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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

DENMARK

FROM 09 TO 18 NOVEMBER 2011

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN RELATION TO AQUACULTURE ANIMALS

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 Denmark, from 9 to 18 November 2011.

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 due to a long-established animal health strategy, Denmark benefits at present from a favourable animal health situation concerning aquatic animals. The CA has also implemented most of the requirements in the Directive and secondary legislation therein. In particular the CA, although having a very small number of staff, has adequate expertise on diseases of aquatic animals and more than adequate laboratory facilities. There is also a transparent notification system and a contingency plan which significantly reduces any risk of spreading aquatic animal diseases within the Union or abroad. This is in spite of the fact that the implementation of the new rules concerning the animal health in aquatic animal cannot be considered as satisfactory in all aspects, in particular:

- *APBs have not all been authorised or registered as appropriate;*
- *results on control activities do not allow the level of compliance with the requirements of the Directive in APBs to be assessed due to lack of proper recording;*
- *lack of procedures in certain parts of the system including reporting of activities and auditing within the control chain from the CCA to the CA level, and collaboration with the laboratory;*
- *the certification procedure adopted so far is not in compliance either with the requirement of the Directive and secondary legislation or with the general principles of EU legislation on certification.*

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
APB	Aquaculture production businesses
BKD	Bacterial kidney disease
CA	Competent Authority
CCA	Central Competent Authority
DVFA	Danish Veterinary Food Administration
EC	European Community
EHN	Epizootic haematopoietic necrosis
EU	European Union
EUS	Epizootic ulcerative syndrome
FVO	Food and Veterinary Office
GS	Infection with *Gyrodactylus salaris*
IHN	Infectious haematopoietic necrosis
IPN	Infectious pancreatic necrosis virus
ISA	Infectious salmon anaemia
KHV	Koi herpes virus disease
MS	Member State
NRL	National Reference Laboratory
NVI	National Veterinary Institute
PCR	Polimerase Chain Reaction
RVFA	Regional Veterinary Food Administration
SAK	Section of aquaculture
SVC	Spring viraemia of carp
VHS	Viral haemorrhagic septicaemia

1 Introduction

This audit formed part of the Food and Veterinary Office's (FVO) planned programme. It took place in Denmark from 9 to 18 November.

The audit team comprised two inspector(s) from the FVO and one expert from a European Union (EU) country. Representatives from the central competent authority accompanied the audit team for the duration of the audit. An opening meeting was held on 9 November 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 Directive 2006/88/ EC and associated legislation.

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

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	**Central**	2	Opening and closing meetings with the CCA; two meetings with the CA
	Regional	2	
LABORATORIES		1	National, EU and OIE Reference laboratory
Aquaculture production Business (APB)		5	All APB keep fish (including salmonids, cyprinids and other species) either for food or ornamental purposes.

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 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 mission is the first audit carried out in Denmark in order to evaluate application of animal health requirements in live fish and the requirements laid down in Directive 2006/88/EC for aquaculture animals and products thereof.

4.2 Aquaculture industry in denmark

The aquaculture industry in Denmark is dominated by rainbow trout production for food. Some 40-45000 tons of aquaculture products are produced yearly including freshwater and marine farms (about 400 APBs in total). Due to the favorable animal health situation in this sector, Denmark is very active in trading live fish both Intra-union (fish for human consumption and eggs for reproduction) and to third countries (salmonids eggs). Only 3 farms were registered for carp at the time of the audit. There are currently about 50 APBs producing shellfish and production of mussels is about 1550 tons. Oyster production is at the experimental stage but a significant production of oysters exists from the natural environment in a fjord.

4.3 Health status

4.3.1 Legal requirements

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, and in particular:

- Lays down a list of MS and parts thereof in the second and fourth column of the table in Annex I thereto that shall be regarded as free of the diseases listed in the first column of that table (disease-free areas); and
- Approves the eradication programmes adopted by the MS listed in the second column of the table in Annex II thereto for the diseases listed in the first column of that table, in respect of the areas listed in the fourth column thereof (eradication programmes).

4.3.2 Diseases of fish

The country is considered free of two of the listed diseases (Annex IV part II to the Directive) : infectious haematopoietic necrosis (IHN) and infectious salmon anaemia (ISA) in accordance to Commission Decision 2009/177/EC. All continental trout farms are currently also free from viral haemorrhagic septicaemia (VHS) with most of them (254) being classified in category I, 61 in category II and 28 (marine farms) in category III according to Part A of Annex III to Directive 2006/88/EC.). The last outbreak of VHS was reported in January 2009. The CA has been

implementing an EC approved eradication programme for VHS (Art. 44(2), of the Directive), since 2009 in collaboration with the industry. Complete eradication of this disease is foreseen for 2013. Koi herpes virus (KHV) has never been reported in Danish carp farms. The disease was made notifiable in 2009 and since then the virus has been reported only twice and both times in ornamental ciprinids, in closed ponds.

Concerning the non-listed diseases Denmark is recognized as free from spring viraemia of carp (SVC) according to Commission Decision 2010/221/EC. According to the CA bacterial kidney disease (BKD) occurs sporadically and 33 farms are considered as free by the Danish Veterinary and Food Administration. A voluntary surveillance programme has been in place for infectious pancreatic necrosis (IPN) since 1970; 47 farms are considered free of this disease. Due to an unresolved internal legal issue Denmark has so far not filed an application to the EC, to apply any measures for BKD and IPN in accordance with article 43 of the Directive.

4.3.3 Diseases of Molluscs and Crustaceans

Marteillia refringens and *Bonamia ostreae* have never been reported in Denmark. The area of the Limfjord, the natural production site of oysters, was recognized as free of diseases by Commission Decision 2005/104/EC. The CA have prepared an application for a surveillance programme in the same fjord, to maintain the free status regarding the two diseases.

Concerning crustacean diseases, the situation with regard to white spot disease in Denmark is unknown.

5 Findings And Conclusions

5.1 Legislation

5.1.1 Legal requirements

Article 65 of Directive 2006/88/EC require 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.

5.1.2 Findings

The general Danish provisions relating to the control of epizootic diseases in domestic animals including fish are laid down in the Animal Health Act of 2004. The aquatic animal health requirements of the Directive are transposed by a series of executive orders.

The main executive orders relevant to the transposition of Directive 2006/88/EC are:

- Executive Order No. 1218 of 12. December 2008 on surveillance and control of certain infectious diseases in aquatic organisms.
- Executive Order No. 1219 of 12. December 2008 on the approval and operation of aquaculture farms and the marketing of aquatic organisms and products thereof.

Other relevant executive orders for the audit are:

- Executive Order No. 54 of 26. January 2011 on lists of infectious diseases.
- Executive Order No. 216 of 23. March 2009 on special measures and compensation in connection with eradication of viral haemorrhagic septicaemia.

A legal act concerning the introduction of live fish in compartments free of of BKD and IPN is under discussion at the time of the audit. The outcome of the discussion could mean less power for the CA to restrict the introduction of live fish in certain compartments.

5.1.3 Conclusions

The CA of Denmark have adopted and published the laws, regulations and administrative provisions necessary to comply with Directive 2006/88/EC in accordance with Article 65 therein.

5.2 COMPETENT AUTHORITIES

5.2.1 Legal requirements

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

- to designate their CA for the purposes of this Directive. The CA shall operate and perform their duties in accordance with Regulation (EC) No 882/2004;
- to ensure that effective and continuous cooperation based on the free exchange of information relevant to the implementation of this Directive is established between the CA 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;
- to ensure that the CA 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 CA and laboratories.

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 CA and that they comply with the functions and duties laid down in Part III of Annex VI thereto.

5.2.2 Findings

5.2.2.1 Organisation

The Central Competent Authority for animal health is the Danish Veterinary and Food Administration (DVFA) of the Ministry of Food, Agriculture and Fisheries. Within the DVFA, all responsibilities for animal health fall under the Animal Health Division. Within this structure one person is in charge of coordinating the policy on fish animal health under the supervision of the deputy head of the division. Two Regional Veterinary and Food Administration (RVFA) offices are responsible for the implementation and enforcement of legislation and disease preparedness in their regions. The CA responsible for aquatic animal health in the country is the section of aquaculture (SAK) attached to one of those two RVFAs.

The SAK is responsible for the overall implementation of aquatic animal health policy in the country. The three officials that constitute the SAK are in charge of all official controls and any other related duties and tasks to be carried out to satisfy the requirements in the Directive. According to representatives of the CA met, in delivering their responsibilities on aquatic animal health, they work closely with stakeholders in the aquaculture industry including the ornamental fish, fisheries managers and their relevant trade associations. The audit team noted that, in spite of the very small number of staff, frequent contacts between the relevant CA and the operators had been taking place in all APB visited. This is mainly due to the fact that in carrying out their activities the SAK officials try to optimize the use of their time, availing of the opportunity to visit the APBs to carry out advisory work or controls when, for instance, they visit an APB within an animal health surveillance scheme.

The main activities of the inspectors include statutory inspection, sampling and testing programmes, investigation of disease outbreaks in aquatic animals, enforcement of statutory disease controls and implementation of controls on the import and export of live aquatic animals. Staff of the CA met showed a high level of expertise and experience in aquatic animal health, and matters related to aquaculture business in general. They have accumulated knowledge since they started their operation many years ago (all 3 members of staff have been working for over 10 years in the sector). The work of the CA staff is supported by the diagnostic services offered by the laboratories in Aarhus and Copenaghen (see 5.2.2.3).

The staff of the CA are not permitted to have any involvement or business interest in the industries for which they have any regulatory responsibilities. All staff are required to disclose any potential conflict of interest between their role and any personal business.

5.2.2.2 Documentation of controls

The CA did not prepare any special written procedure (Article 8 of Regulation (EC) 882/ 2004) to control the implementation of the requirements of the Directive. It was explained that due to the very small size of the structure (only three members of staff) and because of the daily close contacts between the members, it was not considered necessary to produce written working procedure. The CA extended the system used to document the fish diseases control activities to any other control activities carried out in APBs.

Consequently the CA report their visits to the APBs in a form that has been used since the disease control activities started, well before the Directive came into force. The form consists of a single page; attached to this document is a form for sample taking and submission. The form is filled

whenever a member of the CA visits an APB, for any reason. The original copy of that document is left at the farm and the manager should sign it, to acknowledge that he has received it. No other record concerning any official visit exists, apart from this at the APBs level.

An aide memoire was also available for the three members of SAK, to be used during the visits to an APB. However, due to the limited recording of activities described above, it was not possible to know if this aide memoir was of any use or help. It should be said concerning this point that the three members of SAK have a very strong and long experience in the field and very deep knowledge of the fish production in the country. However, very little trace remains of their activities in the APBs apart from the sampling. Also, no written procedure was agreed with the laboratory concerning the taking, storing, dispatching and analyzing of samples taken in the animal health control operations.

The audit team saw that the three members of SAK provide APB operators with copies of the reports of the inspections they carry out. However, contrary to what should be the procedure, many of the reports were not signed by the managers of the APBs. This was explained to be due to the fact that on many occasions nobody from the APBs would be present during the visit of the CA. On the other hand the signature in the report is the only proof available to confirm that the APB operator agrees with the findings and operations carried out during any CA visit. It was also verified that copies of the above mentioned reports on inspections, sampling and testing results are kept at the head quarters of SAK. The CA keep also, for internal use only, a sort of a diary where every single visit to an APB is entered. The name of the APB, the date of the visit, the identity of the visitor are the only information entered in the book

5.2.2.3 Laboratory services

The diagnostic testing service for the SAK is provided by the laboratories in Aarhus for fish diseases and by the laboratory in Copenhagen for bivalve molluscs.

National Veterinary Institute

The National Veterinary Institute (NVI) of the Danish Technical University is the National Reference Laboratory (NRL) for fish, mollusc and crustacean diseases. No other laboratory in Denmark is licensed to deal with notifiable fish diseases. The NVI is responsible for conducting diagnostic research and provides education and advice on infectious animal diseases in farm livestock and pet animals. It covers all disciplines relating to infectious diseases: pathology; bacteriology; virology; parasitology; immunology; vaccinology and serology; as well as epidemiology and risk assessment.

The NVI has three departments: “Veterinary Diagnostics and Research” in Copenhagen; “Virology” on the isle of Lindholm; and Poultry, Fish and Fur Animals in Aarhus. These departments are central to the Danish contingency plan for outbreaks of animal diseases. The section for fish and crustacean diseases is in the NVI department of Aarhus in Jutland. The section is divided into 2 units, one dealing with basic research on host pathogen interaction in aquatic animals and one with responsibility for diagnostics, surveillance and related research. This section acts also as NRL for all aquatic animal diseases and is at the same time the EU RL for fish diseases and the OIE RL for VHS.

The unit carries out all the analyses on the routine samples taken in surveillance programmes for fish diseases, as well as the samples taken in connection with suspicions of the respective diseases. In addition the NVI performs all diagnostic tests for fish diseases in Denmark. On-call

arrangements are in place and samples can be delivered from all parts of Denmark in less than 4-6 hours.

The Danish NRL for bivalve mollusc diseases is in the section for bacteriology at NVI in Copenhagen. This unit is conducting the surveillance and diagnostics of mollusc diseases in Denmark, using mainly histopathology and PCR.

Concerning the above distribution of activities it was noted that although the NVI in Aarhus has been designated as NRL for crustacean diseases it has not yet put in place the diagnostic techniques necessary for this function. Consequently no standard operating procedures regarding crustacean diseases were yet available at the time of the audit, and only histology is used for crustacean diseases. Only limited checks are carried out at sample reception, which do not allow the previous treatment of the sample to be traced back. Samples do not always arrive within the stipulated times.

The NVI laboratories are accredited to ISO17025 and to ISO 17043 by the National Accreditation Body (DANAK). Diagnosis of all fish disease listed as exotic and non-exotic in Directive 2006/88/EC are included in the accreditation of the unit for fish diseases. Full revision of the accreditation is carried out every five years and internal audit is carried out every six months with procedures for follow up if shortcomings are found.

The NRL for fish diseases participates in the annual inter-laboratory proficiency test provided by the EU RL for Fish Diseases. The NRL for mollusc diseases participates in the inter-laboratory proficiency test organised by the EU RL for mollusc diseases. In addition both NRL's participate in proficiency tests on bacteriology. The audit team had access to the results obtained in the various trials. Results were constantly good for the period considered; to find out any negative results one had to go as far back as 2004.

5.2.2.4 Verification and auditing

No written records exist of any auditing activity carried out to evaluate the work of the official staff, across the control chain. The CA stated that "inter-calibration" visits were carried out yearly at SAK level. In this activity the senior staff member of the team would accompany the other members on a visit to an APB. It was explained that the aim of those visits is to check that all members use the same procedures. However no follow-up of those visits was made from the central level to the field. Furthermore as explained in other parts of the report, no written procedures exist against which audit the staff activities. SAK staff are subject to an annual audit concerning general administrative matters. This audit, however, does not concern the performance of the staff in the implementation of their duties in relation to the controls of the application of the requirements of the Directive.

5.2.3 Conclusions

The CA has addressed the requirements of Article 54 of Directive 2006/88/EC by:

- designating a CA for the purposes of this Directive;
- ensuring that the CA has access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology.

However, not all requirements have been correctly addressed, especially the requirement that the CA should operate in accordance with Regulation (EC) No 882/2004. The general lack of procedures, minimal documentation of controls (un-informative reporting) and absence of proper auditing preclude full compliance with the above mentioned Article.

The CA has also addressed the requirements of Articles 56 and 57 of Directive 2006/88/EC by:

- designating NRLs for diagnosis of diseases of fish, molluscs and crustaceans and ensuring that they liaise with the EU reference laboratories in those areas;
- ensuring that the designated NRLs are 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;
- ensuring that laboratory examinations for the purposes of this Directive are carried out only in laboratories designated for such purpose by the CA and that they comply with the functions and duties laid down in Part III of Annex VI thereto.

5.3 AUTHORISATION AND REGISTRATION OF AQUACULTURE PRODUCTION BUSINESSES

5.3.1 Legal requirements

Article 4 of Directive 2006/88/EC requires MS to ensure that each APB is duly authorised by the CA in accordance with Article 5 therein. They may require, under certain conditions, only the registration by the CA 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 CA 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 that corresponds with that included in the above mentioned register.

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 CA. 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 Commission 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.

5.3.2 Findings

5.3.2.1 Conditions for authorisation and requirements for registration

The CA implemented the authorization of APBs starting from the beginning of 2011. APBs that had already been registered in the past within the framework of the aquatic animal health control activities were all authorized. The authorization procedure consisted of issuing an authorization document to the APBs. In the document the CA referred to the legal acts transposing the requirements of the Directive for authorization. The reasoning behind this procedure was that registered APBs already satisfied the requirements for authorization. No particular controls were carried out at that time to verify that this was indeed the case.

However during the FVO audit it was noted that not all authorized farms complied with the fundamental requirements for authorization. Of the five APBs visited two did not comply with the requirements of Article 8 of the Directive concerning the recording obligations (mortality records in particular). APBs visited had in general biosecurity plans, based on a template prepared by the industry and endorsed by the CA. However those plan did not reflect the specificity of the business or were not completed.

Furthermore the records on official controls carried out on the visited APBs by the CA in the years previous to the authorization did not contain enough information to indicate that the APBs complied with the requirements, first for registration and consequently for authorization. The CA provided to the audit team statistics of the APBs present in the country. This information has also been provided through the internet and made easily available to the general public. However the CA themselves recognized that the statistics given do not give the exact numbers of APBs in total or the the APBs in the different categories (farms, farms per species etc). The CA stated that data would be revised to have the correct numbers of APBs active at present.

5.3.2.2 Official controls and animal health schemes

SAK's official controls of APBs farms are first and foremost animal health control visits ie. surveillance activities (see chapter 5.3.2.1). Nevertheless the CA stated that all APBs are visited at least once a year independently from the surveillance activities. The animal health surveillance of APBs in Denmark is based on passive, active and targeted surveillance. The passive surveillance is the disease notification system and will be described under chapter 5.4.2. During the routine inspections conducted as part of the official surveillance, all farm facilities (cages, tanks and ponds) are checked for dead or weak fish, and fish showing abnormal behavior.

The CA concluded a study for the risk categorisation of APBs recently`(November 2011). However the results of the study will not be taken into consideration to establish the frequencies of controls in APBs until VHS has been eradicated. At present, targeted surveillance is carried out at established frequencies, according to the susceptibility to certain diseases of the aquatic animals

present in an APB. SAK performs a targeted surveillance for VHS, IHN and SVC. All APBs are inspected at least annually, and samples are taken at least every second years. Brood stock holdings are inspected twice a year, and samples are taken in connection with each inspection. APBs that are classified in category II with regard to VHS are inspected twice a year and samples are taken in connection with each inspection, until EU approved free status is achieved. A sample for laboratory examination consists of 30 fish divided into three pools of 10.

APBs that are registered free of IPN are inspected and a sample of 30 fish is taken for virological examination twice a year from brood stock holdings and once a year from production holdings. APBs that are registered free of BKD are inspected and a sample of 30 fish is taken for bacteriological examination twice a year from brood stock holdings and once a year from production holdings.

Shortcomings were found regarding:

- The keeping of mortality records (either not taken at all, discontinued or not properly kept) and/or disinfection records;
- The availability of records for audit;
- Inaccurate declarations for certification purposes;
- Inappropriate bio security plans;

No mention was made of any of these shortcomings in the official documents related to visits of the CA to the farms.

5.3.3 Conclusions

The CA has addressed the requirements of Article 4 of Directive 2006/88/ EC, but the procedure chosen for authorising the APBs did not guarantee that they fulfilled all the conditions laid down in Article 5 therein.

The CA has addressed the requirements of: a) Article 6 of Directive 2006/88/EC by establishing and keeping publicly available a register of APB containing at least the information set out in Annex II to the said Directive; and b) Article 2 of Commission Decision 2008/392/EC by establishing an Internet-based information page to make available information on farms or mollusc farming areas of APBs which are authorised. However the data base on APBs is not kept up to date.

The CA has also addressed the requirements of Article 7 of Directive 2006/88/EC and official controls are planned and carried out. However, in spite of the high frequency of visits the controls are not satisfactory regarding the assessment of compliance with the basic requirements of the Directive. This is due mainly to the fact that the emphasis on any visit is put almost exclusively on the animal health status of the animal at the moment of the visit in itself and there is insufficient evidence of controls on the general compliance with all the requirements of the Directive.

5.4 Measures for control of diseases of aquaculture animals

5.4.1 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 CA; b) increased mortality in aquaculture animals, to the CA 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.

5.4.2 Findings

5.4.2.1 Notification, suspicion and confirmation of diseases

The CA has elaborate a comprehensive notification system, which is the same as that used for diseases in other animal species. The system has been applied to aquatic animal diseases since the 2010 KHV outbreak. The Danish Animal Health Act of 2004 is the legislative basis for the notification procedure in general while the Executive Order No. 1218 of 12 December 2008 is the legislative basis for the notification procedure for notifiable diseases of aquatic animals. The notifiable animal diseases are listed in the executive order No 54 of 2011.

In accordance with Executive Order No. 1218 of 12 December 2008 (§5), a farmer is obliged to immediately call a veterinarian if he suspects a notifiable or emerging disease. The veterinarian shall immediately notify the RVFA if the veterinarian suspects a notifiable or emerging disease. A veterinary officer from the SAK will inspect the farm and inform the DVFA of the suspicion. If the veterinary officer cannot rule out the suspicion of a notifiable or emerging disease the farm is placed under official restrictions and test material is collected and dispatched to the National Veterinary Institute, Technical University of Denmark.

All suspicions of notifiable diseases are immediately announced on DVFA's website. The suspicion data base displays information on individual suspected cases of notifiable diseases. This is done to increase the awareness of farmers and veterinarians of the potential presence of a notifiable disease. If the event is of general interest to the public or export markets, this information will be followed by press releases and targeted information to the embassies of the main export markets. The function of the notification system was fully explained to the FVO team using some examples of suspected or confirmed cases of fish diseases outbreaks, including a suspect triggered by a

communication from an other MS.

5.4.2.2 Contingency planning for emerging and exotic diseases

A national contingency plan for diseases in aquaculture animals was elaborated in November 2010 in accordance with Directives 2006/88/EEC and submitted to the Commission on 3 December 2010. The contingency plan deals with exotic diseases (EHN and EUS), non-exotic diseases (ISA, IHN, VHS, SVC, KHV, BKD and IPN) or emerging diseases which can affect freshwater or sea water aquatic animals. This also applies to aquatic animals which are kept in pet shops, garden ponds, commercial aquaria or with wholesalers. The contingency plan should be used in conjunction with the overall strategy and resource plan.

The contingency plan is publicly available and can be downloaded from the DVFA homepage:

http://www.foedevarestyrelsen.dk/Dyr/Veterinaert_beredskab/Beredskabsplaner/Sider/forside.aspx (in Danish)

The plan does not contain provisions to deal with emergencies in respect of mollusc diseases. The CA stated that molluscs are not a priority in Denmark. Moreover it would also prove technically difficult to apply the standard operations foreseen for aquatic animals to mollusc farms.

5.4.3 Conclusions

The CA has satisfactorily addressed the requirements of Chapter V of Directive 2006/88/EC by making obligatory the notification of suspicion or confirmation of a disease listed in part II of Annex IV to the said Directive.

The CA has satisfactorily addressed the requirements of Article 47 of Directive 2006/88/EC by drawing up contingency plans for exotic and emerging diseases.

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

5.5.1 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 Directive 2006/88/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) 1251/2008 lays down:

- animal health conditions for the placing on the market of: a) ornamental aquatic animals either originating from or intended for closed ornamental facilities (Article 4 therein); and b) 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 therein);

- 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) 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.

5.5.2 Findings

5.5.2.1 Import controls

The Danish Chief Veterinary Officer has the overall responsibility for animal health in relation to imports of animals and animal products. Animal products imported from Third Countries are subject to checks at the port or airport of entry into the EU. Imported consignments for intra-Community trade are subjected to non-discriminatory random checks. All consignments imported from Third Countries are subjected to checks at the port or airport of entry into the EU at an approved Border Inspection Post (BIPs). There are only three BIP approved to inspect live animals including aquatic animals and 9 BIPs approved to inspect animal products in Denmark.

5.5.2.2 Certification: Placing of aquaculture animals on the market

Certification is one of the major tasks of the SAK. More than 3000 certificates for export or for intra-union trade are delivered each year. The activity accounts for a great proportion of the working time of one staff member of the SAK. Certification in relation to intra-union trade and import export is done using the relevant model animal health certificates as defined in EU Regulations.

However it was noted that in the case of export of either eggs or live animals the SAK procedure for certification does not satisfy all the requirements in the relevant certificates. In fact the requirement concerning the inspection to be carried out 72 hours before loading live animals (point II.1.1 in the certificates: Part A Annex II to Regulation 1251/2008) is never respected. This is due to the fact that the certificates are done at the SAK offices, and no inspection is carried out in the premises from where the animal or eggs have been dispatched. The inspection is substituted by a owner declaration that no health problems are present in the APBs. The health declaration, it was noted, could be signed by anybody involved in the business who not necessarily new the situation at the farm or had been at the farm within the 72 hours. Furthermore, considering that one of the problems in the APBs visited is the keeping of records of mortality, point II.1.2 on unresolved mortality in the certificates is also not always satisfied, due to lack of adequate information.

The CA has decided to systematically issue certificates for intra-union trade even in cases when a TRACES notification would be enough. However it was noted that the rule is not always applied for movements within Denmark itself. For instance regarding VHS, movements between category 1 farms situated within a category 2 area were not subject to a health certificate as it should be according to article 5 of Regulation (EC) 1251/2008.

5.5.3 Conclusions

The CA of Denmark is not in a position to ensure compliance with all animal health conditions and certification requirements for the placing on the market of aquaculture animals and products thereof laid down in Chapter III of Regulation (EC) 1251/2008.

The CA has set up an effective import control system in order to ensure compliance with requirements of Chapter IV of Regulation (EC) 1251/2008 laying 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.

6 Overall Conclusions

Due to a long-established animal health strategy, Denmark benefits at present from a favourable animal health situation concerning aquatic animals. The CA has also implemented most of the requirements in the Directive and secondary legislation therein. In particular the CA, although having a very small number of staff, has adequate expertise on diseases of aquatic animals and more than adequate laboratory facilities. There is also a transparent notification system and a contingency plan which significantly reduces any risk of spreading aquatic animal diseases within the Union or abroad. This is in spite of the fact that the implementation of the new rules concerning the animal health in aquatic animal cannot be considered as satisfactory in all aspects, in particular:

- APBs have not all been authorised or registered as appropriate;
- results on control activities do not allow the level of compliance with the requirements of the Directive in APBs to be assessed due to lack of proper recording;
- lack of procedures in certain parts of the system including reporting of activities and auditing within the control chain from the CCA to the CA level, and collaboration with the laboratory;
- the certification procedure adopted so far is not in compliance either with the requirement of the Directive and secondary legislation or with the general principles of EU legislation on certification.

7 Closing Meeting

A closing meeting was held on 18 November with representatives of the CA and the SAK. 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. Clarification was given on the issue of certification and the CA explained why it had not been considered as necessary to perform inspections within the 72 hours before loading.

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 CA should review the authorisation procedure to satisfy themselves that authorisation conditions are fulfilled by all APBs before an authorisation is granted, in compliance with Article 5 of Directive 2006/88/EC.
2.	The CA should review the register of authorized APBs to include only those that meet the conditions in article 5 of Directive 2006/88/EC.
3.	The CA should ensure that they operate and perform their duties in accordance with (EC) Regulation 882/2004, as required in point 1 of Article 54 of the Directive, and in particular Articles 8 and 9 of that Regulation.
4.	The CA should change the certification procedures to ensure that the general principles of certification set out in Council Directive 96/93/ EC and all requirements in the relevant certificates annexed to Regulation 1251/2008 are complied with.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2011-6411

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
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
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