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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

MALAYSIA

FROM 04 TO 14 JULY 2011

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE FOR AQUACULTURE ANIMALS DESTINED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in Malaysia, from 4 to 14 July 2011.

The objectives of the mission were to:

• assess whether the organisation of the Competent Authority (CA) and the implementation of national provisions, by which the CA controls the production, movement and import of live aquaculture animals intended for export to the EU, can be considered as at least equivalent to the EU requirements for these commodities;

• evaluate the systems and procedures in place, in order to certify that aquaculture animals exported to the EU meet the animal health requirements set out in Commission Regulation (EC) No 1251/2008, laying down the conditions and certification requirements for import of aquaculture animals and products thereof and laying down a list of vectors [Annex IV parts A &B];

The main conclusions are:

- *In spite of the considerable effort by the Malaysian CA to organise the control system in the sector audited the requirements and standards applied are not yet equivalent to standards required by EU legislation to import aquatic animals. The CA structure, the legal framework and the practical instruments to apply the rules, i.e. SOPs, check lists and training modules are now all in place for officials to use. However, too little time has elapsed since the time these procedures have been established for the staff at any level to be sufficiently acquainted with the daily implementation of the rules and standards in the field.*

- *The animal health situation in aquatic animals is at best inconclusive due to the limited surveillance carried out so far, the shortcomings in the notification system and limited movement controls. Furthermore, the standards applied in general by the APBs cannot guarantee the animal health situation at any point in time. It should be noted, however, that for some of the aquatic animal diseases Malaysia could be declared free at country level due to its particular ecological conditions. The present diagnostic capacities are not able to guarantee a reliable diagnosis in spite of the use of high quality equipment and of significant efforts made to train staff. The system is, however, moving towards the application of quality systems and accreditation.*

The report makes a number of recommendations addressed to the Malaysian authorities, aimed at rectifying the shortcomings identified.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AAA	Aquaculture &Aquatic Animals
APB	Aquaculture Production Business
CCA	Central Competent Authority
CA	Competent Authority
DOF	Department of Fisheries
EC	European Commission
EHN	Epizootic Haematopoietic Necrosis
EU	European Union
EUS	Epizootic Ulcerative Syndrome
FBD	Fishery Biosecurity Division
FVO	Food & Veterinary Office
FQC	Fish Quality Certificate
KHV	Koi Herpes Virus
MAQIS	Malaysian Quarantine and Inspection Services
OIE	World Organisation for Animal Health
RL	Reference Laboratory
SVC	Spring Viraemia of Carp
SOP	Standard Operation Procedure
TC	Third countries
VHS	Viral Haemorrhagic Septicaemia
WSD	White Spot Disease

1 Introduction

This audit took place in Malaysia from 4 to to 14 July. The audit team was composed of two FVO auditors and one expert from a European Union (EU) Member State.

The team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA).

2 Objectives

The objectives of the audit were:

• to assess whether the organisation of the Competent Authority (CA) and the implementation of national provisions, by which the CA controls the production, movement and import of live aquaculture and aquatic animals (AAA) intended for export to the EU, can be considered as at least equivalent to the relevant EU requirements;

• to evaluate the systems and procedures in place, in order to certify that AAA exported to the EU meet the animal health requirements set out in Commission Regulation (EC) No 1251/2008, laying down the conditions and certification requirements for import of aquaculture animals and products thereof and laying down a list of vectors [Annex IV parts A &B];

In pursuit of the mission objectives, the following meetings were held and sites visited:

Visits/Meetings		Comments
Competent Authorities	**4**	Opening and closing meetings. Three additional meetings with representatives of the three CA in the three states visited
Laboratories	**3**	Sepang, Perack & Johor
Aquaculture Production Businesses	**9**	Farms and traders

3 Legal Basis

The audit was carried out in agreement with the Authorities of Malaysia and under the general provisions of EU legislation[1] 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 rules;

• Article 58 of Council Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

Legal references cited in this report are listed in the Annex and refer to the latest amended version.

4 Background

Serious shortcomings were identified throughout the production chain of AAA animals and ornamental fish in Malaysia during the mission DG (SANCO)/2008-7679. As a consequence the

[1] EU legislation (Internet): http://europa.eu.int/eur-lex/en/search/search_lif.html

Commission adopted Decision 2008/641/EC, which was subsequently repealed and replaced by Commission Regulation (EC) No 1252/2008, suspending imports of consignments of certain aquaculture animals into the Community from Malaysia. Imports into the EU of AAA decreased greatly in 2009 and 2010 following those restriction measures. The only AAA exported now from Malaysia to the EU are ornamental tropical animals.

5 Findings And Conclusions

5.1 Legislation

5.1.1 Legal requirements

Article 23 of Directive 2006/88/EC requires the Commission to take account of the national legislation in force and the powers of the CA when drawing up or updating the list of third countries (TC) approved to export live AAA to the EU.

5.1.2 Findings

The CA has made a considerable effort in the last two years to set up standards for the production, trade and export of AAA. Most of the standards and rules are in the form of Standard Operating Procedures (SOPs). For some of the rules, however, it was not clear if the SOP had legal status or not. This was in particular the case of the compulsory notification of the fish diseases mentioned in the certificates to export the commodity to the EU. The CA stated that rules on fish import/export animal health are to be finalised by the end of 2011.

5.1.3 Conclusions

The legal framework and standards set up by the CA can enable them to control the AAA sector, once the effective legal status of disease notification has been clarified and the animal health rules on import export completed.

5.2 CA and official controls

5.2.1 Legal requirements

Article 23 of Directive 2006/88/EC requires the Commission to take account of the following factors when drawing up or updating the list of TC approved to export live AAA to the Community: the organisation of the CA and its inspection services; the powers of these services; the supervision to which they are subject; and the means at their disposal, including staff capacity, to apply their duties and powers.

5.2.2 Findings

<u>Management structure</u>

The CA for all matters related to fish and fisheries in Malaysia is the Department of Fisheries (DOF) of the Ministry of Agriculture and Agro-based Industry. Following the Report DG (SANCO)/2008-7679, the CA established the Fishery Biosecurity Division (FBD). The FBD includes the network of laboratories performing tests on fish diseases. In this regard it should be noted that the reference laboratory (RL) in Sepang has not yet received a proper designation. The FBD is organised in two levels: central and regional or state level ("state level", as regions in

Malaysia are constituted as states). More than 200 staff were employed at the time of this audit, including the laboratory staff.

The establishment of a new department, probably to be attached to the FBD in the near future, was at the final stage at the time of the FVO audit. This department is now operating under the Malaysian Quarantine and Inspection Services (MAQIS), performing controls on import and export of AAA. In spite of the fact that the activities of this new body should be carried out according to a comprehensive SOP the FVO team found a certain number of shortcomings that affect the controls, which are discussed in Chapter 5.5.

Resources for the performance of controls

The FBD staff at regional level are in charge of the official controls on the AAA production businesses (APBs). The control activities are to be carried out following the standards established in a set of SOPs. The CA has since the mission in 2008, invested a lot in producing SOPs for all the different aspects of the official controls on the sector (farm registration, farm quality certification (FQC) farm auditing etc.). The SOPs include check lists to be used during the controls. From the information provided prior to the FVO audit and from the findings of the audit itself, it was understood that most of the SOPs had been finalised in the last months or even weeks before the FVO audit itself.

For the reasons above the standards and procedures in the official controls started to be implemented only very recently. The findings in the following chapters (especially on registration and authorisation of APBs) show that at present staff are not always properly acquainted with the application of standards and procedures. Also, check-lists in certain cases are not designed to allow the staff in the field to assess the respect of crucial requirements, such as the mortality records (in one case the audit team found that a case of high mortality in fish during quarantine had gone unnoticed by the CA during the 72 hours pre-export visit). Concerning training the CA provided the audit team with evidence of several training activities carried out for staff performing official duties and for laboratory staff.

<u>Organisation of controls and enforcement measures</u>

The CA has established a system to organise and to plan the official controls, including the renewal of APBs Fish Quality Certificate, according to a specific frequency. The audit team found documentation of the different kinds of controls in all APBs visited. However due to the fact that the system of controls has only started recently it was not possible to assess the capacity of the CA to maintain the frequency of controls, as established, over a certain period.

No proper system of routine supervision is in place yet from the central level to the state level of the CA, although both registration number and FQC are given at central level. Ad *hoc* supervisory activities would, however, be carried out by the CCA if problems would arise, for instance in case of complaint from operators of the sector. Supervision by the CCA of the CA activities can also be considered, to a certain extent, as participation of the CCA in the compliance audit done before granting the FQC to the APBs (refer to chapter 5.3.2 for more details). The CA also considers as supervision activities meetings at which regional staff are present such as a meetings held when an APB is found positive for AAA diseases or a meeting on laboratories accreditation. The CAs are also required to send monthly reports on certificates issued and on surveillance activities to the CCA.

Concerning enforcement powers, at least in one case repeated breaching of export requirements by one exporter did not lead to any specific sanction apart from stopping the export of the specific shipments.

5.2.3 Conclusions

A considerable effort has been made by the Malaysian CA to organise the control system for the sector audited. A structured CA is in place and is staffed with trained officials. Officials have now a set of working instruments in the form of SOPs for all aspects of the official controls. However part of the system (including the SOPs) has been either very recently completed or is not complete. This can expose the official staff in the field to shortcomings in the implementation of the official controls. Thus the system still does not guarantee equivalence with the EU requirements such as the diagnostic capacities or the real capacity of enforcing the rules with adequate sanctions. The lack of a structured supervision from the centre to the states could also explain mistakes in the implementation of the system, in spite of the fact that the CCA are involved themselves in certain activities.

5.3 OFFICIAL CONTROL IN THE ORNAMENTAL AAA SECTOR

5.3.1 Legal requirements

Article 23 of Directive 2006/88/EC establishes that countries may only appear in the list of TC approved to export if they can provide appropriate guarantees as regards compliance or equivalence with the relevant animal health requirements of EU legislation, in particular, with those that apply to the production, manufacture, handling, storage and dispatch of live AAA intended for export to the EU.

The general animal health requirements established in the model health certificate for the export of live AAA to the EU are laid out in part A and B of Annex IV to Regulation (EC) No 1251/2008.

Articles 4 to 9 of Directive 2006/88/EC establish requirements and conditions for the authorisation and official control of APB.

5.3.2 Findings

<u>Registration and authorization of the APBs</u>

A procedure has been established to register and to give the FQC (authorisation) to APBs specifically to export to the EU. As described above, comprehensive check-lists and SOPs are available for the CA to carry out these activities. Only farms which are registered and are free from the relevant diseases at the time of the pre-registration are allowed to follow the procedure to obtain the FQC. Registration of the farms started in 2010 and testing started in May 2010. In spite of SOPs, check-lists and training provided to staff carrying out registration and authorisation the audit team noted that farms can frequently be registered and/or approved without complying with basic standards as required by the EU or by the Malaysian rules (treatment of inlet and outlet water system, documentation etc.).

It should also be noted that the change of status for a given fish disease, for instance from negative to positive, does not necessarily change the registration/authorisation status of an APB. In such case the APB is not entitled to sell animals for export but it maintains the registration and authorisation

and can continue selling the animals in the internal market. This can expose exporters to buying fish from non eligible farms (as was shown to have happened in one of the states visited).

Supervision of APBs (official controls)

The supervision system established for the APBs with an FQC allows for a compliance audit at the yearly renewal of the authorisation and for a surveillance visit six months later. As already mentioned the system of official controls as it is now had only been in place for a very short time at the time of the audit. It was, however, possible to verify that in case of non compliance, found for instance during the compliance audit for renewal of authorisation, the CA have a system to follow up the progress made by the operators to address the problems. Reports on the few visits made in the APBs from the start of the system were in general made available to the FVO team.

5.3.3 Conclusions

Although the system is in place to certify and supervise APBs this does not yet guarantee that the standards applied are equivalent to those required to export AAA to the EU. Although training has been provided to staff performing the official controls in the sector, the field experience is still very limited for the officials at any level of the CA to correctly assess the conditions in an APB. Furthermore although the activities carried out were in general recorded, the scarcity of material due to the limited number of official controls carried out so far does not allow conclusions to be drawn on the real capacity of the CA to maintain an acceptable degree of equivalence in their official controls.

5.4 ANIMAL HEALTH SITUATION

5.4.1 Legal requirements

Article 23 of Directive 2006/88/EC establishes that countries may only appear in the list of TC approved to export if they can provide appropriate guarantees as regards compliance or equivalence with the relevant animal health requirements of EU legislation and, in particular, require the Commission to take account of the following animal health factors when drawing up or updating the list of TC approved to export live AAA to the EU:

- the health status of farmed and wild aquatic animals in the TC, with particular regard to exotic animal diseases and any aspects of the general aquatic animal health situation in the country which might pose a risk to aquatic animal health in the EU;

- the regularity, speed and accuracy with which the TC supplies information on the existence of infectious or contagious aquatic animal diseases in its territory, particularly the notifiable diseases, listed by the OIE;

- the rules on the prevention and control of aquatic animal diseases in force in the TC and their implementation, including rules on imports from other countries.

5.4.2 Findings

Current fish diseases situation

The OIE official site reports, for 2010 and 2011, only the presence of white spot disease (WSD) among the diseases listed in the relevant certificates to export AAA to the EU. WSD was widespread in 2010, in particular in crustaceans for food farms. In this regard it should be note that in certain states production of fish for food and production of ornamental fish are carried out in the same areas. During the FVO audit it was understood that Koi herpes virus (KHV) has also been found in ornamental fish since surveillance started in April 2011; in the Penang area 10% of farms among the sampled were found to be positive. However no cases of KHV were reported from fish for food farms, since 2009.

Spring viraemia of carp (SVC) and epizootic ulcerative syndrome (EUS) were also not reported in Malaysia. Other aquatic animal diseases such us Red Sea Bream Iridoviral disease and Viral Nervous Necrosis in fin fish are reported to occur at least in Johor state, in fish for food farms. Infectious Hypodermic & Haemotopoietic Necrosis in crustaceans was also reported in 2010. However as a general remark it has to be said that active surveillance for fish diseases (as discussed further below) started only recently in ornamental fish farms and no structured surveillance plan is carried out in fish for food farms. Shortcomings in reporting mortalities can also bias the real animal health situation concerning certain diseases (see below).

Concerning some of the other listed diseases, Malaysia could apply for freedom at country level. This is the case, for example, of viral haemorrhagic septicaemia, infectious salmon anaemia infectious haemotapoietic necrosis and infectious pancreatic necrosis. In fact concerning those diseaseases, no susceptible species are reported to be present in the country. Furthermore the environmental conditions are in general (with the probable exception of a mountainous area in the North West) not suitable for the susceptible species and for the viruses causing those diseases.

Notification system

Notification rules are established in a SOP. As discussed in chapter 5.1.2, a list of fish notifiable diseases is annexed to the SOP . The list includes all fish diseases listed by the OIE and by the EU. According to the SOP, farmers, exporters/importers and all stakeholders are supposed to report any suspicion based on increased mortality. If one of the listed diseases is confirmed, the farm is informed that it is no longer allowed to export.

However, in spite of the comprehensive SOP in place, the FVO team found that high mortalities are not always reported: in one case 50% mortality in ornamental fish in a quarantine were not reported to the CA; in an other case the FVO team remarked that more than a 20% of mortality was not reported; in another APB forms for recording mortality were not available. From discussions held with operators and CA and from the evaluation of a check list it was understood that the CA had marked as a limit for abnormal mortality 25%, although none of the APB s operator would think that this percentage would be acceptable, being extremely high. Apart from those shortcomings the FVO team verified that the notification system works correctly when positive cases are found during surveillance. Evidence was seen that in such cases follow-up of positive result is carried out and an epidemiological investigation is performed.

Disease prevention in farms and during transport

APBs are not required to have a set of good hygiene practices procedures, in order to minimise the risk of introducing a disease. Only from March 2011, however, they are required to keep records for several items (waste water treatment, mortality records, treatment records, etc). In general farms do not have their own surveillance programme and no guidelines have so far been established for farmers with positive results for a given disease. More in particular, shortcomings found during the FVO visits includes:

- inlet water treatment not always correctly implemented: water from dirty stream,

susceptible species of unknown health status in water source.

- waste water treatment not existent or not efficient in several occasions: UV lamp not working in one case, inadequate concentration of chemical for treatment in some others cases no information on treatment of waste water after import although this should be applied according the procedures established by the CA.
- concentration of disinfectants in foot baths not adequate.
- introduction of fish of unknown origin jeopardizing the health status of farms and the efficiency of any surveillance campaign.

Movement requirements

There are no strict measures established to control the movement of any live fish within the country, the only exception being the transport of fish from the Malaysian peninsula to Sabah or to Sarawak. In that case, the biosecurity unit of the state of origin has to issue a health certificate before shipment of live ornamental fish to those two states in Borneo. For any other kind of internal movement, farms can buy fish from any other farm with little possibility of controlling the movements for the CA. Invoices kept by the APBs (requirement introduced in March 2011) are the only means to know the movement of fish.

During the audit it was in fact found out that uncontrolled and/or undocumented movements of fish between farms can happen frequently (introduction of brood stock, movement of fish to other farms for growing). This problem is to a certain extent mitigated by the possibility of tracing back aquatic animals by the operators and by the CA. In fact, in spite of the shortcoming highlighted, when traceability exercise were performed, fish could be traced back to a farm or to a group of farms.

Surveillance, monitoring and eradication

A detailed SOP was created in January 2010 and revised in 2011 for the sampling of fish, to assess the presence of certain diseases. Training was provided to field staff on how to implement surveillance and the CA provided to the FVO team the evidence of the training sessions carried out. Surveillance activities started in different periods and different areas for the different diseases (surveillance for WSD started in 2010 in the South, surveillance for KHV and SVC also started in 2010 but not all over the country). In March 2011, an extensive surveillance programme started also for goldfish haematopoietic necrosis virus. So far no structured surveillance is in place for EHN and very limited surveillance has been carried out recently for EUS.

Concerning the results of the surveillance as described in 5.3.2 when notifiable fish diseases are detected in a farm, this remains registered but the DOF informs the farm in a letter that it is no longer allowed to export fish. However, the CA has no power to stop the production or internal movement/trade of fish from such farms, although such a farm would appear as not fit for export in an official website. As a result, considering also the limited control on movements, fish from infected farms can freely circulate in the country and has been repeatedly detected in exporting premises by the CA. Moreover, although random sampling for controls of diseases is carried out prior to export, results of these checks may be obtained only after the animals have already been exported. This creates risk that animals from infected farms enter the international market. In fact the CA has no legal basis or power to stop the export of AAA without a positive result.

Contingency plans, establishing disease free areas.

A basic SOP has been prepared to operate in case of emergency. This procedure gives a framework of a system to be applied in case a notifiable disease is reported in the country. Concerning the establishment of fish disease free areas, a final decision has to be taken on what level would be

more convenient to operate. Comments were made by the CA on the possibility of working towards a disease-free status only at farm level. Considering that surveillance for the diseases mentioned in the certificate has started at most one year ago, at the time of the FVO audit no APB has sufficient data to be declared as free from any of the relevant diseases

5.4.3 Conclusions

The status of Malaysia for the aquatic animal diseases relevant for export to the EU can, in general, be considered as inconclusive. Surveillance for these disease has started too recently and too limited in an area to have more precise information. Incertitude on this aspect is also due to the inadequate notification system. Continuation of surveillance activities might give more valuable information in the near future. For some of the aquatic animal diseases, Malaysia could declare freedom at country level, but no scientific proof for this has yet been compiled for submission to the international community.

Concerning the controls on the risk of spreading fish diseases Malaysia does not yet implement a system that can be considered equivalent to the system required by the EU rules. Measures of disease prevention in farms and especially rules on animal movements are such that it is not always possible at any point in time to define the health status of an APB, with regard to a specific disease. The situation could be improved, and is to a certain extent mitigated, by the recently introduced record keeping in farms.

5.5 IMPORT AND EXPORT

5.5.1 Legal requirements

Article 23 of Directive 2006/88/EC establishes that countries may only appear in the list of TC approved to export aquaculture if they can provide appropriate guarantees as regards compliance or equivalence with the relevant animal health requirements of the EU legislation and, in particular, require the Commission to take account of the rules on the prevention and control of aquatic animal diseases in force in the TC and their implementation, including rules on imports from other countries.

Animal health requirements for the importation into the EU of aquaculture animals are established by Regulation (EC) No 1251/2008, in part A of Annex IV thereto; the requirements for aquatic ornamental animals are established in part B of the same Annex.

In addition, Annex V to that Regulation lays down the general principles to be applied when completing the model certificates, prescribing that the CA of the country of origin shall ensure that principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.

Directive 96/93/EC establishes the following principles:

- in Article 3, point 2, that certifying officers do not certify data of which they have no personal knowledge, or which cannot be ascertained by them. However, point 4 of the same Article permits certifying officers to certify data ascertained by an authorized person acting under their supervision and data obtained within the context of monitoring programmes, quality assurance schemes or epidemiological surveillance systems, provided they can verify the accuracy of those data;

• in Article 3, point 3, that certifying officers do not issue certificates for animals that they have not inspected or which have passed out of their control;

5.5.2 Findings

Import/export in general

Certificates/requirements for import and export to and from Malaysia were harmonised by the CA in 2011. Concerning imports a SOP was established and entered into force in June 2011. That procedure is based on the principle that countries exporting aquatic animals to Malaysia should declare freedom from a list of diseases. The list is consistent with the EU listed diseases for the same animals. However during the FVO visit to a MAQIS border control post it was revealed that imports were still accepted with all kinds of health declarations. Import certificates from certain countries had only a very general health declaration; in other cases the declaration of freedom was available for some diseases but not for others. That means that if any ornamental fish is imported (or transits) to be re exported to the EU it is not always possible to know the real health status of that fish regarding the diseases mentioned in the EU certificates. No remarks had been made by the CA on this shortcoming to MAQIS at the time of the FVO audit.

A procedure has also been in place from March 2011 for the export of AAA. This procedure allows for a general health attestation to be signed by the CA complemented by a document specifying the country requirements. Different procedure for export were designed to take into consideration specific requirements of importing countries; a special export procedure has been established for the EU.

Exporters are not allowed to buy and export fish from a farm which is not on the updated list of registered farms. However, the experience in the last two years demonstrates that the measures in place are not always effective to prevent exporters from doing so. In fact the rule is very difficult to implement due to the shortcomings in movement control and due to the rules on authorisation/registration (refer to the relevant chapter 5.3.2).

In 2010 a case of WSD was reported by an EU member state, in ornamental crustaceans imported from Malaysia. However the CA said that although they were able to trace back the origin and movements of those animals they were not able to confirm the presence of the disease in the investigated premises.

No sanction has been implemented, so far, in case of breaches of the above described rule, even when the same operator kept breaching the same rule (refer to chapter 5.2.2 last paragraph). Furthermore, although pre-quarantine for export to the EU is also applied, the required duration (7-14-21 days according to the species to be exported, and to the specific diseases) is not always respected or applied at all. In one case an exporter who had had an FQC issued in 2010 was not even aware of the quarantine requirement.

Concerning in particular the exports to the EU the team could verify that in general the requirement to inspect animals within 72 hours prior to export is correctly implemented. However the control was not always carried out in the established way, namely the records of the quarantine were not always evaluated. Furthermore, in one case, the control was not done in the farm but at the airport, where it was not possible for the official in charge to check the necessary records concerning the batch of animals exported.

5.5.3 Conclusions

As for other aspects of the system to control the sector of AAA the CA has now established clear

procedures. However these procedures are very new and not yet properly implemented. So far the system is insufficient to guarantee the health status of the farms of origin and/or of the country.

5.6 LABORATORIES

5.6.1 Legal requirements

Article 46, 1 (d) of regulation (EC) 882/2004 allows for the Commission to evaluate the resources available to the CA of a third countries to carry out their duties, including the diagnostic capacities. The same requirement is established in Article 8, 1 (b) of Council Directive 2002/99/EC.

Article 23 of Directive 2006/88/EC establishes that countries may only appear in the list of TC approved to export aquaculture animals if they can provide appropriate guarantees as regards compliance or equivalence with the relevant animal health requirements of EU legislation and, in particular, in point 3 (h) require the Commission to take account of the regularity, speed and accuracy with which the third country supplies information on the existence of infectious or contagious animal diseases in its territory, particularly the notifiable diseases, listed by the OIE.

5.6.2 Findings

Organisation of the services

The laboratory network involved in the official controls consists of four laboratories (Sepang, Johore, Penang and Kedah). At present the diagnostic responsibilities have been allocated as follows: the laboratory in Penang carries out only screening, the one in Sepang does diagnosis for KHV and SVC, Johor for EUS, WSSD and other crustaceans diseases (both exotic and non exotic). The laboratory in Sepang is also supposed to be the reference laboratory. However there is no official assignment and definition of duties. At present the laboratory provides training for staff of the other laboratories and distributes some SOPs. It does not carry out any supervision of the activities of the other laboratories. In fact the laboratory in Sepang has no responsibilities in the confirmation of positive samples or in the distribution of reference materials, so no comparison of the diagnostic activities exists within the laboratory network.

The laboratories in the network have in general good state of the art equipment and trained people. However staff have not enough experience for certain analyses due to the fact that surveillance started only recently for certain diseases so there has not been enough time or samples to analyse for the staff to be fully acquainted with the practicalities of the different methods. Moreover after the training no comparative analyses or proficiency tests were, in general, carried out to verify if the different laboratories could work to the same standard. This is especially true for a disease such as EUS for which training was acquired in Thailand. In this regard some more activities were carried out for KHV and WSSD.

Accreditation

None of the laboratories in the network has so far achieved ISO 17025 status. The laboratory in Sepang was due for evaluation for accreditation soon after the FVO audit. The scope of the accreditation in this case includes the analyses for KHV and SVC using PCR methodologies. The quality systems in place in the laboratories visited were in general incomplete and were constituted only by some specific SOPs for particular diagnostic methods. A more complete quality system is in place in Sepang. Only one of the four laboratories has ever participated in a proficiency test and for only one disease (KHV), with very good results.

Methods

Concerning the methods used in the four laboratories some remarks were made:

- in Sepang the method used for KHV diagnosis is not in accordance with the internationally recognised method (OIE method); furthermore the method used in reality (gills used as a screening material) is not the one described in its own SOP.
- Different methods are used across the network for KHV and SVC. In Sepang the OIE method is used while in Penang a commercial kit is used. This kit has not been validated and no validation data are available from the manufacturer. No diagnostic comparative analyses of the two test are carried out.
- The method used in Johore for WSD has been validated by the manufacturing company but not by the laboratory itself. However both the company and the laboratory follow the OIE protocol for the analyses, so are internationally recognised.
- In general, no matter the laboratory or the method used for any disease no reference reagents are used.

5.6.3 Conclusions

Although the laboratory network is progressing towards a quality system, especially as far as the quality of the equipment available and the training of staff are concerned at present the diagnostic standards can not be considered equivalent to those required in the EU. The absence of a coordinating-reference laboratory has a major impact on the reliability of the diagnostic results across the network.

6 OVERALL CONCLUSIONS

In spite of the considerable effort by the Malaysian CA to organise the control system in the sector audited the requirements and standards applied are not yet equivalent to standards required by EU legislation to import aquatic animals. The CA structure, the legal framework and the practical instruments to apply the rules, i.e. SOPs, check lists and training modules are now all in place for officials to use. However, too little time has elapsed since the time these procedures have been established for the staff at any level to be sufficiently acquainted with the daily implementation of the rules and standards in the field.

The animal health situation in aquatic animals is at best inconclusive due to the limited surveillance carried out so far, the shortcomings in the notification system and limited movement controls. Furthermore, the standards applied in general by the APBs cannot guarantee the animal health situation at any point in time. It should be noted, however, that for some of the aquatic animal diseases Malaysia could be declared free at country level due to its particular ecological conditions. The present diagnostic capacities are not able to guarantee a reliable diagnosis in spite of of the use of high quality equipment and of significant efforts made to train staff. The system is, however, moving towards the application of quality systems and accreditation.

7 Closing Meeting

The closing meeting took place at the head quarters of the CA on 14 July. At this meeting the FVO audit team presented the finding and the preliminary conclusions.

8 Recommendations

The CA of Malaysia are invited to submit an action plan describing the actions taken or planned in response to the following recommendations and setting out a timetable for their completion. This information should be presented to the Commission within 25 working days of receipt of this draft report.

N°.	Recommendation
1.	The CA should review the capacity of their control system to apply legislation and standards effectively, to provide appropriate guarantees that the provisions of Article 23,3 (b) of Council Directive 2006/88/EC, are met
2.	The CA should implement a supervision system on their official control system to provide appropriate guarantees that the provisions in Article 23, 3 (b) of Council Directive 2006/88/EC, are met.
3.	The CA should implement enforcement measures to provide appropriate guarantees that the provisions in Article 23, 3 (b) of Council Directive 2006/88/EC, are met.
4.	The CA should satisfy itself that the notification system implemented allows it to provide appropriate guarantees that the provisions in Article 23, 3 (g)&(h) of Council Directive 2006/88/EC, are met.
5.	The CA should ensure that standards applied by the APBs operators provide appropriate guarantees that the provisions in article 23, 3 (c) of Council Directive 2006/88/EC are met. Furthermore CA should also ensure, when controlling the APBs, that all the requirements established in the Articles 8, 9 and 10 of the same Directive, for the sake of equivalence, are met.
6.	The CA should complete its system of official controls with a diagnostic network of laboratories that can provide appropriate guarantees that the provisions in Article 23, 3 (h) of Council Directive 2006/88/EC, are met.
7.	The CA should review the capacity of their control system to apply correctly the standards established for the import-export official controls, to provide appropriate guarantees that the provisions in Article 23, 3 (i) of Council Directive 2006/88/EC, are met.

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=2011-6116

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 1251/2008	OJ L 337, 16.12.2008, p. 41-75	Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive 2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species
Dir. 2002/99/EC	OJ L 18, 23.1.2003, p. 11-20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Dir. 2006/88/EC	OJ L 328, 24.11.2006, p. 14-56	Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals
Dec. 2008/946/EC	OJ L 337, 16.12.2008, p. 94-101	2008/946/EC: Commission Decision of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals
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