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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ECUADOR

FROM 26 NOVEMBER TO 05 DECEMBER 2013

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE  
PRODUCTION OF FISHERY PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN  
UNION

## ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office audit in Ecuador carried out from 26 November to 05 December 2013, as part of its programme of audits in third countries.*

*The primary objective of the audit was to evaluate whether the official controls put in place by the competent authority can guarantee that the conditions of production of fishery products in Ecuador, destined for export to the European Union, are in line with the requirements laid down in European Union legislation.*

*The audit also verified the extent to which measures taken to address the recommendations of the previous Food and Veterinary Office audit report on fishery products of 2010 have been implemented and enforced by the competent authority.*

*The report concludes that in principle the current organisation and implementation of official controls could guarantee that the conditions of production of fishery products in Ecuador intended for EU export meet standards equivalent to the requirements laid down in EU legislation. However deficiencies identified, in particular concerning training, non-EU listed facilities participating in the EU export production chain, the supervision of establishments, the system in place to ensure the eligibility of raw materials for EU export and some elements of the official controls on fishery products, undermine the guarantees given in the health attestations of fishery products for EU export.*

*Since the last 2010 FVO audit, corrective actions have been implemented and enforced by the CA in order to address the recommendations of the previous audit report. The Ecuadorian competent authority addressed satisfactorily recommendations No 2. Recommendations Nos. 3, 4 were partially addressed and recommendation No 1 of that audit report is still considered as not satisfactorily addressed.*

*The report addresses to the country competent authority 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>
CA	Competent Authority
Cd	Cadmium
CCP	Critical Control Point
CRL	Community Reference Laboratory
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EN	European Norm
EU	European Union
EU listed	Facility approved by the CA for EU fishery products export and listed on the internet site of DG SANCO
EUROSTAT	Statistical Services of the European Union
FVO	Food and Veterinary Office of the European Commission
MAGAP	Ministry of Agriculture, Animal Husbandry, Aquaculture and Fisheries
HACCP	Hazard Analysis Critical Control Points
Hg	Mercury
HPLC	High Performance Liquid Chromatography
INP	The National Institute of Fisheries
ISO	International Organisation for Standardisation
NCP	National Control Plan
OJ	Official Journal of the European Union
PAH	Polycyclic Aromatic Hydrocarbons
Pb	Lead
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
Sn	Tin
TVB-N	Total volatile basic nitrogen

## 1 INTRODUCTION

The audit took place in Ecuador from 26 November to 5 December 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme. The FVO audit team (hereinafter the FVO team) comprised two inspectors from the FVO of the Health and Consumers Directorate-General (DG SANCO).

## 2 OBJECTIVES AND SCOPE OF THE AUDIT

The objectives of the audit were:-

- To evaluate whether the official controls put in place by the Competent Authority (CA) can guarantee that the conditions of production of fishery products in Ecuador intended to be export to the European Union (EU) are in line with the requirements laid down in EU legislation, and in particular with the health attestations contained in the certificate of Appendix IV to Annex VI to Regulation (EC) No 2074/2005.
- To verify the extent to which the guarantees and the corrective actions submitted to Commission services in response to the recommendations of a previous FVO fishery products audit report of 2010 have been implemented and enforced by the CA.

In terms of scope the audit focused on the organisation and performance of the CA the official control system in place covering production, processing and distribution chains applicable to fishery products to be exported to the EU and the export certification procedure. 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 audit team proceeded as follows:

- An opening meeting was held in Guayaquil on 26 November 2013 with CA, the National Institute of Fisheries (INP) which is under the Ministry of Agriculture, Animal Husbandry, Aquaculture and Fisheries (MAGAP). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for its satisfactory completion.
- The following sites were visited.

<b>COMPETENT AUTHORITY</b>		
INP	2	INP main office in Guayaquil and Manta's office
<b>LABORATORY VISITS</b>		
	2	The CA laboratory and one private laboratory
<b>PRIMARY PRODUCTION</b>		
Aquaculture farms	3	One farm producing shrimp and tilapia and two farms producing shrimp
Fishing vessels	2	Seiners
<b>LANDING AND FIRST SALE</b>		

Landing sites	2	
<b>FACILITIES HANDLING FISHERY PRODUCTS</b>		
Freezer vessels	2	One freezer EU-listed vessel and one freezer vessel which is not EU listed
Processing Plants	9	Eight EU listed processing plants and one cold store which is not EU listed
Ice Factory	2	

- representatives from the CA accompanied the audit team during the whole audit.

### **3 LEGAL BASIS FOR THE AUDIT**

The audit was carried out under the general provisions of EU legislation and, in particular Article 46 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.

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

### **4 BACKGROUND**

#### **4.1 GENERAL BACKGROUND**

Ecuador is presently listed in Annex II to Commission Decision 2006/766/EC establishing the list of third countries and territories from which imports are permitted of fishery products for human consumption, other than those covered by Annex I.

Ecuador is also listed in the Annex to Commission Decision 2011/163/EU, indicating that the Ecuadorian residue monitoring plan (RMP) for aquaculture is approved in accordance with Directive 96/23/EC and therefore can export aquaculture fishery products to the EU.

A previous audit took place in 2010 (ref. DG SANCO/2010/8536) which highlighted deficiencies in the official control system, in particular regarding the standards applicable to freezer vessels, hygiene during unloading operations, sanitary supervision of establishments and official controls on fishery products.

