controls over certain parts of the production (including primary production), processing and distribution chain, and the poor follow-up by the CAs of non conformities. The report – published on the Health and Consumers Directorate-General (SANCO) internet site at [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm) – made a number of recommendations in respect of the action required to the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations.

The follow-up of the recommendations of the FVO audit report of 2008 which were assessed as "in progress" in the 2011 General Follow-Up Audit is reported under the relevant parts of this report.

An overview of how control systems are organised in Spain, based on information supplied by them, is provided in the Country Profile for Spain (DG(SANCO)/2011/6074-Final) and is available at the following link: [http://ec.europa.eu/food/fvo/controlsystems\\_en.cfm?co\\_id=ES](http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=ES).

In Spain, EU rules for the fishery sector are part of the Multi-Annual National Control Plan 2011-2015 (MANCP) which facilitates their implementation in a consistent way at Autonomous Communities (ACs) level. The MANCP is available at the following link: [http://ec.europa.eu/food/fvo/msm\\_en.cfm?co\\_id=ES](http://ec.europa.eu/food/fvo/msm_en.cfm?co_id=ES).

#### **4.2 PRODUCTION AND TRADE INFORMATION**

According to EUROSTAT, in 2010, Spain produced 992,531 tonnes of fishery products and imported 854,226 tonnes from third countries and received 440,858 tonnes from other EU Member States.

According to the list set up by the CA and available on its internet site, there are a total of 4287 establishments (these include 229 auction halls, 111 wholesale markets, 304 freezer vessels and 91 factory vessels) authorised to place fishery products on the EU market.

#### **4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS**

Between January 2011 and April 2013, 68 RASFF alert notifications were issued. Their distribution was as follows:

- Thirty seven concerning the presence of mercury (Hg), mainly in chilled and frozen swordfish (*Xyphias gladius*) – 16 in 2011 and 21 in 2012;
- Fourteen concerning the presence of parasites, mainly *Anisakis*, in chilled fishery products – 13 in 2011 and one in 2012;
- Seven concerning the presence of cadmium (Cd), mainly in frozen squids (*Illex spp.* or *Loligo spp.*) - three in 2011, two in 2012 and two in 2013;
- Six concerning the presence of histamine, mainly in chilled and canned tuna – three in 2011, two in 2012 and one in 2013;
- One concerning the presence of sulphites in frozen prawns, in 2011;
- One concerning the presence of broken glass in octopus in brine, in 2011;
- One concerning the presence of *Listeria monocytogenes* in smoked trout, in 2012.

### **5 FINDINGS AND CONCLUSIONS**

#### **5.1 COMPETENT AUTHORITY**

##### **Legal requirements**

Articles 3 to 10, 54 and 55 of Regulation (EC) No 882/2004.

##### **Findings**

###### Structure and organisation

As mentioned in the Country Profile for Spain in the section “Designation of Competent Authorities”, at national level (General Administration of the State), the responsibility for the official control system of fishery products is shared mainly between two ministries, the Ministry of Agriculture, Food and Environment (MAGRAMA) and the Ministry of Health, Social Services and Equality (MSSSI). MAGRAMA has principal responsibility for primary production of fishery products. MSSSI is responsible for all successive stages of fishery products production through the

Spanish Food Safety and Nutrition Agency (ASEAN) and the Sub-directorate General for External Health (SGSE), which is responsible for controls on imported products.

In the official control system of fishery products (except for import controls of fishery products), the General Administration of the State plays the role of coordination and cooperation with the 17 ACs and the two autonomous cities of Ceuta and Melilla (through a number of national coordination committees and technical working groups, with ACs representation), develops framework legislation and represents Spain at EU level and in international organisations.

The structure and organisation of the different CAs involved in the official control systems and the co-operation within and between them are described in the Country Profile for Spain (in Section 1 “Designation of competent authorities”) and in the MANCP. Updates or changes are mentioned in the 2011 Annual Report which is also available at the following link: [http://ec.europa.eu/food/fvo/msm\\_en.cfm?co\\_id=ES](http://ec.europa.eu/food/fvo/msm_en.cfm?co_id=ES).

Under the Spanish Constitution (Article 148) the 17 ACs and the two autonomous cities of Ceuta and Melilla are responsible for the implementation of official controls of fishery products. In general, these are operated through the “Consejerías” or “Departamentos” of Agriculture, of Health or of Fisheries.

The audit team visited four ACs (Catalonia, Galicia, the Canary Islands and the Basque Country) and one technical unit from the municipality of Madrid (UTM).

#### *Catalonia*

In Catalonia, the services of the “Maritime Affairs and Fisheries Inspection” have the competences for controlling primary production of fishery products, including aquaculture. Their staff is composed of one head of unit and six inspectors.

The “Catalonia Public Health Agency (ASPCAT)” is responsible for the control of fishery products after primary production. The ASPCAT Regional Services are responsible at territorial level for the implementation of official controls of fishery products in the production chain post primary production (104 veterinarians work at territorial level in Catalonia).

At retail level, the “Catalonia Consumers Agency” and the municipalities have responsibilities for the official control of fishery products.

The municipality of Barcelona also has competences for official controls of fishery products, through the “Barcelona Public Health Agency”. These are carried out in coordination with ASPCAT.

#### *Galicia*

In Galicia, the “Veterinary Inspection Service” has competences for controlling primary production of fishery products, including aquaculture. It is composed of nine “Operative Units” throughout the “Territorial Delegations” in the AC (seventeen fisheries veterinary inspectors in the “Veterinary Inspection Service” of which six are working in the “Territorial Delegations”).

The “Innovation and Public Health Management Directorate General” has competences to coordinate the control of fishery products after primary production. In total there are 284 staff in the “Public Health Veterinary Services” at territorial level, of which 148 are inspectors that implement the official controls of fishery products.

#### *The Canary Islands*

In the Canary Islands, the “Fisheries Structures Service” of the Fisheries Viceconsejería



which operates under the “Regional Ministry of Agriculture, Livestock, Fisheries and Water” is responsible for controlling primary production of fishery products, including aquaculture. Its staff is composed of one inspector.

The “Canary Islands Health Service”, which forms part of the “Regional Ministry of Health”, has a central unit known as the “Public Health Directorate”, which is organised into a “Food Safety Service” and seven regional units that constitute the seven “Health Areas” (one per island). In total there are 186 staff in the “Health Areas”, including technical, administrative and laboratory staff, etc. Of the total, 68 are inspectors with 25 in Grand Canary and 23 in Tenerife.

#### *The Basque Country*

In the Basque Country, the “Fisheries Inspection Service” is responsible for controlling primary production of fishery products, including aquaculture. Their staff is composed of one inspector and one supervisor.

The “Public Health Directorate” - through the three “Delegations”, nine “Public Health Regions” and three “Municipalities” - is responsible for controlling post primary production of fishery products.

#### *The UTM*

The UTM (composed of three inspectors dedicated to fishery products) operates in a wholesale market and is a specific service of “Madrid-Health”, the CA in the municipality of Madrid that has responsibilities for the official control of fishery products.

The CAs visited have designated official laboratories for the official controls of fishery products. The National Reference Laboratories (NRL) are listed in the Country Profile for Spain and the ACs official laboratories are listed in Annex V (Document 8) of the MANCP.

Concerning direct landings and imports of fishery products, MAGRAMA and MSSSI share the main responsibilities for the implementation of official controls of landing of fish caught by vessels flying a third country flag.

The “Sub-directorate General of Control and Inspection (SGCI)” at MAGRAMA is responsible for documentary controls and fisheries inspection duties (access to port services, landing, transshipment of fishing vessels flying a third-country flag, imports of fishery products – Article 2(8) of Regulation (EC) No 1005/2008 – by any means of entry) in accordance with Regulation (EC) No 1005/2008. The “Sub-directorate General for External Health (SGEH)” at MSSSI is in charge of the implementation of official import/transit controls of fish/fishery products intended for human consumption via the Border Inspection Posts (BIPs) listed in Annex I to Decision 2009/821/EC.

The SGEH is responsible for the control of direct landings of fresh fish falling under the derogation of Article 19(2) of Directive 97/78/EC. However, according to the statements of the CAs of Galicia and the Canary Islands, no direct landings of fresh fish caught by vessels flying a third country flag has occurred in the last five to seven years.

Port authorities are responsible for the safety and monitoring of operations in the Spanish ports. Landing or transshipment requests for fishery products from vessels flying a third-country flag are received, processed and authorised or refused by the SGCI without prejudice to the powers vested in the port authorities, in accordance with Article 25 of Royal Legislative Decree No 2/2011 of 5 September 2011 approving the Consolidated Text of the Law on State Ports and the Merchant Navy.

Customs are in charge of the customs clearance of fish caught by vessels flying a third-country flag not benefiting from the derogation laid down in Article 19(2) of Directive 97/78/EC. Before customs clearance can be granted for the import/free movement in the EU of fishery products (fresh

or otherwise) (Article 2(8) of Regulation (EC) No 1005/2008), by any means of entry (sea, land, air) and by any mode of transport, a favourable report must be submitted by the SGCI. The SGCI report is compulsory and binding for the Customs authorities (article 11, Order ARM/2077/2010).

### Powers, Independence and Supervision

Powers of the AC CAs, the independence of their staff and the transparency and confidentiality of their official controls are defined in the MANCP.

- In all CAs visited the audit team observed that these powers (to enter food business operators facilities, to scrutinise documents and inspect facilities, to seize and order the destruction of products, to suspend or withdraw approvals) are used proportionally when necessary.
- No conflict of interests was observed by the audit team during the visits.
- The audit team noted that the information that is of interest to the general public is published in the internet sites of the different CAs.

Concerning the supervision of official controls of fishery products, the audit team noted different degrees of implementation in the CAs visited. The internal supervision of the official controls carried out by their staff is generally described in the MANCP.

The supervision of the official controls performed at primary production follows established procedures and is of two types: documentary check and accompanying the inspectors on-site. A description of these is presented in the MANCP.

The supervision of the official controls performed after primary production includes also the two above mentioned elements (documentary check and accompanying inspectors on-site) and is also described in the MANCP.

### *Catalonia*

In Catalonia, the CA established a frequency (every three months, inspection reports should be sent to the Fisheries and Maritime Affairs Directorate-General of Catalonia and annually to MAGRAMA) for this supervision which was not respected during the second half of 2011 and throughout 2012<sup>1</sup>.

In this AC, the supervision of the official controls performed after primary production follows a guide which includes an annual programme that has two parts: continuous supervision (by the hierarchy) and priority sectors supervision (by a team of peers). The aspects covered include, among others: training followed, correct use of documented procedures, execution of official controls, adoption of corrective measures and follow-up of corrective measures. The fishery products sector was supervised in 2012 (16 supervisory visits, all with satisfactory results) and new visits are foreseen in 2013.

### *Galicia*

In Galicia, one supervisory visit was carried out on 19/04/2013 to review the official controls performed in primary production sector. This visit only verified the number of

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<sup>1</sup> In their response to the draft report the CA stated that on 26/07/2011, due to the restructuring of the Directorate-General for Fisheries and Maritime Affairs, the Service for the Protection of Marine Resources was assigned the task of performing hygiene controls for primary production in both fisheries and aquaculture. These controls used to be carried out by another service. In the second half of 2011 and during 2012 these controls were performed by a fisheries inspector and the Head of the Maritime Unit for Fisheries Monitoring (the person in charge of running the official hygiene control programme for primary production in fisheries and aquaculture). Supervision was not carried out during this period because, due to staff shortages, the person who would be in charge of the supervision was carrying out the controls with the fisheries inspector.

official controls carried out. The CA provided to the audit team the new version of the “General Control Plan of the Primary Production of Fishery Products” (May 2013) where a procedure for the verification of the official controls has been introduced.

In this AC, a frequency, as well as documented procedures for the supervision of official controls performed after primary production (since January 2013) were defined. The supervisory procedure covering the performance of inspections (regular monitoring or alert related activities) was explained to the audit team and associated records were shown. However, no documented evidence of supervisory visits to the fishery products sector was provided to the audit team.

#### *The Canary Islands*

In the Canary Islands, no supervisory procedures have been established to verify the official controls carried out in primary production sector.

In this AC, during the stages following primary production, frequencies, as well as documented procedures for supervision (since April 2013) were defined. Results of the supervisory checks carried out in 2012 in Grand Canary were provided to the audit team. The deficiencies detected were reported in a note of March 2013 to be included on the 2012 Annual Report.

#### *The Basque Country*

In the Basque Country, the official controls' supervision in primary production sector was carried out in 2012 and one report was issued with satisfactory results.

In this AC, the supervision of official controls performed after primary production is limited to the verification of the number of inspections carried out, by using the CA's electronic database within a defined frequency. There are no joint visits or evaluation of the content of the inspection reports. At the time of the visit to the CA, the audit team noted that the database was not working properly – the number of visits in the categories “planned” and “executed” did not match the visits that were really carried out (lower number).

Concerning internal audits of official controls, general rules and procedures are established in the MANCP. A list of the audits carried out by the different CAs in 2011 is presented in the 2011 Annual Report (in Section 3 “Annual Report Results”; Part C “Audits to the Official Controls”).

MAGRAMA coordinates the programming of audits of official controls performed at primary production level performed by the AC CAs. The current audit programme covers the period 2011-2015.

Specific rules for audits of official controls of fishery products in primary production are specified in the MANCP. The 2011 Annual Report presents the conclusions of these audits in Section 4 “Conclusions”; Point 3 “Conclusions of Part C (Audits to the Official Controls)”; Point 3.1 “Audits to the Official Controls within the scope of MAGRAMA and the “Consejerías” of Agriculture, Livestock, Fisheries and Quality”; Official Control Programmes II.1 (Hygiene of Primary Production in Extractive Fishing) and II.2 (Hygiene of the Primary Production in Aquaculture).

The conclusions of the 2011 audits concerning controls carried out in primary production sector highlighted some deficiencies in relation to the respect of frequencies of official controls, the fact that the controls were not risk based and that inspectors needed further training.

#### *Catalonia*

In Catalonia, internal audits to verify the official controls at primary production level are carried out. These include partial and full audits in accordance with official control programmes' risks. Independent examinations of this internal audit procedure are also

carried out. The CA provided to the audit team the reports of 2010, 2011 and 2012 and associated action plans and follow-up of corrective actions taken by the CA. Results were in general satisfactory, except for the supervision of the official controls, which was not carried out.

### *Galicia*

In Galicia, the new version of the “General Control Plan of the Primary Production of Fishery Products” (May 2013) includes general rules for internal audits. No audits to verify the official controls carried out in the primary production sector have been carried out since May 2013.

### *The Canary Islands*

In the Canary Islands, one internal audit was carried out in 2008 to verify the official controls performed in the primary production sector, specifically in aquaculture. The audit report was provided to the audit team and the outcome detected shortcomings in the distribution of competences, in the supervision of official controls and in the absence of documented procedures.

### *The Basque Country*

In the Basque Country, one audit was carried out in 2012 to the “Official Control Programme for the Hygiene of the Primary Production in Extractive Fishing”. Several non conformities were detected. An action plan with corrective actions was presented and corrective actions were implemented. An audit programme for the period 2011-2015 was provided to the audit team.

The conclusions of the 2011 audits presented in the 2011 Annual Report (Section 4 “Conclusions”; Point 3 “Conclusions of Part C (Audits to the Official Controls)”; Point 3.2 “Audits to the Official Controls within the scope of AC CAs and SGEH”) concerning official controls after primary production, not only related to the fishery products sector, highlighted an improvement in the number of audits carried out, in the definition of procedures and in the implementation of supervision of official controls.

The document “Official Control Audits” of 22/11/2010 was approved by the Institutional Committee of AESAN in December 2010 and defines the procedures for audits of official controls to be carried out after primary production by AESAN, the SGEH and ACs. Nonetheless, in the meeting of the Forum of Technical Discussion (technical working group that supports the Committee mentioned before) AESAN reached the conclusion that the procedures agreed in 2010 were not being met and that further discussions on how the audit system should be organised were needed.

- AESAN informed the audit team that a meeting is foreseen for the end of 2013 (with the participation of the FVO and other Member States) to exchange experiences on audits of official controls.

### *Catalonia*

In Catalonia, no documented evidence of audits carried out to the official controls after primary production were provided by the CA to the audit team.

### *Galicia*

In Galicia, the CA provided audit reports of 2008 for four “Territorial Delegations” and for 2009 for nine local CAs in relation to general official controls. The CA informed the audit team that a specific audit to the official controls of fishery products in one auction hall took place in 2013. The draft report for this audit was made available to the audit team but the

final results were not available at the time of the FVO visit.

### *The Canary Islands*

In the Canary Islands, one internal audit was carried out in 2011 to the official controls of two control programmes (biological risks in foodstuffs and animal welfare). The associated action plans and follow-up of corrective actions taken by the CA were provided to the audit team.

### *The Basque Country*

In the Basque Country, audits to verify the official controls performed after primary production have not been carried out in accordance with the MANCP general rules. The CA presented to the audit team a document (from February 2013) concerning a proposal to start this type of audit.

The supervision and audits of the official controls carried out by the UTM was not assessed.

Concerning direct landings of fresh fish and imports of fishery products, the supervision and audit of the official controls are within the competence of the SGEH and MAGRAMA and are explained in the MANCP

The 2011 Annual Report also presents the conclusions of these audits in Section 4 “Conclusions”; Point 3 “Conclusions of Part C (Audits to the Official Controls)”; Point 3.2 “Audits to the Official Controls within the scope of AC CAs and SGEH”. The conclusions highlighted the lack of budget to carry out all planned audits in 2011 (three out of seven) and the fact that the supervision of official controls is still a weak point.

Detailed information on supervision and audits at BIPs can be found in the FVO audit report (ref. DG(SANCO)2012-6500) that evaluated the compliance of BIPs with approval requirements.

### Training

The general rules for official staff training in the different CA levels are laid down in the MANCP. A list of the training courses followed by the staff of the different CAs is presented in the 2011 Annual Report (in Section 3 “Annual Report Results”; Part A “General Aspects”; Part A.6 “Official Controls Staff Training”).

In all ACs visited, annual training programmes for 2012 and 2013 were provided for staff involved in the official controls of fishery products. The training courses covered the requirements of EU legislation for the whole production chain of fishery products.

- Official staff met during the visits had adequate knowledge of EU legislation related to this sector.
- In two ACs visited, SGEH staff were able to demonstrate that they had the necessary qualifications for carrying out official controls of direct landing of fresh fish caught by vessels flying a third country flag and that the training that was provided was relevant to their official tasks.

### Documented Control Procedures

The general rules for establishing documented control procedures in the different CA levels are laid down in the MANCP as well as the list of documented procedures followed by the CAs.

The 2011 Annual Report (in Section 3 “Annual Report Results”; Part A “General Aspects”; Part A.7 “New Procedures for Official Controls”) reflects the most recent changes related to documented procedures.

Specific documented procedures have been established by AESAN and MAGRAMA for the official

control programmes related to primary production and after primary production. These can also be found in the MANCP.

In the UTM and all ACs visited, documented procedures are in place and most of the time correctly implemented.

In the UTM, these procedures cover the inspection tasks related to the official controls of fishery products in the wholesale market and associated sub-units.

In the ACs visited, these procedures cover the official controls performed at primary production and after primary production. In most of the ACs, electronic databases are used to record the actions carried out by official staff.

Specific documented procedures have been established for the official controls related to direct landings of fish and imports of fishery products and these can be found in the MANCP.

- The audit team noted that instructions on control of direct landings of fresh fish were included in the manuals of procedures issued by two CAs of the Health Areas (under the Sub-delegations of the Government) visited. These comprise standard operating procedures, check-lists and inspection report templates.
- New instructions for detention procedure and criteria for approval of detention warehouses and for documentary checks of fishery products were issued by SGEH for the BIPs staff in 2010 and modified in 2012.

### Enforcement

General enforcement measures are described in the Country Profile for Spain in Section 1 “Enforcement measures”. In relation to the fish sector, specific legal basis for the application of enforcement measures can be found in the MANCP.

Additional instructions for the application of enforcement measures when carrying out official controls after primary production are also established in the MANCP.

- The audit team noted that all CAs visited enforce the EU legislation related to the official controls of fishery products whenever non conformities are detected.

### **Conclusions**

In Spain, CAs have been designated for the official controls of fishery products, throughout the whole production chain. Their structure, their organisation, and the documented procedures they have put in place allow the implementation of official controls of fishery products that, in general, respect the requirements of Regulation (EC) No 882/2004 for CAs.

The official staff met during the audit was qualified and updated in their area of competence in accordance with Articles 4(2) and 6 of the Regulation (EC) No 882/2004.

Adequate cooperation and coordination of official controls between relevant CAs is documented in relation to direct landings and import controls of fishery products.

Nevertheless, the audit team also concluded that:

- The supervision of official controls of fishery products in the whole production chain most of the time takes only into account the number of actions carried out by official staff, based on a documentary check (no joint visits in some cases).
- The audits of the official controls of fishery products in the whole production chain have not been considered a priority by the CAs in recent years. The procedures for auditing are still under development and it is expected that in 2013 these will be carried out by the AC CAs.

## 5.2 REGISTRATION/APPROVAL OF FOOD BUSINESS OPERATORS ESTABLISHMENTS

### Legal requirements

Article 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004, Article 3 of Regulation (EC) No 854/2004 and Article 31 of Regulation (EC) No 882/2004

### Findings

The registration of fishing vessels is carried out at central level by MAGRAMA. Fishing licenses are also managed by MAGRAMA.

- The audit team noted that the fishing and freezer vessels visited had a valid fishing license on board.
- The audit team also noted that there is no exchange of information about fishing licenses between the CAs for Fisheries and for Public Health.

The registration of aquaculture farms is also carried out by MAGRAMA. Each aquaculture farm has a registration number, included in a national database for all types of animal farms, the “General Registration of Livestock Farms (REGA)”.

- The audit team noted in the aquaculture farm visited that sea bream (*Sparus aurata*) and sea bass (*Dycentrarchus labrax*) were farmed. Nevertheless, the authorisation provided to the audit team was only for farming sea bream<sup>2</sup>.

Spain has a national register of all food business operators that deal with products of animal origin, the “General Health Registration of Food and Food Establishments (RGSEAA)”. The national law for this registration is described in the Country Profile for Spain. This registration allows the separation of two types of food business operators: the ones that only need a registration and the ones that need to be approved in accordance with the EU legislation (and that ultimately will use an identification mark for placing fishery products on the EU market). The codes used to identify both types of food business operators are the same (in the case of fishery products, the code is “12”).

The activities carried out by food business operators are authorised by the CAs. These activities are recorded in the RGSEAA and when any changes occur, new activities are added to the register. Activities are listed using specific sector codes as set out in the General Health Register Guide of June 2012. The MANCP mentions that the control will also verify that the registration reflects exactly which activities are carried out in the establishments.

- AESAN provided to the audit team the latest version of the “General Health Registration Guide”, of June 2012.

The procedure in place for the approval of food business operators is in line with EU requirements (including an on-site visit before approval). However this procedure is not properly followed on every occasion. Freezer vessels that operate far from Spanish waters are inspected by a team of inspectors from one AC (or a mixed team of inspectors from different ACs) that can have a mandate from other ACs to also inspect the freezer vessels under their jurisdiction.

- The audit team noted that AESAN keeps an up-to-date list of the registered and approved food business operators, which is publicly available through its internet site.

Nevertheless, the audit team noted:

- The existence of approved establishments with activities that are not carried out by the establishments (e.g. imports of frozen fishery products; storage of smoked, dried salted or

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<sup>2</sup> In their response to the draft report the CA provided evidence that the registration document had since been corrected to cover sea bass (*Dycentrarchus labrax*) as well.

frozen fishery products; freezing in brine; storage of different products of animal origin).

- The existence of approved establishments or vessels which do not respect completely the EU requirements (e.g. absence of an HACCP plan; absence of temperature recording devices in freezer vessels) or that don't have the hygiene and structure conditions to be approved (e.g. auction hall units in one auction hall in Galicia).
- The existence of activities carried out by the establishments that are not included in their approval notification (e.g. freezing; storage of received by-products; repackaging; wholesale market subunits cutting fresh tuna and frozen swordfish).
- That the approval of an establishment, which was still in operation, expired on 29/11/2010 (before the Royal Decree 191/2011 of 18.02.2011 was in force) and no renewal of the approval was carried out.
- That the "General Health Registration Guide", of June 2012, states that establishments carrying out wrapping of unprepared fishery products from aquaculture in boxes with ice or in individual trays for the consumer do not have to be approved in accordance with EU requirements. This contradicts the EU regulations.
- The existence of Spanish freezer vessels (seven in total) which were not approved in accordance with Regulation (EC) No 853/2004, operating in West African waters, registered by and with fishing licenses from the CA for Fisheries, for at least the last two years. The approval of these freezer vessels was carried out recently (April 2013) and the approvals were given even if some EU requirements were not fulfilled (e.g. absence of an HACCP plan and of temperature recording devices). The Basque Country "Public Health Directorate" informed the audit team that in this specific case, an affidavit ("declaración juramentada") and proof of corrective actions need to be provided within a defined deadline. If nothing is received, the approval will be withdrawn.

The "Public Health Directorate" stated that they were unaware of the existence of freezer vessels that were not approved under Regulation (EC) No 853/2004 or that the fishery products from those vessels (tuna frozen in brine) were being shipped to Spain, mainly through the AC of Galicia, from a third country with customs and fisheries documents (the T2M document and the catch certificate) and without an export health certificate from the third country CA.

- In the Basque Country, the audit team was informed that the "conditional approval", foreseen in Article 31.2.(d) of Regulation (EC) No 882/2004, could not be used in the AC. On the other hand, since September 2012, the "conditional approval" is used in Catalonia regularly.

## **Conclusions**

National provisions for registration and approval of food business operators are in place and are respected by the CAs.

Nevertheless, the audit team concluded that:

- The approval of establishments and vessels, and their inclusion in the RGSEAA, presented discrepancies and in some cases was not in line with EU requirements or with the instructions of the MANCP (related to the activities carried out).
- There had been freezer vessels not approved under Regulation (EC) No 853/2004 flying the flag of Spain, for a period of at least two years, that were producing and placing products on the EU market, which is not in accordance with Regulation (EC) No 882/2004.



## 5.3 OFFICIAL CONTROLS OF FISHERY PRODUCTS

### 5.3.1 Production and placing on the market

#### Legal requirements

Article 4 of Regulation (EC) No 852/2004.

Article 3 and Section VIII of Annex III to Regulation (EC) No 853/2004.

Article 4 of Regulation (EC) No 854/2004 and Chapter I of Annex III to Regulation (EC) No 854/2004.

Regulation (EC) No 2073/2005.

Article 50 of Regulation (EC) No 178/2002.

#### Findings

##### 5.3.1.1 Official control system in place

The MANCP, in Part B “Official Control Programmes”, describes the official control programmes for fishery products that have to be implemented by Spanish CAs, at all levels.

The official control programmes related to fishery products primary production can be found under Section II “Official Control Programmes in Agriculture, Livestock, Fisheries and Food”. In this section, two programmes are specific to primary production of fishery products. Both programmes are executed by the AC CAs and coordinated by MAGRAMA:-

- “Programme II.1. Official Control Programme for the Hygiene of the Primary Production in Extractive Fishing” – only in the ACs with sea coast.
- “Programme II.2. Official Control Programme for the Hygiene of the Primary Production in Aquaculture” - in all ACs.

Both programmes have defined objectives, legal requirements that have to be respected, CAs designated to plan and execute the programmes, procedures for the execution and management of the official controls (where and what to control, criteria for risk assessment, minimum frequency of official controls (3%), control methods and techniques, documented procedures, verification and audits of official controls).

- In all ACs visited, both official control programmes were available and provided to the audit team. These followed, in general, the principles established in the MANCP.
- The audit team noted that, across the visited ACs, the structure and organisation of these two programmes was very similar. The programmes include standard operating procedures that were created for the execution of the programmes, with specific checklists and inspection reports. The audit team noted that the official staff follows the procedures in place and uses the associated documentation correctly.

The audit team also noted that:

- The programmes description in the MANCP, and the ones presented by the AC CAs did not always include organoleptic examinations of fishery products (to verify compliance with the requirements of Chapter II.A of Annex III of Regulation (EC) No 854/2004)<sup>3,4</sup>. Several CAs

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3 In their response to the draft report the CA of Catalonia stated that in the second half of 2013 an official control programme for hygiene standards in the primary production stage of extractive fishing and aquaculture was being prepared using as a basis the National Programme, adapted to the situation in Catalonia. The same is being done with the control protocols. Organoleptic checks are included in the new inspection reports to be used to carry out the hygiene controls in order to ensure that the fishery products meet the basic freshness criteria as a minimum.

4 In their response to the draft report the CA of Canary Islands noted that the Anisakis control programme includes

stated that this is done at the auction hall level.

- In Catalonia, for 2011 the programmes established a minimum frequency of visits of 10% for extractive fishing and 50% for aquaculture. For 2012 the frequency for both was set at 3%. The CA explained that this reduction in frequency was due to staff shortages<sup>5</sup>. For extractive fishing, of almost 1,000 fishing vessels – 87 were visited in 2011 and 17 were visited in 2012. For aquaculture of 14 sites - three were visited in 2011 and two in 2012. Only the 2012 target set for visits to aquaculture sites was met.

For 2013, the “Maritime Affairs and Fisheries Inspection” of Catalonia has defined new criteria for the risk assessment and will apply the minimum frequency established in the MANCP (3%) for aquaculture and a minimum frequency of 5% for extractive fishing. This means that it will take seven years to complete the aquaculture control programme and 20 years to complete the extractive fishing one.

New checklists for 2013 inspections for fishing vessels and aquacultures are updated and include reference to EU legislation.

- In the ACs of Galicia and the Canary Islands, taking into account the foreseen frequencies for official control visits (two days per week dedicated to primary production in Galicia; 40% of visits to aquaculture farms and 10% of visits to fishing vessels in the Canary Islands) and the number of units that have to be controlled, the audit team noted that the frequencies were not always respected and that the official controls carried out are not yet sufficient to cover primary production of fishery products effectively.
- In the Basque Country, the implementation of these programmes only started in 2011 and the aim was to do 20% of visits to fishing vessels and aquaculture farms per year. Both in 2011 and 2012 (only for fishing vessels) the number of inspections carried out exceeded 20%. Aquaculture farm visits were not carried out in 2012 and 2013 as there was only one (the one visited in 2011) in operation.
- The implementation of these programmes in the AC of Madrid was not assessed.

The official control programmes related to the production and placing on the EU market of fishery products after primary production can be found under the Section III “Official Control Programmes in Food Establishments”. In this section, and for the scope of this audit, two generic programmes were evaluated. The programmes are executed by the AC CAs and coordinated by AESAN:-

- Programme III.1 “General Control of Food Establishments”.
- Programme III.2 “Control of Food Establishments' Own Checks”.

The programmes have defined objectives, legal requirements that have to be respected, CAs designated to plan and execute the programmes, procedures for the execution and management of the official controls (where and what to control, criteria for risk assessment defined by each CA, minimum frequency of official controls to be established by each CA, control methods and techniques, documented procedures), description of the possible non compliances and resulting actions to be taken by the CAs, evaluation indicators and verification and audits of official controls.

Control techniques foreseen in these programmes include inspections (Programme III.1) and audits (Programme III.2).

Each AC visited has implemented its own control programmes which may, or not, follow the structure and organisation presented in the MANCP.

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instructions for inspectors to perform organoleptic checks on fish subject to controls.

<sup>5</sup> In their response to the draft report the CA of Catalonia stated that the inspectors who carried out controls from mid 2011 to end 2012 had other duties in addition to these inspections.

In Catalonia, one control programme, the “Control System of Food and Food Establishments (SICA)”, is implemented and covers the production and placing on the EU market of fishery products. This programme also includes sampling.

In Galicia, one control programme, the “Control Programme of the Fisheries Industry”, is implemented and covers the production and placing on the EU market of fishery products.

In the Canary Islands, the CA executes the same two generic control programmes as mentioned in the MANCP.

In the Basque Country, one control programme, the “Control System of Food Establishments”, is implemented and covers the production and placing on the EU market of fishery products.

- All the control programmes provided to the audit team cover the same official controls for fishery products after primary production that the MANCP covers.

The ACs programmes include documented procedures that were created for the execution of the programmes, for the risk assessment and classification of each establishment in accordance with the risk and subsequent minimum frequency of inspection and for specific checklists and inspection reports.

- The audit team noted that the official staff follow the procedures in place, correctly evaluate the risk and classifies the establishments, respect, in general, the established minimum frequency of inspections and use the associated documentation correctly. Some ACs use electronic databases that help them to manage the official controls.

In addition to these, unannounced inspection visits can take place at any time for different purposes: suspicion of a public health problem, food alerts or follow-up of corrective actions.

Audits to the HACCP plans of the establishments are also carried out regularly and in accordance with the planned frequency.

- The audit team also noted that some ACs have developed guides of good practices or reference standards to help both the food business operators in their understanding and compliance with EU legislation and the official staff when carrying out their official control tasks. Examples of these guides included, among others, good practices for primary production (fishing vessels and aquaculture), for auction halls, for wholesale markets and their subunits and for HACCP implementation.
- The full implementation of these programmes in the AC of Madrid was not assessed. Instead, the specific part that corresponds to the UTM was verified.

Nevertheless, the audit team noted that:

- The UTM only inspects or audits the subunits that follow the published guides of good practices. Other activities, for which there are no published guides (e.g. cutting of fresh or frozen fish), are not inspected and the subunits of the wholesale market continue operating without any measures taken by the CA.
- The AC of Madrid proceeded to an update of the approval and made some remarks concerning the structures (notification of 24/03/2006) of the wholesale market. The food business operator committed to correct the non conformities (letter of 25/10/2006). No evidence of a follow-up was provided to date to the concerned CA.
- In one case in Catalonia, the CA carried out an inspection visit in July 2010 and gave the food business operator three months to present an action plan, which it didn't. No follow-up has been carried out by the CA. The territorial CA stated that it was foreseen in the 2012 planning but it did not occur. The audit team noted that it was not included in the planning

for 2013 either.

- The audits to the HACCP plans of the establishments, in the ACs of Galicia and the Canary Islands, are, in some cases, not carried out or not totally efficient (problems detected in the identification of hazards and in the risk analysis which were not detected by the CAs inspectors; inspection limited to the records produced).
- Inspection visits to the wholesale market in the Basque Country are not registered in inspection reports. The CA stated that any repairs are carried out when needed and/or when pointed out by the CA. No risk assessment and subsequent classification of the wholesale market was done. Since the revalidation of the approval in 2006, no inspection was carried out by the CA. The evaluation of the HACCP plan (version 2008) is foreseen for October 2013.
- In one case in the Basque Country, the transmission of data to the electronic database, related to an establishment inspection report, was not correct (in the checklist evaluation produced by the database, one item was classified as “correct”, when in the inspection report the same item was linked to a non conformity – absence of pest control). This misleading input has an impact on the establishment's risk assessment, as it is done automatically by the electronic database.

#### *5.3.1.2 Primary production*

The audit team visited five fishing vessels and one aquaculture farm and also observed the unloading operations in two occasions.

In general, the hygiene and structure conditions of the fishing vessels are adequate for the type of operations carried out on board.

Nevertheless, the audit team noted that:-

- In one fishing vessel, the area where the fish is unloaded on board when opening the net presented parts made of wood, not properly covered so that no direct contact with the fish can happen.
- In one fishing vessel, when preparing for unloading, the food business operator used water from the harbour to wash the fish (a bucket was used to collect the water). No action was taken by the CAs present at the time.
- In two unloading quays, adjacent to approved auction halls, there was no network for the distribution of potable water.

The aquaculture farm visited by the audit team is located at sea and its structural and hygiene conditions are adequate for the species being farmed. Records of the daily management of the aquaculture (including mortality, use of feed and veterinary medicines, maintenance of the cages, cleaning and disinfection of means of transport and traceability of the products) were provided and considered satisfactory.

#### *5.3.1.3 Landing and first sale*

In the reply to the pre-audit questionnaire, the CA provided information on landing sites (without any associated auction halls).

- During the audit, no evidence of official controls of landing sites was provided to the audit team.

#### Auction halls

The audit team visited six auction halls. The hygiene and structure conditions, in general, were

adequate and respected the EU legislation.

Most of the auction halls visited had implemented, with different degrees of compliance, an HACCP plan.

Nevertheless, the audit team also noted that:-

- In Catalonia, there is free access to the reception area and quays of the auction hall visited. The distribution area, after the auction, is not completely closed – walls allow possible introduction of pests or animals and contamination with dust.

In the same auction hall, an example of a label from one subunit presented two identification marks: one from the auction hall and one from another establishment. The activities related to the establishment's are “cold storage” and not packaging (as it is foreseen in the approval of the auction hall). The later approval corresponds to an establishment that is located elsewhere in the AC, not in the auction hall.

- In Galicia, the HACCP provided for one auction hall did not include the activity of freezing or freezing in brine.
- Also in Galicia, a forklift that uses gas as fuel was used inside another auction hall. The presence of people without adequate clothing or protective equipment, the presence of boxes directly on the floor (potential contamination when stocked) and wrapping activity (associated with washing of fishery products) carried out outside the auction hall, in the truck loading area, were also noted. Fishery products labelling was not properly done (absence of identification mark – which was immediately corrected in one case but not in a second one).
- In the Canary Islands, in the auction hall visited, the freezing activity is not covered by the approval and the CA informed the audit team that because it is an infrequent and marginal activity it does not need to be approved for that purpose. This situation is in contravention of Regulation (EC) No 853/2004. The HACCP plan of this auction hall presented an incomplete hazard identification and risk analysis and the identification of critical control points was made without taking into account if the control was essential to prevent or eliminate the hazard or to reduce it to acceptable levels.
- In the Basque Country, no HACCP plan was implemented in the auction hall. The CA has provided a document to the audit team where it proposes to start in 2013 the control of the implementation of HACCP plans on what was considered “low priority” food business operators, where the auction halls of the AC are included.

### Wholesale Markets

The audit team visited two wholesale markets. In general, both presented adequate hygiene and structure conditions for the common areas and were adapted to the activities carried out (access of buyers to subunits, transport of fish with pallet jacks).

Nevertheless, the audit team noted that:-

- The wholesale market in Madrid presented versions of individual plans for cleaning, disinfection and maintenance (2008), by-products disposal (February 2012), control of water (2008) and pest control. No records were presented to the audit team or record templates were included in these plans.

The administration of the wholesale market presented a draft document (dated version of 2012), integrating all the plans concerning the pre-requisites for an HACCP plan. This document was not presented to the UTM for revision yet.

Inside the wholesale market, the audit team noted the presence of fish in wooden boxes and in direct contact with the wood (coming from Andalusia and the Basque Country auction halls).

Some subunits carry out activities (e.g. cutting of fresh tuna, cutting of frozen swordfish) in conditions that were not approved by the CA. The majority of the subunits have not yet been inspected (only 45) for the approval of their activities.

- In the wholesale market in the Basque Country, the CA is currently proceeding to the approval of the subunits (two have not yet started, 12 are on-going and 11 are approved).

Inside the wholesale market, the audit team noted:-

- the presence of two labels, from two approved establishments, with two identification marks and two different commercial (grouper vs. wreckfish) and scientific names (*Epinephelus marginatus* vs. *Polyprion americanus*) for the same product. The traceability and explanation given by the provider of the subunit, by fax, was considered not satisfactory because it insisted on the wrong scientific name for the species displayed (wreckfish).
- Presence of boxes with labels without the scientific names of the fishery products displayed.
- Presence of boxes with labels without date of production of aquaculture products. In addition, one approval (which was not in the form of the identification mark) was struck out.
- Presence of wooden boxes with fish in direct contact with the wood from the Basque Country auction halls. The CA provided to the audit team a document addressed to the subunits warning them about the use of wooden boxes. The CA intends to stop this practice by the end of the year 2013.

#### 5.3.1.4 Facilities, including vessels, handling fishery products

The audit team visited one freezer vessel, one cold store and nine processing plants. The audit team also analysed records related to the official controls of freezer and factory vessels.

The establishments and vessel visited presented hygiene and structure conditions that can be considered, in general, as adequate and respecting the EU legislation.

As for the implementation of HACCP plans, all establishments had a documented HACCP plan available when the visits occurred.

- Own-check analyses are carried out regularly, either in external accredited laboratories or internal laboratories and the results provided to the audit team were mostly satisfactory.
- Records associated with pre-requisites control plans were available and, in general, correctly completed by the establishments.

However, the audit team also noted that:-

- Deficiencies in the implementation of the HACCP plans were not always detected by the CAs inspectors (e.g. absence of records, incomplete hazard identification and risk analysis).
- One subunit in the wholesale market in Madrid, whose structures were acceptable, needed maintenance (presence of insects, broken walls and door of the cold store).
- In Catalonia, in one establishment, in the cold store for frozen products, the presence of by-products was noticed. The establishment was not authorised for dealing with this type of

product. The food business operator stated that these were fishery products fit for human consumption when they were received and that they are only used as feed for the food business operator's aquaculture farm. The audit team noted that the fishery products were not fit for human consumption (stored in broken boxes, products not protected, fishery products placed directly on wooden pallets with protective black plastic film ripped apart).

In the same establishment, the storage of clean plastic boxes used for freezing in the room where dirty plastic boxes are stored together with other materials and equipment (cleaning equipment and detergents) was noted.

- In Catalonia, in another establishment, the location of the changing rooms was outside the unit and no cleaning and disinfection area was foreseen for the workers before entering the processing room.
- In Catalonia, in one establishment, the temperature of the frozen fishery products (cuttle fish – *Sepia* spp.) was not compliant with the EU regulations (-18°C) at the exit of the freezing tunnel (temperatures measured were of -4°C to -9°C).
- In Galicia, one establishment has improved since the last FVO audit in 2008, in terms of structures. Nevertheless, the flow of the products still allows the possibility of cross contamination; the unloading of frozen fishery products is done directly on the floor; the changing rooms are outside of the unit, in another building, and no cleaning and disinfection area is foreseen for the workers before entering the processing unit.
- In the Canary Islands, in one establishment, the flow of the products allows the possibility of cross contamination.
- In the Basque Country, in one establishment, the presence of insects and dust in the processing room, especially on the doors that communicate with the outside, was detected. In the changing room, the lockers for outdoor clothes and working clothes storage were not used correctly.
- In the Basque Country, in another establishment, the presence of condensation on pipes that pass directly over the products and that can be a possible source of contamination was noted.

#### *5.3.1.5 Direct landings and import controls of fishery products*

All operations concerning landings and access to port services of any fishing vessels, freezer vessels or other types, with or without fishery product on board, must be notified to the SGCI. In the case of landings of frozen fishery products, the Master/representative of the vessel must notify the estimated time of arrival to the port at least three days in advance.

- SGCI informed the audit team that it receives 100% of the notifications, even if not always completed.

In case of incomplete notifications or incomplete or missing catch certificate(s), the SGCI allows the landing of the fish and, in accordance with Article 7(3) of the Regulation (EC) No 1005/2008, orders the storage of the consignment under CA control until the documentation required by Article 6 of the above Regulation is completed.

The SGCI informs the relevant CAs (via e-mail, fax, etc.) about the authorisation for landing or transshipment operations in Spanish ports if the notification submission requirements and catch certificates information are met in accordance with Article 7(1) of Regulation (EC) No 1005/2008.

The Port Authorities, after giving the vessel an authorisation for landing in the port, inform the local veterinary authorities allowing them to carry out the necessary veterinary controls.

- The audit team notes that, at least in one port visited, the Port Authority video-monitors all

operations during the landing or transshipment operations.

- In case a consignment of fish caught by vessels flying a third country flag needs to be detained, there is documented evidence of the existing coordination between MAGRAMA, MSSSI and the Customs.

Landings of frozen fish caught by vessels flying a third country flag shall undergo veterinary controls at the BIPs. These consignments are correctly notified and submitted to the BIPs for the relevant checks. The veterinary checks carried out at BIPs remain unchanged since the last FVO import control audit in 2012 (ref. DG(SANCO)2012-6500).

Spanish BIPs issue the Common Veterinary Entry Document (CVED) directly in the Trade Control Expert System (TRACES), after satisfactory veterinary checks of the consignments. Since March 2013, the relevant information in TRACES is automatically transmitted to the Customs information system. The CVED is handed over to the person responsible for the load, who is obliged to submit it to the Customs for clearance. The system-to-system data transmission speeds-up the Customs clearance procedure.

- At one BIP visited, three cases of delayed or missing official decisions on consignments were identified by the audit team. In all cases, the BIP staff stated that this happened due to incomplete data or documentation provided by the person responsible for the load.

However, the BIP staff allowed the movement of the consignments into a cold store without a decision of rejection or detention, which is not in compliance with Article 17 of Directive 97/78/EC. The BIP staff stated, that they could not apply the current national detention procedure due to the absence of any available approved detention warehouse and capacity of their own storage facilities at the BIP which are not sufficient for the bulk consignment of frozen fish (the latest consignment was approximately 1 200 tonnes).

The absence of an approved detention warehouse for BIP use was due to a misunderstanding between Customs and SGSE as to the approval requirements for such a facility within the port customs area<sup>6</sup>.

In addition, the stored consignment of the frozen fish was not separated from the EU complying goods.

The EU legislation requires a third country CA to issue a health certificate for frozen fish caught by an EU vessel, transhipped or containerised in that third country ports and subjects the consignment to BIPs controls.

- However, during the visit to one of the establishments, the audit team identified a consignment of frozen tuna caught by an EU vessel and transhipped in a third country port to a vessel flying the flag of another third country, landed in a nationally designated port. The consignment was accompanied by a T2M document and did not undergo the veterinary checks at the BIP.

The Spanish CA in charge of BIPs and the one for Fisheries informed the audit team that their interpretation of the origin of the frozen fish caught by EU vessels, transhipped or containerised in third country ports, does not require the consignments to undergo the obligatory veterinary controls by the BIPs.

#### *5.3.1.6 Follow-up of RASFF notifications*

In the reply to the pre-audit questionnaire, AESAN explained that the notifications through the RASFF are transferred to the AC CAs through the “Coordinated System Rapid Information

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<sup>6</sup> In its response to the draft report the CA stated that the issue had now been clarified (no specific Customs authorisation required) and SGSE has now sanctioned the use of the cold store as an approved detention warehouse.



(SCIRI)”, proceeding, in turn, those CAs to report through the system which actions were taken.

- AESAN provided to the audit team the actions taken for eight chosen examples of RASFF notifications. These actions were considered satisfactory.

## **Conclusions**

There is an official control system for the production and placing on the market of fishery products, implemented in the ACs visited, with regular official controls, based on risk and with appropriate frequencies.

The establishments visited respect, mostly, the hygiene and structure conditions defined in Regulation (EC) No 852/2004 and 853/2004. The implementation of HACCP plans was widespread in the establishments visited.

Nevertheless, the audit team concluded that:-

- There are approved establishments and vessels with no HACCP plans (auction halls and wholesale markets) that are putting fishery products on the market, is in contradiction with the EU legislation.
- The audits of the HACCP plans of the establishments are not implemented or present significant shortcomings that undermine the achievement of the objectives set in the control programmes described in the MANCP, for the fish sector.

The procedures for official controls of direct landings of fresh fish and imports of frozen fishery products caught and processed by vessels flying a third country flag were generally correctly implemented. On the other hand, official controls of imports of frozen fish caught and processed by Spanish vessels, transhipped and/or containerised in third country ports, were not implemented<sup>7</sup>.

The selected files at the BIPs visited shown satisfactory final veterinary decisions on the consignments. However, the incorrect application of Article 17 of Directive 97/78/EC, in the cases of non-compliance of the fish consignments with import/transit rules, cannot ensure that the non-compliant products will not be placed on the market.

The actions taken to address recommendation 1 of the previous 2008 FVO audit have been implemented in the ACs visited. Nonetheless, the inspection visits to fishing vessels are still not able to cover all the fleet within a reasonable time frame, taking into account the total number of fishing vessels registered in Spain.

### *5.3.2 Fishery products*

## **Legal requirements**

Article 7 of Regulation (EC) No 854/2004 and Chapter II and III of Annex III to Regulation (EC) No 854/2004

## **Findings**

The official control programmes related to fishery products after primary production can be found under the Section III “Official Control Programmes in Food Establishments”. In this section, and for the scope of this audit, four specific programmes were evaluated. The programmes are executed by the AC CAs and coordinated by AESAN:-

- Programme III.3 “Control of Biological Risks in Foodstuffs”.

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<sup>7</sup> In its response to the draft report the CA commented that the main issue regarding the landing of fish in Spain concerns a difference in interpretation between, on the one hand, the competent authorities responsible for fisheries and for border inspection posts and, on the other hand, the EU Commission on the legal origin of frozen fish caught by Spanish flagged vessels, transhipped or containerised in a third country and thereafter imported into the EU.

- Programme III.4 “Control of Biological Toxins: Marine Biotoxins in Foodstuffs”.
- Programme III.5 “Control of Contaminants in Foodstuffs”.
- Programme III.9 “Control of Certain Substances and their Residues in Products of Animal Origin”.

Control techniques foreseen in these programmes include inspections (Programme III.3) and sampling (Programmes III.3, 4, 5 and 9).

Two types of official control by sampling are defined in the MANCP:-

- “Suspicious control” - carried out when there is prior information, about previous alerts or non-compliances, which makes the establishment concerned subject to priority and/or more rigorous control. Samples taken during this control are called “regulatory” samples and the CAs have to follow the procedure established by Royal Decree 1945/1983 of 22 June, regulating the offences and penalties related to consumer protection and food production. This sample is composed of three sub-units.
- “Random / Directly targeted control” - carried out when there is no information to suspect the existence of non-compliances in selected establishments, targeting the sampling to the points defined in the official control programmes of each ACs. Samples taken during this control are mainly called “prospective” samples (composed of at least one sub-unit), in order to obtain information on the status of the products or the sector and set the necessary priorities in successive control programmes. “Regulatory” samples can also be collected.

Samples from both types have to be analysed in accredited laboratories designated by the CAs. The number of samples to be taken is defined by each AC CA, which will then decide where to collect the samples in accordance with the objectives of the control programmes.

If the result of a “prospective” sample is not satisfactory, no decisions can be taken by the CA regarding the establishment but the product can be seized until a “regulatory” sample is taken and the result of its analysis issued.

In Catalonia, the “Food Surveillance System (SIVAL)” is implemented and covers the official controls of fishery products by means of the two types of sampling described above.

In Galicia, the control programme mentioned in section 5.3.1.1 includes a specific “sampling plan for the fisheries industry”.

In the Canary Islands, the CA executes the same four specific control programmes as mentioned in the MANCP.

In the Basque Country, two sampling programmes are implemented for the official controls of fishery products:

- The “Chemical Food Safety Programme” - one part of the programme is run every month, includes 91 samples of foodstuffs which are analysed for organoleptic criteria, heavy metals and Polychlorinated Biphenyls (PCBs). Dioxins are also determined, but not every month. The second part is selective for fishery products (“Target Control”) and includes analysis for histamine, heavy metals (including arsenic) and sulphites.
- The “Microbiology Food Safety Programme” which includes sampling of products placed on the market (“Random control”) and also at establishment level, for all foodstuffs (“Targeted control”). The CA informed the audit team that 100% of the fishery products establishments were already sampled for the period of the most recent MANCP.

*Organoleptic examination*

Organoleptic examinations are carried out by the official staff responsible for the official controls of fishery products after primary production. These are mainly carried out at the auction halls and wholesale markets and are regular.

- The audit team noted that the fishery products present in the auction halls and wholesale markets visited were fit for human consumption and when they were not, the CAs concerned took appropriate measures (e.g. seizure and destruction of the product).

#### *Freshness indicators*

In Catalonia and the Basque Country, analyses of total volatile basic nitrogen were carried out in 2011 and 2012 and results were satisfactory.

No documented evidence of analyses of total volatile basic nitrogen or trimethylamine nitrogen were provided to the audit team for the ACs of Galicia and the Canary Islands.

#### *Histamine*

In all ACs visited, samples of fishery products for histamine determination have been collected (composed of nine subunits). Results provided to the audit team were mainly satisfactory.

#### *Residues, contaminants and additives*

The CA of Catalonia provided to the audit team results of analysis of fishery products for 2012 that included the surveillance of polycyclic aromatic hydrocarbons (PAH) and heavy metals (Cd, lead (Pb), Hg, arsenic and methyl-mercury). The testing of dioxins and Polychlorinated Biphenyls (PCBs) was interrupted between 2011 and 2013 because of budget restrictions. Additives were also tested for in fishery products (including sulphites in crustaceans).

The CA of Galicia provided to the audit team the sampling plan for 2012 which included analysis of heavy metals (Cd, Pb, Hg and tin). Sulphites were also tested for in crustaceans. Evidence of the testing of dioxins, PCBs and PAH was not provided.

The CA of the Canary Islands provided to the audit team the results of analysis of fishery products for 2012 that included the surveillance of heavy metals (Cd, Pb and Hg). Additives were also tested for in fishery products (including sulphites in crustaceans). Evidence of the testing of dioxins, PCBs and PAH was not provided.

The CA of the Basque Country provided to the audit team results of analysis of fishery products for 2012 that included the surveillance of PAH, heavy metals (Cd, Pb, Hg and tin), dioxins and PCBs. Additives were also tested for in fishery products (including sulphites in crustaceans).

- The results presented to the audit team by the CAs were mostly satisfactory and when they were not, the CAs concerned took appropriate measures.

#### *Microbiological checks*

In all ACs, samples of fishery products were collected for microbiological analyses. These are targeted in accordance with the type of fishery products (smoked, ready-to-eat, canned, frozen, fresh or cooked). The analysis results provided to the audit team were satisfactory.

When non conformities were found, the CAs took appropriate measures to control the risk (e.g. product recalled, seizure and destruction of the product).

#### *Parasites*

The CAs informed the audit team that the control of parasites is mainly carried out during the organoleptic examinations.

In addition, in accordance with the Royal Decree 1420/2006, of 01/12/2006, on the prevention of

parasitosis from *Anisakis* in fish products supplied by businesses serving food to end consumers or to communities, the CAs implement specific controls (the ones included in the MANCP Programme III.3 “Control of Biological Risks in Foodstuffs”) that target this parasite.

All CAs have provided results of these analysis, which were mostly satisfactory. The CAs also took appropriate measures when the presence of *Anisakis* was detected.

#### *Poisonous fishery products*

The audit team did not observe in the ACs visited the placing on the market of poisonous fishery products.

In the Canary Islands, a specific programme for the control of ciguatoxin in fishery products is in place since 2009. The programme is under the coordination of the “Public Health Directorate” and the “Fisheries Viceconsejería”. During the period 2009-2010, a rapid test was used to determine the presence of ciguatoxin in fishery products samples collected at first sale sites, establishments, small retail shops and restaurants.

From 2011 to 2012, due to the lack of the rapid test on the market, samples were collected at the first sale sites only and analysis were carried out using a quantitative method (presence/absence of cellular toxicity). When results were suspicious, confirmation by a chemical method was done at the EU Reference Laboratory for marine biotoxins. Results provided to the audit team were, in general, satisfactory.<sup>8</sup>

#### *Official controls on water and ice*

The water (and ice) used in the establishments visited comes from the public distribution networks. The control of the quality of the water is carried out by the distributors and by other CAs. Food business operators also have to monitor the quality of the water used in their facilities. The results available at the establishments visited were satisfactory.

### **Conclusions**

The official controls of fishery products are carried out regularly, cover the parameters established in EU and Spanish legislation and resort to official control laboratories that are accredited and use the EU reference methods.

Nevertheless, not all the CAs control the totality of the parameters (e.g. dioxins, PCBs and PAH) prescribed in the EU legislation.

## **5.4 LABORATORIES**

### **Legal requirements**

Articles 11, 12 and 33 of Regulation (EC) No 882/2004.

Article 1 and Annex I to Regulation (EC) No 2073/2005.

Article 2 and Section II of Annex II to Regulation (EC) No 2074/2005.

Regulation (EC) No 1881/2006.

Regulation (EC) No 333/2007.

Regulation (EU) No 252/2012.

### **Findings**

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<sup>8</sup> This programme is implemented at the beginning of the production chain and aims at total protection for consumers. However, the risk of ciguatoxin outbreaks exists as was demonstrated by incidents over the last three years related to sports fishing. It is to be noted that sports fishing activity is only covered under Regulations (EC) Nos 852/2004, 853/2004 and 854/2004 where the catch (fishery products) are commercially traded e.g. to local restaurants.

The audit team visited one National Reference Laboratory (NRL) and four official control laboratories.

#### The “National Food Centre (CNA)”

The CNA is the NRL for microbiology and virology of live bivalve molluscs; for *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, *E.coli*, *Staphylococcus* coagulase positive and enterotoxins in foodstuffs; for parasites; for toxins; for PAH and for dioxins and PCBs.

The laboratory is accredited by the Spanish Accreditation Body (ENAC) to the European Norm (EN) ISO/EC 17025, since 1999. It regularly participates in proficiency tests, either organised by the EU Reference Laboratories or by international bodies (e.g. Food Analysis Performance Assessment Scheme “FAPAS”).

National comparative tests were organised by the CNA, only for PAH and *E.coli* and *Salmonella* in live bivalve molluscs (not for dioxins, PCBs, microbiological parameters or histamine in fishery products).

The facilities are adequate and well maintained and the staff met was very knowledgeable and competent. The CNA fulfils the obligations of a NRL.

#### Official Control Laboratories

The four official control laboratories were all accredited by ENAC to EN ISO/EC 17025. They all participate regularly in international proficiency tests and in the national comparative tests.

The analyses carried out by the laboratories visited, in the scope of this audit, were:

- In Catalonia – total volatile basic nitrogen, histamine, PAH, heavy metals (Cd, Pb and Hg), *Salmonella* and *Listeria monocytogenes*.
- In Galicia – heavy metals (Cd, Pb and Hg), *Salmonella* and *Listeria monocytogenes*.
- In the Canary Islands - heavy metals (Cd, Pb and Hg), sulphites, *Listeria monocytogenes*, *Staphylococcus* coagulase positive, *E.coli*, coliform bacteria and *Salmonella*.
- In the Basque Country – heavy metals (Cd, Pb, Hg and arsenic), sulphites, *Enterobacteriaceae* at 37°C, *Salmonella*, *E.coli*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Vibrio cholerae* and *Vibrio parahaemolyticus*.

The results provided to the audit team were, in general, satisfactory.

Their cooperation with the NRL is regular (e.g. participation in annual workshops organised by CNA) and staff of these laboratories participate in training courses provided by the NRL.

All laboratories have modern and well kept facilities and high performance equipment to carry out the analyses requested by the ACs CAs.

All staff met in these laboratories was competent and motivated.

Nevertheless, the audit team noted that:-

- In the Public Health Laboratory of Pontevedra, the limit of detection for the determination of lead was not in line with the EU regulations.
- In the Public Health Laboratory of Bilbao, the presence of bottles of expired ingredients (dates of the years 2006, 2008 and 2009) for the preparation of culture media were mixed with bottles of ingredients which are being currently used.
- In the Public Health Laboratory of Grand Canary, the performance criteria established in the analytical methods for heavy metals is only the Limit of Quantification – the Limit of Detection has been calculated during the internal validation of the methods but it was not

converted and expressed correctly for the methods concerned. The Limit of Quantification for Hg (0,1 mg/kg) is in line with EU requirements but the ones for Cd (0,025 mg/kg) and for Pb (0,08 mg/kg) are not.

## **Conclusions**

All laboratories visited were accredited and used EU reference methods for the official analysis of fishery products and can be considered in line with the requirements of Article 12 of Regulation (EC) No 882/2004. However, shortcomings were detected in relation to the Limits of Detection and Quantification established for the heavy metals methods.

As a NRL, the CNA role is in line with the requirements defined in article 33 of Regulation (EC) No 882/2004.

With respect to the official controls of fishery products and official control laboratories that support those official controls, the actions taken by the Spanish CAs have fully addressed recommendation 5 from the 2008 FVO audit.

## **6 OVERALL CONCLUSIONS**

Improvements have been made since the last audit and in principle, the current organisation of the CAs visited, the standards set and their documented operational procedures, provide an acceptable system of official controls of fishery products.

The deficiencies noted in relation to the supervision and audit of official controls and the shortcomings found in their implementation (related to the approval of establishments and vessels, the controls over the primary production sector, the evaluation of HACCP plans and the monitoring arrangements for certain contaminants), weaken the ability of the CAs to guarantee fully that all fishery products comply and were produced in accordance with EU legislation.

## **7 CLOSING MEETING**

During the closing meeting held in Madrid on 31 May 2013, the audit team presented the main findings and preliminary conclusions of the audit to the CAs.

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the audit team.

## **8 RECOMMENDATIONS**

The CA should provide Commission services with an action plan, including a timetable for its completion, within 25 working days of receipt of the report, in order to address the following recommendations for fishery products to be placed on the EU market.

<b>Nº.</b>	<b>Recommendation</b>
1.	The CA should ensure the quality and consistency of official controls at all levels, in particular the effectiveness and appropriateness of official controls of fishery products at all stages of production, processing and distribution, as required in Article 4(4) of Regulation (EC) No 882/2004.
2.	The CA should ensure that internal or external audits are carried out, and should take appropriate measures in the light of their results, to ensure that it is achieving the objectives of Regulation (EC) No 882/2004 - as required in Article 4(6) of Regulation

Nº.	Recommendation
	(EC) No 882/2004 - in particular to the official controls of fishery products.
3.	The CA should ensure that establishments and vessels are approved for the activities concerned only if the food business operators have demonstrated that they comply with the requirements of Regulation (EC) No 852/2004 and those of Annexes II and III of Regulation (EC) No 853/2004, as required by Article 31(2)(c) of Regulation (EC) No 882/2004.
4.	The CA should ensure that food business operators place fishery products on the EU market only if they have been prepared and handled exclusively in freezer vessels that the CA has approved, as required in Article 4(1)(b) of Regulation (EC) No 853/2004.
5.	The CA should ensure that all approved food business operators put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles, as required by Article 5(1) and 5(3) of Regulation (EC) No 852/2004.
6.	The CA should ensure that, when carrying out audits of HACCP based procedures, it verifies that food business operators apply such procedures continuously and properly, as required in Article 4(5) of Regulation (EC) No 854/2004.
7.	The CA should ensure that consignments of fishery products that are unloaded from a vessel flying the flag of Spain in a third country - this third country is considered the country of dispatch as referred to in Article 6(1)(a) of Regulation (EC) No 853/2004 and in paragraph 1 of Annex VI to Regulation (EC) No 854/2004 – and are then introduced into the EU, undergo veterinary checks in accordance with Directive 97/78/EC and with Regulation (EC) No 882/2004.
8.	The CA should ensure that border inspection posts reject or detain all non-compliant consignments of fishery products in accordance with Article 17 of Directive 97/78/EC and that the detained consignments are separated from the compliant products.
9.	The CA should ensure that official controls, as required by point 1(b) of Chapter I of Annex III of Regulation (EC) No 854/2004, are put in place in order to ensure that primary production fishing vessels are in compliance with the requirements foreseen in Regulations (EC) No 852/2004 and No 853/2004.
10.	The CA should ensure that official controls, as required by point D of Chapter II of Annex III of Regulation (EC) No 854/2004, are put in place in order to ensure that monitoring arrangements are set up to control the levels of contaminants in fishery products - in particular of dioxins, PCBs and PAH - in accordance with EU legislation.
11.	The CA should ensure that the performance criteria – such as Limits of Detection and Quantification – established for the analytical methods to determine the presence of

<b>N°.</b>	<b>Recommendation</b>
	heavy metals in fishery products are the ones defined in Regulation (EC) No 333/2007.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2013-6672](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6672)



## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2009/821/EC	OJ L 296, 12.11.2009, p.1	2009/821/EC: Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dir. 97/78/EC	OJ L 24, 30.1.1998, p. 9-30	Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries
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
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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 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. 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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Reg. 1005/2008	OJ L 286, 29.10.2008, p. 1-32	Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999
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
Reg. 1224/2009	OJ L 343, 22.12.2009, p. 1-50	Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006