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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

VIET NAM

FROM 11 TO 20 SEPTEMBER 2012

IN ORDER TO EVALUATE THE 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 audit in Viet Nam carried out from 11 to 20 September 2012, as part of its programme of audits in third countries.

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

The report concludes that there is an official control system in place for the production of fishery products that can, in general, be considered in line with EU requirements.

In principle the current organisation of the Vietnamese competent authority and the control system implemented offer sufficient guarantees concerning public health conditions of fishery products to be imported to the EU.

However, to fully ensure that all the fishery products exported to the EU respect the requirements set out in the health certificate model in Regulation (EC) No 2074/2005, corrections and improvements are needed in particular concerning the standards of vessels, landing sites, ice factories and in relation to aquaculture, the information available to the competent authority, particularly at farm level.

The report addresses to the Vietnamese 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
CA	Competent Authority
CRA	Central Regional Agency
DAH	Department of Animal Health
D-Fish	Directorate of Fisheries
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
EUROSTAT	Statistical Services of the European Union
FVO	Food and Veterinary Office of the European Commission
GAP	Good Agricultural Practice
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
MARD	Ministry of Agriculture and Rural Development
OJ	Official Journal of the European Union
ppm.	Part per million
PAH	Polycyclic Aromatic Hydrocarbons
RASFF	Rapid Alert System for Food and Feed
SRA	South Regional Agency
TVB-N	Total Volatile Basic Nitrogen

1 INTRODUCTION

The audit took place in Viet Nam from 11 to 20 September 2012 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme. The audit team comprised two teams from the FVO, one for fishery products and one for residues and contaminants (ref. DG(SANCO)2012-6535) with two separate reports. An opening meeting was held in Hanoi on 11 September 2012 with the competent authority (CA) for European Union (EU) exports of fishery products, the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD) of the Ministry of Agriculture and Rural Development (MARD). At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit.

2 OBJECTIVES AND SCOPE OF THE AUDIT

The objectives of the audit were:

- to evaluate whether the official controls put in place by the CA can guarantee that the conditions of production of fishery products in Viet Nam destined to be imported into the EU are in line with the requirements laid down in EU legislation, and in particular with the health attestations contained in the health certificate laid down in Appendix IV to Annex VI to Commission Regulation (EC) No 2074/2005;
- to verify the extent to which the guarantees and the corrective actions submitted to the Commission services in response to the recommendations of the previous FVO audit report of 2009 have been implemented and enforced by the CA.

In terms of scope the audit focused on the organisation and performance of the CA, the export certification procedure, the official control system in place covering production, processing and distribution chains applicable to fishery products to be exported to the EU. Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as a technical basis for the audit.

In pursuit of these objectives, the following sites were visited:

COMPETENT AUTHORITY		
Central level	2	The CA headquarters in Hanoi, South Regional Agency in Ho Chi Minh city
Regional level	2	Branch 4 in Ho Chi Minh city Branch 6 in Can Tho
Local level	3	Binh Thuan (Phan Thiet), Soc Trang, Dong Trap
LABORATORY VISITS		
	2	Branch 4 and 6 laboratories (microbiology, chemistry)
PRIMARY PRODUCTION		
Aquaculture farms	7	Pangasius 4, shrimp 3
Fishing vessels	1	Tuna
Transport vessel	1	
LANDING AND FIRST SALE		

Landing site	1	
FACILITIES HANDLING FISHERY PRODUCTS		
Freezer vessel	1	
Middlemen	1	
Processing Plants	6	
Cold stores	1	
OTHER		
Ice factory	1	
Veterinary pharmacy	1	

- 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

Viet Nam 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.

Viet Nam is listed in the Annex to Commission Decision 2011/163/EU and therefore can export aquaculture fishery products to the EU.

A previous audit took place in 2009 (ref. DG(SANCO)/2009/8056) which had highlighted deficiencies in relation to imported raw material, the standard of landing sites and vessels, the production of ice and official controls of histamine, dioxins and organoleptic examinations. The report – published on the Health and Consumers Directorate-General (SANCO) Internet site at http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2289 – made a number of recommendations in respect of the action required of the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations. The follow-up of these earlier recommendations are done under the relevant chapter of the current report.

4.2 PRODUCTION AND TRADE INFORMATION

According to information provided by the CA (see table below), the main fishery products exported to the EU are as follows: frozen fish and fish fillets (*Pangasius hypophthalmus*, *Pangasius*

pangasius, *Sphyrna lewini*, *Lutjanus argentimaculatus*, *Epinephelus chlorostigma*, *Katsuwonus pelamis*), frozen shrimp (*Penaeus monodon*, *Panulirus ornatus*, *Metapenaeus affinis*) and frozen squid/octopus (*Loligo chinensis*, *Sepia spp*, *Octopus spp*). The main importing Member States are (by decreasing order): Spain, Germany, the Netherlands, Italy, France and the United Kingdom. In total 9,465 tonnes of fishery products were imported into Vietnam as raw material and were later on exported to the EU. The main products were 6,627 tonnes of tuna (*Thunnus tonggol*, *Katsuwonus pelamis*), 1,328 tonnes of shark (*Prionace glauca*) and 1,292 tonnes of marlin (*Makaira indica*, *Xiphias gladius*).

According to the list drawn up by the CA and available on the DG SANCO web site (list valid as of 21/11/2011), imports of fishery products from Vietnam into the EU are authorised from a total of 393 establishments including 365 establishments processing only or partially materials derived from aquaculture.

Cold stores and freezer vessels are not listed for export to the EU and there are no factory vessels approved.

This list is available on the SANCO web site at the following address:

http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm.

Table 1 summarises the exports from Vietnam of fishery products to the EU.

**Table 1 – Volume of Exports of fishery products from Viet Nam to the EU
(source Eurostat)**

Commodity	2011 (tonnes)
Fish, fresh or chilled (0302)	13
Fish, chilled and frozen (0303)	10,731
Fish fillets, chilled and frozen (0304)	218,900
Fish, dried, salted or in brine (0305)	86
Crustaceans (0306)	29,066
Fats and oils (1504)	544
Prepared and preserved fish (1604)	10,984
Crustaceans, molluscs (1605)	24,530
Total exports to the EU	294,855

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

In 2010 there were four alerts (mercury in marlin and swordfish, histamine in canned tuna, nitrofurans in shrimp) and 23 border rejections due to findings of residues, contaminants, broken cold chain or bacteriological contamination including eight findings of *L. monocytogenes* in frozen, raw fish in the RASFF system for Vietnamese fishery products. In 2011 there were two alerts (undeclared sulphite, *Salmonella*) and 24 border rejections mainly due to findings of residues in a variety of fishery products.

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

Since the previous FVO audit a large number of legal texts have been revised and updated.

No 55/2010/QH12 is the current Vietnamese Food Law and Decree No 38/2012/ND-CP gives detailed provisions for its implementation.

No 55/2011/TT-BNNPTNT is a circular on food safety inspection and certification of fish and fishery products and obligations and powers of the CA at different levels. It also includes requirements concerning official control of production and placing on the market, official controls of fishery products, such as organoleptic examinations, freshness indicators, histamine testing, residues and contaminants testing, microbiological checks, parasites tests and poisonous species. It also contains requirements for labelling of products, sampling methods and methods for analyses of contaminants.

Decision No 190/QD-CLTY dated September 12, 2006 on the application of certain relevant EU regulations including microbiological criteria, maximum levels for contaminants and methods for sampling and analysis of contaminants.

No 47/2009/TT-BNNPTNT promulgating the National Technical Regulations on food safety and hygiene conditions in fishery production, such as QCVN 02-01:2009/BNNPTNT with general hygiene requirements for fishery production and trade establishments and QCVN 02-02:2009 with requirements for HACCP based quality and food safety assurance programmes. There are in total 18 technical regulations defining specific requirements for different parts of the production chain and different types of processing.

No 25/2010/TT-BNNPTNT is a circular with guidance on food hygiene and safety controls of imported foodstuffs of animal origin.

Decision No 2864/QD-BNN-QLCL of 24 November 2011 and Decision No 1471/QD-BNN-QLCL of 20 June 2012 regulates the quality, food safety and chemical criteria to be tested for in export fishery consignments.

Decree No 31/2010/ND-CP of 29 March 2010 prescribes legal powers in relation to infringement procedures, product seizure and disposal.

Conclusions

From a limited review of the Vietnamese legislation in force and the standards applied to fishery products and its production chain these can, in general, be considered as in line with the relevant EU requirements.

5.2 COMPETENT AUTHORITY

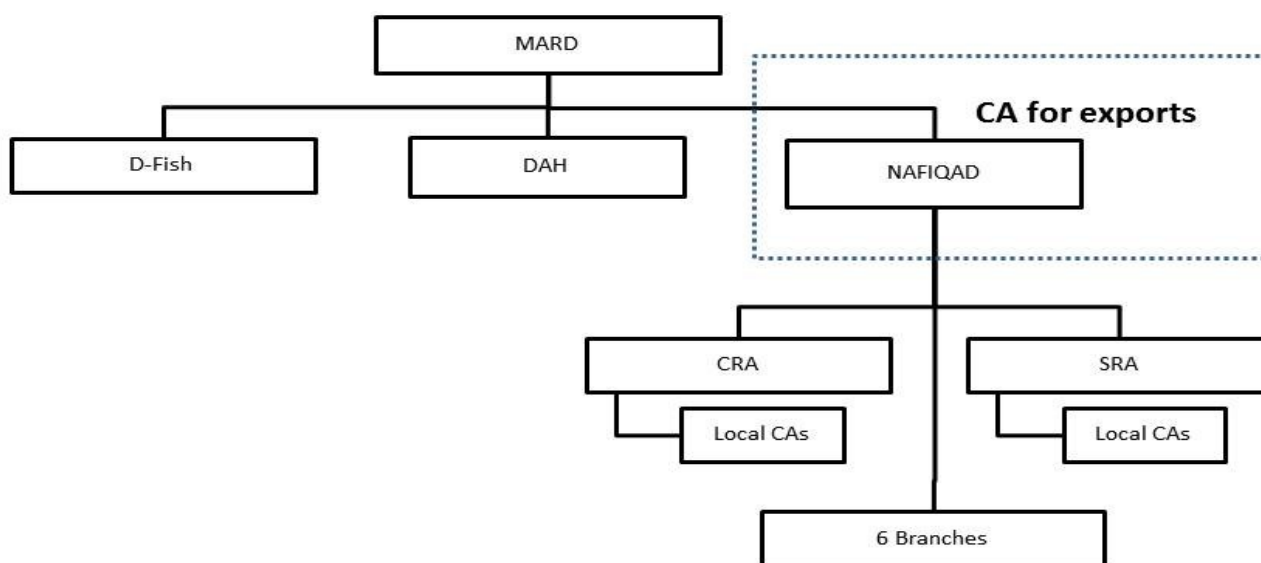
Legal requirements

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. Points g) and h) are covered in Sections 5.4 of this report.

Findings

Structure and organisation

The different authorities participating in the official control of fishery products exported to the EU and its production chain, as understood by the audit team, are set out below:



Since 1 July 2011, and in compliance with the Vietnamese Food Law, the MARD is responsible for official control of fish and fishery products at all stages of production. The Ministry of Health is responsible for food safety in general, potable water, food additives and functional foods.

Within MARD there are three departments involved in the fishery products production chain:

1. The Directorate of Fisheries (D-Fish) is responsible for capture and aquaculture including registration and inspection of farms.

2. The Department of Animal Health (DAH) is responsible for import control of products of animal origin and management of aquatic animal health as well as for authorisation of medicines and their distribution.
3. The CA headquarters is located in Hanoi. This has two regional arms, Central Regional Agency (CRA) and South Regional Agency (SRA) that implement monitoring programmes, inspect and approve export establishments and audit local CA offices twice per year on the residue monitoring programme. Other tasks may be assigned by the headquarters as necessary.

The CA has six regional branch offices (No 1 to No 6) including laboratories throughout Viet Nam. Inspectors from branch offices do routine inspections of export establishments, take samples for official controls and inspect export consignments before certifying them. The laboratories in all Branches can perform testing for all parameters of official controls of fishery products, including chemical criteria, microbiology examinations and freshness indicators including Total Volatile Basic Nitrogen (TVB-N).

The local CAs inspect fishing vessels, landing sites, middlemen, non-exporting establishments and collect samples from farms for the residue monitoring programme.

Powers, Independence and Supervision

The Food Law and the Decree on its implementation specify the responsibilities of MARD such as:-

- Formulate strategies, plans and legal documents on food safety.
- Manage food safety in primary production including aquatic products.
- Manage food safety throughout production, processing, transport, import and export.
- Report on the management of food safety.
- Inspect, examine and handle violations of the food safety law during the process of production, import, export and trading.

Circular No 55/2011/TT-BNNPTNT specifies the responsibilities for the CA at all levels. It includes requirements for inspectors to be qualified, trained and to be free from conflicts of interest as well as for approval/withdrawal procedures for establishments and actions to be taken concerning non-compliant products.

The CA headquarters carries out annual audits to regional offices (SRA, CRA) and its branches. Every six months the CA headquarters or SRA/CRA carry out inspections of the implementation of activities at local CA level.

Local CAs send monthly, quarterly and annually reports on inspections, monitoring and handling of sanctions to the SRA/CRA.

Training

The CA gives technical directions and instructions to local CAs and branch offices and organises annually, or on request, meetings on the implementation of plans and quality assurance to the local CAs.

Documented Control Procedures

There are written procedures concerning:-

- Registration/approval and suspension/withdrawal of processing establishments, fishing vessels and landing sites.
- Checklists for inspection of aquaculture farms.
- Checklists for inspections including HACCP assessment.
- Inspection reports including deadlines for corrective actions.
- Classification of establishments with a grading for inspection frequency.
- Actions to be taken following non-conformities.
- Pre-export checks and analytical parameters for analysis.

Conclusions

The CA responsible for official controls on fishery products is clearly designated, structured and organised and has the power to register or approve vessels and establishments and to suspend and take actions due to non-conformities. The audit team found that the official staff had an adequate knowledge of EU requirements.

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

An establishment applies for export approval by sending in a registration form, a copy of the business registration certificate and a report on food safety conditions, e.g. an inspection report done by the local CA. For inspection purposes, a standardised checklist is used and it includes the classification of the establishment.

The central CA (headquarters, SRA, CRA) carries out an approval inspection of the establishment to verify compliance on-the-spot and gives it an export approval number. Staff from branch offices can participate in these inspections. The CA maintains and updates annually a list of establishments authorised to export fishery products.

If a major change in the production occurs or new products are introduced, the CA performs an assessment to document and verify the changes with a new inspection visit and a report.

The establishment has to apply for this and send an updated HACCP plan, so the CA can assess it before visiting the establishment.

The audit team visited one establishment that had a cold store on the premises. The cold store was approved and given a separate identification number, but this was not used when signing health certificates for export consignments. The CA does not put cold stores on the list of EU export establishments.

Conclusions

There is an adequate system, in line with EU requirements, for approval and listing of establishments authorised to export to the EU. However, exports occur from cold stores which are not listed by the CA for participation in the EU export chain for fishery products.

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 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

According to the CA, fishing vessels shall be inspected twice every three years, landing sites once per year, transport vessels once per year and middlemen once per year by the local CA. Fish farms are inspected once per year by the local D-Fish. From 2012 the DAH has started to check animal health conditions on farms, but the farms visited by the audit team had not been subject to this kind of inspection. Official controls by the CA are restricted to random samples taken for the residue monitoring programme.

Establishments are graded as A, B or C according to their performance and how many remarks and non-compliances are recorded in the inspection reports. The audit team noted that the CA applies the requirements for grade A establishment strictly. Establishments are inspected according to their classification where grade A establishments are inspected once per year and grade B twice per year. Grade C establishments have unsatisfactory inspection results with dead-lines for corrections to be made. Grade C establishments may not export fishery products.

5.4.2 Primary production

The audit team visited three vessels, one tuna fishing vessel, one vessel storing fish, collected from small fishing boats, on ice and one vessel that collects squid from smaller fishing vessels and freezes the product on board.

The audit team noted non-compliances in regard to hygiene such as no running water, cigarette butts on deck, a hold with loose parts of a non-permeable material on the floor, manual reading and records of the temperature in the freezers, rusty trays for products, dirt and wooden parts of holds.

The audit team noted the following findings related to the official control system in place:-

- All three vessels were regarded as fishing vessels and had a registration number. The freezer vessel was not approved as such and had no HACCP plan in place.
- Inspection reports for two of the vessels were available identifying some of the non-compliances cited above. In one report a dead-line for corrective actions was set, but not in the other.
- Serious non-compliances were not remedied within the official deadline – three months, according to the CA's rules.

A block ice factory was visited. Public water was used and own checks of the water were sent to a public laboratory. Chlorine is used to 0.5 ppm maximum. The provincial Department of Health takes water samples twice a year and is responsible for approval and control. A certificate of approval from 2008 was available. The ice factory is open to the street, the roof is full of holes and a tarpaulin covers the rusty ice molds but it was dirty. In the open area the molds are thawed in a tank with water before the ice is emptied into a truck. The audit team noted visible contamination of the ice. Once the ice is in the port and at the landing site, the local CA takes over official controls. The port authorities stated that they had asked the ice plant owner to upgrade the factory.

5.4.3 *Aquaculture farms*

The audit team visited four Pangasius and three shrimp farms. Aquaculture farms are registered and inspected by D-Fish local inspectors. This can be done in cooperation with the DAH local staff and/or the local CA. However, not all farms, particularly small ones, are surveyed. One farm visited was also inspected by the local government's Agriculture Management Division and in this case the Department of Environment had first approved the area as suitable for shrimp farming. Inspections are performed by local D-Fish once per year of farms with intensive production. The definition for intensive farming is for shrimp a density of 30-50/m² and for Pangasius 30/m² and for both types that feeding is required and medicines are used. Pangasius ponds are 4-5 meters deep. A checklist is used for inspections. Inspection reports were available to the audit team at five of the seven farms visited. For one of the farms these had to be sent by fax from the CA office. One shrimp farm had, according to the farm manager, reports stored at the company head-office. In one farm a D-Fish inspector informed the audit team that they inspected the farm four times per year, but no records of these visits were available and had not been given to the farm staff. The reports shown to the audit team were not very informative as they were general and the conclusion in all reports was that the farm meets requirements.

Production records for each pond were kept at all farms. Drugs used, except in one case, and other treatments applied were noted in the records, but withdrawal periods were not. The records did not contain the weight of harvested product. The audit team was informed that water testing was done, but results were in general not available. The detailed pre-harvest inspection results including residues analyses performed by the buying processing establishments were not available on the farms.

Drugs are used regularly and directly obtained from a drug producer or a pharmacy by the farm technician without securing a definitive diagnosis and without a prescription. Analysis of dead fish/shrimp was in general not performed and results/diagnoses were not available. In one case a

drug treatment docket was present, but the treatment had not been entered in the pond record.

5.4.4 *Landing*

Inspection of landing sites is in general once per year. The audit team visited one landing site where the following was noted:

- The local CA checks this landing site every six months.
- The landing site consists of a roof and a platform where crates with fish under ice are placed before being loaded on to trucks.
- There are no hand washing facilities.
- Block ice is stored in a container where fish were being stored at the time of the visit. The ice is crushed in a rusty machine situated outdoors under a dirty cover that was dragged along the ground when removed for inspection of the machine. The crushed ice is placed in plastic crates stored on the ground without cover beside the machine.

5.4.5 *Facilities, including vessels, handling fishery products*

The audit team visited one middleman, six establishments and one cold store.

At the middleman's facility, fish was rinsed and stored under ice in containers inside the premises. The local CA had carried out an inspection just prior to the FVO visit and a report was available. Non-compliances concerning items such as an open door, rust, pest control, work clothes and traceability were noted and dead-lines for corrective actions were set. The CA demands good manufacturing practices and sanitary operation procedures for middlemen but HACCP plans are not formally required as they only handle chilled fish. The middleman transmits a signed delivery document to the receiving establishments which includes the vessel registration number and fish species and the customer to whom the product is supplied.

Six establishments producing fishery products mainly from aquaculture raw material were visited during the audit.

The inspection frequency set was generally respected in the establishments visited by the audit team. A standardised checklist is used for inspections. It is wide ranging and covers most of the EU hygiene requirements and includes quality systems and HACCP. The CA accepts temperatures of up to 4°C in raw material.

Inspection reports were available in all visited establishments. If non-compliances are noted, an action plan is required. Corrective actions can be followed-up when the next pre-export visit occurs or at the time of the next regular inspection.

In Branch 6 a separate document for follow-up of non-compliances had been drawn up. In Branch 4 the follow-up was done by filling out a new checklist at the next visit.

One of the visited establishments had been suspended and the production stopped due to the falsification of the date for raw materials used in production. A follow-up inspection was performed before allowing production to resume and the follow-up report was available to the audit team.

The audit team noted the following findings regarding hygiene in the establishments:-

- stagnant water for rinsing hands after dipping in chlorinated water.

- stagnant water for rinsing products.
- excessive water flow over floors.
- water from condensation was ducted away but flowing freely on the floor.
- chemicals stored in production rooms (chlorine).
- chlorine and polyphosphates used in processing.
- gaps around doors and hatches.

The audit team reviewed the HACCP plans and their implementation in the establishments including examples of records as well as verifying the CA's supervision of these plans. The establishments using chlorine and polyphosphates, due to demands from customers in Japan and the USA, had either separate flow charts for the EU market or clearly indicated in the flow charts that their use is not allowed for EU products.

The establishments' own-checks included, in general, microbiological analyses for *E.coli*, *Staphylococcus aureus* and *Salmonella species*. In addition, total plate count, coliforms, *Vibrio spp.* and *Shigella* were checked. Checking for residues is part of the pre-harvest controls as are sulphite checks on shrimp.

The visited establishments, except one (see below), showed excellent traceability with unique codes printed on carton boxes. When their own farms provided raw material, it was possible to trace back to the pond from which the fish or shrimp had come. For wild or farmed raw material bought-in, traceability to the middlemen providing the raw material was possible, but not always back to the vessels or farms.

One cold store within the premises of one processing plant was visited during the audit. It had its own individual approval number, but Vietnam does not list cold stores separately on the EU list. The site visited was in general kept in good order and well maintained. In the cold store traceability exercises were performed for one imported product, for one product in intermediate storage and for one finished product. For the imported product, one pallet was not labelled properly undermining the traceability. In the exercise with a carton box containing their own product in intermediate storage there was not a clear production code (only a date and hand written letter codes referring to the factory/middle men) and after a protracted delay, uncertainty remained with regard to its origin. In this case cartons had been re-used. The finished product had both a production code and a lot number and traceability to the raw material was clear. The CA acknowledged that the establishment had encountered some difficulties with the software used to trace product on the cold-store inventory and needed to be more familiar with its use.

5.4.6 *Import controls of fishery products*

Imported products of animal origin are inspected by DAH following the requirements for documentary checks, physical examination and sensory evaluation set out in Vietnamese legislation. The Vietnamese CA performs inspections of establishments in other countries for their own listing purposes.

Before health certificates for export can be signed (see point 6 below), a copy of a certificate from the DAH on the inspection of the imported raw material and a catch certificate from the exporting country must be presented to the signing officer.

5.4.7 *Follow-up of RASFF notifications*

In its answer to the pre-audit questionnaire the CA explains the procedure for the follow-up of the notifications. In general, the establishments are contacted as soon as the notification is known to the

CA and an explanation and preventive measures are required. The CA informed the audit team that the irradiation had been used in a small number of establishments and during a limited time and that all establishments were made aware of the EU requirements.

Conclusions

There is an official control system in place covering the production chain for fishery products, which also covers imported raw material. Recommendation No 1 of the previous FVO report concerning controls of imported fishery products can be considered addressed.

Due to the absence or incomplete nature of records of medicines used on aquaculture farms, the CA is not in a position to guarantee that the owners of the farms meet EU requirements in Regulation No 852/2004, Annex I Part A, III.

Since the previous FVO audit in 2009, the local CA has increased the frequency of control of hygiene conditions at the landing site. However, the fishing vessels, the landing site and the ice factory visited and ice produced do not meet EU requirements. Recommendations 6, 7 and 8 in the previous FVO report cannot be considered as addressed.

In general, the establishments visited were in line with EU requirements.

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 of Regulation (EC) No 2074/2005, in particular official controls laid down in Annex III, Chapter II of Reg. (EC) No 854/2004.

Findings

- Organoleptic examinations, for fish quality, are performed by inspectors from the local CA at landing of fish twice a week and records are kept with vessel ID, type of product, temperature (2-5°C recorded) and details of the checks done. The audit team noted that the checks were always assessed as good despite temperature records indicating that products delivered were above the CA limits. Organoleptic checks are also performed at middlemen inspections and at pre-export testing. TVB-N analysis is performed when uncertain results of freshness are obtained.
- Samples for histamine testing are taken at establishments and as part of the post-harvest monitoring programme. The results observed by the audit team were satisfactory.
- Mercury, Lead and Cadmium are tested for in pre-export samples (see point 6). The results observed by the audit team were satisfactory.
- In the pre-audit questionnaire the CA replied that no official controls of dioxins was performed in 2011. In the Branch 6 office, official dioxin test results from 2010 (one in tilapia, one in catfish and two pre-export analyses of Pangasius), 2011 (two results from pre-export testing of Pangasius) and 2012 (one pre-export testing of Pangasius) were available, all with satisfactory results. Pre-export testing for dioxins is done when it is demanded by customers, mainly in the Middle-East. The audit team was informed by the CA that they did not regard those results as official samples when they were done on request of customers. 15 samples for dioxins are planned in the Post-Harvest Monitoring Programme for 2012.
- Polycyclic Aromatic Hydrocarbons (PAH) is not monitored for.

- Samples for microbiological analyses are taken at establishments yearly by the CA. There is also a pre-export testing including *E.coli* and *Salmonella* for raw fish, *E.coli*, *Salmonella* and *L. monocytogenes* for cooked products and for ready-to-eat products total plate count, *E.coli*, *Staphylococcus aureus*, *Salmonella* and *L. monocytogenes* are done. The results observed by the audit team were satisfactory.
- Parasites are checked for by establishments staff at the establishments. Light tables are used to examine every fillet of *Pangasius*. The CA informed the audit team that parasites are included in the CA's organoleptic examinations.
- Additives: Metabisulphite can be used after harvesting shrimp at the farms and some results of own checks were available, but official controls are not done. Phosphates are part of the standard parameters for pre-export testing as the CA is aware that the EU does not allow polyphosphates in raw fish. Cooked finished products had labels with information on both additives.
- Water/ice samples are taken by the CA and analysed for *E.coli*, *Enterococci*, Coliforms and colony count 22°C. Copies of results were available at the establishments visited and they were satisfactory. All processing plants are supplied with public water.

Conclusions

Official controls on fishery products cover most EU requirements. An official sampling programme, in line with EU regulations, is in place covering most of the relevant microbiological and chemical parameters. However, no checks for metabisulphite are done and some tests for histamine are performed with an ELISA screening method.

Of the recommendations made in the 2009 report, No 12 concerning organoleptic examinations can be considered as addressed. Recommendation No 13 concerning histamine testing is partly addressed. Recommendation No 14 concerning monitoring for dioxins and PAH can be considered as partly addressed.

6 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

Pre-export checks are done by the branch offices before the directorate (Branch director and vice directors) can sign export and catch certificates. The procedure is the following:-

- An application is received from the exporter with information about the consignment including raw material used and the destination.

- A packing list of the consignment is also provided.
- A pre-check of documents including own-check test results is carried out.
- Catch certificates for imported wild caught fish as raw material and a copy of the import control certificate from DAH are verified.
- Physical checks including organoleptic examination, identity, labelling and traceability are done.
- Results of laboratory tests for microbiological and chemical parameters (from 1/3 of consignments from grade A plants and 1/2 from grade B) are reviewed.
- Pre-export laboratory analyses are performed according to the food safety risk and aquaculture raw material is considered highest, histamine sensitive species second and heat treated products third.

The health certificate used follows the model in the EU legislation. Examples of issued health certificates were correctly filled out.

Conclusions

There is an adequate system in place for the issuance of EU export certificates for fishery products in line with EU requirements.

7 LABORATORIES

Legal requirements

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004 stipulate that EU 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

Branch 4 microbiological laboratory was visited. It is ISO-17025 accredited, but the latest certificate expired 30 June 2012. The audit team was informed by the CA that an audit took place 2-3 July 2012 and that a new certificate had not been sent out at the time of the FVO visit. The laboratory makes 100-150 analyses per day of both official and private samples of fishery products, water and ice.

Branch 4 and 6 chemical laboratories were visited. Both are ISO-17025 accredited and have up-to-date equipment for dioxin and heavy metal analyses and a good standard in general. Validation files for dioxins are complete.

Training records demonstrate that the staff is well trained. Several staff are trained in other countries, including EU Member States.

All instruments are identified and a label with the status of calibration is present. Maintenance is done regularly and logbooks are kept up-to-date.

In the Branch 4 histamine testing is performed with an ELISA method detecting up to 50 mg/kg and in Branch 6 tests are done with an ELISA method detecting up to 10 mg/kg. Results exceeding the limits are tested by a HPLC method. No results observed by the audit team were above the EU limit.

In the Branch 6 laboratory most of the analyses are in samples of *Pangasius*.

Cadmium, mercury, lead and arsenic are measured by means of Inductively Coupled Plasma – Mass Spectrometry. In order to prevent contamination, samples for these elements are prepared and analysed separately from other samples. Control charts for the four elements are kept. Certified reference material is analysed as positive control sample.

The laboratories participate in proficiency testing schemes organised by FAPAS, the Korea Food and Drug Administration and the CA. Performance is generally very good and when questionable ($2 \leq |z| \leq 3$) or unsatisfactory results ($|z| > 3$) are obtained, immediately cause analysis and corrective actions are initiated.

Conclusions

The laboratories responsible for official analyses on fishery products are accredited according to ISO-17025, both for chemistry and microbiology. Other than the screening method for histamine, analytical methods used are in line with EU requirements.

8 OVERALL CONCLUSION

There is an official control system in place for the production of fishery products that can, in general be considered in line with EU requirements

In principle the current organisation of the Vietnamese CA and the control system implemented offer sufficient guarantees concerning public health conditions of fishery products to be imported to the EU.

However, to fully ensure that all the fishery products exported to the EU respect the requirements set out in the health certificate model in Regulation (EC) No 2074/2005, corrections and improvements are needed in particular concerning the standards of vessels, landing sites, ice factories and in relation to aquaculture, the information available to the CA, particularly at farm level.

9 CLOSING MEETING

During the closing meeting held in Hanoi on 20 September 2012, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

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

The CA pointed out that there is work to be done in relation to good agricultural practice (GAP) at aquaculture farm level. A new technical regulation has to be put in place. They have a GAP under development for which a close cooperation between itself, DAH and D-Fish is required.

10 RECOMMENDATIONS

The CA should provide the 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.	To ensure that aquaculture farms providing fishery products to establishments, listed by the CA for participation in the EU export chain, keep records to a standard at least equivalent to the requirements laid down in Regulation (EC) No 852/2004, Annex I, Part A, point III.
2.	To ensure that fishing vessels providing fishery products to establishments, listed by the CA for participation in the EU export chain, meet standards at least equivalent to the requirements laid down in Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter I.
3.	To ensure that fishery products intended for export to the EU are landed at landing sites which meet standards at least equivalent to the requirements laid down in Regulation (EC) No 852/2004 Annex I, Part A and Regulation (EC) No 853/2004, Annex III, Section VIII, Chapter II, point 1.
4.	To ensure that the production of ice which comes in contact with fishery products meets standards at least equivalent to the requirements laid down in Regulation (EC) No 852/2004, Annex II, Chapter VII, 4.
5.	To ensure that, as established in the Part II.1 of the health certificate, that fishery products exported to the EU have satisfactory undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004, in particular Chapter II, point C regarding histamine and point D regarding PAH and meet the requirements laid down in Regulation (EU) No 252/2012.

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=2012-6547

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
<i>Audits by the Commission Services</i>		
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
<i>Food Law and official controls</i>		
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. 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

Legal Reference	Official Journal	Title
<i>Microbiological criteria</i>		
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
<i>Contaminants</i>		
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
<i>Certification and imports</i>		
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
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