The report - published on SANCO's website at [http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=2516](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2516) - made a number of recommendations in respect of the actions required of the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations which were assessed by Commission services and found satisfactory. The follow-up of these recommendations are reported under the relevant parts of this report.

## 4.2 PRODUCTION AND TRADE INFORMATION

According to information from EUROSTAT, Ecuadorian fishery products exported to the EU amounted to approximately 207,000 and 202,000 tonnes in 2011 and 2012 respectively. Those exports were distributed as follows: canned fish (mainly tuna species) around 50%; fresh and frozen crustaceans (mainly shrimp) approximately 43%. These fishery products were exported by decreasing order of importance to Spain, Italy, United Kingdom and the Netherlands.

The data provided by the CA differs from that of EUROSTAT with regard to quantities (total and by species). According to information provided by the CA, fishery products exported to the EU amounted to approximately 145,000 and 175,000 tonnes in 2011 and 2012 respectively. The main fishery products exported to the EU in 2012 were as follows: Shrimp (*Penaeus vannamei*) around 55% and tuna (mainly *Katsuwonus pelamis*) around 43%.

According to the information provided by the CA, from the total amount exported to the EU, approximately 64,500 tonnes of raw material (tuna) were imported into Ecuador from freezer vessels with foreign flags that are currently operating under Ecuadorian fishery agreements.

According to the list established by the CA and available on the DG SANCO website (list published on 05/12/2013 and valid from 07/11/2013), imports of fishery products from Ecuador into the EU are authorised from a total of 69 processing establishments, of which 37 establishments process materials only or partially derived from aquaculture, and 38 freezer vessels.

Also participating in the production chain for export are the food business operators integrated in several INP internal lists, available on the CA website, that includes around 1,300 aquaculture farms and 1,300 fishing vessels, 84 freezer vessels, 17 pre-processing plants (aquaculture shrimp de-heading establishments), 41 establishments that handle fresh fishery products (storage of refrigerated products), 17 ice factories and 25 intermediary traders (food business operators that buy fishery products from primary producers and transport and sell them to processing plants).

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

Since the last FVO audit nineteen RASFF notifications were issued for fishery products of Ecuadorian origin (ten border rejections, seven information for attention and two alerts). Six were due to fraud (false certificates and illegal imports), four to the rupture of the cold chain of products and altered organoleptic characteristics of products, five due to heavy metals, two due to mislabelling and two related with histamine. Details on how these notifications were handled are presented in Section 5.6 below.

## 5 FINDINGS AND CONCLUSIONS

### 5.1 LEGISLATION

#### Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 states that Commission experts may carry out official controls in third countries in order to verify the compliance or equivalence of third countries legislation with the relevant EU legislation.

Article 11(4)(a) of Regulation (EC) No 854/2004.

## Findings

According to the information provided by the CA in their response to the pre-audit questionnaire and during the audit, the main legislation and standards in force in Ecuador to control fishery products to be exported to the EU and its production chain remains the one mentioned in previous audit reports:-

- Supreme Decree No 2026 (Official Gazette No 486 of December 19, 1977), publishing the constitutive law of the INP which establishes the duties and authority of the institution.
- Decree No 3198 (Official Gazette No 690 of October 24, 2002), publishing the Fisheries Law and Fisheries Development Act.
- Ministerial Agreement No 06 177-A. (Official Gazette No 302 of June 29, 2006), that establishes the jurisdiction of the INP as the CA for fishery product exports to the EU.
- Resolution ADM-INP-011-2010, of May 27, 2010, that establish the technical protocol to authorise laboratories to perform official analysis under the National Control Plan (NCP).

The following Ecuadorian legislation and standards have been published after the previous audits:-

- Ministerial Agreement No 241 (Official Gazette No 228 of July 5, 2010) that establishes the minimal sanitary requirements to be fulfilled by the fish and aquaculture industry.
- Resolution ADM-INP-001-2013, January 31, 2013, that defines the procedures that food business operators must adopt to be included or withdrawn from the official list of INP.

As a complement to the legislation mentioned above, there is a NCP that establish the organisation of official controls and the rules to be fulfilled by the food business operators in order to give guarantees that that the standards equivalent to those of EU legislation have been applied.

The food business operators that want to export to the EU and that are included on the list of facilities approved by the CA to participate in the EU export chain (hereinafter referred to as “EU listed”) and those who want to supply EU listed establishments (hereinafter referred as “internal list”) must sign a declaration stating that they agree to be subjected to CA assessment against rules based on EU requirements.

From a limited review of the legislation made available by the CA the FVO team noted that the requirements for EU listed establishments and freezer vessels are defined in Ministerial Agreement No 241. However, according to the CA, these requirements are not applicable to food business operators from the internal list, which include pre-processing establishments, cold stores and freezer vessels. As a result, despite being involved in the production chain to export to the EU, no requirements exist for these internal list food business operators to meet standards equivalent to those foreseen in Section VIII of Annex III to Regulation (EC) No 853/2004 and Article 5 of Regulation (EC) No 852/2004 as required in Part II.1 of the health certificate defined in Regulation (EC) No 2074/2005 as regards temperature recording devices and the implementation and maintenance of permanent procedures based on HACCP principles.

## Conclusions

The Ecuadorian legislation and standards applicable to fishery products to be EU exported and their production chain, are generally in line with the EU requirements, except for facilities not EU listed but participating in the EU export chain.



## 5.2 COMPETENT AUTHORITY

### Legal requirements

Article 46 of Regulation (EC) No 882/2004 stipulates that EU controls in third countries shall verify compliance or equivalence of third countries' systems with EU food law. These controls shall have particular regard to points b) to (e), (g) and (h) of the aforementioned article.

### Findings

#### Structure and organisation

The structure and organisation of the CA has not changed since the last 2010 audit concerning the export of fishery products to the EU.

The current service, within INP, that performs the official control tasks is the Department of Fisheries, Aquaculture and Environmental Quality Assurance. There is an INP office in Manta from where officials issue export health certificates.

The CA informed the audit team that there is currently 22 staff performing official controls. These include one national coordinator, sixteen verification officers, three officers performing tasks related to official certification and two with administrative functions. CA staff is assigned to different control tasks in accordance with their knowledge and experience. Three groupings can be identified – officials in charge of EU listed facilities (the most experienced staff), officials in charge of aquaculture farms and officials in charge of the remaining facilities participating in the EU fishery products production chain.

#### Powers, Independence and Supervision

The powers and responsibilities of the CA can be found in the legal framework mentioned in Articles 1 to 5 of the Ministerial Agreement No 06 177-A. The CA is invested with powers to enter and inspect premises, check hygiene conditions and relevant documentation, collect samples for analysis, suspend certification if required and order the suspension or withdrawal of establishments from the lists (internal and EU lists). During the audit the FVO team saw several examples (inspection reports, records of sampling and withdrawal from the list) of these powers.

Procedures are in place to avoid conflict of interest (P-VRF-15). All staff performing official controls sign a “*Confidentiality Protocol*” that ensures that staff do not perform activities that could undermine their capacity to independently perform official tasks. Officials in charge of the verification of establishments are not assigned to particular facilities of food business operators.

In order to ensure that official tasks are performed in a uniform, consistent and adequate way checklists and procedures have been created and supervision of newcomers by more experienced staff is performed during their first monitoring visits to establishments.

#### Training

The CA provided the FVO team with information regarding different training courses attended by their staff on the last 3 years. Auditing, sampling and inspection techniques, EU food and feed law, HACCP evaluation, official health certification systems, organoleptic examinations, RASFF, traceability were some of the areas focussed on in these training sessions. Records of these trainings were made available to the audit team (lists of attendees, contents programmes, etc.)

The FVO team noted that official staff presented knowledge of the EU requirements which in general was shown to be adequate for the duties performed. Nevertheless important gaps were noted regarding assessment of HACCP systems (see point 5.4.4 of this report).

### Resources

The FVO team noted that the CA staff is located in adequate offices and have available the necessary means for the performance of their tasks, which include amongst others, vehicles, communication equipment/computers, material for sample collection, etc. The CA also has access to the official laboratory and to two private laboratories for the performance of official testing of fishery products.

### Documented Control Procedures

The FVO team noted that a system based on standard procedures was established to insure that official controls are performed according to rules defined in NCP. These procedures cover several areas of official controls:-

- Approval and listing of food business operators involved in the production chain for fishery product exports to the EU.
- Regular monitoring through inspections of food business operators involved in the production chain for export to the EU setting the frequency for different types of facilities.
- Official controls on fishery products (Residues Monitoring Plan and Contaminants and Microbiological Control Plan and Organoleptic and Landing Conditions Control Plan).
- Official certification for export, and
- Contingency crises management and RASFF notifications.

The following checklists were also created to be used during inspections of the different types of facilities (fishing vessels and freezing vessels, aquaculture farms, establishments and transport):-

- F01 – on structural requirements for establishments;
- F02 – on pre-requisites of HACCP;
- F03 – documental revision of HACCP plans;
- F04 – on HACCP plans implementation and performance;
- F05 – on the use of veterinary medicinal drugs, traceability and the hygiene conditions on aquaculture farms;
- F06 – on hygiene and structural requirements for ice factories;
- F07 – on hygiene and structural requirements for cold stores;
- F08 – on hygiene, structural and traceability requirements for freezer vessels;
- F09 – on hygiene and structural requirements for fishing vessels;
- F10 – on hygiene and structural requirements for transports/traders;
- F11.1 – form for application to be EU listed;
- F11 – on traceability requirements;
- F14 – on organoleptic evaluation;
- F15 – on verification of landing conditions;
- F16 – form for follow up of corrective actions;
- F17 – on hygiene and structural requirements for establishments that handle fresh fishery products.

### **Conclusions**

The CA designated for the official control of fishery products has a structure and organisation that is

adequate for the performance of their official control tasks. Furthermore, the CA has been given enforcement powers, resources and has put in place the necessary written procedures to perform the official controls required. However deficiencies were noted as regards the training of staff to perform official controls, in particular assessment of HACCP systems.

### **5.3 NATIONAL PROVISIONS AND PROCEDURES FOR LISTING ESTABLISHMENTS EXPORTING TO THE EU**

#### **Legal requirements**

Article 12(1) and (2) of Regulation (EC) No 854/2004.

Part I.11. of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.

#### **Findings**

The CA has in place procedures for listing of facilities exporting to the EU (processing establishments and freezer vessels). The listing process starts with an application from the food business operator (F11.1) and the approval is granted after documentary assessment (mainly documents that prove the legal existence of the operator) and an on-the-spot check where requirements based on EU legislation are verified. Checklists based on EU requirements are used during these visits as follows:

- freezer vessels – checklists F03, F04 and F08;
- processing establishments - checklists F01, F02, F03, F04, F11 and F14.

If considered in compliance, a register number is assigned and the CA proposes to the European Commission the inclusion of the establishment on the EU list.

Once included on the EU list, the food business operator is informed and the establishment is included in the regular inspection programme (visits at least every six months for processing establishments and once a year for freezer vessels) in order to verify if initial requirements are fulfilled and if the establishment maintains the conditions to be listed.

The CA also has procedures to include in internal lists those food business operators authorised to supply raw material to EU listed facilities. These facilities, which include fishing vessels, freezer vessels, aquaculture farms, cold stores, pre-processing establishments, intermediary traders, transporters and ice factories, are included in these lists based on similar procedures (documentary and on-the-spot assessment). According to the type of facilities the following checklists are used during regular inspections their assessment for inclusion on the internal lists:

- fishing vessels - checklist F09;
- aquaculture farms - checklist F05;
- freezer vessels – checklist F08;
- cold stores - checklist and F11;
- pre-processing establishments - checklist F01, F02, F11 and F14;
- establishments that handle fresh fish products - checklist F17, F11 and F14;
- ice factories - checklist F06;

- transporters and intermediary traders - checklist F10.

As for EU listed, these internal list facilities should be subject to regular official controls in order to be kept on the list.

De-listing is foreseen in cases where establishments are considered “Non-compliant” during official controls or when the food business operator requests delisting.

The FVO team noted that:-

- Listed establishments (internal list and EU-list) were checked on-the-spot prior to inclusion on a list. Control visits take place at the prescribed frequencies to reassess the maintenance of conditions required.
- The assessment made on these establishments in order to list them generally cover EU requirements for EU listed facilities. However for establishments from the internal list (cold stores, pre-processing facilities and freezer vessels) requirements regarding temperature-recording devices and the implementation of a programme based on HACCP principles (check list F03 and F04) are not assessed during visits for listing as they are not considered compulsory by the CA. Thus, the establishments from the internal list involved in the EU export production chain are not required to comply with standards equivalent to the requirements (see point 5.1 of this report)

## **Conclusions**

The provisions and procedures for listing facilities for EU export adopted by the CA are, in principle, adequate and provide satisfactory guarantees as required by point II.1 of the health certificate defined in Regulation (EC) No 2074/2005. However those guarantees are undermined due to the fact that for certain establishments that currently provide raw materials to EU-listed facilities, EU equivalent requirements regarding temperature-recording devices and the implementation of a programme based on HACCP are not applied.

Recommendation No 1 of the previous audit report concerning the guarantees that should be provided by the CA regarding the implementation of HACCP systems and temperature recording devices in freezer vessels involved in the production chain of fishery products for EU export still remains to be addressed satisfactorily.

## **5.4 OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET**

### **Legal requirements**

Article 12(2) of Regulation (EC) No 854/2004.

Requirements contained in point II.1 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.

Article 11(4) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal

origin are permitted, shall take particular account of the extent and operation of official controls on imports of animals and their products (Article 46(1)(g) (h) of Regulation (EC) No 882/2004).

Article 11(4) (j) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal origin are permitted, shall have regard to any experience of marketing of the product from the third countries and the results of any import control carried out and the assurances, which the third countries can give regarding equivalence to EU requirements.

## **Findings**

### *5.4.1 Official control system in place*

The official control system in place is based on the NCP and its attached procedures. This system covers the entire fishery products production chain. Official controls on the production and placing on the market of fishery products are foreseen as follows:-

- A regular check on the hygiene conditions of landing - performed during visits to fishing vessels when landing take place, using checklist F15.
- Inspections at regular intervals of fishing vessels on the hygiene conditions on board and temperature requirements – Once every two years for artisanal vessels and once every five years for small artisanal boats, using checklist F09.
- Inspection at regular intervals of aquaculture farms to check the adequate use of veterinary medicinal drugs, traceability procedures in place and the hygiene conditions – Once a year, using checklist F05.
- Inspections at regular intervals of establishments on land to check in particular whether the structural and hygiene conditions for listing remain fulfilled, whether the fishery products are handled correctly, for compliance with temperature requirements, traceability and performance of HACCP system (only for EU-listed establishments).
- After the inspections, these facilities are classified in three levels according to the compliance degree: C – compliant (above 90% of full compliance), CP – partially compliant (between 80 and 90% of compliance) and NC – Non-compliant (less than 80%). Establishment classification as compliant and non-compliant will result in an increased frequency of control visits.
- Where any non-conformities are detected, a follow-up is foreseen. In case of partially compliant or non-compliant establishments a timeframe for corrective actions is defined. In case of establishments qualifying as compliant but less than 100%, a follow-up is performed in the subsequent routine visit.
- The records of the inspections performed in the facilities listed under the NCP (EU-list and internal list) are kept in a database that is used by the CA as a risk management tool to perform official controls and to keep updated internal and external list of food business operators.

### *5.4.2 Primary production*

The FVO team visited three aquaculture farms on the CA's internal list. Evidence was noted by the audit team that these farms were under regular official control (once a year) and that the prescribed checklist was used for their inspections.

The FVO team noted that:-

- There were adequate records in relation to the origin of feed, health status of stock, a system to control the use of veterinary medicinal products, records of harvesting dates, quantities harvested and dispatched, origin of the ice and destination of the final product.
- The records of INP visits were kept and examples of corrective actions adopted after the detection of non-compliances were made available to the audit team. During the INP visits official control samples were taken by the CA within the scope of the residues monitoring plan.
- These aquaculture farms were found to be in compliance with EU equivalent requirements.

The FVO team made a limited review of the vessels list in the database and noted that inspection files were available for fishing vessels. The FVO visited two fishing vessels and noted that:-

- INP visits took place once a year. Reports of previous controls were available. The use of the prescribed checklist and the follow-up of non-compliances were confirmed by the audit team.
- The vessels visited were found to be in compliance with EU equivalent requirements.

Ice plants, which are included on the internal list of suppliers to EU listed establishments, are provided with a registration number and are subject to routine visits. These plants mainly supply flake ice to operators engaged in primary production.

The FVO audit team visited two suppliers of flake ice to fishing vessels and noted that:-

- INP visits took place at regular intervals to both establishments. Reports of previous controls were available at the establishments. The use of the prescribed checklist and the follow up of non-compliances were confirmed by the audit team.
- One of the establishments had adequate facilities. It received water from a municipal provider which was transported in tankers to the factory by a food business operator. The water receives a treatment/chlorination and is regularly controlled (chemical and microbiological analysis). The FVO team noted satisfactory microbiological results for samples taken by the food business operator (*E.coli*, faecal coliforms, total coliforms and *Salmonella*).
- The second ice plant visited supplied local fishermen only. This ice factory cannot be considered as in line with EU requirements due to a structural deficiency that allows ice contamination (freezing tower not adequately protected from exterior contamination). Moreover, the FVO team saw that the ice used at the time of unloading was kept inside bags that were dirty and the ice itself was also dirty.

#### 5.4.3 *Landing and first sale*

After the previous FVO audit the CA organised, over the last three years, several training/awareness actions to fisherman's and workers involved in the landing operations in order to promote the improvement of hygiene conditions during landing operations. Examples of several of these trainings activities were present to the FVO team.

The audit team visited two landing and noted the following:-

- Examples of previous checks on the hygiene conditions of landing carried out by the CA at the time of landing were presented to the audit team.
- The prescribed checklist was used to verify compliance with EU requirements.
- The landing operations taking place at the time of the visit in both landing sites were conducted in adequate hygiene conditions.

#### 5.4.4 *Facilities, including vessels, handling fishery products*

The FVO team visited nine EU listed facilities (eight processing plants and one freezer vessel) and noted that:-

- These establishments have been visited with the stipulated frequency and that during the visits official control samples have been taken by the CA.
- The foreseen checklists have been used, findings are recorded and deficiencies registered. The follow-up of deficiencies was carried out on the following inspection.
- In general, adequate structural conditions were found in establishments and a fully implemented HACCP system was in place that addresses the significant hazards identified for the activities performed. In traceability exercises the food business operator was able to identify the supplier of raw materials and the destination of final products and own-check analyses (i.e. microbiology in water and ice, environmental contaminants and chemicals such as sulphites) were performed regularly.

Regarding the EU listed facilities, from the eight processing plants and one freezer vessel visited, four establishments and the freezer vessel were considered broadly in line with EU requirements, three were considered partially in line and one could not be considered, at the moment of the visit, as in line with EU requirements.

For those three establishments considered partially in line with EU requirements the FVO team found the following irregularities (not all were noted in every establishment):-

- Structure - in some areas doors opening to the outside not sufficiently pest and dust proof, presence of insects in areas where processed product is exposed after cooking, condensation on some areas of the ceilings of rooms where exposed product is prepared, lack of drainage in floor leading to water pooling and damaged floors not easy to clean in some areas visited where exposed product was handled.
- Traceability - deficiencies concerning the origin of raw materials. In the only establishments visited that worked with "intermediary traders", the FVO team noted that when these traders are involved in the production chain, no guarantees could be supplied by the CA or food business operator that the product came from an authorised producer. In this establishment, examples of shrimp destined for the EU market were presented to the FVO team and the food business operator was not able to identify the aquaculture farm of origin of the product that had been supplied by one of these traders and thereby determine the shrimp's EU eligibility. During this visit the FVO team was informed that these traders do not exclusively work with EU export production chain.
- Hygiene - cleaning operations near exposed product with possible contamination from splashing of pooled water on the floor, unclean equipment in contact with product (dirty cooking trolleys).
- HACCP - Inadequate risk analysis. Absence of use of a logical approach to decide on critical control points. Lack of implementation of defined monitoring procedures for a Critical Control Point (CCP) (histamine control at reception). Corrective actions not defined for critical operations. Critical limits set to differentiate between acceptability and

unacceptability not always adapted to the process. Poor knowledge of the food business operator's quality control team as regards risk analysis and identification of CCPs.

Many of these deficiencies, in particular regarding HACCP, had not been recorded by the CA in previous monitoring inspection reports.

In the establishment visited that was not considered, at the moment of the visit, as in line with EU requirements the FVO team noted:-

- Structure and equipment - Changing facilities open to the exterior and with damaged floor. Facility not pest proof. Floor with inadequate water drainage and maintenance. Product and staff flows do not prevent cross-contamination. Ice store not pest proof with damaged and rusty door to exterior. Knives used to prepare fishery products very oxidised, kept in iodine solution between use and were not rinsed before being reused.
- Hygiene - Inadequate hygiene practices during operation. Pooling of water. Cleaning procedures with splashing. Improper storage inside cold store.
- HACCP - Deficient hazard identification and risk analysis. Inconsistencies between CCP limits set as part of own-checks and the limits defined in HACCP proper.

In this establishment despite several parts of the plant being in a poor state of repair, the use of unsuitable equipment and presenting poor hygiene conditions, the establishment had been classified as fully compliant by INP in the preceding and earlier CA control visits.

Regarding establishments from the internal list, the audit team visited one freezer vessel and one cold store authorised to supply establishments exporting to the EU.

Both facilities visited presented adequate structural, equipment and hygiene conditions. Temperature records were kept and traceability exercises were easily managed by the quality team in the cold store. However requirements regarding temperature recording devices were not present in the freezer vessel and inconsistencies were found in the HACCP system implemented on board. As regards the cold store no procedures based in HACCP principles were in place as these are not requirements for internal list establishments (see point 5.1 of this report).

Examples of the lack of application of HACCP principles were also seen by the FVO team for other "pre-processing" establishments from the internal list in the records of official controls available in the data base used by the CA.

#### *5.4.5 Checks on the EU eligibility of imported raw materials*

The FVO team was informed by the CA that no imports of fishery products take place from land-based establishments of other third countries or EU Member States in order to be later processed and exported to the EU. According to the CA, all fishery products imported to Ecuador for further processing and export to EU countries come from freezer vessels that are currently operating under Ecuadorian fishery agreements.

Traceability exercises are carried out by INP officials, during inspections visit to establishments on EU eligibility of fishery products exported. During the visits and interviews the FVO team noted that both food business operators and CA inspectors are aware of the requirements that raw material should be obtained only from EU approved countries and EU-listed facilities.

The FVO team performed several traceability exercises on products already exported to EU and noted that:-



- In all cases reviewed, the food business operator was able to provide all the necessary documentation regarding the origin of the product. In most of the cases reviewed by the audit team the products came from Ecuadorian flagged freezer vessels.
- As regards fishery products provided from freezer (and reefer) vessels with foreign flag that are EU listed, no attestation concerning the applicable EU requirements is required in order to ensure the eligibility of those products for the EU market other than attesting that the vessels are EU listed.
- Freezer vessels not EU listed but from EU-listed countries are included on the list of foreign vessels that are currently supplying fishery products to EU-listed establishments (this list was made available to the FVO team by the CA). These vessels, which are currently operating in Ecuadorian waters, were included in the internal list after a visit by INP and are under the regular control of this CA. These procedures call into question the accuracy of the guarantees that should be provided by the CA with regard to point 2 of Article 12 of Regulation (EC) No 854/2004.

## **Conclusions**

The control system in place covers the entire production chain of fishery products for EU export and allows the CA to provide guarantees with regard to the application of EU equivalent rules to the official control of production of fishery products. However, these guarantees are weakened by the shortcomings noted with regard to the assessment of deficiencies in establishments and the evaluation and implementation of HACCP procedures and by the lack of temperature-recording devices and implementation of procedures based in HACCP principles in establishments participating in the EU export production chain.

The control of the EU eligibility of raw materials is generally performed adequately, however, these controls cannot guarantee fully that all those materials are eligible for EU export due to the shortcoming related to the products imported from foreign flagged vessels and the products supplied to EU listed establishments by "intermediary traders".

Recommendation No 2 of the previous audit report concerning hygiene deficiencies during unloading operations can be considered addressed.

Recommendation No 3 concerning the guaranties that should be provided by the CA that the establishments and vessels EU-listed should fulfill the conditions laid down in the relevant EU legislation can be considered as partially addressed.

## **5.5 OFFICIAL CONTROLS OF FISHERY PRODUCTS**

### **Legal requirements**

Point II.1 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005, in particular official controls laid down in Annex III, Chapter II of Regulation (EC) No 854/2004.

### **Findings**

There are no significant changes between official controls of fishery products currently implemented and those in place at the time of the last FVO audit. Official controls of fishery

products are performed by the CA in accordance with the NCP and the following monitoring plans:-

- Monitoring of environmental contaminants and microbiology.
- Monitoring of residues in aquaculture products.
- Monitoring of organoleptic criteria, parasites and landing conditions.

The FVO team noted that:-

- Organoleptic checks of fresh fishery products are carried out according to a checklist when visiting establishments or landing sites. Records of these examinations were presented to the FVO team in some establishments and one vessel visited.
- Fishery products are regularly tested for histamine by the CA (every 6 months in the EU listed establishments and once a year in all freezer vessels). Nine unit samples are taken and reporting times are adequate.
- Official checks for environmental contaminants are carried out by the CA and include heavy metals (lead (Pb), Cadmium (Cd), Mercury (Hg) and Tin (Sn)) and Polycyclic Aromatic Hydrocarbons (PAH). Tests were performed every 6 months in the EU listed establishments and once a year in all freezer vessels. The reporting time is adequate.
- As regard dioxins and Polychlorinated Biphenyls (PCBs) the FVO team noted that these tests are not yet performed. The CA presented to the FVO team the Resolution ADM-INP-153-2013, of 4/09/2013 published by the CA designating the laboratory to perform these tests (expected to start in the beginning of 2014).
- Official checks for residues are performed monthly in all EU listed aquaculture processing plants and in farms less frequently, based on volume produced and previous results. Results from annual sampling were available in the aquaculture farms visited.
- Regarding microbiological checks, a sampling plan has been implemented by the CA to ensure compliance with EU requirements. Tests are performed (*Listeria monocytogenes*, *Salmonella* and *E. Coli*) every six months in fish possessing plants and freezer vessels. Results are assessed against EU limits. No results of microbiological tests performed in establishments producing cooked crustaceans were seen by the FVO team as no official tests are performed there, allegedly because of the small quantities exported. As a result, guarantees foreseen in Point II.1 of the model health certificate as regard the satisfaction of the criteria laid down in Regulation (EC) No 2073/2005 cannot be fully assured.
- Evidence was presented to the audit team that the CA regularly verify the own-checks of food business operators as regards parasites and additives controls (sulphite tests).
- The CA implemented arrangements to verify that the food business operators have procedures in place to adequately label fishery products from the Germicidal family.

## Conclusions

The CA implements official controls on fishery products exported to the EU that adequately covers most EU requirements (organoleptic check, parasites, microbiology, additives, environmental contaminants and residues). However official controls on fishery products for dioxins and PCBs have yet to be implemented and no microbiological official controls exist for cooked crustaceans for EU export.

Actions to address recommendation No 4 of the previous audit report, concerning guaranties that should be provided by the CA as regards monitoring of contaminants and histamine has been partially addressed (histamine sampling is now performed with nine units) .

## 5.6 LABORATORIES

### Legal requirements

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004 stipulate that Community controls shall have particular regard to the resources including diagnostic facilities available to CAs and the training of staff in the performance of official controls.

Points 41 and 42 of Guidelines of Codex Alimentarius CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

Chapter 1 of Annex I to Regulation (EC) No 2073/2005,

Section II of Annex II to Regulation (EC) No 2074/2005

Regulations (EC) Nos 1883/2006 and 333/2007.

### Findings

Three laboratories are authorised by INP to perform analysis of samples for official controls on fishery products. These are INP's own laboratory and two private laboratories. In order to be authorised to participate in the NCP, Residue Monitoring Plan and Microbiological and Contaminant Control Plan these laboratories must fulfil the requirements of Resolution ADM-INP-011-2010, which includes amongst other conditions that the laboratory must be accredited according to ISO/IEC 17025 and that the methods used should be the official ones and within the scope of accreditation. This authorisation is valid for four years and during this period the laboratory must be assessed once a year by INP.

The FVO team visited two laboratories and noted that:-

- The INP laboratory is accredited to ISO 17025 by Accreditation Body of Ecuador. Annual audits are performed by the accreditation body and the last revalidation of accreditation took place in March 2013. This laboratory is also mandated to perform the assessment of private laboratories involved in official controls in order to be authorised according to Resolution ADM-INP-011-2010.
- The following analysis for official controls of fishery products (also food business operators own-checks) are performed in the INP laboratories:
  - TVB-N, histamine, Cd, Pb, Hg, Sn, PAH (only Benzo(a)pyrene and Benzo(b)fluranthene), *Listeria monocytogenes* and *Salmonella*, all within the scope of accreditation.
  - Water analysis tests are also performed for FBO own-checks, i.e. - E. coli, Enterococci, *Clostridium perfringens*, coliform bacteria, colony count 22°C.
- The laboratory participated in several proficiency tests, at least once every four years except for heavy metals where tests are performed annually. A review of proficiency tests was done by the audit team with acceptable results.
- Traceability of samples was considered adequate and reporting times observed in several reports were also adequate.
- The private laboratory visited is also accredited to ISO 17025 by a recognised international accreditation body and the following tests are within its scope of accreditation:
  - Several substances under the residues monitoring plan, heavy metals (Cd, Pb, Hg, Sn,)

*Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, total coliforms and *E.coli*.

- In this private laboratory, in most of the cases reviewed, proficiency tests presented satisfactory results and corrective actions were adopted when results were unsatisfactory. The FVO team noted that, in one case, the problems detected in the performance of the heavy metals determination during an INP audit, had led to the suspension of the laboratory until full guarantees were available regarding the performance of the methods. The equipment was changed, the tests were validated and a recent proficiency exercise (November 2013) showed satisfactory results.
- Both laboratories were found to be well equipped and sufficiently resourced to undertake the necessary analyses.

## Conclusions

The laboratories performing official control analysis are accredited against ISO 17025 and work under satisfactory quality assurance schemes which allow them to provide adequate guarantees with regard to the reliability of the analysis results.

### 5.7 FOLLOW-UP OF RASFF NOTIFICATIONS

#### Legal requirements

Article 11(4) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal origin are permitted, shall take particular account of amongst other factors:-

- Any experience of marketing of the product from the third country.
- The results of any import control carried out.

#### Findings

The contact point for RASFF notifications is the Ministry of External Trade. The CA informed the FVO team that notifications related to fishery products are received in INP within two or three days of issue. The national coordinator of the NCP should then establish a management team with one responsible officer in charge of all necessary communications with stakeholders.

Regarding the management RASFF notifications, the audit team noted that:-

- INP has drafted and adopted procedures for the follow-up of notifications (Chapter No 5 of the NCP - Protocol of Crises Management). These procedures include an investigation with an on-the-spot visit, carried out by official staff.
- In all three cases reviewed by the FVO team (concerning heavy metals and histamine), in two of the establishments visited, measures were taken to investigate the source of the problem and adequate corrective actions were taken by the food business operator in the establishments involved.

In these cases a detailed verification of the own-check controls of the food business operator was carried out by INP during an on-the-spot visit and reports were produced and later sent to RASFF

management team, in Commission services, with technical information regarding the follow-up performed.

## **Conclusions**

The measures taken by the CA following RASFF notifications were adequate and led to a strengthening of the mechanisms in place to ensure that fishery products exported to the EU from Ecuador comply with the health attestations mentioned in the model health certificate of Regulation (EC) No 2074/2005.

### **5.8 OFFICIAL CERTIFICATION**

#### **Legal requirements**

Article 14 of Regulation (EC) No 854/2004.

Article 6 of Regulation (EC) No 2074/2005, in particular the model health certificate for imports of fishery products intended for human consumption established in its Appendix IV to Annex VI.

Article 6 of Directive 96/93/EC establishes that the Commission shall ensure that the rules and principles applied by third countries certifying officers offer guarantees at least equivalent to those laid down in this Directive.

#### **Findings**

The CA has in place procedures for certification that include a documentary evaluation of an export request submitted by the food business operator regarding the consignment to be exported. No physical or identity evaluation of the consignment concerned is performed. Guarantees are based on the monitoring plan implemented (NCP). Prior to issuing a certificate the official veterinarian should verify on an up-to-date list of approved establishments, the classification status of the establishment concerned. Only establishments with the classification “compliant” and “partially compliant” are allowed to export to EU. This list was available for consultation during the FVO team visit.

During routine inspections the CA performs traceability exercises and checks conformity of production records for the batches already exported. In these exercises, CA officials verify, via the documentary records, the EU eligibility of the products previously exported. Examples of these traceability exercises were made available to the FVO team during the visits and were found to be in accordance to EU requirements. However the system implemented does not include any physical or identity checks of the products to be exported prior to attestation in order to ensure the EU eligibility of the products.

The model health certificate currently in use, is the one in Regulation (EC) No 2074/2005.

#### **Conclusions**

The CA procedures in place do not fully ensure that consignments of fishery products are eligible for export to the EU and that export certification is performed correctly in order to offer guarantees at least equivalent to the requirements of Directive 96/93/EC.

## 6 OVERALL CONCLUSION

In principle the current organisation and implementation of official controls could guarantee that the conditions of production of fishery products in Ecuador intended for EU export meet standards equivalent to the requirements laid down in EU legislation. However deficiencies identified, in particular concerning training, non-EU listed facilities participating in the EU export production chain, the supervision of establishments, the system in place to ensure the eligibility of raw materials for EU export and some elements of the official controls on fishery products, undermine the guarantees given in the health attestations of fishery products for EU export.

Since the last 2010 FVO audit, corrective actions have been implemented and enforced by the CA in order to address the recommendations of the previous audit report. The Ecuadorian competent authority addressed satisfactorily recommendations No 2. Recommendations Nos. 3, 4 were partially addressed and recommendation No 1 is still considered as not satisfactorily addressed.

## 7 CLOSING MEETING

During the closing meeting held in Guayaquil on 5 December, 2013, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting, the CAs acknowledged all the findings and preliminary conclusions presented by the audit team and provided commitment to correct the deficiencies.

## 8 RECOMMENDATIONS

The CA should provide Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report, in order to address the following recommendations for fishery products exported to the EU.

N°.	Recommendation
1.	The CA should ensure that staff in charge of performing official controls is adequately trained to perform the assessment of standards equivalent to the requirements of Article 5 of Regulation (EC) No 852/2004.
2.	The CA should ensure that establishments from which fishery products have been dispatched, obtained or prepared, in particular those not exporting directly to the EU, comply with standards equivalent to the requirements of Article 5 of Regulation (EC) No 852/2004 and Section VIII of Annex III to Regulation (EC) No 853/2004, in order to be able to provide all the necessary guarantees required in Article 12 (2) of Regulation (EC) No 854/2004.
3.	The CA should ensure that EU listed facilities maintain compliance with all the requirements referred to in Article 5 of Regulation (EC) No 852/2004 and Section VIII of Annex III to Regulation (EC) No 853/2004, in order to be able to provide the guarantees required in point II.1 of the health certificate defined in Regulation (EC) No 2074/2005.

N°.	Recommendation
4.	The CA should ensure the EU eligibility of raw materials used in the production of fishery products for EU export. In particular it should ensure that imported raw materials and those supplied by intermediary traders to EU listed establishments are produced in accordance with the applicable EU rules, in order to provide the guarantees required by the Health Attestation of point II.1 of the health certificate defined in Regulation (EC) No 2074/2005.
5.	To ensure that, as established in Part II.1 of the health certificate defined in Regulation (EC) No 2074/2005, fishery products exported to the EU have satisfactorily undergone the official controls laid down in Chapter II of Annex III to Regulation (EC) No 854/2004, in particular concerning dioxins and PCBs.
6.	To provide the guarantees foreseen in Point II.1 of the model health certificate defined in Regulation (EC) No 2074/2005 as regards the satisfaction of the criteria laid down in Regulation (EC) No 2073/2005, for all fishery products for EU export, in particular cooked crustaceans.
7.	The CA shall have procedures in place to fully ensure that export certification is performed correctly in order to offer guarantees at least equivalent to the requirements of Directive 96/93/EC.

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=2013-6711](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6711)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2006/766/EC	OJ L 320, 18.11.2006, p. 53-57	2006/766/EC: Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
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. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption



<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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. 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. 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. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 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