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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE PHILIPPINES

FROM 15 TO 23 JUNE 2011

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

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 mission in the Philippines carried out from 15 to 23 June 2011, as part of its programme of inspections in third countries.

The primary objective of the audit was to evaluate the public health conditions for the production of fishery products intended for export to the European Union. The audit covered the relevant EU legislation for the public health sector.

The report concludes that improvements in the implementation of official control have been made. However, to fully ensure that all fishery and aquaculture products exported to the EU respect the requirements mentioned in the health certificate as set out in the model defined in Regulation (EC) No 2074/2005 corrections and improvements are needed, in particular concerning the deficiencies identified for the laboratory analyses for contaminants.

Once the identified deficiencies in relation to laboratories and testing have been addressed the competent authority should be in a position to guarantee that the required sanitary conditions of fishery and aquaculture products for EU export can be met.

The report addresses to the Philippine 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

Abbreviation	Explanation
BFAR	Bureau of Fisheries and Aquatic resources
FHMQAS	Fish Health Management and Quality Assurance Section of BFAR
CA	Competent Authority
CCA	Central Competent Authority
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EU	European Union
EU listed	Facility approved by the CA for EU fishery products export and listed on the internet site
EUROSTAT	Statistical Services of the European Union
FAO	Fisheries Administrative Order
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
PAH	Polycyclic Aromatic Hydrocarbons
PNS	Philippine National Standards
RASFF	Rapid Alert System for Food and Feed
TPC	Total plate count
TVB-N	Total volatile basic nitrogen

1 INTRODUCTION

The audit took place in the Philippines from 15 to 23 June 2011 and was undertaken as part of the Food and Veterinary Office's (FVO) mission programme.

The audit team (the Team) comprised two inspectors from the FVO.

2 OBJECTIVES

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 (fishery products) in the Philippines destined for export to the European Union (EU) are in line with the requirements laid down in European Union (EU) legislation;
- 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 mission report of 2006 have been implemented and enforced by the CA;

In pursuit of these objectives, the Team proceeded as follows:

- an opening meeting was held in Manila on 15 June 2011 with the CA. At this meeting the Team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit;
- the following sites were visited:

Competent Authority		
Central level	1	Manila
District level	1	CA of Manila
	1	CA of General Santos (present in Manila)
Laboratory visits		
Official laboratory	1	Manila
Facilities handling fishery products		
Landing sites	0	No landing site visited due to administrative difficulties and bad weather conditions
Processing plants	7	Region 4a and 3

- representatives from the central competent authority (CCA) accompanied the Team during the whole audit.

3 LEGAL BASIS

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 verify the equivalence of third-country rules with EU feed and food laws, as well as with animal health and animal welfare legislation;

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

4 BACKGROUND

4.1 GENERAL BACKGROUND

The Philippines is presently listed in Annex II of 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.

The Philippines is listed in the Annex to Commission Decision 2004/432/EC which lists the countries with approved monitoring plans for aquaculture.

A previous FVO fishery products mission took place in 2006 (ref. DG(SANCO)/2006/8312) which highlighted deficiencies in relation to the official control system for vessels, analytical methods used in laboratories, and some deficiencies in establishments. The report – published on the Health and Consumers Directorate-General (SANCO) Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm – 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.

4.2 PRODUCTION AND TRADE INFORMATION

According to information provided by EUROSTAT the main fishery products imported into the EU are, in round figures, as follows: 45,000 tonnes of canned tuna, 20,000 tonnes of frozen tuna for further processing, 40 tonnes of chilled tuna, 600 tonnes of frozen octopus, 300 tonnes of chilled fillets from salt-water fish (mainly tuna), 260 tonnes of frozen shrimps and 10 tonnes of smoked fishery products.

The main importing Member States are (by decreasing order): Germany, the UK, Spain, Italy, and Belgium.

Similar but slightly higher figures for fishery product exports to the EU were received from the CCA.

According to the information provided by the CA, 17,000 tonnes of tuna were imported into the Philippines as raw material and were later on exported to the EU.

According to the list established by the CA imports of fishery products from the Philippines into the EU are authorised from a total of 34 processing plants (these include 9 establishments processing only or partially materials derived from aquaculture), 3 cold stores and, 47 freezer vessels.

This list, list valid as of 20/02/2011, is available on the SANCO web site at the following address: http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm.

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

There have been twelve RASFF notifications concerning fishery products since 2006. Five on high levels of histamine, three on high levels of cadmium, two on the absence of health certificates, one on damaged packaging and one on bad temperature control. The Team visited two establishments which had received RASFF notifications on high levels on histamine. The Team noted that the CA had followed the prescribed procedures to deal with these RASFF notifications. In the cases reviewed by the audit team the CA took action to investigate the source of the problems and the appropriate corrective actions were taken in the establishments involved.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal requirements

Requirements laid down in Article 46(1)(a) of Regulation (EC) No 882/2004 and Article 11(4)(a)(i) of Regulation (EC) No 854/2004.

Findings

The legal basis covering the organisation of the Bureau of Fisheries and Aquatic resources (BFAR) as the competent authority for fish and fishery / aquatic products in the Philippines is the Republic Act 8550 known as the Fisheries Code of 1998, which sets out its organisation, duties and functions, competencies, rights and powers.

The main legal texts which regulate the official control of fishery products for EU export are the:

- Fisheries Administrative Order (FAO) No 227. S 2008 - Rules and regulations governing the export of fish and aquatic products to the European Union Member States.
- Fisheries Administrative Order (FAO) No 228. S 2008 - Rules governing the organisation and implementation of official controls on fishery and aquatic products for human consumption intended for export to the EU market

These Orders are complemented by codes of practice which proscribe the procedures and guidelines for their implementation. However the Team noted that in the code of practice of FAO No 227 the maximum values for heavy metals are not in line with EU requirements. In the code of practice of the FAO No 228 there are no microbiological checks foreseen for *Listeria monocytogenes* for ready to eat fishery products and as a consequence no maximum values have been defined for this microbiological parameter. The Philippines export smoked milkfish to the EU.

Conclusions

Legislative improvements have been made since the previous mission in 2006. Generally, legislation is in line with EU requirements and. However for equivalence, some adjustments are needed to deal with the exceptions listed above concerning heavy metals and microbiological checks.

5.2 COMPETENT AUTHORITY

Legal requirements

Requirements laid down in Article 46(1)(b) to (e), (g) and (h) of Regulation (EC) No 882/2004.

Findings

Following the FVO mission in 2006, all the units dealing with fish product safety and quality assurance (such as the Fish Inspection Unit (FIU), the Fishery Products Testing Laboratory, the Fish Health Management and Quality Assurance Section (FHMQAS) as well as the Administrative Support and product Certification Unit (ASPCU)) were placed under the direct supervision and control of the Director of BFAR by virtue of a Fisheries Office Order. The same reorganisation was established at regional level notably in the export-active regions where the units concerned are at the same time under the direct supervision of the regional directors of BFAR. BFAR headquarter serves as the policy-making body while implementation of policies is devolved to the regional level. Each of the units involved in the food control system have developed their own written manuals of

procedures and protocols on which set out how their duties are to be performed.

The CA has the power to launch sanctions for non-compliances (infringement procedures) on food business operator and to seize fishery products at production and distribution levels. This power is provided by Article 20 of FAO No 228. This article also empowers the CA to suspend an establishment from export, to request a delisting of an establishment from the EU list for approved establishments and to impose fines.

FAO No 228 requires that the staff of BFAR must operate to criteria that ensure their impartiality. Furthermore the Republic act No 6713 requires that government employees have to be free from any conflict of interest. The Team found no evidence that these criteria were not being met.

The staff of BFAR have benefited from numerous training sessions under the framework of the EU funded Trade Related Technical Assistance programme. At the time of the audit this technical assistance was still ongoing. The Team noted that, generally, staff are well aware of most EU requirements other than some members who were unfamiliar with the maximum limits for heavy metals and the requirement that smoked fish should be monitored for *Listeria monocytogenes*.

Documented control procedures are set out in the codes of practice of the FAO Nos. 227 and 228. Comprehensive checklists are available for inspection visits. BFAR has drafted for its inspectors a "Fish Inspector Manual" to guide them during inspection visits to vessels and land-based establishments. These checklists are based on EU requirements, in particular, Regulations (EC) Nos. 852/2004 and 853/2004.

The Team noted evidence that official controls are carried out by CA officials on imports. BFAR Inspectors are aware of the requirements that raw material should be obtained only from EU listed establishments. The main source of imports is Papua New Guinea but they also come from Japan and South Korea. These countries provide raw material mainly for the tuna canneries.

Conclusions

The current structure and organisation of the CA, including its powers and authority, are adequate to perform the official controls of the production chain of fishery products intended for EU export. These official controls are based on national legislation and associated manuals of procedures that can be considered to be in line with EU requirements.

The CA staff has had training and presents a relatively satisfactory knowledge of EU requirements applicable to fishery products.

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

Legal requirements

Requirements laid down in Article 12(1) and (2) of Regulation (EC) No 854/2004 and contained in 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

Aquaculture farms must be registered with BFAR. The aquaculture farms are controlled by FHMNAS. There are about 200 aquaculture farms in the Philippines registered to provide raw material to EU listed establishments. To be registered a food business operator first applies to BFAR for registration, who carry out an inspection visit during which samples are taken and if the farm meets BFAR's requirements it will be listed for two years. The Team noted that the species of fish produced on the farm are not mentioned on the Certificate of registration. However at BFAR level there is an "Aquaculture Farm Registration" sheet on which the species, size of the farm, stocking

density, annual production etc. are recorded.

Small fishing vessels which provide fishery products to EU listed establishments must be on BFAR's register of approved fishing vessels. These vessels refrigerate their catches using ice. Boats undergo an inspection visit before being put on this register. They are approved for a period of three years. At the time of the FVO audit 175 vessels were on this register.

Landing sites get also approved by BFAR to receive fishery products for processing in EU listed establishments. One landing site is already approved and a second is in the process of approval.

Establishments (fish processing establishments and cold stores) must be approved by the CA to be listed for fishery products exports to the EU. Establishments are approved under Article 8 of FAO No 228. The detailed procedure is described in the "BFAR registration and HACCP recognition procedure". The steps are as follows:-

- written application completed by the food business operator,
- pre-evaluation of the documents submitted by the CA,
- pre-assessment during an on-site inspection carried out jointly by regional and national inspectors,
- desk review of inspection results followed by
- an on-site verification of the implementation of the food safety programme,
- lastly a final inspection report based on this on-site verification is prepared.

If the establishment has passed these checks it will be included on the list of HACCP approved fishery establishments allowed to export fishery products to the EU and a certificate of approval is issued to the food business operator. Establishments are approved for six months or one year depending on the classification attributed by the CA.

Freezer vessels undergo the same approval procedure as land-based establishments, except that an approval certificate is not issued by the CA. If the food business operator of the vessel wants a certificate of inspection and compliance, BFAR will issue one which mentions the date of inspection and the classification (fully compliant, partially compliant, non-compliant) of the vessel.

Conclusions

The CA has drafted and follows rules and procedures to list establishments exporting to the EU in line with EU requirements. There is also adequate provision for the registration of aquaculture farms and fishing vessels providing raw material to EU listed establishments. The Team noted during their visits that the procedures for registration and approval were followed.

5.4 OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET

Legal requirements

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.

Findings

5.4.1 Official control system in place

The official control system in place for fishery products exported to the EU is based on FAO Nos. 227 and 228 and their codes of practice. Official controls cover the entire fishery products

production chain (fishing vessels, aquaculture farms, landing sites, cold stores, freezer vessels and land-based establishments). Regular inspection visits to registered and EU listed facilities are carried out with a defined frequency. Checklists and forms are completed indicating the results of the inspection visit and the deficiencies are noted. During the inspection visits samples of fishery product are taken by the CA for official analyses of microbiological and chemical parameters in line with an annual sampling programme for each establishment.

5.4.2 Primary production

The Team noted the following findings related to the official control system in place:

- Aquaculture farms are under the control of FHMQAS. All registered aquaculture farms take part in the official National Control Plan for Residue Monitoring. Inspections are carried out every year. For these inspections visits a quite comprehensive checklist is used. FHMQAS inspectors verify during these visits if drugs are used on the farm.
- The official list of registered fishing vessels was put in place in February 2011. In Mamburao the vessels are inspected on a yearly base by the regional inspectors of BFAR. The state of hygiene of the holds of vessels is primarily checked during these inspection visits.

5.4.3 Landing and first sale

The Team noted the following findings related to the official controls:-

- According to the code of practice, landing sites are inspected every second year.
- BFAR has located a food safety training officer in the port of General Santos, where the main quantity of fish is landed,
- The 2009 inspection report for this port indicated that numerous deficiencies were found at the landing site.
- The inspection report from 2011 for General Santos also shows some deficiencies for which a corrective action plan has been established.

5.4.4 Facilities, including vessels, handling fishery products

Freezer Vessels

The Team was informed that freezer vessels are inspected when they are in port. They can be at sea for up to two years, during which time, carrier vessels take the catch to shore. There are 47 freezer vessels on the EU approved list. Slightly more than half of these are reefer vessels. Vessel inspection reports are based on a checklist and the inspection visit itself is subject to the same procedure as for the land-based establishments (reports, action plan for corrections and verification of remedial works at the next inspection).

There are no factory vessels flying the flag of the Philippines.

The Team verified some of the inspection reports and noted that they are comprehensive and well detailed.

Land based establishments

The inspection visits in these establishments are carried out by both central and regional inspectors of BFAR. The frequency of these visits depends on the classification of the establishment.

Establishments classified A/A are inspected annually. Establishments classified A/B or B/A every six months (the first letter considers the structural state and maintenance and the second letter the hygiene conditions of operation). This classification is based on the number and significance of deficiencies (minor, major, serious or critical) found during the inspection visits. Inspection reports are detailed and based on a comprehensive checklist. The Team noted that the inspection reports reflected well the situation in the establishments and were in line with the Team's observations. After each inspection visit the food business operator establishes an action plan with a time-frame which he submits to the CA for agreement. If the CA agrees with the time-frame the food business operator carries out the corrections of the deficiencies. At the end of the time-frame the regional inspector verifies through an on-the-spot visit whether the deficiencies have been corrected and make a notes (called "a close down" by the CA) in the corrective action plan. Following this the inspector sends a "compliance audit" report to the central office.

In addition to these inspection reports the regional inspectors carry out pre-shipment reports for the shipments to the EU. During these pre-shipment visits the inspectors verify the labelling, the results of the laboratory testing of the fishery products, the temperature of the product and the export manifest.

The Team visited seven land-based establishments. Two were processing milkfish from aquaculture and had a cold store attached. Milkfish is processed into different products (whole deboned, belly parts, marinated and smoked). Two establishments were processing small wild caught shrimps into paste. Three establishments prepared fresh tuna loins for export by airplane. Two of these tuna plants were the subject of a RASFF notification in 2007 for high levels of histamine.

The Team reviewed the inspection reports of these establishments and verified that non-conformities are identified and followed-up in line with defined deadlines. Reports seen confirmed that visits are carried out according to the frequency established under Philippine legislation.

During the visits in the establishments the Team noted that in general the structural maintenance was adequate and that the fishery products were processed hygienically. However the Team noted that in one establishment a deficiency found during the previous FVO visit in 2006 had not been corrected by the food business operator.

HACCP procedures were in place in all establishments visited and can be considered as adequate. The Team noted that the CA approves the HACCP plan.

Own-checks performed in the establishments are carried out regularly for all relevant fishery products covering microbiology, heavy metals, PAH for smoked fish, histamine and metabisulphite in shrimp. Own-checks for *Listeria monocytogenes* in ready to eat food (smoked milkfish) are not however done. Based on the documents reviewed, the Team noted that the results were all under the limits required in EU legislation other than one result for histamine. The Team noted, however, evidence of corrective action by the food business following this high result.

Concerning the own-checks for heavy metals, mainly analysed in private laboratories which are not approved by the CA, the Team noted that limits of detection for cadmium, lead and mercury are very often above the limits of detection required in Regulation (EC) No 1831/2003 and that sometimes they were even found to be above the maximum level of cadmium in FP required by EU legislation. In addition to this the Team noted that in one case the results of the laboratory analyses on the test result sheet were under the limit of detection set on the same test result sheet.

The Team carried out some exercises on traceability in the establishments and noted that a system of traceability is in place.

The approved stand-alone cold stores are located in General Santos. The Team did not visit any of these, but reviewed documentation dealing with official controls carried out therein. The frequency

of inspection for these facilities is the same as for the fish processing establishments. The Team noted evidence in the inspection reports that the temperature in one cold store was sometimes one or two degrees above -18°C , the value required under EU legislation. In a cold store attached to an establishment visited the Team noted that the temperature was sometimes above -18°C outside the period for defrosting. The Team noted that no corrective action had been taken by the food business operator in order to ensure that the temperature remains below -18°C .

5.4.5 Import controls of fishery products

Imports of fishery products are permitted by BFAR but these products are only permitted for further processing, including in EU listed establishments and for their distribution in "institutional markets" (restaurants, canteens, etc.) in the Philippines. After having verified the health and catch certificate the CA issues an import permit in which is recorded the quantity to be imported. Fisheries quarantine officers verify the sanitary certificate of the country of origin, inspect the fishery products and take samples. After these steps the fishery products are released to the buyers, mainly tuna canning factories.

5.4.6 Follow up of RASFF notifications

The Team checked the CA's procedure for follow-up of RASFF notifications. First the CA investigates the reasons for the notification, and in cases of contamination, they simultaneously carry out detailed inspections of subsequent shipments from the establishment and take samples. The Team reviewed two cases where high levels of histamine were notified. The food business operator also makes investigations and for the two cases reviewed he was able to explain to the Team the reasons for high levels of histamine. Furthermore one of the food business operators concerned bought a histamine analysis machine to ensure non-repetition of the event.

Conclusions

The CA has an adequately functioning official control system in place for the production of fishery products for EU export that covers the entire production chain. Primary production is under control and generally in line with EU requirements. A system to check regularly the hygiene conditions of landing of fishery products is in place. However according to the inspection reports, hygiene conditions at landing are sometimes not in line with EU requirements.

The official control system for establishments approved for exports to the EU is adequate and the establishments visited meet EU requirements.

All land-based establishments visited have HACCP plans which meet requirements at least equivalent to those set out in EU legislation. However the system of own-checks has deficiencies concerning the reliability for the control of heavy metals and on ready-to-eat foods. The temperatures in one cold store visited did not meet the EU requirements.

The CA has a system for control of imports of fishery products in place which permits some traceability. RASFF notifications are followed up by the CA and the food business operators.

5.5 OFFICIAL CONTROLS OF FISHERY PRODUCTS

Legal requirements

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.

Findings

The Team noted that samples are taken by BFAR staff. Random organoleptic checks are carried out by regional inspectors at several levels of production. In case of doubts as to the freshness of product the CA has foreseen in its system of official controls the possibility to carry out laboratory analyses for freshness indicators (TVB-N).

Random histamine testing is organised in establishments where species with a high content of histidine is processed. In 2010 three official samples were analysed in the laboratory designated by BFAR for official analyses. Since December 2010 testing for histamine has been interrupted in this laboratory. The Team noted that the CA is aware that nine samples from one lot of fishery products should be submitted for analyses. The method used for these analyses is the fluorometric method. The EU legislation prescribes the HPLC method or another method which has the same reliability and has been validated. The Team was not shown evidence that the method in use has been validated. The Team was informed by the CA that all batches for export to the EU are tested for histamine in a laboratory in General Santos where the fluorometric method is also used.

A monitoring system to control the level of contaminants has been set up by the CA. The monitoring arrangements are integrated in the supervision of establishments. At BFAR level a national sampling plan is established. It lays down the number of samples to take and determines the establishments where these samples will be taken. No official controls are carried out for tin or dioxins. The CA relies on the food business operator's own-test results for tin. The Team noted that as regards official analyses for the detection of heavy metals, the limit of quantification is above the EU limit. No official checks are carried out for PAH, again the CA relies on the food business operator's own-checks.

Microbiological checks are carried out regularly by the CA. However no analyses are carried out for *Listeria monocytogenes* in smoked fish.

During the inspection visits BFAR inspectors do random testing for parasites.

The CA has a system in place to ensure that no poisonous fish is exported to the EU.

Conclusions

The official controls of fishery products implemented by the CA do not cover all the requirements mentioned in the health certificate and in Chapter II of Annex III to Regulation (EC) No 854/2004. They do not include testing for dioxins, PAH, tin or *Listeria monocytogenes*.

Official analyses for heavy metals and histamine are carried out but the reliability of the analyses results cannot be assured.

5.6 OFFICIAL CERTIFICATION

Legal requirements

Requirements laid down in Article 14 and Annex VI to Regulation (EC) No 854/2004 and 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.

Certification procedure has to be at least equivalent with the requirements of Directive 96/93/EC.

Findings

The CA has a manual of procedures on the certification of fishery/aquatic products for EU export. Recently the CCA decided to delegate the issuing of health certificate to the regional CA. Currently eleven officials from BFAR are authorised to sign this certificate. The Team noted that the officials

issuing the health certificates follow the prescribed procedures. However the Team noted that one health certificate had been issued for unlabelled cans of tuna.

Conclusions

The certification procedures designed by the CA can be considered as at least equivalent to the requirements of Directive 96/93/EC. However, traceability cannot be assured where cans are not labelled.

5.7 LABORATORIES

Legal requirements

Requirements laid down in Article 46(1)(d) of Regulation (EC) No 882/2004, Chapter 1 of Annex I to Regulation (EC) No 2073/2005, Section II of Annex II to Regulation (EC) No 2074/2005 and Regulations (EC) Nos 1883/2006 and 333/2007.

Findings

The Team visited the laboratory in which official analyses are carried out. This laboratory also analyses samples from food business operators. Samples are brought from Region 9, General Santos and 4A.

The situation in this laboratory is similar to that encountered during the 2006 FVO visit. The laboratory is still not yet accredited, but in April 2011 it applied for accreditation for heavy metals testing. Once this is finalised it will apply for accreditation for histamine. The laboratory carries out analyses in microbiology for total plate count (TPC), coliforms, *E. Coli*, *Salmonella*, *Shigella* and *Staphylococcus aureus*. In 2010 it participated in a proficiency test for coliforms, *E. Coli* and faecal coliforms and the results were satisfactorily.

For heavy metals the last proficiency test was carried out in 2004. In 2010 the laboratory introduced the graphite furnace atomic absorption method for analysing for heavy metals, but the method has not yet been validated.

For histamine the fluorometric method is used but since December 2010 the device is out of service. In 2010 eight lots samples were analysed. No analyses are carried out for *Listeria monocytogenes*.

Water is analysed for TPC, *E. Coli*, coliforms and Enterococci but not for *Clostridium perfringens* where surface water is used in establishments. However the Team noted that one establishment carries out own-checks for *Clostridium perfringens* but this was not done using surface water.

Conclusions

The CA has designated a laboratory for the official controls. However, the methods used in the context of the official controls for histamine and heavy metals are neither accredited nor validated. Consequently, the tests currently used to monitor fishery products cannot be considered as fully meeting EU equivalent standards and the results must be considered as not reliable.

6 OVERALL CONCLUSIONS

Improvements in the implementation of official control have been made. However, to fully ensure that all fishery and aquaculture products exported to the EU respect the requirements mentioned in the health certificate as set out in the model defined in Regulation (EC) No 2074/2005 corrections and improvements are needed, in particular concerning the deficiencies identified for laboratory analyses for contaminants.

Once the identified deficiencies in relation to laboratories and testing have been addressed the competent authority should be in a position to guarantee that the required sanitary conditions of fishery and aquaculture products for EU export can be met.

7 CLOSING MEETING

During the closing meeting held in Manila on 23 June 2011, the 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 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.

Nº.	Recommendation
1.	The CA should ensure that standards applied to fishery products exported to the EU are fully equivalent to EU requirements in particular regarding maximum values of heavy metals.
2.	The CA should ensure that temperatures in the cold stores meet the requirements of point B of Chapter III of Annex III to the Regulation (EC) No 853/2004.
3.	The CA should provide guarantees that fishery products for export to the EU have satisfactorily undergone all official controls laid down in Chapter II of Annex III to Regulation (EC) No 854/2004, in particular, monitoring of certain contaminants (histamine, heavy metals, PAH, dioxin, tin and <i>Listeria monocytogenes</i>).
4.	The CA should ensure that laboratories involved in official controls apply the principles of internationally recognised quality assurance techniques and are evaluated and/or accredited under officially recognised quality management and assurance programmes equivalent to international standards, such as ISO/IEC 17025, to ensure the reliability of analytical results.
5.	The CA should ensure that laboratories involved in official controls take into account in particular, the analytical method for histamine and the performance criteria for heavy metals as is laid down in Regulation (EC) No 2073/2005 and Regulation (EC) No 333/2007 respectively.

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

http://ec.europa.eu/food/fvo/ap/ap_ph_2011-8896.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2004/432/EC	OJ L 154, 30.4.2004, p. 44-50, corrected and re-published in OJ L 189, 27.5.2004, p. 33	2004/432/EC: Commission Decision of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
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
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
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the

Legal Reference	Official Journal	Title
	191, 28.5.2004, p. 1	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. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs