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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

MALAYSIA

FROM 30 APRIL TO 10 MAY 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

The audit was carried out as part of the Food and Veterinary Office audit programme for 2012.

The primary objective was to evaluate the public health conditions for the production of fishery products intended for export to the European Union. The scope of the audit covered the relevant European Union legislation for the public health sector. The audit also verified the implementation of the recommendations of the previous 2010 audit visit covering the same subject.

Although the fact that recommendation No 2 cannot be considered as fully addressed (knowledge of official staff) the overall follow-up of the previous FVO audit report was adequately performed.

In principle the current organisation of Malaysian Competent Authorities and the control systems implemented offer sufficient guarantees concerning the sanitary conditions of fishery products to be exported to the European Union as per the export health certificate defined by Regulation (EC) No 2074/2005.

Nevertheless shortcomings were noted by the audit team with regard to standards and legislation, knowledge levels of all staff involved, the implementation of the approval procedures for landing sites, the approval requirements for European Union listed establishments, the official control of the establishments and the certification procedures.

The report makes recommendations to the Competent Authorities aimed at addressing areas in which further improvements are required.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent authority
EU	European Union
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
SANCO	General Directorate for Health and Consumers
CCA	Central Competent Authority
FSQD	Food Safety and Quality Division
DOF	Department of Fisheries
LKIM	Fisheries Development Authority of Malaysia
RASFF	Rapid Alert System for Food and Feed Notifications
SOP	Standard Operating Procedures
ARMP	Aquaculture Residues Monitoring Plan
PAH	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
TVB-N	Total Volatile Basic Nitrogen
Cd	Cadmium
Pb	Lead
Hg	Mercury
CAR	Corrective Actions Request
FExCIS	Food Export Certification Information System
Sn	Tin
LOD	Limit of Detection
LOQ	Limit of Quantification

1 Introduction

This audit took place in Malaysia from 30 April to 9 May 2012 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. An opening meeting was held in Kuala Lumpur on 30 April 2012 with the competent authorities (CAs), the Food Safety and Quality Division (FSQD) of the Ministry of Health (Malaysian Central CA (CCA) for EU exports of fishery products), the Department of Fisheries (DOF) and the Fisheries Development Authority of Malaysia (LKIM), both under the Ministry of Agriculture and Agriculture-based Industry. At this meeting the objectives of, and itinerary for the audit were confirmed, and the FVO team requested additional information required for its satisfactory completion.

2 Objectives and Scope

The objective of the audit were to:

- To evaluate whether the official controls put in place by the CA can guarantee that the conditions of production of fishery products destined for export to the EU are in line with the requirements laid down in EU legislation, and in particular with the health attestation contained in the certificate of 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 fishery products audit report of 2010 have been implemented and enforced by the CA (ref. DG(SANCO)/2010-8532 – MR – FINAL, published on SANCO's website - http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2483.

In terms of scope the audit focused on the organisation and performance of the CAs, the export certification procedure, the official control system in place covering production, processing and distribution chain 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 technical basis for the audit. Full references to EU legal acts quoted in this report are provided in that Annex and refer, where applicable, to the last amended version.

In pursuit of this objective, the following sites were visited:

MEETINGS / VISITS	no.	COMMENTS
Competent Authority/ies		
Central Level	1	CCA
	2	CAs
Regional Level	1	Penang Regional CAs (the 3 involved)
Laboratory/ies		
Official for fishery products (includes residues)	3	Kota Kinabalu, Petaling Jaya and Sungai Buloh
Primary Production		
Aquaculture Farms	3	Fin fish (1) and shrimp (2)
Fishing Vessels	4	

Landing Sites	2	
Food Processing Facilities		
Processing Establishments	8	One not in operation at the time of the visit (selected by the FVO team on the spot)
Cold Store	1	

Representatives from the CCA and the other CAs accompanied the two FVO teams 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 ensure the verification of compliance with feed and food law, animal health and animal welfare.

4 Background

4.1 General Background

Malaysia is currently listed in Annex II to Commission Decision 2006/766/EC: List of third countries and territories from which imports of fishery products are permitted. It is also listed in the Annex to Commission Decision 2011/163/EU as having an approved residues monitoring plan for aquaculture products.

The last FVO fishery products audit to Malaysia was a follow-up of a 2009 audit and it took place in 2010. The 2010 audit report identified shortcomings in EU rules knowledge of official staff, in the structural conditions of the primary production fishing vessels, in the testing of fishery products for histamine and heavy metals and in the reliability of the results of the official analyses performed by the official laboratories. Written guarantees in response to the recommendations of the previous report were received from the CA and the FVO assessment found them to be satisfactory.

Following an earlier 2008 FVO audit on fishery products (ref. DG(SANCO)/2008-7679) the Malaysian CCA requested the de-listing of all its EU approved establishments. After the 2009 FVO audit (ref. DG(SANCO)/2009-8319) the CCA was only allowed to add to the EU list establishments producing fishery products from aquaculture origin and/or processing fishery products imported from EU eligible sources. Finally, subsequently to the 2010 FVO audit (ref. DG(SANCO)/2010-8532) the CCA was also allowed to add to the EU list establishments producing fishery products of wild caught origin.

4.2 Production and trade information

Malaysian imports into the EU of fishery products are authorised from a total of 23 establishments, as indicated in the Malaysian establishments list published on 08/11/2011 on SANCO's website (http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm).

Additionally the CAs have national lists of other facilities not exporting directly to the EU but authorized by them to participate in the production chain of fishery products for EU exports, such as, aquaculture farms (16 aquaculture farms for crustaceans and 3 for fin fish), fishing vessels (42 artisanal fishing vessels), transport vehicles (45 currently in operation), landing sites (6 currently

approved and in operation) and cold stores (1 independent cold store).

In accordance with the information provided by EUROSTAT Malaysia fishery product exports to the EU amounted to approximately 4,400 tonnes in 2010, of which 72% were crustaceans (mainly *Litopenaeus vannamei*) and 20% were prepared or preserved molluscs, crustaceans and fish (mainly surimi of *Nemipterus japonicas*). The main importing EU member states were, by decreasing order, Italy, France, Spain and United Kingdom (accounted to 83% of the imports). With regard to 2011, and in accordance with the same source, the exports to the EU amounted to approximately 2,900 tonnes, distributed as follows: 38% of prepared or preserved molluscs, crustaceans and fish (mainly surimi of *Nemipterus japonicas*), 30% of crustaceans (mainly *Litopenaeus vannamei*) and 27% of molluscs (mainly *Sepia esculenta*).

The main importing EU member states were, by decreasing order, Italy, France and United Kingdom (accounted for 87% of the imports).

4.3 Rapid Alert System for Food and Feed Notifications (RASFF)

Since the 2010 audit one RASFF notification was made on imports of fishery products from Malaysia. This notification was related to an import of fishery products produced in one establishment that had been removed from the EU list at the time the consignment arrived.

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 CAs the main legislation in force applicable to fishery products and their production chain is still the one mentioned and described in the previous FVO reports of 2009 and 2010. This legislation is composed of Acts, Regulations and Rules summarized as follows:

- Food Act 1983 of the Ministry of Health and its regulations: Food Regulations 1985; Food Hygiene Regulations 2009; Food (Issuance of Health Export Certificate for Export of Fishery Products to the EU) Regulations 2009; and Food (Issuance of Health Export Certificate for Export of Fishery Products to the EU) (Amendment) Regulations 2010. These legal instruments are the ones used by staff of FSQD for the official controls of fishery products and its production chain (e. g. processing establishments and ice factories).
- Fisheries Act 1985 of the Ministry of Agriculture and Agriculture-based Industry and its regulations: Fisheries (Quality /control of Fish for Export to the EU) Regulations 2009; and Fisheries (Quality /control of Fish for Export to the EU) (amendment) Regulations 2010. DOF staff uses these legal instruments for the official controls of fishery products and its production chain (e.g. aquaculture farms and fishing vessels).

- Fisheries Development Authority of Malaysia 1971 of the Ministry of Agriculture and Agriculture-based Industry and its regulations and rules: LKIM Regulations 2010; Fish Marketing Regulations 2010; and LKIM Rules 2010. This legislation is used by staff of LKIM for the official controls of fishery products and its production chain (e. g. landing sites).

In general all the legal requirements and standards applied to the fishery products to be exported to the EU and its production chain are defined in the legal texts mentioned above.

Additionally, the maximum admissible levels for certain substances/organisms in fishery products (Total volatile basic nitrogen (TVB-N), histamine, residues (which includes amongst others antibiotics, anthelmintics, dyes, organochlorine compounds and mycotoxins), contaminants (heavy metals, polycyclic aromatic carbons (PAH), dioxins and polychlorinated biphenyls (PCBs)), food additives and microbiological organisms (*E. coli*, *Listeria monocytogenes*, *Salmonella* and Coagulase-positive *staphylococci*)) are defined in several official documents: the DOF Standard Operating Procedures (SOP) for Hygiene on Board, Registration and Monitoring Programme ; the FSQD SOP for Monitoring of Capture Fishery Products; the FSQD SOP for Monitoring of Fishery End Products; the DOF SOP for Antibiotics Usage in Aquaculture Farm; and the DOF Aquaculture Residue Monitoring Plan (ARMP).

From the limited review of the legislation and standards made available by the CAs the FVO team noted that:

- In general there were no significant differences between Malaysian standards applicable to fishery products to be exported to the EU and the applicable EU requirements.
- However the following shortcomings were noted:
  - The LKIM regulations and rules state that the EU applicable requirements are the ones to be complied with by the landing sites. Nevertheless they also allow the preparation of fishery products on a place or premises on the landing sites prescribed by LKIM. The legislation supplied to the FVO team did not indicate what are the structural and hygiene requisites to be complied with in the case that fish preparation takes place in a building located in a landing site. Moreover, the need for a permanent procedure based on the HACCP principles is not a requirement of Malaysia legislation authorizing fish processing in this locations. The CA informed the FVO team that no fish preparation occurs in any of the landing sites authorized to take part on the production chain of fishery products to the EU, but agreed that from a legal point a view that could happen.
  - The DOF ARMP defines a maximum admissible level of cadmium for aquaculture fish which is above the EU limits.
  - The FSQD SOP for Monitoring of Fishery End Products includes formaldehyde and hydrogen peroxide under the category of food additives. In accordance with the EU regulations those substances are not considered as food additives and as such cannot be used in food..
  - The DOF SOP for Antibiotics Usage in Aquaculture Farm defines maximum residues limits for danofloxacin, difloxacin and tilmicosin in aquaculture fish which are above the EU requirements. To note that analyses to determine the level of residues of several substances for which the SOP defines maximum residue limits (which also includes the three substances previously mentioned) are not included in the ARMP and that DOF informed the FVO team that, according to their knowledge, only tetracyclines are used by aquaculture farmers.

Conclusions

From the limited review of Malaysian legislation and standards in force the FVO team concludes that the rules covering the export of fishery products to the EU gives an adequate basis to provide guarantees as to compliance/equivalence with most EU requirements for the sector.

However, this legislation/standards is not fully in line with the EU rules with respect to: the requirements of places/locations where fish can be prepared; the maximum admissible levels of cadmium in aquaculture fish; the indication of formaldehyde and hydrogen peroxide as food additives; and the maximum residue limits of certain antibiotics.

5.2 COMPETENT AUTHORITIES

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) of the aforementioned article.

Findings

Structure and Organisation

The CAs responsible for the official controls of fishery products for EU export and its production chain are still the ones mentioned in the previous FVO audit report: the FSQD of the Ministry of Health that acts as the CCA at central level and is also represented at regional level; the DOF central level and its regional representatives; and the LKIM.

- The FVO team noted that the structure and the organisation of the different CAs has not changed since the previous FVO audit for the sector and a description of them can be found in the FVO reports of these earlier audits.

Powers, Independence and Supervision

The powers and duties of the CAs are defined in the various pieces of legislation mentioned in point 5.1 and they have not changed since the last FVO audit. With regard to the independence of staff the CAs informed the FVO team that each staff member is a civil servant and it is obliged to follow the rules and provisions applicable to them which ensure the requirements concerning independence.

The CCA informed the FVO team in its answer to the Pre-Audit Questionnaire that their note issued on 23 September 2008 (copy provided) with regard to the distribution of competences between the different CAs is still valid and fully implemented throughout all Malaysian regions.

- The FVO team noted that the tasks and competences indicated in that note were effectively applied by all CAs.

The CCA performs yearly audits over the other CAs (DOF and LKIM central level) with the objective of supervising the participation of those CAs in the official control system for fishery products.

Each one of the CAs also has implemented yearly internal audits of its central and regional services.

Technical meetings chaired by the CCA are also held with the other CAs three times per year with the objectives of harmonizing procedures and sharing information. These technical meetings are replicated at regional level by the Technical Committees which also take place twice per year with the participation of all CAs concerned and chaired by the regional representative of the CCA.

- The FVO team saw the schedules and some reports of the different audits and noted that they took place with the defined frequency. The audit reports viewed by the FVO team presented findings (including the identification of shortcomings where applicable), conclusions and recommendations for the rectification of the identified shortcomings (corrective actions request (CAR)) with defined deadlines. The FVO team also saw evidence of CARs' follow-up.

Training – knowledge of EU requirements

The different CAs informed the FVO team that training on EU requirements for fishery products was given to staff involved in official controls of fishery products. That training included amongst other topics the following: Hazard Analyses of Critical Control Points (HACPP) principles; Auditing, Inspection and Sampling Techniques; EU legislation specific to the Fishery Products Sector; Export Certification; Organoleptic Checks. Summaries and presence lists of some of the training were presented by the CAs to the FVO team. These training session were also part of the CAs follow-up of Recommendation No. 1 of the previous audit report, concerning training.

In general, central and regional offices staff interviewed by the FVO team showed an adequate level of knowledge concerning the applicable EU legal requirements. However, regional staff performing on-the-spot routine activities showed deficiencies in this area. This situation was most evident concerning staff controlling the landing sites.

Resources available to the CA

During the audit the FVO team noted that official staff had access to appropriate facilities, documents and equipment to perform their tasks.

The FVO team also noted that there is a network of official laboratories which is available for performing official controls analyses on fishery products (including residues of pharmacologically active substances), water and ice.

Documented Control Procedures

Several documented procedures for the implementation of official controls were issued by the different CAs at their central levels. These procedures were listed in the 2009 FVO audit report and since then only minor updates have been introduced. Together with the procedures the CAs also developed several guidance documents and checklists for the performance of official controls.

- The FVO team noted that the procedures cover completely the full range of activities performed by the CAs during the official control of fishery products, such as, inspections, audits, sampling, registration, approval and listing of facilities, export certification, import controls and management of alert notifications. Some of the procedures also contain, apart from staff instructions and the frequency for controls, the permitted maximum levels for certain substances in fishery products for EU export.

Conclusions

Competent authorities for the official controls of fishery products have been designated. Their current structure, organisation and legal powers allow for the effective official control and enforcement in the full production chain of the fishery products sector.

Mechanisms for supervision of the official activities are adequately implemented and allow for a uniform and consistent implementation of the official control system.

The control system, based on written procedures, provides an appropriate basis for the CAs to guarantee the implementation of adequate and consistent official controls of the sector under their competence.

The resources available to the CAs allow the execution of the official controls. Higher level CA staff are generally knowledgeable of the relevant EU requirements. Nevertheless, staff at lower levels (i.e. staff performing on-the-spot routine activities) presented gaps in that knowledge which undermines the reliability of these controls.

Although follow-up was made by the CAs on Recommendation No 1 of the previous FVO audit report, this recommendation cannot be considered at the moment as fully addressed due to the deficiencies noted.

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 of Annex VI to Regulation (EC) No 2074/2005.

Findings

The CCA has in place a system for approving establishments to be listed as authorized to export fishery products to the EU.

The FSQD SOP for National Approval and Listing Protocol sets out the steps and procedures to be followed by food business operators (FBO) and by official staff for establishment approval. The approval has a desk study step and an on-the-spot verification step. During the desk study phase the CA evaluates the documentation supplied by the FBO (which includes the HACCP certificate issued under the CCA HACCP certification scheme). During the on-the-spot verification a CA official performs an inspection based on the CCA "official verification protocol" to evaluate the level of compliance of the establishment with the applicable requirements. After the approval, which is given without expiry date, the establishments are subject to supervision by FSQD staff (including its regional representatives). See also section 5.2 - *Official control system in place*.

Following approval the name of the establishment, its approval number and the activities for which it is approved for are recorded in the Malaysian FExCIS (Food Export Certification Information System) database.

- The FVO team noted that the procedures mentioned above were adequately implemented by

FSQD staff and all establishments visited had a valid approval (including the identification of the authorised products).

- Nevertheless the FVO team noted in one establishment visited that it has been approved to export fishery products produced from bivalve molluscs (scallops) even though the country is not currently authorized to export that commodity. Both the CCA and the FBO informed the FVO team that this kind of fishery product has neither been produced nor exported to the EU. At the closing meeting the CCA presented to the FVO team evidence that action had been taken to correct this deficiency (revised approval document).

FSQD is also in charge of the approval of means of transport and other facilities involved in the fishery products production chain that are not EU listed (i.e. pre-processing establishments, cold stores and ice factories). FSQD presented to the FVO team the corresponding lists of means of transport and other facilities. The information regarding these FBOs is also recorded in FExCIS database.

- The FVO team noted that the procedures for approval were correctly implemented and followed by the relevant official staff.

FExCIS also has the relevant information with regard to aquaculture farms, fishing vessels and landing sites that are involved in the production chain of fishery products for EU exports. This information is recorded in that system by the responsible CA.

Aquaculture farms and fishing vessels are registered and approved by DOF in accordance with the procedures that are defined in their SOPs and following an on-the-spot verification. The registration and approval are valid for one year and a new on-the-spot verification is needed for the new approval. DOF is also in charge of their official supervision.

- The FVO team noted that the procedures described in the SOP were implemented and correctly followed by the relevant officials. DOF made available to the FVO team a list of approved farms and fishing vessels.

Landing sites are approved and supervised by LKIM. The approval of landing sites is also done based on procedures set out in the relevant SOP and is granted after an on-the-spot verification. Approval of landing sites is valid for one year.

- The FVO team noted that the approval procedures were implemented and in general adequately followed. Nevertheless, shortcomings with regard to the recent withdrawal of approval for two landing sites were noted: in one case the approval cancellation was communicated to the CCA and introduced in FExCIS database three weeks after the expiry of the approval; in another case the FBO requested the cancellation of the approval one month after its expiry and LKIM communicated this fact to the CCA another month later (two months in total), when at this stage the FExCIS database was updated.

Conclusions

The general procedures and provisions in place for listing Malaysian establishments exporting fishery products to the EU and for the control of the other facilities supplying the EU listed establishments can be considered as generally in line with the EU requirements. The implementation of those procedures is sometimes unsatisfactory which could compromise the

overall effectiveness of the system, in particular with regard the landing sites and the approval of establishments (concerning the products authorised for EU export).

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 points II.1 and II.2 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV of 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

Official control system in place

The official control system currently in place is implemented by three competent authorities, FSQD, DOF and LKIM, based on the Malaysian legislation and their written procedures.

As mentioned in section 5.2 the distribution of competences between the different CAs is set out in the CCA note of 23 September 2008 and can be summarised as follows: FSQD (CCA) is in charge of the controls over the processing establishments (EU listed and others), cold stores and transport vehicles; DOF is in charge of the controls over primary production (aquaculture farms and fishing vessels); LKIM is in charge of the controls over landing sites.

As a general rule each one of the above mentioned facilities are inspected by CAs staff every six months, one at the time of approval with a more thorough inspection (called a compliance audit) and the other six months later (called a surveillance audit).

Although the approval of processing establishments and cold stores has no expiry date these facilities are also thoroughly inspected by the CA every six months (surveillance audit). These facilities must have in place permanent procedures based on the HACCP principles. The HACCP plans are evaluated and approved by the CCA, under the HACCP certification scheme. The CCA issues an approval certificate for the HACCP plan valid for two years in which are also identified the products authorized for production.

The interval between audits can be reduced in the case of detection of non-compliances: if in one audit it is concluded that the FBO unit is partially compliant a new audit within three months must take place; if the outcome of the audit indicates that the FBO unit is non-compliant a new audit must take place within 14 days.

During each audit a report must be drafted, indicating the conclusion of the audit and requesting the correction of the deficiencies identified. A CAR is then issued where deadlines for the implementation of those actions is indicated.

Spot checks can be performed (specially to evaluate the hygiene conditions of operation, traceability, reception and storage of raw materials, labelling, documentary records and general structural conditions) in parallel with other official activities of the CAs staff, such as, export certification and official sampling and monitoring.

Primary production fishing vessels and aquaculture farms

With regard to the aquaculture farms and fishing vessels the FVO team noted that:

- The aquaculture farms and fishing vessel visited were under the supervision of DOF and were audited by CA staff with the defined frequencies and following the adopted procedures. DOF made available records of those visits which were in line with the situation observed by the FVO team. CARs were issued when deficiencies were identified and deadlines for correction were set. The FVO team also observed written evidences of the follow-up of the deficiencies.

- Various files of other aquaculture farms and fishing vessels were reviewed by the FVO team. The records were found to be compliant with CA procedures and in general those facilities were in compliance with requirements equivalent to the ones of the EU.

- In the aquaculture farms visited there were records regarding the production cycles, source of the fingerling, mortality or survival rates, medical treatments given to fish/shrimp, feed (origin, usage and residues analyses), pond treatments, and fishery products analyses (mainly for residues of pharmacologically active substances). All the analyses results observed by the FVO team were within EU tolerances.

- The aquaculture farms and fishing vessels visited by the FVO team can be considered as in line with the EU requirements.

Landing sites

With regard to the landing sites the FVO team noted that:

- The CA files reviewed indicated that the frequency of the visits was broadly respected and that the adopted procedures were followed by the CA staff. Records of the landing site activities, which includes temperatures, organoleptic checks, analyses on water, ice and fishery products, were provided by the site owners and found generally as adequate.

- Verification of the unloading conditions is performed by LKIM officials three times per year during official controls of fishery products. Samples of water and ice are also taken to verify compliance with requirements equivalent to EU rules.

- The landing sites visited were approved by LKIM and under its supervision. Nevertheless, the FVO team noted that to one an approval had been granted that would allow the preparation of fish (mainly gutting) in spite the fact that the landing site lacked permanent

procedures based on HACCP principles (see section 5.1). However, the CA informed the FVO team that no preparation of fishery products had occurred in this or in any other landing site.

- The two landing sites visited can be considered as in line with EU requirements. Nevertheless, in one of them the CAs officials were not able to provide evidence that an appropriate follow-up had been done of the corrective actions to address a shortcoming concerning the microbiological quality of water.

Facilities handling fishery products

With regard to the facilities handling fishery products the FVO team noted that:

- All establishments visited (which includes one cold store) were approved by FSQD and were under its official supervision. Records of official controls were made available both by the CA and the FBOs. The official controls were performed in accordance with CA procedures and following the defined frequencies. At the time of their visits the CA officials drafted inspection reports with the respective conclusions and indicating the deficiencies noted (when applicable). When deficiencies were indicated a CAR requesting corrective actions was issued and deadlines for their implementation were fixed.

- In general the majority of establishments visited could be considered as broadly in line with EU requirements. Nevertheless, in almost all cases it was noted that the temperature sensor in the cold stores was wrongly located, which undermines the reliability of the temperature records for the storage of frozen fishery products. Other minor deficiencies regarding production hygiene, equipment and structures were found in some establishments, nevertheless, those deficiencies do not have a significant impact on the safety of the product.

- Traceability exercises showed that the control system in place is fit for purpose and provides a reliable identification of the source of raw materials.

- The CA also samples, at establishment level, water/ice to test for parameters equivalent to EU requirements. The CA also takes samples of fishery products for additives testing, where applicable, in accordance with their procedures and within the defined frequencies. Several analyses results were checked by the FVO team and the results were in the majority of the cases in line with EU rules.

- However, two establishments could not be considered as meeting EU equivalent standards due to the shortcomings observed during the FVO visit. In one case the FVO team found structural and hygiene deficiencies in the sealing area and shortcomings with regard to the control of parasites (not carried out in line with the EU requirements or providing equivalent assurances). In the other establishment the FVO team noted shortcomings regarding the own-checks for histamine in fishery products (TVB-N analyses were performed for each incoming batch of raw materials and their results were used to decide on the need to perform additional histamine checks – the species concerned were *Scombridae* and *Clupeidae* for which the EU has not defined TVB-N maximum admissible levels).

Import controls of fishery products

The control system currently implemented for imported raw material for processing and further export to the EU is still the one described in the last FVO audit report and is based on written procedures.

The FVO team noted that:

- The system for controlling those imports is correctly implemented by CA staff and follows principles comparable with those of the EU.

- At the time of EU export certification, documentary checks verify the eligibility of the imported raw materials used for the production of the fishery products intended for export. The checks include the verification of the exporting country's approval for EU exports, whether the establishment of origin of the raw materials is EU listed and if the raw materials are accompanied by a health attestation covering the EU import health requirements.

Follow-up of RASFF notifications

Since the last FVO audit only one RASFF notification (news) was issued with regard to the import of fishery products to the EU and it was related to "unauthorised import of fish and fishery products from Malaysia". This notification was issued following the information sent by the CCA to Commission services as regards batches produced from raw materials not EU eligible.

The CCA has also drafted and implemented a SOP to handle RASFF notifications. The FVO team received a copy of the SOP which in general can be considered as fit for purpose. Its implementation could not be assessed due to the absence of other RASFF notifications since last FVO audit.

Conclusions

The CAs followed-up satisfactorily Recommendation No 2 of the previous FVO audit report which can be considered as adequately addressed.

The official control system of production and placing on the market of fishery products covering the entire fishery products production chain is well designed and provides an adequate basis to provide the necessary guarantees regarding the export of fishery products to the EU.

However shortcomings were noted by the FVO team in the implementation of that system, in particular in the controls over the establishments visited, which undermines the ability of the CA to deliver the guarantees required for the export of fishery products to the EU.

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

Findings

Official controls of fishery products to be exported to the EU are carried out by the different CAs based on SOPs and control programmes defined by each one of them and implemented throughout the production chain in accordance with their defined competencies. These SOPs define the controls that need to be carried out on fishery products, the forms and procedures to be used during the performance of those controls and their frequency.

In this regard the FVO team noted that:

- Organoleptic examinations are carried out all along the production chain, in general respecting the set frequencies, by DOF at the fishing vessels, by LKIM at the landing sites and by FSQD at the establishments. Records of those controls were made available by the CAs to the FVO team which found them as adequate, in accordance with the adopted procedures and respecting the EU applicable rules.

- Samples of fishery products are taken regularly all along the production chain by the CAs to verify compliance with the freshness criteria. The CA can also take any additional samples where the organoleptic examinations reveal doubts concerning the freshness of fishery products. The FVO team verified some of the analytical results for the official samples and found all of them compliant with EU standards.

- Official testing of fishery products for histamine is performed by FSQD and DOF staff within the defined frequencies and for fish species associated with a high amount of histidine. Sampling is random and covers the entire production chain. Each of the official samples is made of nine units and the analyses conclusions are based on the results of the sample units concerned. The analytical method used is the EU one. Analyses results observed were in line with the EU requirements.

- Official samples to control the level of environmental contaminants in fishery products are taken by FSQD and DOF staff in accordance with the applicable procedures and with the defined frequencies. The samples are analysed for heavy metals (mercury (Hg), lead (Pb), cadmium (Cd) and tin (Sn)), PCBs and PAH. Both CAs have adopted, in their SOPs, the sampling rules and the analytical methods (including their performance criteria) defined in EU requirements.

- Fishery products of aquaculture origin are subject to official sampling for contaminants and residues of pharmacologically active substances under the framework of the Malaysian "Aquaculture Residues Monitoring Plan" (hereinafter the Plan).

    - All aquaculture farms approved for participation in the production chain for EU export are covered by the Plan. The Plan sets up the number of yearly samples to be taken for each substance which is then divided amongst all aquaculture farms according to their production figures and species.

    - During the implementation of the 2011 plan analyses on ivermectin residues were carried out only in one region. The CA stated that in 2012 this test will be carried out in all regions (with aquaculture farms). The CA also informed the FVO team that analyses on amoxicillin residues started only in 2012. As referred to in section 5.1 currently aquaculture fishery products are not analysed for all their potential residues.

    - Although the information from the CA indicated that only tetracyclines were used, the

FVO team was informed by an operator that amoxicillin was also used.

- Samples are taken by the farm operators under the supervision of DOF staff from ponds selected by the latter. Sampling bags are closed but not sealed, which is not line with Commission Decision 98/179/EC. There are cases where an official sample is not under CA control, e.g. in the case where it is transported by an outside transport provider such as via air freight. A sampling form accompanies the samples from the aquaculture farms to the laboratories. The part the of sampling form that is delivered to the laboratory ensures the confidentiality of the sample and indicates the substances to be checked for.

- The CAs perform, along the production chain, checks on fishery products to ensure that poisonous fishery products are not exported to the EU.

- Samples of fishery products are taken, where necessary, by the CAs to test fishery products for the EU regulated microbiological criteria. The sampling is carried out with the defined frequencies in accordance with CAs procedures. The FVO team verified some of the analytical results for the official samples and found all of them compliant with EU regulations.

- Fishery products are subject to official sampling for parasites. Both FSQD and DOF take official samples for parasite analysis by the official laboratories. The sampling methods and frequency is defined in the CAs SOPs. The FVO team verified some records regarding to the parasite testing and found that the frequencies were respected and the results were in line with the EU requirements.

Conclusions

The official controls of fishery products (including aquaculture) are performed adequately by the CAs and they include organoleptic checks, test of freshness indicators, poisonous fishery products checks, histamine tests, monitoring arrangements for residues and contaminants, parasites checks and microbiological analyses. These are generally in line with EU requirements. However, the shortcomings noted do not allow the CA to ensure the legal and analytical integrity of all official samples.

5.6 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 country certifying officers offer guarantees at least equivalent to those laid down in this Directive.

Findings

With regard to official certification the findings described in the previous FVO audit report are still valid – the CA has in place procedures for the export health certification, only authorized officials

can signed the health certificates and checks on the origin of the raw materials are performed.

The FVO team noted that:

- The issuance of export health certificates is carried out in accordance with the defined procedures. Currently the CA uses the FExCIS system for electronic certification; if the informatics system is not operational the certificates are issued manually.

- The CA has a list of authorised certifying officers (supplied to the FVO team) which are the only ones allowed to sign the certificates.

- The export health certificate used is in line with the model defined by Regulation (EC) No 2074/2005.

- The CA performs physical and identity checks on the products to be exported. During these checks CA officials confirm the EU eligibility of the raw material and verify the production and storage conditions and also the packaging and labels of the products concerned.

- In one establishment it was noted that for the same consignment two original certificates in two different languages (bearing the same certificate number but being two separate and identical certificates) were issued and signed by the CA official. This situation occurs when the FBO requests the issuance of the certificate in two EU languages. However, the FVO team found that depending on the entry point in the EU one of the original certificates stays in Malaysia in the possession of the FBO.

Conclusions

The export health certification implemented by the CA is, in general, adequate and in line with the EU requirements. Although these guarantees are adequate, the system as implemented could result in the misuse of the original certificates issued.

5.7 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

The CA has access to a network of designated and accredited official laboratories capable of performing the analyses defined in the official control programmes and equipped for that purpose.

With regard to the laboratories visited the FVO team found that:

- The laboratories were accredited to ISO 17025, the scope of the accreditation included the relevant tests performed by each laboratory, the methods used have been validated in house (validation files were made available to the FVO team) and were the EU reference ones or equivalent, and have participated in several relevant international proficiency test with satisfactory results.

- They had a quality manual in place together with written procedures that ensure an adequate handling and traceability of the official samples. Training procedures for staff are also in place.

- The laboratories have in place quality control schemes (including quality charts) in order to ensure the reliability of the test results. No major deviations were observed by the FVO team with regard to the results of these controls.

- The laboratories have in place a system of internal audit and are also audit by a specific service of the CCA. Reports of those audits were presented to the FVO which found them as adequate and fit for its purpose.

- In one laboratory it was observed that the data related to the performance criteria of the methods used for the determination of heavy metals levels (mainly Cd and Pb) varied between different documents – validation files, analyses results (official bulletins) and internal documents. In accordance with the data found in the validation studies the performance criteria were in line with EU requirements, but in according to the internal laboratory documents and the official bulletins those performance criteria were not in line with EU requirements. Moreover, the term "Limit of Quantitation" was being used in the official bulletins without being clear if this limit referred to the Limit of Detection (LOD) or the Limit of Quantification (LOQ) – to note that the values mentioned on the official bulletins as the "Quantitation Limit" were the same as the ones indicated in the internal documents as LOD.

- Additionally, the FVO team also found that the LOD for Pb and Cd defined in the CA ARMP were not in line with EU requirements.

Conclusions

The CAs followed-up satisfactorily Recommendations No 4 and 5 of the previous FVO audit report which can be considered as adequately addressed.

The official laboratory network available to the CA for the performance of official analyses can be considered as adequate and broadly in line with the EU requirements.

Although the FVO team concludes that while the performance criteria of the analytical methods used for heavy metals is in line with the EU rules, the shortcomings do not enable the CA to have full confidence in the results presented to them.

6 Overall Conclusions

Although the fact that recommendation No 2 cannot be considered as fully addressed (knowledge of official staff) the overall follow-up of the previous FVO audit report was adequately performed.

In principle the current organisation of Malaysian CAs and the control systems implemented offer sufficient guarantees concerning the sanitary conditions of fishery products to be exported to the EU as per the export health certificate defined by Regulation (EC) No 2074/2005.

Nevertheless shortcomings were noted by the audit team with regard to standards and legislation, knowledge levels of all staff involved, the implementation of the approval procedures for landing sites, the approval requirements for EU listed establishments, the official control of the establishments and the certification procedures.

7 Closing Meeting

During the closing meeting held in Kuala Lumpur on 10 May 2012, the FVO team presented the main findings and preliminary conclusions of the audit to the CAs. The CAs acknowledged the findings and preliminary conclusions presented by the FVO team and committed to correcting the deficiencies found.

In addition the CCA presented to the FVO the official note correcting the approval of one establishment and other additional documentation requested during the audit.

8 Recommendations

The Malaysian CCA 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:

N°.	Recommendation
1.	The CAs should ensure that standards at least equivalent to EU requirements are applied to fishery products to be exported to the EU, in particular, as regards the maximum levels for contaminants defined in Regulation (EC) No 1881/2006 and the maximum limits of certain antibiotics defined in Commission Regulation (EU) No 37/2010.
2.	The CAs should ensure that standards at least equivalent to EU requirements are applied to fishery products to be exported to the EU, in particular, as regards the substances allowed to be used as additives which are set out in Regulation (EC) No 1333/2008.
3.	The CAs should ensure that standards at least equivalent to EU requirements are applied to landing sites and associated facilities where preparation of fish to be exported to the EU can take place, in particular, as regards the applicable requirements of Chapter II and Annex II of Regulation (EC) No 852/2004 and of Section VIII of Annex III to Regulation (EC) No 853/2004 concerning HACCP, structures and hygiene.
4.	In order to provide the guarantees required by point II.1 of the model for the health certificates for imports defined in Appendix IV to Annex VI to Regulation (EC) No 2074/2005, in particular when it refers to awareness of EU relevant provisions and the attestation of fishery products manufacture requirements, the CAs should ensure that all relevant staff performing official controls (including officers signing export health certificates) is aware of relevant EU requirements applicable to fishery products to be

N°.	Recommendation
	exported to the EU and its production chain.
5.	The CAs should ensure that the EU listed establishments are only authorised to export to the EU fishery products for which Malaysia is currently approved, as defined in Annex II to Commission Decision 2006/766/EC and Commission Decision 2011/163/EU (for aquaculture products).
6.	The CAs should endure that the fishery products exported to the EU have their origin from or were handled in establishments/facilities that comply with the relevant EU requirements, in accordance to point 2 (a) of Article 12 of Regulation (EC) No 854/2004, in particular the landing sites.
7.	The CAs should ensure that EU listed establishment are in line with the applicable EU requirements defined in Chapter II and Annex II of Regulation (EC) No 852/2004 and of Section VIII of Annex III to Regulation (EC) No 853/2004 concerning HACCP, health standards (in particular histamine), structures and hygiene.
8.	The CAs should ensure that official samples taken in the framework of the ARMP are sealed in accordance with the requirements of Commission Decision 98/178/EC in order to ensure their legal and analytical integrity.
9.	The CAs should ensure that the certificates issued are in line with the requirements of Directive 96/93/EC, in particular when the certificates are issued in more than one language.

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=2012-6461

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live 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
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
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Reg. 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

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin