EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6784 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

HUNGARY

FROM 04 TO 13 SEPTEMBER 2013

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE FOR LIVE AQUACULTURE ANIMALS AND PRODUCTS THEREOF

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Hungary, from 4 to 13 September 2013. The overall objective of the audit was to assess the implementation of national measures, aimed at the control of animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, as laid down in Council Directive 2006/88/EC and associated legislation implementing some of the provisions contained therein.

The report concludes that the implementation of Council Directive 2006/88/EC started recently and the competent authority does not yet have systems in place to ensure that the aquatic animal health rules in EU legislation are adhered to or that aquaculture production businesses referred to as authorised meet the conditions in the Directive. However, there is a functioning passive surveillance programme in place and the approved KHV surveillance programme is mostly implemented as planned, albeit by the industry. The planning of controls and implementation of these rules are undermined by the lack of a contingency plan and lack of training, documented procedures, instructions for staff carrying out official tasks in the field of aquaculture animal health.

Although the national reference laboratory is using the appropriate analytical methods and has been successful in annual comparative tests a higher sensitivity for KHV could be achieved by following the advise of the EU reference laboratory. Certain deficiencies in the quality control measures make it difficult for the competent authority to evaluate the reliability of the test results.

Incorrect health certification, failure to identify incorrect incoming health certificates for live fish and the lack of insight into, and checks on, the trade and storage of live fish ultimately intended for human consumption jeopardise the favourable health status of susceptible fish populations.

The report makes a number of recommendations addressed to the competent authority aimed at rectifying the shortcomings identified.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
AAHP	Aquatic Animal Health Professional
APB	Aquaculture Production Business
CVO	Chief Veterinary Officer
DFCC	Department of Food Chain Control (of the MRD)
EC	European Community
ELISA	Enzyme-Linked Immuno-Sorbent Assay
EU	European Union
FVO	Food and Veterinary Office
IHN	Infectious Haematopoietic Necrosis
ISA	Infectious Salmon Anaemia
ISO/IEC	International Organisation for Standardisation/International Electrotechnical Commission
IUT	Intra-Union Trade
KHV	Koi Herpes Virus
MRD	Ministry of Rural Development
MS	(EU) Member State
NFCSO	National Food Chain Safety Office
NFCSO-VDD	NFCSO Veterinary Diagnostic Directorate
NRL	National Reference Laboratory
OIE	World Organisation for Animal Health
PCR	Polymerase-Chain Reaction
SVC	Spring Viraemia of Carp
TIR	National Animal Holding Register
TRACES	Trade Control and Expert System
VHS	Viral Haemorrhagic Septicaemia

1 Introduction

This audit formed part of the Food and Veterinary Office's (FVO) planned programme. It took place in Hungary from 4 to 13 September 2013.

The audit team comprised two inspectors from the FVO and one expert from a European Union (EU) Member State (MS). Representatives from the central competent authority accompanied the audit team for the duration of the audit. An opening meeting was held on 4 September with the central and local competent authorities. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the authorities.

2 Objectives

The overall objective of the audit was to assess the implementation of national measures, aimed at the control of animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals, as laid down in Council Directive 2006/88/EC and associated legislation.

The table below lists the sites visited and meetings held in order to achieve that objective:

Meetings / Visits		n	Comments
Competent authorities	Central	2	Opening and closing meeting with the Ministry of Rural Development, the National Food Chain Safety Office and representatives from County Government Offices
	Regional	4	County Government Offices in Pest, Baranya, Tolna and Hajdú-Bihar. Representatives from District (local) Government Offices and Official veterinarians present
Laboratory		1	The Veterinary Diagnostic Directorate (Budapest) of the National Food Chain Safety Office, which is the national reference laboratory for fish diseases
Aquaculture Production Businesses		4	Four aquaculture farms keeping different carp species, sander, pike, catfish, African catfish and trout
Other sites		3	One transporter / exporter/transit pond for fish; one fish processing plant; one importer of ornamental fish

3 Legal Basis

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

- Article 45 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 8, paragraph 1, 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.

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

4 Background

4.1 Summary of previous FVO audits

This is the first audit carried out in Hungary in order to evaluate the controls on animal health requirements for aquaculture animals and products thereof, and the prevention and control of certain diseases in aquatic animals, as laid down in Directive 2006/88/EC and associated legislation.

4.2 The aquaculture industry in Hungary

The aquaculture industry in Hungary is dominated by extensive production in ponds for food. According to production data from the Hungarian Agricultural Research Institute and the Fishery Research Institute (production year 2012), the pond production of different carp species is approximately 17 868 tonnes. The two main species are common carp (15 158 tonnes) and silver carp (1 894 tonnes), which together represent 95% of the national carp production. The other species produced in ponds are catfish (313 tonnes), northern pike (82 tonnes), sander (88 tonnes), tench (9 tonnes), other noble fish (38 tonnes) and wild fish species (711 tonnes). There are also 2 350 tonnes of fish produced in intensive aquaculture production systems, mainly African catfish (2 081 tonnes), sturgeon (159 tonnes) and trout (71 tonnes). The competent authority stated that there is no aquaculture production of molluscs or crustaceans in Hungary.

4.3 Health status of aquaculture fish, molluscs and crustaceans

Diseases listed in Part II of Annex IV to Directive 2006/88/EC:

- the whole territory of Hungary is listed in part B of Annex I to Commission Decision 2009/177/EC as declared free from infectious salmon anaemia (ISA) in accordance with Article 49(1) of Directive 2006/88/EC. No cases of ISA have been detected in Hungary. The competent authority stated that, for ISA, Hungary is classified as Category I according to Part A of Annex III to Directive 2006/88/EC;

- the whole territory of Hungary is listed in Part A of Annex I to Decision 2009/177/EC as subject to an approved surveillance programme for Koi herpes virus (KHV) in accordance with Article 44(1) of Directive 2006/88/EC. Prior to the start of this programme KHV had not been detected in Hungary. The operator-financed surveillance programme started in 2010 and five outbreaks of KHV have been detected; two in 2012 and three in 2013 to date. The competent authority stated that, for KHV, Hungary is classified as Category II according to Part A of Annex III to Directive 2006/88/EC;

- one outbreak of infectious haematopoietic necrosis (IHN) was detected in 2013. This was the first case of IHN detected in Hungary;

- none of the other exotic and non-exotic diseases and infections in fish, molluscs and crustaceans, which are listed in Part II of Annex IV to Directive 2006/88/EC, have been

detected in Hungary.

Certain diseases not listed in Part II of Annex IV to Directive 2006/88/EC:

- the whole territory of Hungary is listed In Annex I to Decision 2010/221/EC as free from spring viraemia of carp (SVC) in accordance with Article 43(2) of Directive 2006/88/EC. SVC was most recently detected in Hungary in 2003. An operator-financed surveillance programme has been in place since 2003.

5 Findings And Conclusions

5.1 Legislation

Legal requirements

Article 65 of Directive 2006/88/EC requires MS to adopt and publish, not later than 1 May 2008, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall apply those provisions from 1 August 2008.

Findings

In their response to the pre-audit questionnaire the competent authority stated that National Decree No. 127/2008 of the Minister of Agriculture and Rural Development comprises the legal requirements of Directive 2006/88/EC as well as the related EU legislation: Commission Regulation (EC) No. 1251/2008; Commission Decision 2008/946/EC; Commission Decision 2008/896/EC; Commission Decision 2009/177/EC; Commission Decision 2010/221/EC; and Commission Decision 2008/392/EC.

Commission Decision 2001/183/EC (viral haemorrhagic septicaemia (VHS), and IHN) and Commission Decision 2003/466/EC (ISA) have been transposed into national Decree No. 113/2008 of the Minister of Agriculture and Rural Development.

General rules for food chain safety are laid down in Act No XLVI of 2008 on the food chain and its official control. Chapter IV of the Act lays down legal consequences and rules of sanctions and penalties and Government Decree 194/2008 defines the procedures for establishing these penalties.

The FVO team noted that:

- contrary to what was stated by the competent authority, the contents of Commission Decision 2008/896/EC (guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Directive 2006/88/EC) had not been included in or referred to in national Decree No 127/2008;

- in national Decree 127/2008 all notifiable aquatic animal diseases have been listed in Part B of Annex 1. In accordance with paragraph 5 of this Decree, notification to the Commission and to other MS within 24 hours is required only for those diseases listed in Part A of Annex 1. However, since Hungary has an approved surveillance programme for KHV and has been declared free from SVC and ISA, all cases of these diseases should be reported within 24 hours of confirmation in accordance with Article 27(b) of Directive 2006/88/EC (KHV, ISA)

and Article 5(2) of Decision 2010/221/EC (SVC)[1].

Conclusions

Most of the relevant legislation has been transposed into national legislation and the competent authority has the legal basis for enforcement of the legislation. However, the omission of Decision 2008/896/EC hampers the implementation of Article 7 of Directive 2006/88/EC and fails to meet the requirements in Article 10(4) of this Directive. In addition, reporting of confirmed cases to and to the Commission could be delayed due to the incorrect listing of certain notifiable diseases in national legislation.

5.2 COMPETENT AUTHORITIES

Legal requirements

Article 54 of Directive 2006/88/EC requires that MS:

- designate their competent authorities for the purposes of this Directive. The competent authorities shall operate and perform their duties in accordance with Regulation (EC) No 882/2004;

- ensure that effective and continuous cooperation based on the free exchange of information relevant to the implementation of this Directive is established between the competent authorities they designate for the purposes of this Directive and any other authorities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin;

- ensure that the competent authorities have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology, and that there is a free exchange of any information relevant to the implementation of this Directive between the competent authorities and laboratories.

Findings

5.2.1 Organisation

The structure of the competent authorities is slightly different from that described in the most recent version of the Country Profile for Hungary (DG(SANCO)/2011/6078) which is valid as of January 2012.

The Chief Veterinary Officer (CVO) is the State Secretary for food chain control and agricultural administration in the Ministry of Rural Development (MRD).Within the MRD, the Department of Food Chain Control (DFCC) is responsible for policy of the whole food chain, international relations and legislation. These responsibilities include aquaculture animal health, which is the responsibility of the DFCC Animal Health and Coordination Unit, and fish as foodstuffs, which is the responsibility of the DFCC Food and Food Safety Unit.

The National Food Chain Safety Office (NFCSO), which reports directly to the MRD, was established in March 2012, replacing the Agricultural Office. The Deputy CVO is the President of

1 In their response to the draft report the competent authority stated that all KHV cases were notified to the Commission and to other MS in the ADNS system in accordance with EU rules.

the NFCSO. The NFCSO is responsible for managing the operational tasks at central level and for coordinating and supervising the control activities at county and local levels. Aquaculture animal health, including intra-Union trade and import/export, is the responsibility of the Directorate for Animal Health and Animal Welfare which, together with the Animal Breeding Directorate, is also responsible for holding registrations, animal identification and movement controls.

Since January 2011, 19 County Government Offices (hereafter referred to as regional offices) comprise all regional competent authorities involved in official controls of the food chain. The regional offices report to the Ministry of Public Administration and Justice, which is responsible for staffing, infrastructure and operational programmes. Levies on production are collected by the NFCSO and "ear-marked" funding for official controls by regional offices is transferred to the Ministry of Public Administration and Justice. The different directorates/offices in each regional office operate under the professional coordination of their respective central competent authorities. Each regional office has 15 directorates/offices, four of which are involved in Food Chain Control. The Directorates for Food Chain Safety and Animal Health are the regional competent authorities dealing with aquaculture health and are also responsible for the Animal Health and Food Control District Offices (hereafter referred to as local offices), County laboratories and border inspection posts.

At local level, there are approximately 200 local offices which control the activities of official veterinarians and of approved veterinarians, who are private practitioners authorised by the regional offices under Decree 113/2006 to carry out certain official tasks.

The FVO noted that:

- the regional offices visited had staff with expertise in animal health and epidemiology;

- the most recent meeting between NFCSO and the regional office Directors had been held at the beginning of April 2013, although the intention was to hold such meetings every 1-2 months. In April there had also been a meeting between the NFCSO and the Heads of the regional office epidemiology departments where the disease situation, surveillance programmes and implementation of controls in the field of animal health had been discussed;

- regular formal and informal meetings were held between the regional and local offices;

- the private veterinarian for one of the four aquaculture production businesses (APB) visited (trading in live fish with several Member States) was also the official veterinarian issuing intra-Union trade certificates for the same business. The competent authority stated at the closing meeting that such conflicts of interest were not common practice.

5.2.2 Planning and documentation of controls

Registration and authorisation of APBs (see point 5.3) and the subsequent risk-based planning and implementation of official controls of APBs have been delegated to the regional offices by the NFCSO and are to be based on Part B of Annex III to Directive 2006/88/EC as transposed into national Decree No. 127/2008.

The FVO team noted that:

- planning and implementation of risk-based official controls of APBs started in 2012;

- staff in regional and local competent authorities carrying out official controls have not been trained or provided with documented procedures, information or instructions on how to plan and implement official controls in the field of aquaculture animal health (required under Articles 4 and 8 of Regulation (EC) No 882/2004);

- a comprehensive standardised check-list for official controls on APBs had been issued by the NFCSO in 2013 and had been taken into use in recent months by the regional offices visited. There were no instructions on how to assess the different points in the check-list. The control reports were signed by a representative of the APB and a copy was provided to the APB operator;

- although eight persons from central and county levels of the competent authorities had participated in courses on aquaculture animal health within the framework of Better Training for Safer Food, no formal dissemination of the course contents to other members of staff had taken place;

- the specific guidelines for risk-based animal health surveillance schemes, published in Decision 2008/896/EC, had not been provided to the regional offices nor were these guidelines known in the four regional offices visited;

- prior to the issuing of the standardised check list, official controls were planned, carried out and documented in accordance with practices developed in each regional authority. No records of official controls in APBs that had been carried out before 2012 were available in the four regional offices visited;

- the standardised check list covers all important areas: location of the farm; activities (hatchery, nursery, brood stock, rearing for human consumption, put-and-take fishery, other); species kept; farm type; water source; effluent and closeness to other farms; water quality; record keeping; origin of fish; feed; control plan and frequency of visits; test results; medications; mortality; handling of by-products; disinfection; transport; on-the-spot clinical inspection; shortcomings and recommendations.

5.2.3 Verification and auditing

The FVO team noted that:

- neither the MRD nor the NFCSO had carried out any verification of the quality or effectiveness of the planning and implementation of risk-based controls by the regional offices in the area of aquaculture animal health. No audits had been carried out in this area of activity and none were planned;

- neither the MRD nor the NFCSO have an overview over the total number of APBs, information about the risk classification of individual APBs or target numbers for the expected annual numbers of official controls and other controls on APBs in each county or district;

- although reports of the number of official controls carried out, including those for aquaculture animal health, were regularly submitted from the local offices to the regional

offices, these reports had not been used to check if target inspection frequencies had been met nor was the information in the summary reports sufficient for an assessment of the effectiveness of the controls;

- regional offices were not required to provide data about aquaculture animal health controls to the central competent authorities[2];

- in one regional office visited, senior staff from the regional office had carried out joint inspections together with district veterinary officers. Two reports were produced during these inspections and the regional office report would point out inspection elements which may have been missed or misinterpreted by the district veterinary officer.

Conclusions

Although the national legislation has been in place since 2008 as required in Directive 2006/88/EC, the actual planning and implementation of risk-based official controls of APBs only started in the second half of 2012. The lack of adequate training, documented procedures and instructions in the field of aquaculture animal health controls for staff at regional and local levels could lead to the inconsistent application of legal requirements and, although a good example of supervision was seen in one region, there is no system for verification in place which could detect such inconsistencies. In addition, the competent authorities have not ensured that official veterinarians have no conflicts of interest that could affect the reliability of their official controls and certification[3].

5.3 Registration, authorisation and controls of aquaculture production businesses

Legal requirements

Article 4 of Directive 2006/88/EC requires MS to ensure that each APB is duly authorised by the competent authority in accordance with Article 5 therein. MS may require, under certain conditions, only the registration by the competent authority of certain categories of APB. In doing so, MS shall ensure that the activity in question would not pose an unacceptable risk of spreading diseases to other aquaculture animals or to wild stocks of aquatic animals.

Article 5 of Directive 2006/88/EC lays down the authorisation conditions for APB, including requirements to be fulfilled by them as laid down in Articles 8 to 10 therein, and requires MS to ensure that APB operators submit all relevant information in order to allow the competent authority to assess that the conditions for authorisation are fulfilled, including the information required in accordance with Annex II to the said Directive.

Article 6 of Directive 2006/88/EC requires MS to establish, keep up to date and make publicly available a register of APB containing at least the information set out in Annex II to the said Directive. Moreover, Article 2 of Commission Decision 2008/392/EC establishes that MS shall establish an Internet-based information page to make available information on farms or mollusc farming areas of APB which are authorised and, as appropriate, registered and which corresponds with that included in the above mentioned register.

2 In their response to the draft report the competent authority stated that, although there is no obligation to report aquaculture animal health controls to the central competent authorities, counties have several times done so.

3 In their response to the draft report the competent authority pointed out that the case observed by the FVO team was an isolated one, measures have been taken in this case and conflict of interest is not a general problem.

Article 7 of Directive 2006/88/EC requires that, in accordance with Article 3 of Regulation (EC) No 882/2004, official controls on APB shall be carried out by the competent authorities. These official controls shall at least consist of regular inspections, visits, audits and, where appropriate, sampling, for each APB, taking account of the risk the APB poses in relation to the contracting and spreading of diseases. Recommendations for the frequencies of such controls, depending on the health status of the concerned zone or compartment, are laid down in Part B of Annex III to the said Directive.

Article 10 of Directive 2006/88/EC requires MS to ensure that a risk-based animal health surveillance scheme is applied in all farms and mollusc farming areas, as appropriate for the type of production. In addition:

- Part B of Annex III to the said Directive lays down recommendations for the frequencies of such animal health surveillance schemes, depending on the health status of the concerned zone or compartment; and

- The Annex to Decision 2008/896/EC sets out general guidelines to be taken into account by MS for the purpose of applying the risk-based animal health surveillance schemes.

Decision 2009/177/EC implements Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of MS, zones and compartments, and Annex I to the Decision lists MS, zones and compartments subject to surveillance or eradication programmes or for which disease-free status has been approved.

Decision 2010/221/EU approves national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Directive 2006/88/EC. Annex I of the Decision lists MS and parts thereof that shall be regarded as free of certain diseases while Annex II lists approved eradication programmes for such diseases.

Findings

5.3.1 Conditions for authorisation and requirements for registration

The requirement for registration of APBs and the conditions for the authorisation of aquaculture production businesses have been transposed into national Decree No. 127/2008.

Regional offices are required to keep a register of all APBs. In addition, under national Decree No 119/2997 any type of APB which (i) has received (or wants to receive) subsidies from the Government, (ii) is a hatchery, iii) is a processing establishment or iv) covers a water surface area of more than 30 hectares, is required to be registered in the national animal holding register (TIR) which is kept by the NFCSO. The registration into TIR is channelled through the relevant regional office.

A form for making public the required data on APBs and intended to meet the requirements in Decision 2008/392/EC, was introduced in 2011 and most recently modified by the NFCSO during the second half of 2013.

Establishments which have been approved for processing of live bivalve molluscs and fishery products are included in a list of all approved processing establishments, which is publicly available on the website of the NFCSO. No processing establishment has been authorised for slaughtering aquaculture animals for disease control purposes under the criteria in Article 5 of Directive

2006/88/EC.

The FVO team noted that:

- although under national legislation APB operators which do not meet the requirements for TIR-registration are not obliged to make themselves known to the competent authorities, extensive registers of such APBs were available in all four regional offices visited. The information of such APBs had been obtained from local offices and fishery authorities;

- in one of the four regional offices visited also smaller APBs had been registered in TIR if they traded in live fish for farming;

- the procedure for registration in TIR was considered by the NFCSO to meet the requirements for authorisation of APBs as laid down in Directive 2006/88/EC. However, the TIR registration, which in most cases had taken place long before Directive 2006/88/EC was implemented in Hungary, had been based on an application submitted by the operator and had not been linked to any pre-conditions regarding animal health as required under Article 5 of the Directive;

- the NFCSO stated that each operator of a TIR-registered APB was expected to be fully aware of, and meet the pre-conditions for, authorisation laid down in national legislation. These conditions were to be checked during the next risk-based official control on the APB. Such controls had recently started and would be carried out once per 1-4 years, depending on the risk classification of the APB, which was based on a self-declaration by the APB operator;

- for APB which do not meet the requirements for TIR-registration, the competent authorities have applied the derogation from authorisation i) for all APBs meeting the criteria of Article 4(4)(a) and (b) of Directive 2006/88/EC and ii) for all APBs placing fish on the market solely for human consumption. However, no limits have been set or assessments made to ensure that the latter APBs meet the criteria of Article 4(4)(c) of the Directive i.e. that they only directly supply small quantities of fish to the final consumer or to local retail establishments directly supplying the final consumer;

- a form had been drawn up in accordance with the model in Annex I to Decision 2008/392/EC to allow entry of the information required under Part I of Annex I to Directive 2006/88/EC. The model form had not been modified to include a declaration on freedom from SVC (under point 5.1.8 on the form), which Hungary would have been entitled to as the whole territory has been approved to take national measures to prevent the introduction of SVC in accordance with Article 43(2) of Directive 2006/88/EC;

- all operators of TIR-registered APBs had recently been requested to fill in these forms. APB operators had not received any guidelines or instructions on how to fill in the form, which requires *inter alia* information about the presence of susceptible and vector species for a number of listed diseases and declarations about the health status of each farm. No checks had been carried out by the local offices or regional offices visited to verify the correctness of the information provided on the forms before these were published on the internet. The FVO team checked a random selection of 15 published forms for TIR-registered APBs and noted several forms where:

- compulsory information such as registration number and/or geographical location was missing or

- common carp had not been identified as a susceptible species for KHV or

- the APB had incorrectly been identified as declared disease-free for diseases (mostly KHV) other than those (ISA and SVC) for which Hungary has been declared disease-free;

- separate forms had been published on the NFCSO website for approximately 300 APBs, grouped per regional office, and the way the forms had been named (and sometimes grouped together under one weblink) differed between regional offices. This NFCSO website had not been linked to the website provided for this purpose by the EU Commission. Consequently, the information about TIR-registered aquaculture farms on the NFCSO website is very difficult to access.

- in addition to what is registered in TIR, the central competent authorities do not have information on the total number of APBs in the country. Thus, TIR registered APBs represent an unknown proportion of all APBs which have been registered by the regional offices. In one regional office visited, 22% of the registered APBs were also included in TIR.

5.3.2 Official controls and animal health schemes

As described under point 5.2.2, the planning and implementation of risk-based controls in APBs as laid down in Directive 2006/88/EC started less than one year ago.

The FVO team noted that:

- risk classification was under implementation and made only for TIR-registered APBs;

- as the system is still under implementation it is not yet possible to verify if official controls or animal health scheme inspections take place with the frequencies recommended in Part B of Annex III to Directive 2006/88/EC;

- the information gathered from using the 2013 standardised check list for official controls in APBs covered all points needed to determine whether an APB meets the conditions for authorisation as laid down in Article 5 of Directive 2006/88/EC;

- no official controls or health schemes were required in those APBs which had been excluded from the requirement for TIR registration;

- during a recent official inspection (in preparation for the FVO audit) of a farm to be visited by the FVO team, the competent authorities had noted a hatchery which had not been registered in TIR. The TIR registration would cover the hatchery but not the rest of the APB, as it produced table fish which did not require TIR registration;

- One of the four farms visited kept daily records of *inter alia* mortality per tank. The two visited farms where outbreaks of KHV had taken place had no mortality recorded prior to the outbreak and no mortality had been recorded on the fourth farm visited.

5.3.3 EU-approved surveillance programme for KHV

The competent authorities stated that the KHV programme is still implemented as described in 2009, when the programme was submitted to the EU for approval but the programme is currently being revised, against the background of the five recent outbreaks of KHV.

According to the approved KHV surveillance programme, samples are taken from each epidemiological unit with common carp or Koi carp once per year, starting in April provided that water temperatures are above 16 degrees. In addition, samples are taken also in autumn in APBs located in a 20 km "buffer zone" along the national borders. The approved programme (which includes data from 2009) lists 327 fish farm owners, 42 of which are located in the 20 km buffer zone, with a total of 380 ponds and states that samples will be taken from 130 epidemiological units each year. Wild carps from natural waters (from rivers Danube and Rába, lake Balaton and from the dead channels of river Tisza and Körös) are tested for KHV at least once per year, in spring.

The NRL is responsible for drawing up sampling plans and for issuing instructions for sampling. A County-specific plan is sent in spring to each regional office. The plan lists which APBs should be subject to sampling and specifies which dates the samples should be submitted to the laboratory.

Each sample is to comprise 30 fish, which are transported live to the NRL. In accordance with 10§(6) of national Decree 127/2008, the costs for sampling and analysis are borne by the ABPs.

The FVO team noted that:

- since the approval of the KHV surveillance programme in 2010 the competent authorities have not submitted annual reports to the Commission. Such reports are required under Article 9(a) of Decision 2009/177/EC;

- in addition to the APB registers in each regional office and TIR, the NRL keeps an updated register of all active fish farms, irrespective of size, which breed or sell live fish for farming. This register is the basis for the surveillance programmes and currently comprised 174 fish farms in total: 168 keeping species susceptible to SVC; 160 farms keeping common carp or Koi carp (i.e. susceptible to KHV and SVC); and eight farms keeping species covered by the testing programme for IHN/VHS/SVC;

- the sample submissions for KHV in 2010, 2011 and 2012 had come from 130, 121, and 130 epidemiological units, respectively, which is less than the number of APBs keeping fish susceptible to KHV. The NFCSO stated that some of the APBs were likely to have more than one epidemiological unit. There were no procedures or records available to explain how this subset had been selected for sampling;

- one APB visited traded in, and had production and transit ponds for, several fish species susceptible to KHV and SVC. This APB was considered to be one epidemiological unit by the local office but the transit ponds had been excluded when sampling for the KHV/SVC programme took place in 2010-2013;
- the 2013 sampling plan from the NRL stipulated that 30 samples of fish which are 1-2 summers old and which have over-wintered should be taken from different places in the pond or pond-chain. The requested dates for sample submission were in April – June. No further sampling instructions were included, such as the minimum water temperature, sampling of weak or moribund fish if present, and how to identify and sample each

epidemiological unit within the named farms. There is no requirement to record the water temperature on the sample submission form;

- the sampling instructions do not take into account point 6 in Chapter 2.3.6 (KHV) of World Organisation for Animal Health (OIE) Manual of Diagnostic Tests for Aquatic Animals (2009): "Targeted surveillance should rely on regular monitoring of sites holding susceptible species. Sites should be monitored when water temperatures have reached levels that are permissive for the development of the disease (>17°C) and no sooner than 3 weeks after such temperatures have been reached". Nor the recommendation in the draft Sampling and Diagnostic Manual for KHV Disease (2012), published on the website of the EU-RL for fish diseases, that fish should be sampled when they have been kept for 2-3 weeks at 20-26°C water temperatures for optimal sampling results;

- although the NFCSO had stated that sampling is carried out by, or under the direct supervision of official veterinarians, in all four regional offices visited, samples were normally collected by the APB operator (as stipulated in national Decree No 127/2008) who were in direct contact with the NRL. An official or private veterinarian would not be present during sampling but was required to sign the submission form before the fish were sent to the laboratory. However, sometimes personnel from the NRL would carry out sampling in the larger APBs;

- the five KHV outbreaks in 2012 and 2013 were detected through passive surveillance reporting abnormal mortality in the affected ponds starting in the months June, July or August;

- in the four regional offices visited, the 2013 spring sampling plans had been implemented although samples had often been taken later (June, July, August) than indicated by the NRL.

5.3.4 Programmes for maintaining disease-free status for SVC and ISA

In accordance with Article 52 of Directive 2006/88/EC there is no active or targeted surveillance for ISA – this disease is monitored through passive surveillance.

Virological testing for SVC on carp kept in ponds for breeding purposes started in1994. In December 2010 Hungary was listed as SVC-free in Annex I to Decision 2010/221/EC, after having demonstrated *inter alia* through targeted surveillance that the whole territory was free of SVC. Since 2010, samples collected for the KHV surveillance programme (see point 5.3.3) have also been analysed for SVC. SVC (i.e. *Rhabdovirus carpio*) is also tested within a surveillance programme in farmed sturgeon, pike, pike perch and trout.

According to Chapter 2.3.8 (SVC) of World Organisation for Animal Health (OIE) Manual of Diagnostic Tests for Aquatic Animals (2009), fish up to one year old are most susceptible to SVC, disease outbreaks generally occur in water temperatures between 11-17 degrees and isolation of SVC virus from infected but clinically healthy fish at temperatures outside the clinical range for the disease, is problematic.

The FVO team noted that:

- since the approval of the disease-free status for SVC the competent authorities have not met the requirement to submit annual reports to the Commission as required under Article 4(1)

of Commission Decision 2010/221/EC. Such reports should give up-to-date information on significant risks for the animal health situation and the measures taken for maintaining the disease-free status (Article 4(3)(a) and (b)) ;

- the sampling for KHV takes place in water temperatures and fish age groups which are not optimal for isolation of SVC.

5.3.5 Other national surveillance programmes

There is a compulsory surveillance programme for IHN, VHS and SVC in APBs breeding pike, pike-perch, sturgeon or trout. Seven such farms had been sampled in 2012.

Conclusions

The system for authorisation of APBs is not in line with Directive 2006/88/EC as the competent authorities can neither ensure that the TIR-registered APBs meet the conditions in Article 5 of this Directive nor that those APBs left outside the TIR meet the criteria in Article (4)(4)(c) of this Directive. Information about APBs made public on the internet has not been verified by the competent authorities and has been shown to be sometimes incomplete and incorrect. In addition, the competent authorities are not in a position to ensure that production volumes and trade patterns in the fish farms currently left outside TIR are within the limits set in EU legislation.

The substantial delay in implementing official and other controls in the aquaculture sector means that the competent authorities have not yet gained an overview of the fish health status, biosecurity measures and fish health risks in Hungarian APBs.

The sampling for the approved KHV surveillance programme is implemented by the APB industry with little involvement from the competent authorities who cannot ensure that representative samples are taken for the programme (i.e. at the correct water temperatures and from each epidemiological unit on each APB with susceptible species). Sampling for KHV often took place later than advised by the NRL which increases the chances of detecting KHV-infected fish compared to sampling in spring. However, using such samples for SVC surveillance is unreliable.

5.4 Measures for control of diseases of aquaculture animals

Legal requirements

Chapter V of Directive 2006/88/EC establishes notification and minimum measures for control of diseases of aquatic animals, including amongst others:

- Obligations for notification of: a) suspicion or confirmation of a disease listed in part II of Annex IV to the said Directive, to the competent authority; b) increased mortality in aquaculture animals, to the competent authority or a private veterinarian for further investigations;

- Initial control measures and conditions for epizootic investigations to be carried out in case of suspicion of exotic and non-exotic diseases;

- Minimum control measures in the case of confirmation of exotic and non-exotic diseases;

- Control measures in case of emerging diseases.

Article 47 of Directive 2006/88/EC requires each MS to draw up a contingency plan specifying the national measures required to maintain a high level of disease awareness and preparedness and to ensure environmental protection. Contingency plans shall comply with the criteria and requirements laid down in Annex VII to the said Directive and shall be implemented in the event of an outbreak of emerging diseases and of exotic diseases listed in Part II of Annex IV thereto.

Commission Decision 2009/177/EC implements Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of MS, zones and compartments, and provides lists of: MS, zones and compartments subject to surveillance or eradication programmes approved in accordance with Article 44(1) and (2), respectively, of the said Directive; and MS for which disease-free status has been approved in accordance with Article 49(1) and zones and compartments for which disease-free status has been approved in accordance with Article 50(3) of the said Directive.

Commission Decision 2010/221/EU approves national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Directive 2006/88/EC. Annex I to Commission Decision 2010/221/EU lays down a list of MS and parts thereof that shall be regarded as free of certain diseases (disease-free areas) and Annex II to the Decision lists MS and parts therof, with eradication programmes as regards certain diseases, which have been approved to take national measures to control those diseases.

Findings

5.4.1 Notification, suspicion and confirmation of disease

Training and awareness

The NFCSO stated that national legislation was clear and provided sufficient guidance on the legal requirements in the field of aquaculture animal health for veterinarians in regional and local competent authorities and for veterinarians in private practice.

Minimum requirements for Aquatic Animal Health Professionals (AAHP) are laid down in national Decree 127/2008. These professionals should: be private veterinarians; have a diploma in fishery management or fishery engineering; have an academic post-graduate degree in fishery; or have an agricultural engineer diploma and 10 years' experience in the field. In addition, they must have passed the exam after a training course organised by the NFCSO.

The FVO team noted that:

- courses for AAHP had started in 2009. Six courses had so far been organized by the Hungarian Fish Farmers' Association in cooperation with NFCSO, resulting in 242 certified AAHP. The training course for AAHPs comprised 2.5 hours of lessons followed by a test;

- the competent authorities have not provided any other courses, training material or awareness campaigns targeting owners and operators of APBs;

Notification and suspicion

Annex I to national Decree 113/2008 on the notification system of animal diseases contains a list of the notifiable diseases in *inter alia* aquatic animals and Annex II to this Decree lists the diseases which must be reported to the EU Commission. This Decree entered into force on 1 September 2008.

Anyone involved with (aquaculture) animals (e.g. care, control, handling, trade or slaughtering) or the disposal of by-products is covered by the obligation to notify the private veterinarian, aquatic health official, the district office or the official veterinarian. Annex III to the Decree lists the minimum information required in a notification. Article 25 of national Decree 127/2008, which entered into force 1 October 2008, requires that, in addition to the suspicion or confirmation of a disease listed in the Annex to Decree 127/2008, any increased mortality in an aquaculture farm must be notified in line with the rules in national Decree 113/2008.

Once a notification under national Decree 113/2008 has been made, the animal keeper is obliged to isolate the animals or carcasses at the place of detection until further instructions are given by the official veterinarian. An epidemiological investigation must be carried out by the local senior veterinary officer if there is a suspicion of a listed exotic disease or a listed non-exotic disease for which Hungary has an approved control programme or declared freedom.

The FVO team noted that:

- all disease listed in part II of Annex IV to Directive 2006/88/EC, and SVC, are notifiable under national legislation, however see also point 5.1;

- the national rules for notification meet the requirements of Article 26 of Directive 2006/88/EC;

- in the information about KHV on the NFCSO website, APB operators are recommended to notify the authorities if the mortality for the whole holding exceeds 2% per day;

- in the case of the first 2012 KHV outbreak:

    - mortality had been reported from one pond in the APB in June, restrictions were placed on that pond by the local office, samples from fish with KHV-like symptoms were analysed and found negative for KHV and the restrictions were lifted, in line with the rules in national and EU legislation;

    - however, when suspicions of KHV occurred again in August, samples were immediately sent to the NRL but no official restrictions were placed on the farm by the local office until a visit was made by an epidemiological committee (from the central competent authorities and the NRL) eight days after the PCR-positive result in the NRL, 18 days after the notified suspicion. Even then the restrictions were considered to be based on a suspicion;

- in the case of the first 2013 KHV outbreak:

    - mortality records were available starting from 9 July 2013. Lime treatments of the ponds were carried out three times during six days before the local office was notified and fish were sent for analysis on 16 July. The mortality had then exceeded 1% per week which was the APB operator's critical limit;

- official restrictions were implemented immediately on suspicion and a thorough epidemiological investigation was initiated two days later which identified adjacent farms and a number of contact farms (fish in and fish out);

- the first official controls on this APB had been carried out during this outbreak.

Control measures when a listed disease has been confirmed

The NFCSO stated that since there is an approved surveillance programme for KHV, confirmed cases of KHV are dealt with in accordance with the requirements of Article 38(1)(a) of Directive 2006/88/EC which must be applied when a non-exotic listed disease is detected in a MS which has been declared free (health status in Category I) from that disease.

The FVO team noted:

- that the measures taken by the NFCSO when detecting KVH are more stringent than those required under EU legislation, as the health status of Hungary with regard to KHV is Category II.

- for the 2012 KHV outbreak farm visited that:

  - this APB had been sampled for the KHV/SVC programme in May 2012 with negative results;

  - the APB was declared infected by the regional office and a containment zone was drawn up 48 days after they had been notified by the NRL of the PCR-positive result and 12 days after the EURL had confirmed the positive result from the NRL;

  - the epidemiological committee concluded that two inter-connected ponds should be considered infected and should be emptied. The most likely source of KHV was deemed to be water from the Danube which had been pumped into all six ponds on the premises;

  - samples for KHV were taken in October from the interconnected ponds and from one of the other four ponds. All samples were KHV-negative. No samples were taken from the hatching and breeding ponds of this APB upstream in the same water system;

  - the official decision by the CVO to empty the two inter-connected ponds was taken 21 February 2013 and the harvesting of the ponds was finished 27 March after which the two ponds were dried and disinfected. All fish were sent for rendering as there was no suitable processing establishment available;

  - sampling of fish from the other four ponds on the APB took place in March, May and August 2013. The May samples were taken on fish which had first been placed in increasing water temperatures in tanks until sampling took place at 20 degrees in order to increase the sensitivity of the test. All these

samples had been negative for KHV;

- Once the negative results from the August sampling were reported the local office lifted the restrictions on the APB on 28 August. At the time of this FVO audit, the containment zone had not been lifted by the regional office;

- for the 2013 outbreak farm visited that:

  - the most recent sampling for KHV/SVC prior to the outbreak had taken place in May 2012. The 2013 sampling plan had not included this site for this APB, which kept fish on several sites;

  - when the KHV-positive result was reported from the NRL on 24 July the regional office declared the pond as an infected area. A small number of fish was sampled from two other APBs upstream from the infected pond. These samples were KHV negative;

  - based on a hypothesis that the infection would have been introduced within six weeks prior to the outbreak (3 weeks incubation period x2) several supplying farms were excluded from the investigation and only one supplying farm in another county was considered by the regional office as a potential source of the infection. This farm was subject to a clinical inspection but no sampling. No other contact farms were sampled;

  - the operator described symptoms indicative of KHV as a recurring event most recently seen three years ago but not with such high mortality as this year. No suspect samples had been taken before 2013. Antibiotic treatment was administered each year in May;

  - measures to empty this pond were on hold, pending an action plan requested from the APB operator.

5.4.2 Contingency planning for emerging and exotic diseases

There are no contingency plans in place for any diseases in aquatic animals.

Conclusions

The passive surveillance programme has been effective in identifying KHV outbreaks in cases with high mortality. However, the high mortality threshold set by the authorities for official notification of a suspicion and the limited sampling of contact farms, may contribute to farms with a KHV infection causing limited mortality over an extended period remaining undetected. The approved KHV surveillance programme is mostly implemented as planned, albeit with most of the sampling carried out by the operators. KHV is treated as an exotic disease, which is stricter than the minimum requirements in EU legislation. However, the lack of a contingency plan, documented procedures or training of staff for handling an outbreak of KHV (or any other notifiable disease in aquaculture animals) are likely to have contributed to the slow response by the competent authorities in dealing with the 2012 KHV outbreak and the limited follow-up sampling in contact farms to the KHV outbreaks.

5.5 Laboratory network

Legal requirements

Articles 56 and 57 of Directive 2006/88/EC require MS:

- to arrange for the designation of a national reference laboratory (NRL) for diagnosis of diseases of fish, molluscs and crustaceans and ensure that the NRL liaises with the EU reference laboratories in those areas;

- to ensure that any NRL on their territory is adequately equipped and staffed with the appropriate numbers of trained personnel to carry out the laboratory investigations required in accordance with this Directive and to comply with the functions and duties laid down in Part II of Annex VI thereto;

- to ensure that laboratory examinations for the purposes of this Directive are carried out only in laboratories designated for such purpose by the competent authority and that they comply with the functions and duties laid down in Part III of Annex VI thereto.

Findings

The national reference laboratory (NRL) for fish diseases is the Veterinary Diagnostic Directorate of the NFCSO (NFCSO-VDD) in Budapest. This laboratory is the only one authorised to carry out tests for notifiable viral disease of fish. Three laboratories are involved in the NRL function for fish diseases: the Laboratory for Virology; the Laboratory for Molecular Biology; and the Laboratory for Parasitology, Fish- and Bee Diseases, which is responsible for sample reception, examination and tissue sampling, coordination of all analyses and for reporting of all analytical results.

Fish may also be submitted to two regional NFCSO-VDD laboratories or to two laboratories affiliated to universities, which carry out autopsies, parasitological and bacteriological investigations, but should their investigations raise the suspicion of a notifiable viral disease these laboratories must forward the samples to the NRL.

The FVO team noted that:

- all samples from official controls in aquaculture animals, such as investigations of suspect and confirmed cases (as well as other official samples for notifiable animal diseases) have been analysed in a non-accredited laboratory since the accreditation to ISO/IEC 17025 for NFCSO-VDD in Budapest expired in December 2011;

- the regional branches of NFCSO-VDD in Kaposvar and Debrecen are accredited to ISO/IEC 17025;

- the three branches of the NFCSO-VDD operate a common laboratory information management system (LIMS) in which the sample numbers indicate in which branch a sample was first registered. This system provides for traceability of the samples from sample reception to reporting;

- the NRL applied internationally recognised methods and cell lines for the diagnosis of SVC, KHV, VHS, IHN, epizootic haematopoietic necrosis and infectious pancreatic necrosis;

- there are two standard operating procedures for diagnostic methods for fish diseases in the NRL: SVC virus isolation followed by virus identification by enzyme-linked immuno-sorbent assay (ELISA) and KHV detection by polymerase-chain reaction (PCR). These two methods had been included in the scope of accreditation until 2011 and had recently been submitted to the accreditation body again, pending re-accreditation of the laboratory;

- important steps in the diagnostic procedures such as the actual dilution of the sample and the dates for reading of virus inoculation plates were not documented;

- the sample preparation and virus isolation procedures for SVC described by the responsible scientist did not exist in writing and were different from those in the SOP *inter alia* with regard to whether or not samples were frozen before analysis, the level of dilution of tissue samples, the procedures for and frequency of reading the incubated cell cultures;

- the sample dilution levels and incubation temperatures were verbally described to vary between batches of samples tested for the same virus. The checks on incubated cell culture plates would normally not begin until 3-5 days after inoculation;

- there were no procedures in place to check the sensitivity of the cell lines when new cell-lines were started from frozen stock. This would be checked once annually by the participation in international comparative tests. Positive control samples were not used to verify the sensitivity of the virus culture between the annual comparative tests;

- an exact target temperature had been defined for some of the fridges, freezers and incubators in the laboratories visited but no acceptable upper / lower temperature limits had been set to define when measured values which deviate from the exact target would require corrective action;

- the laboratory had regularly participated in annual comparative tests organized by the EURL for fish diseases for the detection of VHS, IHN, SVC, EHN, ISA, KHV virus, with satisfactory results in the last three years.

In the NRL, tissues from the 30 fish in a typical surveillance sample (for KHV/SVC or for IHN/VHS/SVC, depending on the sampled species) are pooled five by five to form six samples for virological analysis. Thus, six virological analyses are carried out on each surveillance sample from an epidemiological unit. In case of suspect samples each fish is analysed individually or tissues are pooled two by two.

The FVO team noted that:

- the pooling of samples are in line with those recommended by the OIE;

- on rare occasions, the LIMS system indicated that a surveillance sample had been unsuitable for analysis. No re-sampling had been requested in such cases;

- the tissue samples used for KHV and SVC surveillance samples were spleen, kidney and liver. Gills were added only when testing suspect KHV cases. For SVC this is in line with the OIE diagnostic manual. However, the EURL recommends the use of gills, kidney and spleen for KHV diagnostics and, in the OIE diagnostic manual for KHV, gills are recommended to be used in all cases, particularly when virus isolation is attempted, whilst

intestines and encephalon are recommended to be added when testing apparently healthy fish (such as in a surveillance programme);

- when the first case of KHV was detected the NRL reported verbally to the regional office and the central competent authorities that there was a suspicion of KHV when positive PCR results had been obtained. The NRL did not confirm the positive result as required by an NRL (Part II of Annex VI to Directive 2006/88/EC). Instead, further samples were collected from the outbreak and 18 days after the first PCR-positive KHV result and all samples were sent to the EU reference laboratory for fish disease for confirmation. A formal report of the confirmed finding was not issued by the NRL until the KHV-positive samples had been confirmed by the EU reference laboratory 20 days later (38 days after the first PCR-positive result).

Conclusions

The test methods used in the NRL are in line with international standards and the laboratory has performed well in annual international comparative tests for the main fish diseases. However, the lack of functioning SOPs for all relevant fish diseases, the non-accredited status of the laboratory and the deficiencies observed with regard to quality controls on cell lines and day-to-day documentation of diagnostic procedures, make it difficult for the competent authority to evaluate the reliability of the test results. In addition, the laboratory contributed to the delay in confirming the first KHV outbreak and the omission of gills when testing surveillance samples for KHV reduces the sensitivity of the method.

5.6 Placing on the market and introduction of aquaculture animals and products thereof

Legal requirements

According to Article 12 of Directive 2006/88/EC, MS shall ensure that the placing on the market of aquaculture animals and products thereof does not jeopardise the health status of aquatic animals at the place of destination with regard to the diseases listed in Part II of Annex IV to the said Directive.

Chapter III of Council Directive2006/88/EC lays down detailed rules on the movement of aquaculture animals, in particular relating to movements between MS, zones and compartments with different health statuses, as referred to in Part A of Annex III to the said Directive.

Chapter III of Regulation (EC) No 1251/2008 lays down animal health conditions for the placing on the market of i) ornamental aquatic animals either originating from or intended for closed ornamental facilities (Article 4) and ii) aquaculture animals intended for farming, relaying areas, put-and-take fisheries, open ornamental facilities and restocking in MS and parts thereof with national measures approved by Commission Decision 2010/221/EU (Article 8a). Chapter III of this Regulation also lays down animal health certification requirements for the placing on the market of aquaculture animals and products thereof, including those intended for human consumption (Articles 5 to 8 therein).

Chapter IV of Regulation (EC) No 1251/2008 lays down animal health conditions and animal health certification requirements for import into the EU of aquaculture animals and products thereof, including those intended for human consumption, and ornamental aquatic animals intended for closed ornamental facilities.

Findings

5.6.1 Transport of live aquaculture animals

Transporters must be authorised by the regional office and vehicles for transport of aquaculture animals must be approved by the local offices. A list of 23 registered transporters of aquaculture animals, with 76 vehicles authorised for animal transports longer than eight hours, was provided by the NFCSO.

Article 14 of national Decree 127/2008 lays down disease prevention requirements in relation to transport and Articles 15-17 cover animal health certificates, placing on the market for farming and restocking, and the introduction of susceptible species and vector species into a disease-free area.

The FVO team noted that:

- the standardised check-list to be used for approval of animal transport vehicles covers the animal welfare requirements of Regulation (EC) No. 1/2005, which does not lay down any specific rules for transport of aquaculture animals;

- with regard to KHV and SVC, Article 16 of national Decree 127/2008 stipulates that these diseases or infectious agents must not have been detected in the APB from which live fish are moved for farming or re-stocking in Hungary. If susceptible species are present in the APB, a document showing negative test results from the NRL in the previous 12 months must be provided by the operator to the AAHP or veterinarian signing the general health declaration (based on clinical inspection) in the movement document. Verification of this information had been included on the movement document checked by the audit team;

- one APB visited routinely sourced consignments of fish from several Hungarian APBs. These fish were mixed, stored in and moved between a number of transit ponds, sometimes for several months, adjacent to production ponds for carp in the same APB. These consignments were considered to be fish for human consumption and were therefore allowed to be moved to this APB without any animal health declaration in the movement document. The operator stated that live fish were regularly sold for human consumption to retailers in Hungary (in smaller batches) or in other MS (larger consignments) while fish from the production ponds were occasionally used for re-stocking of a put-and-take pond. The first official control visit on this APB had taken place in August 2013;
- if the operator of an APB has been approved as an AAHP by the NFCSO this qualifies the person to sign animal health documents for movement of fish to other APBs. The public health documents for live fish intended for processing for human consumption must be signed by a veterinarian.

5.6.2 Import and export

The NFCSO stated in their response to the pre-audit questionnaire that live aquatic animals are rarely imported from third countries directly to Hungary and that there had been no such consignments arriving from third countries in 2012 or 2013. In 2011 there were 44 consignments (206 692 kg) and in 2010 three consignments were imported to Hungary (20 000 kg).

The NFCSO stated that live fish, including carp species, for human consumption were imported from Croatia before 1 July 2013 but since these consignments were for human consumption no

animal health certificates had been required.

With regard to import of live aquaculture fish the FVO-team noted that:

- according to the Trade Control and Expert System (TRACES) three consignments of live East African Nile Perch (*Lates niloticus*) had been imported from Israel in 2012. These consignments had not been known to the competent authorities for aquaculture animal health prior to this audit. The import certificates for these consignments correctly certified the health status of these fish for farming purposes, and listed the species as Barramundi (*Lates calcarifer*).

There are less than ten wholesalers of ornamental fish in Hungary. With regard to import of ornamental fish the FVO team visited one major wholesaler and noted that:

- the regular imports (more than 10 consignments per year) of ornamental fish from third countries to the wholesaler visited were not known to the competent authorities for aquaculture animal health prior to this audit;
- there are very clear rules in national legislation on the keeping of ornamental fish and these rules appeared, from the example seen, to be properly implemented. The trade in ornamental fish, including those fish species susceptible to SVC and KHV, is carried out in line with the rules for closed ornamental facilities;
- both health certificates examined for recent consignments from Thailand of goldfish and Koi carp, respectively, were on the correct model form as set out in Part B of Annex IV to Commission regulation (EC) No 1251/2008 and both consignments were correctly certified with regard to SVC;
- the consignment of Koi carp had not been accompanied by any certification with regard to KHV. This deficiency had not been noted, and no action had been taken to isolate the consignment pending clarification of its health status, by the official veterinarians at the border inspection post.

5.6.3 Intra-Union trade (IUT)

With regard to IUT of aquaculture animals from Hungary the FVO team noted that;

- staff of the local offices had diligent routines for timely inspections of consignments of live fish intended for other MS. There was also a notification system in place at the local level for all consignments destined for other MS;
- although examples of correct certification of live fish for processing for human consumption in a MS with lower aquaculture health status were seen, certain consignment certificates were presented where the wrong model certificate had been used, the wrong health statement completed or no health statement included. Local and regional officials explained that they experienced problems with generating the correct certificates from TRACES and that they had not received any training, procedures or instructions regarding aquaculture fish certificates;
- of particular concern was one shipment of pike perch (*Sander lucioperca*) to Denmark. Pike perch is a vector species for IHN and VHS, but the vector statement on the health certificate had been deleted. Because Denmark has been declared free from IHN and operates a combination of free areas and an approved programme for VHS, and thereby has a higher health status for these fish diseases than Hungary, this consignment should not have been

certified for Denmark;

- when certificates for IUT, for consignments of fish for human consumption from one of the APBs visited, were signed by the official veterinarian these fish were declared as coming from a KHV-free MS, zone or compartment;

- the fish coming into this transit APB from other Hungarian APB were considered to be fish for human consumption and were accompanied by commercial documents only;

With regard to IUT of aquaculture animals to Hungary the FVO team noted that:

- the trade in live aquatic animals into Hungary consists predominantly of (common) carp for human consumption;

- when requested by the FVO team the competent authorities obtained data from TRACES showing that in 2010, 2011 and 2012 several consignments of live carp for human consumption had entered Hungary each year from the Czech Republic and Slovakia, both having a lower health status than Hungary with regard to SVC and KHV. These consignments had not be subject to any checks with regard to animal health certification;

- one regional office visited explained that a combined fish farm and put-and-take fishery brought in catfish (susceptible to SVC) as intended for human consumption from other MS. These fish were not going directly to a retailer but stocked in ponds on the farm, sometimes for several months, before selling them in smaller consignments to retailers. The most recent consignment, which was still kept on the farm four months later, had arrived in May with only a trade identification document but no health certificate or TRACES notification which should have been a legal requirement when live fish were brought into the country for such re-stocking/farming;

- the competent authorities for animal health had no insight into how live fish for human consumption in Hungary were moved or to what extent they were kept in farms and re-packaged before being delivered to retailers. Therefore the competent authorities were not in a position to ensure that the conditions for placing on the market in Article 18(1) of Directive 2006/88/EC and for temporary storage at the place of retail in Article 18(2) of this Directive had been met;

- the NFCSO stated at the closing meeting that consumption-size live carp cannot be packaged in retail-sale packages to meet the requirements in Article 6(2)(c) of Commission Regulation (EC) No 1251/2008 without compromising animal welfare;

- no processing establishment in Hungary has been approved under Article 4 of Directive 2006/88/EC in order to meet the requirements for temporary storage and processing of fish of susceptible species from MS with a lower health status than Hungary for certain diseases, as laid down in Article 18(1)(b) and Article 18(2)(b) of this Directive;

Conclusions

There are systems in place for registration and authorisation of transporters and vehicles and as well as standardised health declarations for movements of live fish for breeding and production between farms in Hungary. The fact that an APB operator can sign health declarations for consignments leaving his own farm if he has been approved as an AAHP allows for a conflict of interest which affects the reliability of these declarations.

Official staff have not received adequate training, have no documented procedures and no instructions to ensure that they can carry out their tasks with regard to controls and certification for trade, import and export of live aquaculture animals. Incorrect health certification has allowed the dispatch of fish for farming to a MS with a higher health status which may have led to an introduction of disease through a vector species. The risk to fish health from the mistakes in checks of import certificates for ornamental aquaculture animals is low as the number of consignments is limited and these fish are only accepted for closed aquaculture facilities. In contrast, while the competent authorities recognise that the trade in live fish for human consumption poses a risk to the high aquaculture animal health status of Hungary, they have no insight into this trade. Together with the ineffective controls on health certificates for live fish these deficiencies jeopardise the favourable animal health status of the susceptible fish populations in Hungary.

6 Overall Conclusions

The implementation of Council Directive 2006/88/EC started recently and the competent authority does not yet have systems in place to ensure that the aquatic animal health rules in EU legislation are adhered to or that aquaculture production businesses referred to as authorised meet the conditions in the Directive. However, there is a functioning passive surveillance programme in place and the approved KHV surveillance programme is mostly implemented as planned, albeit by the industry. The planning of controls and implementation of these rules are undermined by the lack of a contingency plan and lack of training, documented procedures, instructions for staff carrying out official tasks in the field of aquaculture animal health.

Although the national reference laboratory is using the appropriate analytical methods and has been successful in annual comparative tests, a higher sensitivity for KHV could be achieved by following the advice of the EU reference laboratory. Certain deficiencies in the quality control measures make it difficult for the competent authority to evaluate the reliability of the test results.

Incorrect health certification, failure to identify incorrect incoming health certificates for live fish and the lack of insight into, and checks on, the trade and storage of live fish ultimately intended for human consumption jeopardise the favourable health status of susceptible fish populations.

7 Closing Meeting

A closing meeting was held on 13 September 2013 with representatives of the competent authorities. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement with the findings of the audit and stated that potential conflicts of interest among official veterinarians would be investigated.

8 Recommendations

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion, aimed at addressing the recommendations set out below, within twenty-five working days of receipt of this report.

N°.	Recommendation
1.	The competent authority should ensure that staff carrying out official controls:- are free from any conflict of interest as required under Article 4(1)(b) of Regulation (EC) No 882/2004;- receive appropriate training (in the field of aquaculture animal health) as required under Article 6(a) and (b) of Regulation (EC) No 882/2004, and- have documented procedures containing information and instructions for official controls on aquaculture animal health as required under Article 8(1) of Regulation (EC) No 882/2004.
2.	The competent authority should ensure that the requirement to report confirmed cases of ISA, KHV and SVC to the Commission and to other MS within 24 hours, in accordance with Article 27(b) of Directive 2006/88/EC (KHV, ISA) and Article 5(2) of Decision 2010/221/EC (SVC), is correctly transposed into national legislation.
3.	The competent authority should implement the system for authorisation of aquaculture production businesses in line with the requirements laid down in Article 4 of Council Directive 2006/88/EC, taking particular care to ensure through official controls that the authorisation conditions laid down in Article 5 of the Directive are met.
4.	The competent authority should ensure that derogation from the authorisation requirement is granted only to those aquaculture production businesses which meet the criteria laid down in Article 4(4)(a)(b) or (c). With regard to Article 4(4)(c) particular attention should be paid to the limits laid down in Article 1(3)(c) of Regulation (EC) No 853/2004.
5.	The competent authority shall ensure that a risk-based animal health surveillance scheme is applied in all farms in accordance with the rules laid down in Article 10 of Council Directive 2006/88/EC, taking into account the guidelines in Commission Decision 2008/896/EC as required under Article 10(4) of Council Directive 2006/88/EC.
6.	The national reference laboratory designated for analysis of official samples from aquaculture animals should have a quality system as laid down in Part II of Annex VI to Council Directive 2006/88/EC, in order to allow the competent authority to assess the reliability of the analytical results, and preferably be a laboratory which has been assessed and accredited as laid down in Article 12 of Regulation (EC) No 882/2004.
7.	The competent authority should draw up a contingency plan for emerging and exotic diseases in line with the rules laid down in Article 47 of Council Directive 2006/88/EC.
8.	The competent authority should ensure through official controls and certification that the conditions for the movement between Member States of aquaculture animals and products thereof laid down in the relevant articles in Chapter III of Council Directive

N°.	Recommendation
	2006/88/EC are met, in order not to jeopardise the health status of aquatic animals at the place of destination in accordance with Article 12 of Council Directive 2006/88/EC.
9.	With regard to introduction of fish species listed as susceptible to SVC in Part C of Annex II to Commission Decision 2010/221/EU, the competent authority should consider requiring that these fish comply with the rules laid down in Article 2(2) of the Decision in order not to jeopardise Hungary's disease-free status for SVC.

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=2013-6784

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
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
Dec. 2008/392/EC	OJ L 138, 28.5.2008, p. 12-20	2008/392/EC: Commission Decision of 30 April 2008 implementing Council Directive 2006/88/EC as regards an Internet-based information page to make information on aquaculture production businesses and authorised processing establishments available by electronic means
Dec. 2009/177/EC	OJ L 63, 7.3.2009, p. 15-39	2009/177/EC: Commission Decision of 31 October 2008 implementing Council Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of Member States, zones and compartments

Legal Reference	Official Journal	Title
Dec. 2010/221/EU	OJ L 98, 20.4.2010, p. 7-11	2010/221/EU: Commission Decision of 15 April 2010 approving national measures for limiting the impact of certain diseases in aquaculture animals and wild aquatic animals in accordance with Article 43 of Council Directive 2006/88/EC
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dec. 2008/896/EC	OJ L 322, 2.12.2008, p. 30-38	2008/896/EC: Commission Decision of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC
Reg. 1/2005	OJ L 3, 5.1.2005, p. 1-44	Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
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
Dec. 2001/183/EC	OJ L 67, 9.3.2001, p. 65-76	2001/183/EC: Commission Decision of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC
Dec. 2003/466/EC	OJ L 156, 25.6.2003, p. 61-73	2003/466/EC: Commission Decision of 13 June 2003 establishing criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA)