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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SOUTH KOREA

FROM 08 TO 18 APRIL 2013

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE FOR LIVE AQUACULTURE ANIMALS AND PRODUCTS THEREOF, DESTINED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office in South Korea, from 8 to 18 April 2013.

The objectives of the audit were to evaluate

(i) whether the national provisions established and implemented by the Competent Authority (CA), against which the CA controls the production, movement and import of live aquaculture animals (AA) intended for export to the EU, can be considered as at least equivalent to the European Union (EU) standards, and to evaluate

(ii) 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 legislation.

Although the CA have made good progress in putting a system in place for regular official controls and disease surveillance since the relevant national provisions became law in 2008, the evaluation revealed a number of shortcomings that currently prevent the CA from providing appropriate guarantees as regards compliance or equivalence with the relevant animal health requirements of the EU legislation.

The major shortcomings were the following:

The practice of reporting cases of notifiable disease only when characterized by manifested clinical symptoms or by higher mortalities is not in line with the OIE or EU provisions. Containment measures taken in cases of VHS and KHV outbreaks (movement control restricted at tank/pond level, no stamping out) do not prevent the spread of virus to other pond/tanks on the farm or even to other farms.

The national provisions established and implemented for the approval of AA farms intended to export into the EU can not provide guarantees that the animal health requirements for countries, territories, zones or compartments declared free from exotic or non-exotic diseases are met because of (a) the absence of official movement control, (b) the insufficient bio-security measures including isolation conditions of imported fish on approved farms, and (c) the use of untreated seawater at the olive flounder farms.

Weaknesses of the active surveillance programmes established for AA farms authorised for export undermine the effectiveness and reliability of the surveillance system in place for these diseases. In particular (a) representativeness of the samples is not ensured; (b) hatcheries providing fry are not part of the surveillance scheme; (c) insufficient number of samples taken for the VHS testing; (d) not all susceptible species are sampled on the farm and (e) suboptimal water temperatures for collection of KHV samples.

NFRDI laboratories in charge have sufficient analytical capacity, equipment and knowledgeable staff to detect AA diseases. The exclusive use of PCR in the passive surveillance for VHS and the lack of internal and external quality controls in virus isolation in cell culture are not in line with the international standards and may decrease the probability of detecting infections.

Overall the report concludes that:

Although the certification procedure put in place by the NFQS could provide some assurances regarding compliance with the general requirements, officials in charge are not in a position to sign the specific animal health attestations of a certificate for the import into the EU of aquaculture animals and products thereof because the actual animal health status of the place of origin cannot be ascertained due to weaknesses of the control system described in the present report.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AA	Aquaculture animal
APB	Aquaculture production businesses
CA	Competent Authorities
DCM	Aquaculture animal disease control manager
EHN	Epizootic haematopoietic necrosis
EU	European Union
FVO	Food and Veterinary Office
IHN	Infectious haematopoietic necrosis
ISA	Infectious salmon anaemia
KHVD	Koi herpes virus disease
MIFAFF	Ministry for Food, Agriculture, Forestry and Fisheries
MOF	Ministry of Ocean and Fisheries
MS	Member States of the EU
NFQS	National Fishery Products Quality Management Service
NFRDI	National Fisheries Research and Development Institute
NRL	National Reference Laboratory
OIE	World Organisation of Animal Health
OIE Code	Aquatic Animal Health Code of the OIE
OIE Manual	Manual of Diagnostic Tests and Vaccines for Aquatic Animals of the OIE
PT	Proficiency test
SOP	Standard operation procedure
SVC	Spring viraemia of carp
TC	Third Country
VHS	Viral haemorrhagic septicaemia

1 INTRODUCTION

This audit took place in South Korea from 8 April to 18 April 2013 as part of the Food and Veterinary Office (FVO) planned audit programme and was carried out by two auditors of the FVO and one National Expert.

The team was accompanied during the whole audit by representatives of the National Fishery Products Quality Management Service (NFQS) with responsibilities within the scope of this audit.

2 OBJECTIVES

The main objectives of this audit were:

- to assess whether the national provisions established and implemented by the Competent Authority (CA), against which the CA controls the production, movement and import of live aquaculture animals (AA) intended for export to the EU, can be considered as at least equivalent to the European Union (EU) standards;

- to 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 legislation, in particular in the health certificates laid down in Regulation (EC) No 1251/2008.

The standards against which the evaluation was carried out are established by:

- 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 EU of aquaculture animals and products thereof and laying down a list of vector species. This Regulation lays down the animal health veterinary certification requirements for the importation into the EU of live aquaculture animals and of their products;

- Article 23 of the 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 provides criteria that the Commission must take into account when drawing up or updating the lists of Third Countries (TCs) or regions of TCs from which imports of specified products of animal origin are permitted;

- Council Directive 96/93 EC of 17 December 1996 on the certification of animals and animal products;

- Commission Regulation (EC) No 2074/2005 of 5 December 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.

In addition to the standards established by the EU legislation, account was also taken of other international standards. The World Organisation for Animal Health (OIE) publishes the Aquatic Animal Health Code (OIE Code) and the Manual of Diagnostic Tests for Aquatic Animals (OIE Manual), establishing relevant health standards for international trade of aquatic animals including standards on zoning and compartmentalisation and for the diagnosis of the diseases of aquatic animals.

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

Visits/meetings		n	Comments
Competent authorities	National	2	Opening and closing meetings in the headquarters of the NFQS.
	Local	3	Meetings with representatives of NFRDI and NFQS and the local/provincial authorities in their offices and on the farms
Aquaculture production businesses		7	One APB in the Gyeonggi-do region, three in Jeju and two in Chungcheonbuk-do region
Aquatic animal health laboratories		3	The laboratory at the headquarters of NFRDI, two designated laboratories in two regions
Border inspection post		2	At the Incheon International airport and at Jungbu (sea port)

3 Legal Basis

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

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

- Article 58 of Directive 2006/88/EC, which provides for the experts from the Commission to carry out on-the-spot inspections in TC in order to verify conformity with, or equivalence to, animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

A full list of the EU legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

South Korea is not on the list of TCs from which the introduction of AA and products thereof is permitted into the EU but the country had expressed interest in exporting live AA, specifically koi carp and olive flounder, to the EU already in 2008. The present audit is the realisation of the audit planned for 2011 that was cancelled at the request of the CA.

The amount of ornamental fish (mostly koi carp) produced annually in Korea is about 50 tonnes. The amount of olive flounder (*Paralichtys olivaceus*) produced in the country was 36,767 tonnes in 2010, 36,589 tonnes in 2011 and 34,912 tonnes in 2012.

While the koi carp farms are spread throughout the whole country, about 60% of the olive flounder production is concentrated on the island of Jeju due to the favourable natural conditions. Twenty five percent of the total Korean olive flounder production is exported, 93 % of all export originating from the island of Jeju.

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 TCs approved for export of live aquaculture animals to the EU.

5.1.2 Findings

The Aquatic Animal Disease Control Act (Act No. 8789, 21 December 2007) describes the general provisions about AA disease control (reporting obligations of the farmers, monitoring and control of AA diseases, measures to be taken in case of an outbreak), the general provisions for export and import control of AA and the rules on treatment of AA. It has been amended on 22 July 2012 and renamed as Aquatic Life Disease Control Act as, since then, it has also covered measures regarding aquaculture plant health.

The registration of farms producing AA are regulated in the Inland Water Fisheries Act, last amended on 13 March 2013.

A thorough evaluation of the national legislation was not carried out by the audit team because the legal texts were only available in Korean. However, the FVO audit team found that:

- The Aquatic Life Disease Control Act describes the measures to be taken to detect and contain the disease and it enables officials to carry out regular control activities and to apply any measures necessary for the prevention and control of fish diseases.

- The responsibilities and tasks of the three CA involved in the control of AA production, trade and AA disease control in Korea, namely the National Fishery Products Quality Management Service (NFQS), the National Fisheries Research and Development Institute (NFRDI) and the local governments are clearly defined in the Act.

- However, while local governments have to report suspicions or outbreak of AA diseases to the NFRDI there are no legal provisions compelling NFRDI to communicate these suspicions or outbreak of AA diseases to the NFQS.

- Approval and official controls of farms intending to export live AA to the EU are not regulated by law and there are no special national standards established against which candidate farms are checked for approval or for listing as eligible EU exporters.

- There is no legal requirement in the national legislation to keep records on mortality, water temperatures or movement of fish.

- There is no legal requirement to officially control movement of AA except in cases of import and in suspected cases and after confirmation of a notifiable disease.

5.1.3 Conclusions

The national legislation provides adequate powers to the CA in relation to AA health. However, the legal framework does not ensure that the NFQS receives timely information about outbreak of AA diseases and can not offer equivalent guarantees regarding official control of movements of live AA and the approval of the farms intending to export live AA to the EU.

5.2 Organisation of the official control system

5.2.1 Legal requirements

Article 23 (b) of Directive 2006/88/EC requires the Commission to take account of the following factors when drawing up or updating the list of third countries, territories, zones or compartments approved to export live AAs to the EU:

- the organisation of the CA and its inspection services in the third countries, territories, zones or compartments;
- the supervision to which they are subject; and
- the means at their disposal, including staff capacity, to apply their legislation effectively.

5.2.2 Findings

The main features of the organisations involved in the control and supervision of the aquaculture production businesses (APB) are the following:

Due to a recent reorganisation, the overall responsibility for the general administration of establishing quarantine and control policies on fishery products and disease control tasks, held by the Ministry of Food, Agriculture, Forestry and Fisheries (MIFAFF) until March 2013, belongs to the Ministry of Oceans and Fisheries (MOF).

The NFQS and especially its Quarantine and Inspection Division, is responsible for the general administration of the control of import and export of AA including international cooperation. The NFQS approves farms as isolation sites for imported live AA and it is in charge to inspect and control the implementation of the criteria established for the approval. The NFQS is also responsible for the international health certification.

The NFRDI has a general responsibility for the AA health situation in the country and, in particular, is in charge of the establishment of monitoring plans for AA disease, coordination of disease control in cases of outbreaks and for the standardization of diagnostic procedures and the education of officials.

The NFRDI is responsible for disease monitoring in cooperation with the specially trained officials of the local governments (city, county or district), the AA disease control managers (DCM). The CA is also responsible for maintaining the disease control equipment and may carry out out surveys on farms under restriction.

The implementation of controls and measures is the responsibility of the local municipalities (local governments). The AA DCMs at the municipalities are responsible for performing the inspections and collection of samples for monitoring or disease detection purposes. They implement the practical measures in case of an outbreak, they are authorized to carry out investigations on the spot and to prescribe medication to treat bacterial or parasitic infections.

The FVO audit team found that:

- The CA have sufficient resources to carry out official controls related to production, to collect samples for disease monitoring and they are empowered to impose measures in order to control disease.

- The NFRDI has issued instructions to facilitate the harmonised implementation of inspections and sampling, and organises advanced training about fish diseases for the officials of the local governments.

- The NFRDI, the NFQS and the local governments have meetings twice per year on surveillance.

- The officials of the Jeju special local government pay frequent visits to the olive flounder farms but these inspections are not documented.

- On the other hand, the sampling inspections of koi carp farms eligible for export to TCs are documented with the sampling protocol and pictures attached about the facilities, equipment and the fish on the farm.

- The NFRDI provides information about the disease monitoring plans twice per year to the NFQS and to the local governments.

- The NFRDI has developed and is currently loading data into two websites about the disease situation (Safety information system) and about the realisation of the annual surveillance plans (E- surveillance system). However, the NFQS has no access to these websites.

- The NFQS does not receive information about test results obtained by the NFRDI laboratory when fry are tested before transporting them to growing olive farms approved for export.

- A system for verification and review of official controls and procedures still has to be developed. To date, the audits carried out according to the Audit Regulation of the MIFAFF are targeting the organisation, personnel and the budget of the NFRDI and the NFQS. Officials of local governments inspecting the AA farms are not audited by the NFRDI.

5.2.3 Conclusions

The three authorities responsible for the control of production and international trade of live AA cover all stages of this process with their operations. While the cooperation between the NFRDI and the local governments appears to be satisfactory except the lack of audit. Due to the shortcomings in communication between NFQS and NFRDI, there is no guarantee that responsible officials of the NFQS receive timely information about suspected or confirmed cases of disease or test results relevant for signing an EU export certificate.

5.3 Approval and control of aquaculture production businesses (APB)

5.3.1 Legal requirements

Article 23 of Directive 2006/88/EC establishes that countries may only appear in the list of third countries, territories, zones or compartments 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 AAs intended for the EU.

The general animal health requirements established in the model animal health certificate for the export of live fish and products thereof to the EU laid out in part A of Annex IV to Regulation (EC) No 1251/2008 include the declaration that

- the animals to be exported originate from aquaculture farms that are under the supervision of the CA,
- the animals are not subject to any prohibitions due to unresolved mortality and are not intended for destruction or slaughter for the eradication of diseases.

5.3.2 Findings

5.3.2.1 Registration

According to the Inland Water Fisheries Act, all AA producing farms must be registered in Korea.

An AA farm is registered if the basic production data (type of AA to be produced, source of water) and the description of the facilities (buildings, number and sizes of tanks/ponds) submitted to the relevant local government comply with the requirements established in the Act. The registration licence must be renewed in every fifth year. The number of registered farms in the three mainland provinces visited by the FVO audit team varied between 180 and 220, while there were 334 olive flounder farms registered on the island of Jeju.

The FVO audit team found that:

- There are no special requirements concerning animal health for the registration of AA farms in Korea.

- Registered farms are under official control and the farmer is obliged to report production problems, abnormal behaviour of AA or increased mortality.

- The AA DCMs visit the farms with varying frequency in the different provinces. In one province common carp farms are visited at least 2-3 times quarterly, in other provinces the koi carp farms and the flounder farms are inspected at least monthly.

5.3.2.2 Authorisation for export

5.3.2.2.1 Koi carp farms

Currently, there are 18 koi carp farms authorized for export to one third country by the NFQS.

The FVO audit team visited three koi carp farms in two provinces, two of them approved for export to the third country mentioned.

The export requirements of the third country are the following: farms must be under official control and inspected at least twice per year for two years and they must participate in the SVC surveillance programme as described under 5.4.2.2.2. The farms must be visited within 72 hours and the fish clinically examined by officials before dispatch of each consignment.

Two out of the 18 koi carp farms have been also participating in the KHV surveillance since 2010 in order to fulfil the additional NFQS requirement for EU export.

The FVO audit team found that:

- The inspections are carried out by the AA DCMs 2-3 times per year, who are also responsible for the collection and transport of samples for surveillance (twice per year). The team was told that during these visits they check the sanitary conditions, the disease situation and carry out on-the-spot diagnostic investigations using basic laboratory equipment (for example microscope for diagnosing bacterial and parasitic diseases).

- There were no records kept on mortality, water temperatures or fish entering or leaving the premisses on the two export approved koi carp farms.

- When asked, the team was provided with documentary evidence of inspections and sampling carried out according to the surveillance programme.

- Elements of a biosecurity system were in place on the farms (e.g. disinfection of boots) but there were no barriers that prevent from entering the farms.

- The source of water was borehole on the farms visited, except one that used also surface water from a temporary lake without the installation of facilities for water treatment.

- On one farm there were also goldfish present in smaller tanks and fish were frequently moved between different farms owned by the same farmer.

5.3.2.2.2 Olive flounder farms

Out of the 334 registered olive flounder farms, 314 are approved for export to at least one third

country and, although not allowed at the moment. Two of them intending to export to the EU was approved by the NFQS for export to the EU.

The FVO audit team visited two olive flounder farms one of them was approved for export to the EU by the NFQS and one olive flounder brood stock farm producing eggs for the national market.

A regional legislation requires the farmers to report to the local government the arrival of fry on their farms, which must be tested at the hatchery for the absence of VHS before transport. The farms are inspected very frequently. This free of charge service includes technical support, prescription and administration of drugs and continuous check for clinical symptoms of disease. The FVO audit team was told that one of the farms visited was inspected daily by the AA DCM.

- However, no records were available about these visits on that farm.

Farms applying for the special "*eco-seafood producing farm"* status are approved against a special standard established by the NFQS. Compliance with the requirements of this standard is checked twice per year by the NFQS officials using a check-list prepared for this purpose. Currently there are four "*eco"* olive flounder farms operating on Jeju.

- The check-list covers a number of conditions from the origin and disease status of the seedlings on arrival on the farm, general hygiene conditions, facility design, feed, records on treatments, mortality and the disinfectants used.

- The quality of water used on the eco-friendly farms, usually a mixture of borehole seawater and water from the sea, has to be analysed regularly including tests for inorganic and organic contaminants like coliform bacteria.

- The olive flounder farms visited by the audit team had no barriers and used untreated seawater.

The FVO audit team visited one of the two eco-seafood producing *farms also "approved for the EU export"* by the NFQS on 4 September 2012.

The team was told that apart from the requirements established for the eco-seafood producing farms, fish on the farm approved for EU export must be tested for the absence of VHS twice per year.

The FVO audit team found that:

- Records on mortality, water temperature, feed consumption and the results of the annual water quality testing were available on the farm.

- The records about fry moved to the farm since 2010 were not complete; laboratory results were missing for most of the cases checked.

- A batch of seedlings which had arrived 3 months earlier and for which no record was kept was indicated by the operator as excluded from the schemes.

- No NFQS visit had been performed on the farm since the EU approval 7 months earlier, no documented check was performed by the AA DCMs on the application of the scheme or

regional provisions.

- The two VHS testing required for approval for EU export were performed in October and November 2012, after the EU export approval had been granted in September.

- There were no facilities for treatment of the incoming water.

- The NFQS acknowledged that there are no special standards established for the approval of farms intending to export to the EU.

5.3.3 Conclusions

The national provisions established and implemented for the approval of AA farms intended to export into the EU can not provide guarantees that the animal health requirements for countries, territories, zones or compartments declared free from exotic or non-exotic diseases are met because of (a) the absence of official movement control, (b) the insufficient bio-security measures including isolation conditions of imported fish on approved farms and, (c) the use of untreated seawater at the olive flounder farms.

5.4 Animal health surveillance and control of fish diseases

5.4.1 Legal requirements

Article 23 of Directive 2006/88/EC establishes that countries may only appear in the list of third countries, territories, zones or compartments approved to export to the EU 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 TCs approved to export live AAs to the EU:

- the health status of farmed and wild aquatic animals in the third countries, territories, zones or compartments, 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 third countries, territories, zones or compartments supply 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 third countries, territories, zones or compartments and their implementation, including rules on imports from other countries.

5.4.2 Findings

5.4.2.1 Notification and minimum measures for control of fish diseases

According to the Article 9 of the Aquatic Life Disease Control Act, farmers or AA DCMs suspecting one of the 20 AA diseases (8 fish, 5 molluscs and 7 crustaceans diseases) notifiable in the country are obliged to report the disease to the responsible local government. The information on suspicion is forwarded to the President of the NFRDI who initiates on-the-spot investigation carried out by the AA DCMs or by the provincial NFRDI and laboratory investigation in one of the designated laboratories. Results obtained by the designated laboratory must be confirmed by the NFRDI laboratory in Busan. The results are communicated to the Minister of MIFAFF and to the local government. The NFRDI sends quarterly reports to the MIFAFF which is in charge of reports to the OIE since 2009. Disease control measures are taken by either the AA DCMs of the municipality or by the local officials of the NFRDI.

The NFRDI may request an epidemiological survey in accordance with Article 11 of the Act. Articles 15 to 18 provide provisions about isolation and movement control on the AA and conditions of the depopulation of the farm and incineration of carcasses.

The NFRDI has issued guidelines about the responsibilities of the farmers, the municipality and the local NFRDI in case of outbreaks. It concerns the movement control, record keeping during the outbreak, cleaning and disinfection and collaboration between the CAs and the owner. The guidelines also recommends testing of seedlings before introduction to the farm, change of water supply, sterilisation of effluent water and reduction of the density of fish in case of a VHS outbreak.

- The number of outbreaks documented at the NFRDI headquarters was higher than those reported by the MIFAFF to the OIE in 2010-2012.

Year	Cases of KHV reported...		Cases of VHS reported ...	
	....by the NFRDI	...to the OIE	....by the NFRDI	...to the OIE
2010	16	3	5	1
2011	4	1	5	"Present without clinical symptoms"
2012	1	NR*	11	NR

* Not reported

- The FVO audit team was not given access to the chain of information from the Institute to the MIFAFF responsible for the notification, but the CA explained that cases are only reported to the OIE if the infection is accompanied by clinical symptoms or higher mortality. The delay in reporting the 2012 cases is due to the recent reorganisation.

- The audit team was not authorised to visit farms experiencing outbreaks during the last year but received information about the measures taken in three outbreaks and restricted its assessment to documentary review.

The FVO audit team found that

- The country has reported outbreaks of VHS and KHV since the monitoring for notifiable diseases started in 2009.

- Implementation of control measures is the responsibility of the municipality. The FVO audit team was told that the NFRDI has only an advisory role but no obligation to check the implementation.

- Depopulation of the whole infected farm (slaughter) would apply only in confirmed cases of SVC but this disease has not been detected yet in Korea.

- Detection of KHV or VHS on a farm during monitoring or as a result of laboratory investigation performed on suspicion is followed by isolation of the pond (or tank) that is found to be infected.

- However, movement restrictions are imposed only on the infected pond/tank which is isolated with barriers on the farm. The restriction is lifted after two subsequent negative laboratory results which took between 40 days to 3 months to obtain in the cases described by the CA. Other ponds/tanks on the infected farm were not tested.

- The FVO audit team was told that if the infection manifests in higher mortality, the restriction is extended to the whole farm.

- The basis on which restrictions are imposed is not harmonised; they can be taken based on the suspicion of disease, on the first test result obtained from the designated laboratory or after confirmation from the main NFRDI laboratory depending on the province visited.

- The officials involved in the actual outbreaks and staff at the headquarters of NFRDI were not aware of any epidemiological survey carried out in connection with these events.

5.4.2.2 Monitoring and surveillance of fish diseases

5.4.2.2.1 Passive surveillance of fish diseases

Passive surveillance on the registered farms is mainly focus on the bacterial and parasitic diseases which are often diagnosed and treated by the AA DCMs on the spot.

The FVO audit team found that

- Passive surveillance is an effective tool for the early detection of notifiable diseases due to the high number of official visits and on-the-spot examinations, but there was no evidence to support that exclusion of notifiable diseases with laboratory investigations is practised in the case of samples collected from koi carp farms.

- In contrast, samples collected on olive flounder farms experiencing health problems were routinely examined among other pathogens for the presence of VHS virus as well.

- In 2012, out of the 52 VHS suspected cases, 10 were confirmed in olive flounder growing farms in Jeju. Most of the cases were detected during the colder seasons (autumn, winter or early spring).

5.4.2.2.2 Monitoring of fish diseases

Rainbow trout populations kept on sea-based farms at the southern part of Korea are monitored for the presence of EHN and ISA twice per year since 2010 and once per year for IHN since 2012. Fish populations susceptible for RSIV and IPN are also monitored annually for these diseases since 2010.

Common and crucian carp populations produced for restocking are also tested regularly to demonstrate freedom from SVC before placed into natural waters. Similarly, fry have to be tested for VHS before they are moved to olive flounder growing farms.

The FVO audit team found that:

- There is no systematic monitoring in the feral (wild) fish populations susceptible for VHS in the sea around Jeju island, a possible source of infection in the region.

5.4.2.2.3 Active surveillance on the AA farms approved for export

The eighteen koi carp farms authorised for the export of live AA are under active surveillance. Fish on these farms are tested twice per year for the presence of SVC during spring and autumn and samples from the two farms which expressed an interest for export to the EU are also tested for KHV.

Active surveillance for the presence of VHS is performed in the framework of the recently introduced authorization of olive flounder farms for EU export. The fish populations on these farms must be tested twice per year for the disease.

The FVO audit team found that the design and implementation of these active surveillance programmes included a number of weaknesses:

- In general, there was no instruction to ensure that the samples taken from a farm for monitoring are representative.

- Hatcheries providing fry for the olive flounder growing farms are not covered by active surveillance.

- The number of samples taken from olive flounder farms for the monitoring of VHS was lower than required in the OIE and EU legislation (30 samples instead of 150 per farm).

- The number of samples taken to exclude the presence of SVC in koi farms was lower than required by one importer country with 95% probability with an assumed prevalence of 2%.

- The present sampling plan for koi-carp farms precludes the possibility of detecting KHV because the water temperature at spring and autumn is lower than the optimal 17 °C.

- Goldfish found on one of the koi carp farms were not subject to disease control.

5.4.2.3 Import control

Korea imports live AA for breeding or live AA and fishery products for human consumption mostly from the neighbouring countries in South-East Asia but also from other continents.

The import and quarantine requirements are specified in the NFQS instruction 2012-157 describing the procedure to follow. An updated list of notifiable diseases and the susceptible species provides the standards against which the import controls are performed. Official control of the imported live fish (clinical observation) can be carried out at the border inspection posts at the ports, at the airport or on the farm of destination if it was approved as an isolation site.

Apart from the clinical and documentary checks, laboratory investigations are also performed in about 5 % of the import consignments as described in the Quarantine manual compiled by the NFQS. Special attention is paid to first imports from a country, fish with abnormal signs, fish imported for breeding, or if there were risks associated with the country or place of origin.

The FVO audit team found that:

- Health certificates shown to the FVO audit team contained general statements of freedom from SVC and KHV but without describing the standards against which these statements were made.

- The NFQS has an ISO 17025 accredited laboratory for the purpose of laboratory investigations. Most of the accredited tests are used for the analysis of fishery products for public health purposes and the PCR methods for the detection of KHV and SVC are also accredited.

Imported live AA can be kept isolated until the importation procedures are completed, either on designated NFQS sites or on the farm of destination if approved for this purpose. The NFQS has established a check-list and standards against which farms can be approved to have isolation sites.

The sites to be approved must have bird-proof roofing above the place, pest control, proper cleaning and disinfection procedures, only approved disinfectants may be used and the water in the tank used for the isolation of imported fish can not be mixed with waters used in other tanks. Farms with approved isolation sites must be visited by the NFQS once in every year.

The FVO audit team found that

- There are no provisions in the standards for inactivation of effluent water or for use of dedicated equipment.

- There is no minimal isolation time set for keeping the imported fish in the isolation tank/pond.

- On one of the koi carp farms visited the farmer told the team that there is no dedicated tank on the farm for quarantine, any empty one could be used for this purpose.

5.4.3 Conclusions

The practise of reporting notifiable diseases to the OIE only in cases with manifested clinical symptoms or in case of higher mortalities is not in line with the OIE or EU provisions.

Measures taken in cases of VHS and KHV outbreaks (movement control restricted at tank/pond level, no stamping out) and the absence of follow up epidemiological investigations do not prevent the spread of virus to other pond/tanks on the farm or even to other farms.

The disease monitoring system and the passive surveillance in place has the potential to detect the notifiable diseases, but it does not cover the wild fish population susceptible to VHS. SVC or KHV infections on koi carp farms may remain undetected due to the lack of routine laboratory testing in disease investigations.

Weaknesses of the active surveillance programmes established for AA farms authorised for export undermine the effectiveness and reliability of the surveillance system in place for these diseases. In particular (a) representativeness of the samples is not ensured; (b) hatcheries providing fries are not part of the surveillance scheme; (c) insufficient number of samples taken for the VHS testing; (d) not all susceptible species are sampled on the farm and (e) suboptimal water temperatures for collection of KHV samples.

The standard of the animal health information requested from the countries of origin and with the current isolation measures in place for imported fish, are insufficient to guarantee disease-free status of export farms with operating isolation sites.

5.5 LABORATORIES

5.5.1 Legal requirements

Article 46, point 1 (d) of Regulation (EC) 882/2004 allows for the Commission to evaluate the resources available to the CA including diagnostic capacities in order to verify the compliance or equivalence of the systems of the TC with the EU animal health legislation.

Article 23 of Directive 2006/88/EC establishes that countries may only appear on the list of TCs approved to export AAs 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.

5.5.2 Findings

Laboratories carrying out investigations in aquaculture animal and plant diseases in Korea since the

sixties have been reorganised several times in the past, the recent reorganisation was initiated in 2008 resulting in the current network of official laboratories. Both NFRDI and NFQS have laboratories at their disposal to diagnose diseases of aquaculture animals.

5.5.2.1 Laboratories owned or designated by the NFRDI

The NFRDI laboratory has been inaugurated in the headquarters in Busan in 2010. The laboratory performing relevant virological investigations has been developed from the Pathology Division of the institute and carries out pathological, histological, bacteriological and virological tests in order to diagnose fish diseases.

The laboratory in Busan is responsible for the analysis of samples collected in the framework of the surveillance programmes and receives all samples which give positive results in the designated laboratories for confirmation.

Besides the six regional Fisheries Research Institutes, there are 11 laboratories designated by the NFRDI in 2010 for performing analyses of fish diseases with the methods recommended by the main laboratory.

In general, the *designated laboratories* are responsible for the analysis of samples received from the farms experiencing production problems or when the officials visiting the farms suspect infectious diseases and send in samples for further laboratory investigations.

The FVO audit team visited three laboratories: the main NFRDI laboratory in Busan and two designated laboratories in Yangpyeong-gun, Gyeonggi-do and in Seogwipo city in Jeju.

All laboratories visited were well equipped, situated in new buildings and well-staffed.

The main NFRDI laboratory is providing training for the staff of the designated laboratories, distributes reagents and has issued a Laboratory Manual (SP-2010-AQ-001) containing the translated relevant chapters of the Manual of Diagnostic Tests for Aquatic Animals of the OIE to facilitate harmonisation of the methodology.

The FVO audit team found that

- The NFRDI organises technical training for the staff of the designated laboratories twice per year and distributes “blind samples” for identification, proficiency test (PT). The last PT was organised in July 2012.

- The main NFRDI laboratory received 30 samples in 2012 for confirmation of notifiable disease, mostly VHS from olive flounders and KHV from common or crucian carp.

- For the diagnosis of VHS and KHV, designated laboratories use exclusively PCR as the primary method for virus detection and a negative result is considered as a definite result. However, the laboratory in Jeju routinely tries to isolate virus in cell culture from VHS PCR positive samples and even from those with a negative PCR result in cases of high mortality.

- The designated laboratories have a panel of PCR tests available to detect 20 different aquaculture animal diseases including the ones relevant to this audit: KHV, SVC, HVS, IPN and EHN but not Infectious haematopoietic necrosis (IHN).

- Samples collected are pooled (5 in 1) and processed for the PCR tests as described in the NFRDI Laboratory Manual (SP-2010-AQ-001) containing translations of the relevant chapters of the Manual of Diagnostic Tests for Aquatic Animals of the OIE.

- The sensitivity of the cell lines used at the main laboratory for virus isolation has never been tested. Moreover, positive controls are not used to test the reliability of the cell culture system.

- None of the laboratories have participated in PT to demonstrate the capability of the laboratories to isolate VHS or SVC viruses.

- The staff of the main laboratory receives annual training by participating in international technology courses in fish, crustacean and mollusc disease diagnostic methods in the USA, Taiwan, Australia, Norway, France and the UK since 2009.

5.5.2.2 NFQS laboratories

The NFQS is currently operating four regional laboratories. The FVO audit team has not visited any of them but met staff from the only accredited laboratory associated to the Incheon Branch regional office responsible for the import controls at the Incheon International Airport.

The main task of the laboratory which has been accredited by KOLAS (the national accreditation body) in October 2012 is to carry out laboratory tests on imported live fish intended for farming or for human consumption and on fresh or frozen abalones and oysters. Although its main profile is to carry out tests to detect antibiotics, anorganic and organic contaminants, bacteria and toxins in fishery products, the laboratory is capable of diagnosing SVC, KHV RSIV, VHS, EUS, EHN, ISA and Gyrodactylus infections in fish. About 3-5% of all consignments are randomly tested.

The laboratory has been participating in a KHV PCR PT organised twice per year by a private European laboratory since 2012 with satisfactory results. A PCR (commercial kit) and cell culture (EPC cell line) are used for the detection of SVC and the management of the laboratory is planning to participate in the proficiency test organised by the NFRDI from 2013.

5.5.3 Conclusions

The network of laboratories designated by the NFRDI for detection of AA diseases has sufficient analytical capacity to cope with the requirements of a national disease surveillance and control programme. The main NFRDI laboratory harmonizes the methodology, supervises the designated laboratories and organises proficiency tests.

However, the diagnostic pathway chosen for the passive surveillance for VHS and that the virus isolation in cell culture is performed without internal or external quality controls are not in line with the international standards and may further decrease the probability of disease detection in combination with the shortcomings identified in 5.4.

5.6 INTERNATIONAL ANIMAL HEALTH CERTIFICATION

5.6.1 Legal requirements

Animal health requirements and a model animal health certificate for the importation into the EU of live fish and products thereof for farming and open ornamental facilities, are established by Regulation (EC) No 1251/2008, in particular in part A of Annex IV thereto. Part B of the same Annex lays down the model animal health certificate for ornamental aquatic animals intended for closed ornamental facilities.

Annex I to Regulation (EC) No 1251/2008 lays down a list of possible vector species and conditions under which those species shall be regarded as vectors. Accordingly, the model animal health certificate laid down in part A of Annex IV to the said Regulation requires health attestations in respect of exports to the EU of vector species to exotic and non-exotic diseases, including conditions thereto.

In addition, Annex V to Regulation (EC) No 1251/2008 lays down the general principles to be applied when completing these model animal health certificates, which prescribe 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.

Animal health requirements of the health certificate for the imports of fishery products intended for human consumption are established by Regulation (EC) No 2074/2005 in particular in Appendix IV of Annex VI to the Regulation.

5.6.2 Findings

The animal health certification of live AA and fishery products consignments intended for export is the responsibility of the NFQS.

The procedure in place *to certify koi carp export* to other TCs involves the following steps: based on the application document submitted by the owner containing the results of the compulsory testing and the import requirements of the actual country of destination, the appointed quarantine manager at the local NFQS (i) performs a documentary check and (ii) conducts a clinical observation of the fish at the place of origin if approved as an isolation site or at the point of departure (border inspection point at the port or airport). If the result of these checks is satisfactory, the certificate is issued by the local NFQS.

The FVO audit team examined two animal health certificates used for export of koi carp to other countries to check certification procedure.

- One described the zone of origin as being under active surveillance for SVC and KHV for two years, giving detailed information about the test (PCR and cell culture). The audit team double-checked the supporting test results. The certificate also stated that the fish were inspected within 72 hours prior to export and found to be free of any clinical evidence of SVC.

- The other certificate was more general, only stating that the fish exported are free from SVC and KHV.

In the case of *olive flounders exported live for human consumption*, the health certificate may be issued by the local NFQS in Jeju if the fish are transported by sea to the country of destination. Fish exported to other countries are first transported by sea and by land from Jeju to the packing centres situated close to the Incheon international airport. Here the fish are checked and the certificate is issued by the Incheon branch of the NFQS.

The FVO audit team visited one packing centre.

Packing centres are operated by the farmers' association, they are not registered and are not on the list of establishments approved for EU export.

Fish do not spend more than 24 hours here. During this time they are packed, 4 fish in one plastic bag filled with fresh sea water. The seawater used for the packing is purchased from a supplier and analysed annually. There are no animal health requirements specified in the standard for this analysis. The bags are chilled down, the fish become unconscious and the bags are put into boxes with ice, labelled with the date of packaging.

The document issued by the farmers' association (data about the origin of fish and result of unspecified antibiotics tests) and the packed fish are clinically checked by the NFQS before signing the health certificates.

The audit team was told that after arrival the fish are re-immersed in water tanks at the destination and can be kept alive for days (weeks) before further preparation at the restaurants or sushi factories.

The FVO audit team found that:

- The centre visited was used by several operators and fish is delivered by different transporters. One consignment may contain fish from several farms.

- The fish are released into tanks before packing, some of the tanks had no signs indicating the date of arrival or the place of origin.

- NFQS officials signing the export certificates have no information about the result of the recent VHS tests and there is no system in place to inform them about suspected or confirmed cases of notifiable disease in the proximity of the place of origin.

- The animal health risk of the seawater used for the packing is unknown to the certifying officials.

5.6.3 Conclusions

Procedures established by the NFQS for checking the export consignments and signing animal health certificates for export into other countries would, in general, satisfy the requirements of the EU export. However, officials in charge will not be in a position to attest the animal health requirements of the EU certificates before the shortcomings of the control system described in this report were rectified and packing centres were approved providing traceability of olive flounders exported live to the EU.

6 Overall Conclusions

The CA have made good progress in the control of production and international trade of live AA since the national provisions describing responsibilities and empowering the NFRDI, NFQS and the local governments to monitor, detect and contain AA diseases became law in 2008 (Aquatic Life Disease Control Act) by putting a system in place for regular official controls and disease surveillance.

The evaluation carried out in order to assess whether the control system in place can be considered as at least equivalent to the EU standards revealed a number of shortcomings that currently prevent the CA from providing appropriate guarantees as regards compliance with the relevant animal health requirements of the EU legislation. The major shortcomings were the following:

- The practise of reporting cases of notifiable disease only when characterized with manifested clinical symptoms or with higher mortalities is not in line with the OIE or EU provisions.

- Containment measures taken in cases of VHS and KHV outbreaks (movement control restricted at tank/pond level, no stamping out) do not prevent the spread of virus to other pond/tanks on the farm or even to other farms.

- The national provisions established and implemented for the approval of AA farms intended to export into the EU can not provide guarantees that the animal health requirements for countries, territories, zones or compartments declared free from exotic or non-exotic diseases are met because of (a) the absence of official movement control, (b) the insufficient bio-security measures including isolation conditions of imported fish on approved farms, and (c) the use of untreated seawater at the olive flounder farms.

- Weaknesses of the active surveillance programmes established for AA farms authorised for export undermine the effectiveness and reliability of the surveillance system in place for these diseases. In particular (a) representativeness of the samples is not ensured; (b) hatcheries providing fry are not part of the surveillance scheme; (c) insufficient number of samples taken for the VHS testing; (d) not all susceptible species are sampled on the farm and (e) suboptimal water temperatures for collection of KHV samples.

- NFRDI laboratories in charge have sufficient analytical capacity, equipment and knowledgeable staff to detect AA diseases but there is no collaboration with the NFQS laboratories to assure a harmonised approach. The exclusive use of PCR in the passive surveillance for VHS and SVC and shortcomings in the virus isolation techniques are not in line with the international standards may also decrease the probability of detecting infections.

In summary, although the certification procedure put in place by the NFQS could provide some assurances regarding compliance with the general requirements, officials in charge are not in a position to sign the specific animal health attestations of a certificate for the import into the EU of aquaculture animals and products thereof because the actual animal health status of the place of origin cannot be ascertained due to weaknesses of the control system described in the present report.

7 Closing Meeting

A closing meeting was held on the 18 April with the representatives of the NFQS and the NFRDI during which the FVO team presented its main findings and preliminary conclusions.

The representatives of the CAs generally acknowledged the findings made regarding notification procedures, performance of disease surveillance, laboratory testing and certification procedure. They assured the FVO audit team that the CA is determined to take all measures and actions necessary in order to fully meet the aquatic animal health requirements of the EU.

8 Recommendations

The CA is invited to provide, within one month of receipt of the draft report, an action plan containing details of actions taken and planned, including deadlines for their completion, to address the following recommendations:

N°.	Recommendation
1.	The CA should ensure that all CAs involved in the control of production and international trade of aquaculture animals and the OIE receive timely information about outbreaks of notifiable diseases listed by the OIE in order to allow the provisions of Article 23 (3) (g) and (h) of Council Directive 2006/88/EC to be met.
2.	The CA should ensure that in case of confirmation of a non-exotic disease listed in part II of Annex IV to Council Directive 2006/88/EC, containment measures on the farms to be approved for export to the EU are fully met in order to provide equal guarantees to those in Article 39 of the Directive.
3.	The CA should ensure that the animal health criteria used to declare aquaculture animal farms to be approved for export to the EU free from relevant diseases are equivalent with the requirements of disease-free compartments as described in Part II of Annex V to Council Directive 2006/88/EC.
4.	The CA should ensure that the planning, implementation and evaluation of disease surveillance schemes take full account of the international standards and all available epidemiological information on the distribution and risk factors of fish diseases in South Korea. Thus, surveillance schemes can effectively contribute to the accurate determination of the health status of the aquatic animals at farm level and could offer equivalent guarantees to the relevant animal health requirements laid down in Annexes III and V to Council Directive 2006/88/EC.
5.	The CA should ensure that diagnostic laboratories involved in the official control are subject to quality assurance procedures and use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency.

N°.	Recommendation
6.	The CA should ensure that packing centres are approved and are on the list of establishments from which imports into the EU of specified products of animal origin are permitted as required by Article 12 of Regulation (EC) No 854/2004.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6800

Annex 1 - Legal References

There are no specific legal references for this inspection.

Legal Reference	Official Journal	Title
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
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
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1 Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-57	Commission Regulation (EC) No 2074/2005 of 5 December 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. 854/2004	OJ L 139, 30.4.2004, p 206	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
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