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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

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FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

POLAND

FROM 16 TO 26 AUGUST 2010

IN ORDER TO ASSESS THE IMPLEMENTATION OF ANIMAL HEALTH REQUIREMENTS FOR AQUACULTURE ANIMALS AND PRODUCTS THEREOF, AND OF THE PREVENTION AND CONTROL OF CERTAIN DISEASES IN AQUATIC ANIMALS

IN THE CONTEXT OF A GENERAL AUDIT

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 a Food and Veterinary Office (FVO) specific audit in Poland, which took place between the 16 and 26 August 2010, as part of the general audit of Poland carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The specific audit evaluated the implementation of national measures, aimed at the control of the animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

It is concluded that the Polish CA have a system of official controls in place that can allow them to control the implementation of the requirements on aquaculture and fish animal health. The system is at present based on several elements already used in official controls on farming rules and of notifiable fish diseases before the new legislation came into force in 2008. However the system does not cover all the specific elements introduced by the Directive, such as the requirements for laboratories. The control carried out in the aquaculture sector is also limited by the fact that an unknown number of APBs are still unregistered and outside the system of control, and by the unknown status of health of most of the APBs. The very local nature of the aquaculture commodities, as well as movements and controls on APBs mitigates the risk of spreading the listed notifiable diseases in Poland. The very limited export mitigates the risk for other member states and third countries.

The report makes a number of recommendations to the Polish competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	**Explanation**
APB	Aquaculture Production Business
CA	Competent Authority
CCA	Central Competent Authority
DG(SANCO)	Health and Consumers Directorate-General
The Directive	Unless indicated otherwise , Council Directive 2006/88/EC
EC	European Community
EU	European Union
FVO	Food and Veterinary Office
GA	General Audit
IHN	Infectious Haematopoietic Necrosis
KHV	Koi Herpes Virus
MANCP	Single Integrated Multi-Annual National Control Plan
MS	Member State
PVI*	Poviat Veterinary Inspectorate
VHS	Viral Haemorrhagic Septicaemia
VVI*	Voivod Veterinary Inspecorate

* Poviat can be translated as “district”;
* Voivod can be translated as “region”

1 Introduction

The Specific Audit formed part of the FVO's planned mission programme. It took place in Poland from 16/8/2010 to 26/8/2010. The audit team comprised two inspectors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) country. Representatives from the General Veterinary Inspectorate the central competent authority (CCA), accompanied the audit team for the duration of the audit. An opening meeting was held on 16/8/2010 with the representatives of the competent authorities (CA). At this meeting, the objectives of, and itinerary for, the specific audit were confirmed by the audit team and the control systems were described by the authorities.

2 Objectives Of The Mission

The objective of the specific audit were to:

- Verify that official controls are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by Poland.
- To evaluate the system in place to control the implementation of the animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

In terms of scope, the audit concentrated primarily on:

- As regards Regulation (EC) No 882/2004, the organisation of official controls (Art. 3-7) and verification procedures and methods (Art. 8-10), registration and approval of establishments (Art. 31), enforcement (Art. 54-55), and MANCP (Art. 41-42);
- Evaluating the systems implemented for official control on the compliance with EU requirements for aquaculture animals and products, and on the prevention of diseases in aquaculture animals

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

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	**Central**	**2**	Initial and final meeting
	Regional VVI	**2**	Pomorskie and Maloporskie
	Provincial PVI	**2**	Osewicim and Novi Targ
LABORATORIES		**2**	National Reference laboratory (NRL) and 1 Regional laboratory
Aquaculture Production Business (APB)		**4**	3 salmonids farms (two hatcheries) and one Carp farm
ESTABLISHMENTS		**1**	

3 Legal Basis for the Mission

The mission was carried out under the general provisions of Community 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 58, Paragraph 1, of Council Directive 2006/88/EC (hereinafter called the Directive) 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, here applicable, to the last amended version.

4 Background

4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in Member States. The main purpose of such audits is to verify that, overall, official controls take place in Member States in accordance with the multi-national control plans referred to in Article 41 and in compliance with Community law.

This Specific Audit was carried out as a component of a General Audit to Poland. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

Yearly aquaculture production in Poland has been between 30 and 40000 ton per year, for the last 10 years. Half of that production is animals and products from APBs rearing salmonid species and the other half comes from carp farming. The local market is by far the biggest destination, especially for carp farming. Very little export is recorded, and Poland imports a high proportion of these commodities.

4.2 Summary of previous FVO mission results

No previous mission has been carried out in Poland on this subject.

5 Findings And Conclusions related to implementation of Regulation (EC) no 882/2004

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

Responsibility for the implementation of the requirements in the Directive, as transposed in Polish

legislation, relies on the Poviat Veterinary Inspectorate (PVI). PVI are under the supervision of the Voivod Veterinary inspectorate (VVI). The 16 VVIs report to the CCA. The audit team verified that the CCAs have been organising the diagnostic network required by the Directive with the collaboration of the NRL. At the moment only the NRL is designated to carry out analyses on the notifiable fish diseases, listed in Annex IV to the Directive. No laboratory has been designated yet concerning crustacean diseases.
More information on the CA designation can be found in chapter 1 of the Country Profile DG (SANCO) 8112-2009

5.1.2 Co-operation between Competent Authorities

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between CA.

Findings

No other CAs are implicated in the official controls relevant to the implementation of the rules concerning aquaculture and fish animal health.

5.1.3 Co-operation within Competent Authorities

Legal Requirements

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Findings

CCAs have been communicating instructions through the VVIs to the PVIs to implement the new requirements on aquaculture and fish animal health. The relevant information was, in general, immediately transmitted from the VVI to the PVI. However, in at least one case information concerning the implementation of the new requirements was forwarded from one VVI to the PVI with a delay of 6 weeks. A specific internet page site has been added to the Veterinary Inspectorate site. The page is regularly updated with the new legislation or other information on the sector. In this way the WVI, PVI and the public, can have immediate access to the new information relevant to the sector.

More information on this point can be found in the specific sub-chapter 6.1.5.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any

intended delegation.

Findings

No delegated bodies exist in Poland in relation to official controls in the aquaculture and fish animal health sector.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

Findings in relation to this point are discussed in chapter 6.2.3.

Conclusions on Competent Authorities

Responsibilities for official controls within the scope of this mission are clearly defined with the exception of the laboratory responsible for crustaceans. CAs have put in place arrangements in order for the necessary information to be transmitted across the different levels of the structure.

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators to undergo inspection by the competent authorities. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

Findings

The CA has the necessary legal powers to carry out controls, including the power of access to APBs. According to Polish legislation all premises subject to the Directive should apply for registration before starting their activities. Exemptions to this rule have been established and are discussed in chapter 6.1.1. If an APB does not apply for registration it would remain anonymous and the CA would not have the possibilty to control it.

5.2.2 Staffing provision and facilities

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings

The officials controls on APBs are carried out by the PVI staff. The Parliament Act of 2004 allows the veterinary services to employ private vets to carry out specific official tasks (for example taking of samples). However only the PVI has the capacity to decide if private staff are needed to carry out official tasks. To recruit private staff an administrative decision has to be taken, and this can only be taken at Poviat level. In some Poviats private veterinarians have been contracted to carry out the required official controls and take samples for the monitoring of Viral haemorrhagic septicaemia (VHS) and Infectious haematopoietic necrosis (IHN).

Two members of staff have been nominated by the CCA to coordinate at central level the activities in the sector of aquaculture and fish animal health. The team was informed in one Voivod that it was difficult to find private veterinarians who wanted to be contracted to carry out official tasks. Moreover it was difficult to find, in the same Voivod, private veterinarians or services with experience in the aquaculture sector. In general the CCA expressed a need for specialised staff or consultants and in particular for the preparation of contingency plans and the definition of compartments and zones.

5.2.3 Staff qualifications and training

Legal Requirements

Article 6 of Regulation (EC) No 882/2004 requires competent authorities to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

CCAs, VVI and PVI have been active in organising training, meetings and information sessions. These usually focused on the implementation of the new rules in the sector and in certain cases were specific to certain diseases, in particular VHS and IHN. The team received a comprehensive summary of training activities carried out in 11 of the 16 Voivods as well as training organised by the CCAs, PVIs and the NRL**.** This training has involved official staff, private veterinary practitioners, laboratory staff and APB operators. A special training programme was also carried out for the staff based at the border inspection post in the airport of Warsaw.

Training was often done with the collaboration of the NRL and in some cases with the collaboration of foreign consultants. In particular in June-July 2010 a mandatory training session for heads of VVIs was organised involving trainers from France. The team was informed that a further comprehensive training programme on the sector is in preparation. This plan will be finalised when some doubts concerning the implementation of the new rules have been clarified.

A special training session was organised in May 2010 by the NRL in which veterinary officials, private veterinarians and APB operators (50% of participants) were trained, on subjects relevant to the implementation of the Directive. Furthermore training, in general, is organised on an annual basis at central level for staff involved in official controls. This is carried out in a cascade sequence

from the centre throughout the local level. An act to modify the long term training plan for VI staff is in the process of approval.

Conclusions on Resources for Performance of Controls

The CA have in general adequate resources to carry out official controls in the sector concerned by the mission. However, there is still necessity for specialised or experienced staff or consultants. A substantial effort has been made to update the knowledge of staff on the legal and technical issues concerning the application of new requirements, especially in the last year.

5.3 Organisation and implementation of official controls

5.3.1 Registration / approval of food business operators

Legal Requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

Findings

Findings and conclusion on this item are discussed in chapter 6.1.1.

5.3.2 Prioritisation of official controls

Legal Requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the Community, imports into the Community and to product placed on the Community market.

Findings:

No special priority has been attributed so far to the official controls to be carried out in the aquaculture sector. However a risk analysis system is applied to official controls for animal health in all kind of farms including APBs. These controls are carried out using frequency parameters laid down in the Polish legislation in the sector of animal health. The CA stated that the preparation of specific guidelines on official controls in the sectors of aquaculture was delayed by doubts in the application of certain requirements of the Directive.

Other findings in relation to this point are discussed in the chapter 6.1.2.

5.3.3 Control activities, methods and techniques

Legal Requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

Formalised guidelines and protocols on official controls to be carried out in the APBs are being discussed at present by the CCA. In the meantime, official controls, including the authorisation of APBs, have been carried out in the sector concerned, starting from 2009 using general procedures for controls, established since 2005. The team verif ied that basic check lists were being used in which the requirements included in the legislative act implementing the Directive had been taken into consideration. Some differences were noted in check lists used in Poviats of the same Voivod but these were not always of major importance. It was, however noted that the use of those check lists did not address critical biosecurity issues such as the animal health safety of water used in APBs. This item appeared to be taken into consideration only at the hatcheries.

5.3.4 Sampling and Laboratory analysis

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Findings

Findings in relation to this point are discussed in chapter 6.3.

5.3.5 Procedures for performance and reporting of control activities

Legal Requirements

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Findings

Staff involved in official controls apply instructions used in general in other kind of farms. An annual work plan is prepared for all the 3 levels of the CAs. Monthly reports are then prepared by the PVI on the activities carried out in animal health. Voivods collect and forward all the reports from the PVI to the CCA. Documentary evidence was always available of the official controls carried out in APBs. Results of those control were available in all PVI offices, and at the APBs sites. The team verified that follow up action in relation to shortcoming was taken when needed in the form of administrative notes. Documentary evidence was also always readily available of the

reports provided from PVIs to VVI and then to the CCAs.

Other findings in relation to this point are discussed in chapter 6.1.2.

5.3.6 Transparency and confidentially

Legal Requirements

Article 7 of Regulation (EC) No 882/2004 requires that competent authorities carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

Polish veterinary law stipulates which information concerning controls may be made available on its website, including the types of these controls and the results. As mentioned in chapter 5.1.3, the CCA has set up a special page concerning the aquaculture sector and fish animal health to comply with the requirements of the Directive. The page contains the information required under the Directive for the APBs. The team verified that the information is regularly updated and accessible to the public.

Conclusions on Organisation and Implementation of Official Controls

No particular system has been established to control the implementation of the Directive, except the page on the CCA website. The use of well established, effective procedures and standards for official control in the farming and animal health sectors allows in general, for the control of the implementation of most of the fundamental requirements of the Directive. However, although the system of controls, as it is, is able to cover for the delay in the preparation of more specific guidelines, the procedures used so far lack a certain degree of specificity for some critical issues.

5.4 Enforcement Measures

5.4.1 Measures in the case of non-compliance

Legal Requirements

Article 54 of Regulation (EC) No 882/2004 requires a competent authority which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

Findings

The PVIs have the power to enforce the implementation of legal requirements. In one PVI it was described how this power is exercised in 3 steps. Most of the enforcement is carried out through warning decisions issued when non compliances are found during official controls. Evidence of such decisions concerning the sector of aquaculture was made available to the team when requested. Other steps in enforcement include fines. None of these had been issued for the sector concerned by the mission. However the AT was informed that heavy fines had been imposed in other sectors, concerning veterinary public health. A third level of enforcement allows the PVI to bring a case

straight to the court.

5.4.2 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

Refer to chapter 5.4.1.

Conclusions on Enforcement Measures

The CA has a system that allows them to enforce the requirements of the Directive.

5.5 Verification and review of official controls and procedures

5.5.1 Verification procedures

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

Findings

PVIs exercise their official role under the supervision of the VVIs. Evidence was available that this supervision had been regularly carried out in the VVIs visited. In one VVI the supervision of PVIs was carried out according to an ISO 9001 standard. In fact a certain number of Voivods have so far been certified according to the same standard. In another Voivod the team found that the supervision of the PVI was carried out using a general protocol. This protocol does not allow detailed supervision of the requirements in aquaculture, except for the results on the monitoring of VHS and IHN. The team was informed in one other VVI that a new protocol is been implemented where amendments were made to include more specific items on the controls in aquaculture. However, copies of the new protocol were not available at the sites visited by the team.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny

and carried out in a transparent manner.

Findings

The Controlling Office of the CCA has the responsibility for audits. Specific audits concerning the application of the requirements in the Directive and all new rules in the sector of aquaculture and fish animal health have not been carried out.

Conclusions on Verification Procedures

The lack of specific instructions and procedures to supervise the controls carried out in the sector of aquaculture and fish animal health contributes to a lack of uniformity in the implementation of certain requirements.

5.6 Multi Annual National Control Plan

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated multi-annual national control plan (MANCP). According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

Findings

Poland has a MANCP for the period 2010-2014 covering all of the veterinary controls at all the 3 levels (CCA, VVI and PVI). The plan provides procedures for of all the official animal health controls, but not in particular in relation to the aquaculture or fish animal health sectors.

Conclusions on Multi-Annual National Control Plan

The MANCP provides information on the structure and organisation of official controls, in general for all sectors of farming and animal health.

6 Sector Specific findings and conclusions

6.1 Official controls of APBS

6.1.1 Registration and authorisation

Legal Requirements

Article 4 of Council Directive 2006/88/EC requires all APBs to be authorised. Article 5 of the same Directive describes under which conditions an aquaculture production business or an authorised processing establishment can be authorised. Article 6 provides for the establishment of a public register for APBs and authorised processed establishments.
Findings

Registration

A certain number of fish farms had already been registered by the CAs before the transposition of the Directive. A new registration system has been introduced after the transposition of the Directive and a new number has been introduced in the system to allow the registration of APBs. The team was told that exemptions to the registration of APBs have been made since the registration started. The exemption concerns for instance fish ponds used as put-and-take facilities, in old mines or quarries. The CA justified this non-compliance on the grounds that these APBs only produce for a very local market and products go normally for direct consumption. This leaves an unknown proportion of APBs outside the scope of official control.

The number of registered APBs increased from about 1500 in July 2008, to more than 2000 in 2009 to reach 3174 in July 2010. The team verified that the information in the register of APBs and authorised processing establishments was in general updated on a monthly basis, and sent from the PVIs to the CCA. From the figures provided by the CCA it appears that registration of APBs has been intense since the new requirements came into force. The CCA admitted that some inconsistencies existed in the way the health status of the APBs was reported in the registry.

Authorisation

The PVIs started authorising farms, according to the requirements of the Directive at the end of 2008. The team noted that the process of authorisation was carried out in different ways according to the Poviats. Differences were found in the fact that in certain Poviats APBs were authorised only after a specific visit was carried out in the farm, while in other cases the visit was not done before the authorisation. In general an administrative decision was made for each authorisation but in certain cases a single decision had been made for 3 different farms, albeit belonging to the same company. Other more important differences were found in the implementation of the requirements in Articles 8-9 and 10 of the Directive and are discussed in the following 3 sub-chapters.

Concerning processing establishments none has so far been authorised to carry out slaughtering of fish in the framework of disease control activities. The CA contacted establishments across the country, to enquire if any would be interested in applying for this particular authorisation. No establishment so far expressed interest in acquiring the authorisation. No quarantines are present in Poland and no stations to change water in case of long distances transport of live fish.

6.1.2 Good hygiene practice

Legal requirements

Article 9 of the Directive requires that APBs and authorised processing establishments implement good hygiene practices relevant to the activity concerned, to prevent the introduction and spreading of fish diseases.

Findings

Concerning the implementation of good hygiene practices, differences in the implementation were noted across the Poviats with some of them asking APBs to have a comprehensive manual of hygiene practices in order to be authorised and in others not asking this. In some APBs it was not possible to establish which hygiene practices were applied and how these were carried out. Other APBs were found to have good hygiene practice manuals, well tailored for their specific activities.

The CCA is discussing with aquaculture producers organisations how to develop good hygiene practices for the APBs; proposal are now expected from those organisations. Consultation meetings have been held with stake holders on this point.

6.1.3 Surveillance in farms

Legal requirements

Article 10 of the Directive requires that a risk based AH surveillance scheme is applied in all APBs. This surveillance should be able to detect any increased mortality of the aquatic species reared and detect any presence of the listed diseases. Surveillance frequency should take into consideration the health status of the APBs and surrounding areas.

Findings

With the exception of one of the PVIs visited, all APBs had in general a risk level attributed to them, regarding the possibility of introducing or spreading disease. Differences were found in the way the risk assessment to establish the surveillance schemes was carried out. In some Poviats the risk assessment was done by the PVI, and in other cases by the farmers themselves. In some cases evidence was available that risk analyses to establish the surveillance scheme had been carried out, in others such evidence was not available. The risk level attributed to the APBs visited was not appropriate in two cases out of four. In these two cases a medium risk level had been assigned to the APBs, while farming conditions would suggest that the level of risk was high. In fact in one of these cases it was not possible to establish if the possibility of introducing disease with the source of water had been taken into consideration or not when establishing the risk level.

The surveillance schemes in APBs, as provided by Article 10 are not done by the APBS operators. These have so far been substituted by the official controls and monitoring of certain fish diseases, carried out by the CAs and will be discussed in chapter 6.2. Those activities combined can in fact satisfy most of the recommended surveillance frequencies, according to the risk attributed to them. This holds true especially for APBs rearing salmonid species, where monitoring of VHS and IHN is carried out. As far as APBs dealing with carp are concerned, however, no other activity except for one official control per year is carried out. So the frequency of official controls in APBs farming carps would not always be enough to satisfy the requirements for the surveillance schemes, as required by part B of Annex III. Only one of the ABPs visited during the mission had started the surveillance scheme. In this case the surveillance was carried out by a private veterinary service in 2009, and by their own private staff in 2010. APBS will have to carry out their surveillance schemes starting from autumn 2010, when the monitoring for IHN and VHS as it is carried now will be discontinued.

6.1.4 Recording and Traceability

Legal requirements

Article 8 of the Directive requires that APBs have a comprehensive recording system to record in-and-out movements of animals and products, origin and destination of products and animals, mortalities during farming and during transport and data on water changes during transport.

Findings

In some cases records on movements and/or mortalities were either completely missing or badly kept. The keeping of records, apart from being one of the requirements for authorisation, was also one of the items to be checked under the old Polish legislation. In two of the APBs visited major problems were found in the record keeping system. In one case it could be seen from reports of official controls that an administrative note had been issued by the CA to the farm, in order to address the problem. In spite of that and although the problem was not yet solved, the farm had been authorised and was still authorised at the time of the FVO visit **.**

6.1.5 Regular controls

Legal requirements

Article 7 of the Directive requires that CA carry out regular controls on APBs. The frequency of those controls should be based on the risk attributed to an APB, concerning the possibility of contracting or spreading a disease. The category in which the farm is classified in accordance with the AH status as established in part I of Annex III to the Directive and as recommended in part II of the same Annex should also be taken in consideration to establish the frequency of official controls.

Findings

All registered APBs, including the authorised ones are under the control of PVIs. Evidence was always available that according to the status of the APB, registered and authorised or only registered, these were visited with different frequencies but at least once a year. As discussed in chapter 6.1.3, however, the frequency of official controls varies depending on the species farmed. The team was informed by the CCA that the frequency and nature of official activities carried out in APBs will change starting from autumn 2010, when APB operators will be starting their own surveillance schemes.

From the records of the inspections it was noted that the official controls consist of inspections carried out using in general standard check lists. The check lists are based on the fundamental criteria of prevention of infectious diseases established in the Polish legislation, for all farm animals. Although these check lists are not specifically designed with the control of APBs in mind they enable most of the biosecurity criteria and records and traceability requirements for APBs to be checked. However it was noted in some cases that the information in the records of the inspections and in the check list was not consistent with the situation found during the FVO visit, in particular concerning record keeping.

Conclusions

CA could demonstrate that they were able to start implementing the requirements of registration and authorisation as soon as the Directive came into force. However, in spite of all the training and information dissemination, the non compliance with the implementation of the requirements for registration and the incorrect or inconsistent implementation of certain requirements for authorisation diminishes the effectiveness of the work carried out. Nevertheless, considering the significant increase of registered APBs after the coming into force of the Directive, and considering that all registered APBs are under official control, it can be concluded that the CA has an overall acceptable control over the aquaculture sector, with the exception of the part exempted from registration.

6.2 Animal Health Requirements

6.2.1 Fish diseases situation: notification and control measures

Legal requirements

Chapter V of the Directive establishes the requirements for notification and confirmation control of listed infectious diseases. Sections 3 and 4 of the same chapter establish minimum measures to be applied in case of confirmation of disease.

Findings

The monitoring for IHN and VHS, plus a multi annual programme carried out by the NRL and the obligation to report suspects of disease applicable to every citizen, gives a general overview of the prevalence of notifiable fish disease in Poland. According to data given at the NRL, 3 of the non-exotic fish diseases i.e. IHN, VHS and Koi herpes virus (KHV), listed in part II of Annex IV were present in the country in 2009. Spring viraemia of carp and infectious pancreatic necrosis were also present. Sampling activities in 2009 demonstrated that KHV was present in 50 % of the sampled farms. It should also be noted that the outbreaks of VHS reported recently:11 in 2009 and 10 in 2010, were found either in samples of active surveillance or after suspect reports from operators.

From the files of the outbreaks of VHS and and IHN evaluated by the team it was noted that CAs operated in case of disease in an effective way, and with procedures consistent with the procedures required by Directive for exotic disease. Documentary evidence was available to show how CA had controlled the application of movement restriction measures, cleaning and disinfection and and stamping out. Stamping out can be carried out either at the level of the affected APBs or extended to in-contact APBs. It was also reported that while in certain Poviats stamping and destruction of fish on site were carried out, in others the outbreaks were extinguished by slaughtering fish for the market. Due to the fact that no establishments have been approved in the country to slaughter fish in the control of infectious diseases the latter option is not in compliance with Article 4 of the Directive.

6.2.2 Categorisation of aquaculture zones or compartments

Legal requirements

Article 12 of the Directive requires that the placing on the market of aquaculture animals and products does not pose an animal health risk regarding disease listed in Part II of Annex 4. Focus should in particular posed on movement of animals and products of different health status as defined in Part A of Annex III.

Findings

In order to be able to apply the requirements in chapter III of the Directive, MS need to categorise their compartments and zones where aquaculture is carried out, regarding the fish diseases listed in the Directive. Concerning zones and compartments the team understood that the CA still has doubts and on how to define compartments geographically and epidemiologically. It was explained that this was due to difficulty in applying the concept of compartment to the Polish situation. In fact most of the water catchments where fish farming is more developed are interconnected, so that all the APBs

are epidemiologically linked. As a consequence it is difficult to separate the epidemiological units and to assign to the APBs the health status regarding the listed diseases.

Thus apart from infectious salmon anaemia for which Poland (like most of the EU member states) is considered free at country level, only one compartment, constituted by one single APB, is considered free from VHS, and listed as such according to Article 51 of the Directive. A certain number of APBs at any point in time every year are infected, either by IHN, VHS or KHV virus, as demonstrated by the statistics and notifications of the last 3 years . Because of the above and due to the fact that no zones or compartment are at the moment carrying out either a surveillance programme or an eradication programme, as established in Article 44 of the Directive, all APBs are considered to be of unknown health status and classified in the third category established in Part A of Annex III to the Directive. The CA referred to an eradication trial from one compartment, in which VHS, was successfully eradicated but the reintroduction of fish from other Polish APBs led to the reappearing of the disease.

6.2.3 Contingency plans and vaccination

Legal requirements

Article 47 of the Directive requires that MS should draw up contingency plans for emerging and exotic diseases. In the same article minimum criteria to draw up the plans are established as well as the obligation for MS to submit the plan to the Commission Services. Article 48 of the Directive establishes the provisions for vaccination.

Findings

Contingency plans are available for IHN and VHS, but not for exotic diseases as required by the Directive. The CCA explained the delay in the preparation of the contingency plans by the fact that the country had been dealing with other priorities in the sector of animal health and has a shortage of staff specialised in fish diseases. Concerning vaccination the team was informed that this is not done in Poland for the fish diseases listed in the Annex IV to the Directive.

Conclusions on animal health requirements

The CA has a system of notification and intervention in case of outbreaks of fish diseases. However, the efficacy of the system is limited by the fact that the health status of all of APBs but one, concerning these diseases, is unknown. As a result when APBs are repopulated after outbreaks of non exotic disease there is a risk that the animals introduced would be infected, if bought in Poland. The CA is at present not adequately prepared for the occurrence of exotic or emerging fish diseases.

6.3 PLACING ON THE MARKET AND INTRODUCTION OF AQUACULTURE ANIMALS AND PRODUCTS.

6.3.1 Movement controls

Legal requirements

Chapter III of the Directive establishes the requirements to place on the market aquaculture animals and products, in order to prevent the spreading of diseases. In particular Article 13 establishes the

disease prevention requirements in relation to transport.

Findings

The CA explained that movement of live aquaculture animal can happen only under the supervision of a veterinarian. Veterinarians are in general PVI staff. In one case a private veterinarian was contracted to carry out the official control and the control on movements. The team could verify that in general all movements of aquaculture animals were indeed under control. However it was not always possible to verify the nature of these controls. The CA explained some procedures to be applied in case of controls on animal movement. These concerned among the others the checks to be done to ensure that transport means had been cleaned and disinfected, and the issuing of movement documents. During the visit to an APB. The CA explained that specific instructions for private veterinarians on items to check before allowing movements were established in the contract with them. However, because no copies of these contracts were available on site it was not possible to verify this information. Furthermore the movement controls would not be applied to unregistered APBs.

6.3.2 Introduction of aquaculture animals from third countries

Legal requirements

Article 24 of the Directive requires that all consignments of aquaculture animals and products shall be accompanied by a document containing an animal health certificate upon their arrival in the EU.

Findings

The team visited the border inspection post (BIP) in Warsaw airport. A team of 5 veterinarians is in charge of controls at import including live aquaculture animals. It was explained at the site that only a fraction (about 10%) of the aquatic animals imported into Poland would be directly imported through that BIP. Most of the other imports in this sector would be done via other BIPs. Although no specific written set of instructions was available for any animal health controls including aquatic live animals, staff were well aware of the animal health requirements to import these commodities into the EU, and explained what procedures are followed when such imports occur. Staff at the BIP explained the checks to be carried out on the certificates and other documents to avoid importing consignments with no clear animal health conditions. In particular they explained what procedure/actions would be followed in case animal health concerns would be raised when controlling imported live aquatic animals.

The team verified that all the necessary information was available concerning third countries, and regarding animal health in aquatic animals. So far, no alarm in this sector was ever raised at the BIP, and no cases of high mortalities in imported fish were found. As already described elsewhere in the report staff have benefited from specialised training on fish animal health in 2010. The team verified that the most recent legal acts were available concerning imports of aquatic animals, and that all staff were acquainted with them.

Conclusions on placing on the market and introduction of aquaculture animals

The system of official controls carried out either on aquaculture animals imported or put on the market can guarantee that all movements of these animals are under control. However, there is a lack of control on possible movements of aquaculture animals from unregistered APBs.

6.4 SURVEILLANCE AND ERADICATION PROGRAMMES

Legal requirements

Section 1 of chapter VI (Articles 44-45 and 46) of the Directive establishes the conditions a Member State shall satisfy to draw up eradication plans, where a decision is taken to do so.

Findings

A programme to eradicate VHS from the salmonid farms in the north of the country has been rejected by the Polish government. This due to the high costs involved, to the uncertainty of the outcome and to doubts on the interpretation on the new rules on aquaculture and AH. The CCA expressed their doubts concerning the possibility of declaring compartments, APBs or zones free of disease. In fact the difficulties in establishing the epidemiological independence between these aquaculture entities makes it difficult to assess, control and monitor their health status and thus to implement eradication programmes.

The Commission services have so far rejected applications for health free status declaration of compartments for which the information given did not provide sufficient guarantees on the real health status concerning certain diseases. This was mostly due to the fact that farms could not prove the health status of fish introduced in the farms, and could not prove that they had no contacts via the water source with other APBs of unknown health status. CCA are now collecting data to assess if other APBs can be declared free of any of the non exotic diseases listed in Annex 4 to the Directive and then to submit to the Commission services the declaration, before including them in the list set out in Article 51 of the Directive.

Conclusion

Problems in understanding how to define independent epidemiological units have so far been an important impediment in the planning and application of surveillance and/or eradication programmes.

6.5 LABORATORIES

Legal requirements

Article 54 in of the Directive establishes the obligation for a MS to designate a CA for the purpose of the Directive. Point 3 of the same article requires that the CA should have access to adequate laboratory facilities. Free exchange of information shall be established between the CA and designated laboratories. Article 56 sets out the requirements for the designation of a national reference laboratory and the basic obligations for this laboratory. Article 56 sets out the requirements for the analyses and methods to be used and the duties of the designated laboratories.

Findings

The NRL is so far the only laboratory officially designated to carry out diagnostic analyses on notifiable fish diseases. The laboratory is accredited for some of the listed diseases (IHN, VHS, IPN and SVC) and works in general to the standards required from a NRL by the Directive and by Commission Decision 2001/183/EC. The laboratory is also in the last stages to be accredited for KHV. However like the CCA, the laboratory is not yet fully prepared for the diagnosis of exotic diseases. As far as the methods used in the laboratory are concerned it was noted that in the routine analyse for IHN and VHS, no neutralisation of the IPN virus is carried out as required by the recommended EU methods. Considering the relative high prevalence of IPN this could lead to an underestimation of prevalence for both VHS and IHN.

The NRL has been very active in supporting the CA in training activities aimed at local laboratory staff, staff of the VI and stake holders. Evidence was available of the participation of the NRL in proficiency tests, with good results. Evidence was also available of the role of the NRL in the organisation of proficiency tests organised for the Polish official laboratories. The NRL also has a training programme renewed yearly for it own staff.

The CCA has planned to increase the diagnostic network for the sector. Thus four local laboratories have been nominated, to carry out, in the future, diagnosis of the listed fish diseases. These laboratories are now undergoing the necessary training and the accreditation steps. The upgrading of the diagnostic facilities is under close scrutiny of the NRL. However no laboratory has so far been nominated to carry out diagnosis of crustacean diseases as required by the Directive and no laboratory is at the moment in the position to carry out a diagnosis on the listed exotic fish diseases.

Conclusion

While the laboratory network is being finalised by the CA the NRL can generally guarantee a high standard of diagnostic capacity, and effective support to CA in the aquaculture. The good level of competency in the NRL can also guarantee that limitations which still exist concerning the diagnosis of exotic diseases and some inaccuracies in the diagnosis of non exotic disease can be resolved in due course.

7 Overall Conclusion

The Polish CA has a system of official controls in place that can allow them to control the implementation of the requirements on aquaculture and fish animal health. The system is at present based on several elements already used in official controls on farming rules and of notifiable fish diseases, before the new legislation come into force, in 2008. However the system is not completed in all the specific elements introduced by the Directive, such as the requirements for the laboratories. Guidelines, specific instructions and the policy of intervention in fish animal health are still needed to harmonise the implementation of the necessary specific requirements. So far the overall good control carried out in the aquaculture sector is also limited by the fact that an unknown number of APBs are still unregistered and out of the system of control, and by the unknown status of health of most of the APBs. The very local nature of the aquaculture commodities, as well as movements and controls on APBs mitigates the risk of spreading of the listed notifiable disease, in Poland. The very reduced export mitigates the risk for other Member States and third countries.

8 Closing Meeting

A closing meeting was held on 26 August 2010 with representatives of the central competent

authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement with findings of the mission. In particular the CCA expressed their agreement with the finding concerning the non harmonised application of certain requirements. Assurance was given that certain action already in progress would be finalised as soon as possible. This concerns in particular the preparation of guidelines for official controls and supervision of those controls and the completion of the diagnostic network.

Following the final meeting some of information requested during the mission was provided, in particular on statistics of registered farms, and on the MANCP.

9 RECOMMENDATIONS

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

N°.	Recommendation
1.	The CA should finalise guidelines for official controls on the aquaculture sector in order to be able to check that the requirements in Articles 4 and 5 of the Directive are implemented in a harmonised way throughout the country.
2.	The CA should coordinate activities and standardise procedures to ensure a harmonised supervision system of official controls in APBs in all Voivods, as required in Articles 4 and 8 of Regulation (EC) No. 882/2004.
3.	The CA should review their registration procedures in order to register, as required by Article 6 of the Directive, all premises that fall within the definition of an APB in Article 3. 1(c) without exceptions.
4.	The CA should review their registry of authorised farms, to include only APBs that fully implement the requirements in Articles 8, 9 and 10 of the Directive.
5.	The CA should endeavour to prepare a CP for exotic diseases as required in chapter V article 47 of the Directive.
6.	The CA should designate a laboratory to carry out diagnostic analyses on crustacean diseases; furthermore they should satisfy themselves that a laboratory is designated to carry out analyses for the exotic diseases listed in Annex IV part II to the Directive.
7.	The NRL should achieve the accreditation process for the methods used in the diagnosis of the diseases listed in Annex III and required in Article 56 of the Directive.
8.	The NRL should review its methodology of analysis for VHS and IHN to take into

N°.	Recommendation
	consideration the requirements of Decision 2001/183/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_pl_2010-8411.pdf

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
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