Brussels, 26 June 2013
Case No: 72847
Event No: 676243

Final report

EFTA Surveillance Authority mission to

Iceland

from 11 to 20 March 2013

regarding the application of EEA legislation related to

aquatic animal health

Please note that comments from the Icelandic competent authorities to factual errors in the draft report have been included in *underlined italic print* in the body of the report. Comments and information the corrective actions already taken and planned are included in Annex 3 in the report and referred to in footnotes in *underlined italic print*.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Iceland from 11 to 20 March 2013.

The objective of the mission was to verify that official controls related to aquatic animal health were carried out in compliance with the European Economic Area legislation. Due to a long-established animal health strategy in the aquaculture sector, Iceland benefits at present from a favourable animal health situation and is active in trading live fish both intra-community and to third countries.

The mission team found that the main part of the EEA legislation concerning aquaculture animal health has been transposed to the national order, nevertheless, some delays in transposition were noted.

Matvælastofnun (MAST), the responsible competent authority for official controls is clearly designated and legal powers are in place to carry out official controls and to enforce the legislation. Two official veterinarians placed at central level of MAST are in charge of official controls at farm level. The official controls were carried out regularly, on a risk basis, with appropriate frequency and were well reported. However, a possible conflict of interest was identified, since the official veterinarian in charge of official controls at farm level concerning use of veterinary medicinal products is, at the same time, prescribing medicine to the same farms. In addition, the official control system has not yet been subject to audits as set out in Article 4 of Regulation (EC) No 882/2004.

A national reference laboratory (NRL) for diseases for fish, molluscs and crustaceans has been designated in February 2013. The methods used for detecting fish diseases have been accredited in 2011. However, it was noted that the methods used for detection of mollusc diseases have not yet been accredited.

The authorisation process of aquaculture production businesses in line with Article 4 of Directive 2006/88/EC has not yet been initiated by the competent authorities, in particular to ensure that quality management systems and good hygiene practices including appropriate biosecurity plans are in place. Examples were seen in the aquaculture farms visited where quality management systems and good hygiene practices were not yet in place. A register of aquaculture production businesses is established and is publicly available, however, transporters were not included in the register.

A system for notification of the presence of disease is in place in Iceland and a contingency plan for fish diseases has been established in line with Article 27 of Directive 2006/88/EC. However, there are currently no facilities equipped or authorised for slaughtering fish for disease control in Iceland and it is not clear from the contingency plan where and how disposal of carcasses will be done in case of outbreak of disease.

The report includes a number of recommendations addressed to the Icelandic competent authority aimed at rectifying the identified shortcomings and enhancing the control system in place.

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1 INTRODUCTION

The mission took place in Iceland from 11 to 20 March 2013. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority), an observer from the Food and Veterinary Office of the European Commission (FVO) and a national expert.

The opening meeting was held with representatives of the competent authorities *Matvælastofnun* (MAST), the Ministry of Industries and Innovation and the Directorate of Fisheries on 11 March 2013 at the MAST office in Reykjavik. At the meeting the mission team confirmed the objectives and itinerary of the mission. The Icelandic representatives provided additional information to that set out in the reply to the Authority's pre-mission questionnaire.

Throughout the mission, representatives of the head office of MAST accompanied the mission team. In addition, representatives of the relevant district offices of MAST participated during some of the visits to different farms and establishments.

A final meeting was held with representatives of MAST, the Ministry of Industries and Innovation and the Directorate of Fisheries at the MAST office in Selfoss on 20 March 2013, during which the mission team presented its main findings and some preliminary conclusions from the mission.

The abbreviations used in the report are listed in Annex 1.

2 OBJECTIVES OF THE MISSION

The main scope of the mission was to assess the application by the Icelandic Competent Authorities of:

a) *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on the official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules,* as corrected and amended;

b) *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*, as corrected and amended;

c) *Commission Decision 2001/183/EC 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*;

d) *Commission Decision 2002/878/EC of 6 November 2002 establishing the sampling plans and diagnostic methods for the detection and confirmation of the presence of the mollusc diseases Bonamiosis (Bonamia ostreae) and Marteiliosis (Marteilia refringens)*;

e) *Commission Decision 2003/466/EC of 13 June 2003 establishing criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA).*

The assessment was carried out and related to the abovementioned legal acts and other relevant European Economic Area (EEA) legislation referred to in Annex 2 to this report. The assessment was further based on the reply to the pre-mission questionnaire of the Authority.

The objective of the mission was in particular to evaluate the measures in place to monitor and control certain fish diseases, with a particular focus on the following areas:

a) Co-operation between competent authorities and laboratories;

b) Laboratories involved in the monitoring and control of certain fish diseases;

c) Measures for the control of diseases affecting aquaculture animals and in particular the control of infectious salmon anaemia (ISA), infectious haematopoietic necrosis (IHN), viral haemorrhagic septicaemia (VHS) and *Bonamia ostreae (B. ostreae).*

The evaluation included the gathering of relevant information, and appropriate verifications, by means of interviews/discussions, review of documents and records, and on-the-spot inspections, to demonstrate the normal control procedures adopted and measures in place to ensure that necessary corrective actions was taken when necessary.

The meetings with the Competent Authorities and the visits during the mission are listed in Table 1.

Table 1: Competent authorities and establishments/sites visited during the mission

	Number	**Comments**
Competent authorities	**2**	An initial meeting and a final meeting between the mission team and MAST, the Ministry of Industries and Innovation and the Directorate of Fisheries
Laboratory	**1**	National reference laboratory
Aquaculture production businesses	**7**	
Fish slaughterhouses	**2**	
Animal by-products plants	**2**	
Transporter of fish	**1**	

3 LEGAL BASIS FOR THE MISSION

The legal basis for the mission was:

a) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;

b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement);

c) The Act referred to at Point 1.2.74 of Chapter I of Annex I to the EEA Agreement, Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States;

d) Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on the official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules, as corrected and amended.

Legislation referred to in this report is listed in Annex 2.

4 BACKGROUND

4.1 Summary of previous missions by the Authority

Previous missions carried out in Iceland regarding aquatic animal health took place in 2004 (with a follow-up mission in 2005), where both animal health and public health (fishery products) aspects were covered. Nevertheless, this mission is the first on-the-spot inspection carried out by the Authority in order to evaluate application of animal aquatic health requirements after the Directive 2006/88/EC for aquaculture animals and products thereof came into force from the 29 September 2007 according to the EEA Agreement in Iceland.

4.2 Aquaculture industry in Iceland

The aquaculture industry in Iceland is dominated by production of arctic char, salmon and rainbow trout for food purposes. According to information received from MAST there were at the time of the mission 49 aquaculture farms operating in Iceland. Four of these are sea-cage farms for salmonids (salmon and rainbow trout), six are sea-cage farms for cod and the rest are land-based farms (producing mainly arctic char and small amounts of turbot and halibut). There is a small production of blue mussels in aquaculture and about 10 farms are registered for this production. One farm is registered for producing sea cucumbers and abalone mussels (for both species live juveniles are imported from Japan). There is no production of oysters or crustaceans in Icelandic aquaculture.

MAST provided in its reply to the Authority's pre-mission questionnaire information on the production of the aquaculture sector in Iceland. Production of fishery products from aquaculture in Iceland from 2010 to 2012 can be seen in Table 2. The number of smolts/juveniles produced in Iceland can be seen in Table 3. According to information received from MAST the total production of smolts/juveniles in Iceland are almost entirely used for on-growing/farming purposes.

Table 2: Production of fishery products from aquaculture in Iceland (metric tonnes)

	2010	**2011**	**2012**
Atlantic salmon ***(Salmo salar)***	1068	1083	2923
Arctic char ***(Salvelinus alpinus)***	2427	3021	3060
Rainbow trout ***(Oncorhyncus mykiss)***	88	226	401
Tilapia ***(Oreochromis niloticus)***	0	2,5	0,3
Cod ***(Gadus morhua)***	1317	877	893
Halibut ***(Hippoglossus hippoglossus)***	72	33	13
Turbot ***(Psetta maxima)***	46	20	28
Blue mussel ***(Mytilus edulis)***	32	46	30
Total production	**5050**	**5308,5**	**7348,3**

Table 3: Production of smolts/juveniles (number of smolts/juveniles)

	2010	2011	2012
Atlantic salmon ***(Salmo salar)***	1720000	2190000	2630000
Arctic char ***(Salvelinus alpinus)***	2075000	2360000	2915000
Rainbow trout ***(Oncorhyncus mykiss)***	0	0	0
Tilapia ***(Oreochromis niloticus)***	0	20000	5000
Cod ***(Gadus morhua)***	70000	364000	40000
Halibut ***(Hippoglossus hippoglossus)***	175000	20000	0
Turbot ***(Psetta maxima)***	43000	43000	0
Blue mussel ***(Mytilus edulis)***		0	0

Due to the favourable animal health situation in this sector, Iceland is active in trading live fish both intra-community (fish for human consumption and eggs for reproduction) and to third countries (mainly salmon eggs to Chile).

4.3 Health status

Legal requirements

Commission Decision 2009/177/EC implements Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of member states, zones and compartments, and provides lists of:

- Member states, zones and compartments subject to surveillance or eradication programmes approved in accordance with Article 44(1) and (2), respectively, of the said Directive; and
- Member states 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 member states 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 member states 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).

On 9 September 2004, the Authority adopted EFTA Surveillance Authority Decision No. 227/04/COL, by which Iceland is considered as a disease free country free of two of the listed diseases (Annex IV part II to Directive 2006/88/EC): infectious haematopoietic

disease (IHN) and viral haemorrhagic septicaemia (VHS). This decision was adopted on the basis of Council Directive 91/67/EEC, as adapted by way of Protocol 1 to the EEA Agreement (repealed and replaced by Directive 2006/88/EC) and in particular Article 5 of the Directive.

4.3.1 Diseases of fish

According to Icelandic Act No. 25/1993 on animal disease and disease prevention (see section 5.1) ISA, VHS, IHN, IPN, PD/SAV, VNN/VER and BKD are notifiable diseases, that will be subject to stamping-out if they occur in Iceland (see also section 5.4.1).

Non-exotic fish diseases listed in Part II of Annex IV to Directive 2006/88/EC:

Iceland is considered as a disease free country free of IHN and VHS.

As regards infectious salmon anaemia (ISA) the disease has never been detected in Iceland. MAST has submitted a declaration to the Authority for disease-free status for two salmon broodfish farms *and one supplying smolt farm* that have been subject to an intensive sampling and surveillance programme for achieving disease-free status. At the time of the mission and while drafting this report, this declaration was still subject to comments from other EEA states in line with Article 50 of Directive 2006/88/EC. Consequently, Iceland is until further notice to be considered as Category III with regard to health status (in accordance with Annex III to Directive 2006/88/EC), i.e. undetermined, not known to be infected but not subject to a programme for achieving disease-free status.

Koi herpes virus (KHV) has never been detected in Iceland, but has never been subject to a sampling programme for achieving disease-free status.

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

Concerning infectious pancreas necrosis (IPN) the disease has never been detected in Iceland. Routine sampling for IPN has been performed since 1985 as part of a surveillance program to document freedom of the disease.

Pancreas disease (PD) has never been detected in Iceland. Routine sampling for PD has been performed since May 2009 as part of a surveillance program to document freedom of the disease. Viral nervous necrosis/viral encephalopathy and retinopathy (VNN/VER) has never been detected in Iceland. Routine sampling for VNN/VER has been performed since 2000.

Bacterial Kidney Disease (BKD) was first detected in 1968 in Iceland and today occurs sporadically. Routine sampling is performed as part of a surveillance program for BKD to detect the appearance of BKD as early as possible as part of a national eradication program.

4.3.2 Diseases of Molluscs and Crustaceans

Non-exotic molluscs and crustaceans diseases listed in Part II of Annex IV to Directive 2006/88/EC:

Concerning diseases in bivalve molluscs *Marteilia refringens* and *Bonamia ostreae* have never been detected in Iceland. The disease *Marteilia refringens* has been subject to

sampling in 2010 (60 individuals sampled) and 2011 (30 individuals sampled) with negative results. The disease *Bonamia ostreae* has never been subject to a sampling/surveillance program and according to information received from MAST the susceptible species for *Bonamia ostreae* are not present in Iceland.

As regards crustacean diseases the situation with regard to white spot disease in Iceland is unknown.

5 FINDINGS AND CONCLUSIONS

5.1 Transposition of EEA legislation

Legal requirements

Article 7(a) of the EEA Agreement states that, an act corresponding to an EEC regulation shall as such be made part of the internal legal order of the Contracting Parties.

Article 4(2)(e) of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have legal powers to carry out official controls and to take measures provided for.

Findings

According to information provided by MAST in its reply to the pre-mission document of the Authority the Ministry of Industries and Innovation is responsible for implementation of legislation of EEA acts related to fish health. MAST is responsible for enforcing this legislation (see also section 5.2).

The main Icelandic Acts relevant for this mission and surveillance of fish health are:

- Act on import of animals No. 54/1990;
- Act on animal disease and disease prevention No. 25/1993;
- Act on fish diseases and disease prevention No. 60/2006; and
- Act on fishery products No. 55/1998.
- Act on Aquaculture No. 71/2008.

These acts provide the legal basis for regulations in the field of aquatic animal health adopted by the Ministry. These acts also provide the legal powers for MAST to carry out official controls and to take measures in case of infringements and also to take measures in case of suspicion or outbreaks of disease.

The mission team noted that:

- According to information in the pre-mission-questionnaire Council Directive 2006/88/EC and Commission Regulation (EC) No 1251/2008 has been made part of the Icelandic legal order by transposition to national regulations.

- According to information received at the final meeting from MAST the following three Commission Decisions were currently being transposed into the Icelandic national order and would be published on the 25 March 2013 (all of which have been applicable in Iceland since 11.11.2010 according to the EEA Agreement): 1. Commission Decision 2008/392/EC 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; 2. Commission Decision 2008/896/EC of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC; and 3. Commission Decision 2008/946/EC of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals.

- According to information in the pre-mission questionnaire, Commission Decision 2007/240/EC of 16 April 2007 laying down new veterinary certificates for importing live animals, semen, embryos, ova and products of animal origin into the Community pursuant to Decisions 79/542/EEC, 92/260/EEC, 93/195/EEC, 93/196/EEC, 93/197/EEC, 95/328/EC, 96/333/EC, 96/539/EC, 96/540/EC, 2000/572/EC, 2000/585/EC, 2000/666/EC, 2002/613/EC, 2003/56/EC, 2003/779/EC, 2003/804/EC, 2003/858/EC, 2003/863/EC, 2003/881/EC, 2004/407/EC, 2004/438/EC, 2004/595/EC, 2004/639/EC and 2006/168/EC, has not yet been made part of the national legal order and is currently in the process of being implemented (according to the EEA Agreement applicable for Iceland for live aquaculture animals).

Conclusions

The main legal framework for aquatic animal health, i.e. Council Directive 2006/88/EC and Commission Regulation (EC) No 1251/2008, has been made part of the Icelandic legal order. However, Commission Decision 2007/240/EC has not yet been made part of the legal order. In addition, transposition of applicable EEA legislation for aquatic animal health does not in all cases seen take part in line with the deadlines set in the EEA Agreement.

5.2 Competent authorities

Legal requirements

Article 4 (2)(b) and (c) 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 and that staff carrying out official controls are free from any conflict of interest.

Article 54 of Directive 2006/88/EC requires member states:

- to designate their competent authorities for the purposes of this Directive. The competent authorities shall operate and perform their duties in accordance with Regulation (EC) No 882/2004;
- 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 competent authorities they designate for the purposes of this Directive and any other authorities involved in regulating aquaculture, aquatic animals, and food and feed of aquaculture origin;
- to ensure that the competent authorities have access to adequate laboratory services and state-of-the-art know-how in risk analysis and epidemiology, and that there is a free exchange of any information relevant to the implementation of this Directive between the competent authorities and laboratories.

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

- 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.

Findings

5.2.1 Organisation

According to information in the reply to the pre-mission questionnaire official controls and monitoring of aquaculture animal health are the responsibility of MAST under the Ministry of Industries and Innovation.

The Act on Aquaculture No. 71/2008 lays down the requirements for establishing aquaculture farms in Iceland and sets out that applications for approval must be sent to the Directorate of Fisheries (see also section 5.3.1). There is a formal agreement dated June 2012 between MAST and the Directorate of Fisheries (they are under the same Ministry). According to MAST there is no overlap of responsibilities and the responsibility for official controls of aquaculture animal health as set out in Directive 2006/88/EC is solely the responsibility of MAST.

Within MAST two veterinarians based at central level are dealing with aquatic animal health. The more experienced fish health veterinarian has been in charge of coordinating the policy on fish animal health and the use of veterinary medicine in aquaculture farms under the supervision of the Chief Veterinary Officer (CVO).

In addition, there is a Fish Disease Committee that advises MAST in case of fish diseases on fish farms or lakes and concerning importing fish or other live animals for aquaculture purposes. The chairman of the Committee is the CVO and other representatives are members from the Laboratory Keldur (see section 5.2.3), the Institute of Fresh Water Fisheries, the Directorate of Fisheries and the Marine Research Institute.

The two official fish health veterinarians placed centrally in MAST are in charge of all official controls in aquaculture farms and all other establishments falling under Directive 2006/88/EC. The main activities include inspections, sampling and monitoring programmes (see section 4.3.1), investigation of disease outbreaks in aquatic animals, enforcement of statuary disease controls and implementation of controls on the import and export of live aquatic animals. Although the six districts of MAST have the administrative responsibility for all animal diseases including fish diseases within their district, the districts do not perform any official controls in aquaculture farms or other establishments falling under Directive 2006/88/EC and are only required to help with the controls in the case of outbreaks of disease (see also section 5.4.2). Nevertheless, according to the information received, there is a close contact between the fish health veterinarians and the veterinarians working in the districts although the latter group has limited working experience and have received no training in aquaculture animal health issues.

The mission team noted that:

- The official fish health veterinarians worked closely with stakeholders in the aquaculture industry and frequent contacts between MAST and the operators had taken place in all aquaculture farms visited.

- The official fish health veterinarians showed a high level of expertise and experience in aquatic animal health and matters related to aquaculture business in general. The work of the fish health veterinarians is also very well supported by a close cooperation and support from the diagnostic services offered by the national reference laboratory (NRL) in Reykjavik (see also section 5.3.3).

  According to the information received one of the official fish health veterinarian is responsible for prescribing veterinary medicine to aquaculture farms while at the same time in charge of the official controls in the farms. In 2012 one such prescription of veterinary medicine to a fish farm had been given[1].

5.2.2 Documentation of controls

According to information in the reply to the pre-mission questionnaire when aquatic animal health inspections are performed a special form of check-list is used and a written report is sent back to the management of the aquaculture farms as a feed-back with a copy to the respective district veterinarian. If necessary, comments and respective actions taken by MAST will follow up the recommendations of the report.

The mission team noted that:

- In all aquaculture farms visited the latest inspection reports by MAST were checked. In all cases seen the same template report had been used and according to the information received this system has been in place with only minor changes since 1991.

- The inspection reports checked were very comprehensive covering all relevant issues in relation to Directive 2006/88/EC as well as the use of veterinary medicine/chemicals, vaccinations, animal welfare issues and environmental issues.

- The reports checked on-the-spot provided evidence that the official fish health veterinarian had carried out very thorough inspections in the aquaculture farms visited. The inspection reports contained recommendations or suggestions for improvements. Several examples were seen where follow-up of recommendations had been taken by aquaculture farm management in cooperation with the official fish health veterinarian.

- It was confirmed on-the-spot that the farm managements had received the original and the district veterinarians had received copies of these inspection reports issued by MAST.

5.2.3 Laboratory services

The Laboratory of Experimental Pathology at Keldur is appointed as NRL for fish, crustacean and molluscs diseases since February 2013. The staff dealing with these diseases consists of five biologists. The laboratory has made an agreement with the EU Reference Laboratory (EURL) for Fish Diseases concerning examination of samples from fish suspected for the diseases ISA, IHN, VHS and IPN.

The mission team noted that:

[1] *See Annex 3 for additional comments from MAST (recommendation no. 2) concerning the noted potential conflict of interest of the official fish health veterinarian.*

- The NRL has good contacts with the EURL for Fish Diseases and the EURL for Molluscs Diseases. There had been no contact with the EURL for crustaceans. Due to economical restraints representatives of the NRL were not able to participate in annual meetings with the EURL for Fish Diseases since 2008.

- The laboratory is accredited to ISO 17025 by the Swedish Accreditation Body (SWEDAC). Diagnosis of VHS, IHN, ISA and IPN were included in the accreditation documentation checked.

- The laboratory had a Quality Management System in line with ISO 17025 standards. A quality manual and written instructions are available via an intranet based information system. Examples of Standard Operating Procedures (SOPs) were seen. The SOPs are available from the intranet and copies are printed out for use in the laboratory. It was noted that the printouts were missing traceability (no reference to the SOP number and no version number).

- The internal training for two of the staff was checked in the Quality Management System and found to be satisfactory. However, no staff with expertise in crustacean diseases is employed by the laboratory.

- The NRL has participated in the proficiency testing provided by the EURL for Fish Diseases since 2004. The laboratory analysed the samples for VHS, IHN and IPN since 2004, and furthermore for EHN and ISA since 2009 and 2010, respectively. Overall, the performance of the NRL has been satisfactory in the proficiency testing for fish diseases.

- The laboratory is designated as NRL for mollusc diseases but the methods used occasionally have not been accredited.

- The laboratory is designated as NRL for crustacean diseases but has no procedures in place for detection of the listed diseases, nor has it any agreements with other laboratories concerning these pathogens.

- Samples for examination by cell culture and samples for examination by polymerase chain reaction (PCR) are being handled in two different buildings. All samples are sent in Styrofoam boxes with ice packs separately.

- Taking into account the small numbers of samples received annually and the present health status in the country, the layout of the laboratory part processing samples for cell culture is appropriate. The samples are delivered in a sluice with a refrigerator and then the samples are taken into the laboratory where the parcel is opened and the first preparation of samples is done. The cell culture work was performed in a separate, small laboratory. Both clean cells and cells inoculated with samples were handled in the same room but in separate incubators.

- In order to decrease the need for laboratory work with harmful viruses, ampoules with BF-2 and EPC cells received from the EURL are frozen in nitrogen and batches of these are thawed each year at the time of the annual EU proficiency test. This is not in line with the Commission Decision 2001/183/EC in the Annex part I, chapter III, point 3 requesting that cell susceptibility tests have to be performed at least every six months.

- The PCR laboratory works mainly, but not exclusively, with fish diseases. The laboratory fits for the purpose except for the layout for location of the master mix

room which is separated from the rest of the laboratory by only one door. The laboratory was equipped with the necessary equipment.

5.2.4. Verification and auditing

According to information received from MAST at the initial meeting a cycle of internal audits has been initiated in 2012 in line with Article 4 to Regulation (EC) No 882/2004 on different subjects (slaughterhouses, fishery products establishments, feed establishments, animal welfare, etc). However, at the time of the mission MAST was not able to provide a time frame for the planned internal audit in line with article 4 of Regulation (EC) No 882/2004 of aquatic animal health as set out in Directive 2006/88/EC. In addition, MAST indicated at the initial meeting that as part of MASTs quality management system there is a system of auditing of staff in place.

Conclusions

The competent authorities of Iceland have satisfactorily addressed the requirements of Article 54 of Directive 2006/88/EC by designating competent authorities that operate and perform their duties in accordance with Regulation (EC) No 882/2004; nevertheless, a potential conflict of interest was noted for the official fish health veterinarian that is prescribing veterinary medicine while at the same time being responsible for official controls with use of veterinary medicine; moreover, the official control system for aquatic animal health had not yet been audited in line with Article 4 of Regulation (EC) No 882/2004.

A NRL for diseases of fish, molluscs and crustaceans has been appointed in Iceland in line with Articles 56 and 57 of Directive 2006/88/EC. The methods used for fish diseases have been accredited. However, the methods used for the detection of molluscs and crustacean diseases were not accredited and there was no expertise or procedures in place for detection of crustacean diseases available.

5.3 Authorisation and registration of aquaculture production businesses

Legal Requirements

Article 4 of Directive 2006/88/EC requires member states to ensure that each aquaculture production business is duly authorised by the competent authorities in accordance with Article 5 therein. They may require, under certain conditions, only the registration by the competent authorities of certain categories of aquaculture production businesses. In doing so, member states 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 aquaculture production businesses, including requirements to be fulfilled by them as laid down in Articles 8 to 10 therein, and requires member states to ensure that aquaculture production business operators submit all relevant information in order to allow the competent authorities 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 member states to establish, keep up to date and make publicly available a register of aquaculture production businesses containing at least the information set out in Annex II to the said Directive. Moreover, Article 2 of Commission Decision 2008/392/EC provides that member states shall establish an Internet-based information page to make available information on farms or mollusc

farming areas of aquaculture production businesses 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 aquaculture production businesses shall be carried out by the competent authorities. These official controls shall at least consist of regular inspections, visits, audits, and where appropriate, sampling, for each aquaculture production business, taking into account the risk it 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 member states 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 member states for the purpose of applying the risk-based animal health surveillance schemes.

Findings

5.3.1 Conditions for authorisation and requirements for registration

According to information in the reply to the pre-mission questionnaire granting approvals is the responsibility of the Directorate of Fisheries. When an aquaculture operator applies for an operating permit, a work permit from the Local Health Authorities (LCA) is required first which is based on polluting factors and the environmental risk involved with starting up the aquaculture operation. If the work permit is granted from the LCA, a request for an operational permit can be requested from the Directorate of Fisheries. The legal basis for granting and suspending/withdrawing approvals are Act no. 71/2008 on Aquaculture and Regulation No. 401/2012 on Aquaculture (see also section 5.1).

There is a register in place in Iceland of aquaculture production businesses that is kept up-to-date by *MAST* and includes the approval number of each aquaculture farm[2]. The register is publicly available at the homepage of MAST (www.MAST.is). However, this register does not include all the relevant information e.g. coordinates for farm as requested by Commission Decision 2008/392/EC 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.

According to information in the reply to the pre-mission questionnaire and confirmed at the initial meeting there are no establishments in Iceland specifically approved to slaughter aquaculture animals for disease control purposes (see also section 5.4.2.). In general MAST has not demanded any special requirements regarding disinfection treatments of blood water from establishments slaughtering aquaculture animals due to the good fish health status in Iceland.

[2] *See Annex 3 for additional comments from MAST (recommendation no. 6) concerning the responsibility of MAST to make and update the register of aquaculture farms.*

The mission team noted that:

- MAST had not yet started authorising aquaculture production businesses in Iceland according to Articles 4 and 5 of Directive 2006/88/EC.

- In the aquaculture production businesses visited it was confirmed that approvals had been granted by the Directorate of Fisheries. Evidence was seen that these approvals had gone through a hearing process within MAST before being finalised. However, there was no referral to the conditions required for approval of aquaculture farms as set out in Articles 4 and 5 of Directive 2006/88/EC and, in particular, that the aquaculture production businesses fulfil the requirements laid down in Articles 8, 9 and 10 of the same directive.

- In one aquaculture production business visited, that was approved by the Directorate of Fisheries, there was not yet a quality management system in place to ensure good hygiene practice including safe biosecurity plans. It was also noted that dead fish were thrown into the sea by staff. Nevertheless this farm had appropriate mortality records in place.

- Regarding transport of live fish Norwegian well boats are used for transports of live fish within Iceland. In addition, there is one small Icelandic well boat used, however, the well boat is not authorised or registered in line with Article 5.

- The official fish health veterinarians were well aware that well boats can pose a big risk in the biosecurity system. Therefore a system is in place where the well boats, including the Norwegian boats, are required to disinfect the well boats before use, and MAST will check the boats and take bacteriological samples from surfaces before issuing a disinfection certificate to the well boat.

- No transporters of live fish are authorised in Iceland. One transporter of live fish (truck) that was not authorised was visited by the mission team. The driver had a register in place of all transports carried out. However, the information did not include mortality records. According to information received two more transporters mainly transporting live fish during peak seasons were also in operation.

5.3.2 Official controls and animal health schemes

The official fish health veterinarians carry out their official controls and animal health surveillance through regular inspections and sampling. According to the information received the organisation of official controls is risk-based and based on the principles of Commission Decision 2008/896/EC. The territory of Iceland is considered to be one zone as regards health status for fish diseases (with the exception of ISA where three aquaculture production businesses are considered free).

The mission team noted that:

- When requested evidence was provided by the official fish health veterinarian that an individual risk assessment had been carried out on each farm in 2010 following Directive 2006/88/EC and the guidelines of Commission Decision 2008/896/EC. These risk assessments were taking into account species produced, type of farm (landbased or seacage), water source, health situation, etc. On the basis of this risk assessment all farms were categorised in three groups: low, medium or high risk and inspection frequency was calculated in order to organise the inspections more efficiently. The risk assessment was last updated in 2010 and according to the information received no changes had occurred requiring an update of the risk assessment since then.

Passive surveillance: The disease notification system (see also 5.4.2.1).

The mission team noted that:

- When fish farmers have high mortalities it was confirmed on-the-spot that the official fish health veterinarian is contacted and further investigations will be conducted. However, it was noted that no samples had been sent for virological examination in the last six years as part of differential diagnosis when other diseases were suspected (e.g. in the case of detection of atypical furunculosis).

Active surveillance: The fish health veterinarian stated that all farms are visited at least once a year. Although the risk assessment carried out in line with 2008/896 gave a frequency of one inspection every four years, this was considered to be too infrequent and instead annual inspections were carried out.

The mission team noted that:

- During planned routine inspections all farm facilities (cages, tanks and ponds) are checked for dead and weak fish and fish showing abnormal behaviour. It was noted that inspections carried out were very thorough and covered both fish health, animal welfare, use of veterinary medicine, environmental issues etc. A comprehensive report is issued after each inspection with copy to the fish farmer and the district veterinarian of MAST.

Targeted surveillance: MAST performs targeted surveillance including sampling for (see also section 4.3):

- ISA in two salmon broodfish farms that have been subject to an intensive sampling and surveillance programme in the last four years for achieving disease-free status.
- VHS/IHN is performed together with IPN-testing in the same samples, according to the information received in 2012, 345 individuals had been sampled (120 salmon smolt, 100 wild salmon, 30 cod, and the rest from individual broodfish). Rainbow trout had not been sampled for VHS in recent years.
- IPN, where routine sampling has been performed since 1985 as part of a surveillance program to document freedom of the disease.
- PD, where routine sampling has been performed since May 2009 as part of a surveillance program to document freedom of the disease.
- VNN/VER where routine sampling has been performed since 2000.
- BKD where routine sampling is performed as part of a surveillance program to detect the appearance of BKD as early as possible as part of a national eradication program.

The mission team noted that:

- In 2012 177 inspections by the official fish health veterinarian were carried out to the 49 aquaculture farms. These inspections included more than 100 visits to broodstock farms for certification purposes and approximately 80 visits for sampling since this was carried out twice a week all year round. In the aquaculture production businesses visited it was noted that inspection frequencies in general were much higher than planned. (e.g. three times a year instead of the planned once a year, or once a year instead of the planned every four year visit).

- Only one of the farms visited had used a private veterinarian for consultancy. The official fish health veterinarian will still be contacted in case of suspicion of disease outbreaks and for prescriptions of veterinary medicine (see also section 5.2.1 and 5.4.1).

Conclusions

The competent authorities have not yet initiated the authorisation process of aquaculture production businesses in line with Article 4 of Directive 2006/88/EC that requires member states to ensure that each aquaculture production business is duly authorised by the competent authorities in accordance with Article 5 (in particular to ensure quality management systems and good hygiene practice including appropriate biosecurity plans).

The competent authorities have addressed the requirements under Article 6 of Directive 2006/88/EC by establishing and keeping publicly available a register of aquaculture production businesses. Nevertheless, the transporters were not registered or authorised and not included in the register.

The competent authorities have addressed the obligations under Article 7 of Directive 2006/88/EC and official controls are planned and carried out on a risk basis. The official controls and inspections including sampling were carried out in a very thorough and conscientious manner and were well reported and followed-up.

5.4 Measures for control of diseases of aquaculture animals

Legal Requirements

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

- Obligations for notification of: a) suspicion or confirmation of a disease listed in part II of Annex IV to the said Directive, to the competent authorities; b) increased mortality in aquaculture animals, to the competent authorities 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 member state 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. Paragraph 4 of this Article provides that member states shall submit the contingency plans for approval (i.e. submission of contingency plans to the Authority in the case of EFTA EEA member states). 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.

Findings

5.4.1 Notification, suspicion and confirmation of diseases

According to information provided by MAST in its reply to the pre-mission questionnaire, provisions governing animal diseases and preventive measures against them are laid down in Act No. 25/1993 and Regulation No. 403/1986 concerning measures to prevent and control diseases in fish and health inspection of fish farms. The person in charge of the fish farm shall immediately notify the official fish health veterinarian of any signs of disease on the farm.

In case of a suspected contagious disease the official fish health veterinarian shall immediately inform the fish disease laboratory at Keldur, the MAST district and the Fish Disease Committee (see section 5.2.1).

The mission team noted that:

- The obligation to notify diseases is laid down in the Icelandic legislation and the Icelandic contingency plan for foreign diseases (see section 5.4.2) includes instructions and templates for notification to different national and international bodies.
- Although administratively responsible for all animal diseases in their district, in practice the involvement of the MAST districts in control of fish diseases is limited. The fish farms visited confirmed that they would contact the official fish health veterinarian at the central level of MAST directly.
- Out of the farms visited, only one had an arrangement with a private veterinarian for health controls in the farm. Also this farm would nevertheless contact the official fish health veterinarian in case of suspected disease. Further investigations, such as clinical examination, sampling for confirmation of diagnosis and epidemiological investigations would be carried out by the official fish health veterinarian.
- At all sites visited it was confirmed that the official fish health veterinarian would be contacted in case of increased mortality that could not be linked to handling of fish. In most farms visited it was stated that more than 0.1 % daily mortality per epidemiological unit (tank) was considered as the limit for when to contact the official fish health veterinarian.

5.4.2 Contingency planning for emerging and exotic diseases

According to information provided by MAST in its reply to the pre-mission questionnaire of the Authority, outbreaks of diseases listed in Appendix 1A of Act No. 25/1993 would be subject to stamping out. Appendix 1A includes all diseases listed in Part II of Annex IV of Directive 2006/88/EC with the exception of epizootic ulcerative syndrome and the crustacean diseases.

MAST has established a contingency plan for foreign diseases and including fish diseases. The general introduction of the contingency plan describes inter alia the legal powers, financial provisions and chain of command in case of an outbreak of a disease. MAST is empowered to access all relevant premises and sufficient funds to combat a disease are ensured since the cost of personnel and cost of capital equipment, slaughter and destruction, sanitation and compensation to the businesses is to be paid by the State Treasury.

All districts of MAST are equipped with a folder describing initial measures to be taken, including a checklist with corresponding templates and guidelines for notifying, sampling, actions to be taken to prevent spreading of disease, epidemiological survey, etc.

The mission team noted that:

- Although a contingency plan has been established, it has not been submitted for approval to the Authority.
- Not all districts of MAST have available the necessary equipment for sampling of fish. However, the official veterinarian for fish diseases will be the primary respondent in case of fish diseases.

- There is currently no establishment authorised to slaughter fish for disease control purposes in Iceland.
- According to the contingency plan, vaccination against exotic animal diseases is prohibited (includes all relevant fish diseases) and diseases shall be eradicated by stamping out. However, in one smolt farm visited the mission team noted that smolt destined for export to the Faeroes Islands were vaccinated against ISA (vaccinated smolt was kept in separate tanks from smolt destined for the national market).
- Although stamping out is the strategy of choice in case of an outbreak of an infectious fish disease, combined with the fact that no establishment is authorised, or equipped for slaughtering fish for disease control, no further description of the stamping out and how this will be practically arranged is included in the contingency plan.
- According to the contingency plan, the municipalities shall ensure that a site is available for disposal of carcasses and these sites should be authorised by the Environment Agency of Iceland. The mission team was informed that no such sites have been identified at the moment.
- The mission team also noted that arrangements for handling of dead fish from aquaculture production businesses varied from around the country. All of the visited farms collected dead fish from the tanks/nets with different frequencies, further handling of the dead fish varied from throwing dead fish out into the sea to a system where dead fish were collected and sent for mink feed (see also section 5.3.1).

Conclusions

A system for notification of the presence of a disease is in place in Iceland. Iceland has established a contingency plan for fish diseases in line with Article 47 of Directive 2006/88/EC. However this plan has not been submitted for approval to the Authority in line with paragraph 4 of that article.

Presently there are no facilities equipped or authorised for slaughtering fish for disease control in Iceland nor are alternative methods for culling and disposal of diseased fish described. Consequently it is not clear how disposal of carcasses will be done in line with point 12 of Annex VII of Directive 2006/88/EC in case of outbreak of disease.

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

Legal Requirements

According to Article 12 of Directive 2006/88/EC, member states 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 member states, zones and compartments with different health statuses, as referred to in Part A of Annex III to the said Directive.

Chapter III of Regulation (EC) No 1251/2008 lays down:

- Animal health conditions for the placing on the market of: 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 member states 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) No 1251/2008 lays down animal health conditions and animal health certification requirements for import into the EU of aquaculture animals and products thereof, including those intended for human consumption, and ornamental aquatic animals intended for closed ornamental facilities.

Findings

5.5.1 Import controls

MAST is responsible for official inspections in border inspections posts (BIPs). There is only one BIP approved for imports of live aquaculture animals (Keflavik airport BIP).

According to information provided in the reply to the pre-mission questionnaire in general all imports of live aquaculture animals are forbidden. However, the Minister can grant exemption with the legal basis in Act No. 54/1990 governing the import of animals. If an importer wants to apply for import permission, the request must be sent to MAST and MAST and the Ministry must be assisted by the Fish Health Committee (see also section 5.2), that has to handle all applications regarding imports of live fish or eggs/gametes. The final recommendations of MAST (e.g. granting or refusing of import approvals on certain conditions) are based on the risk assessments carried out by the Fish Health Committee. According to the information received this evaluation is based on OIE (Office International Epizootic) procedures on import risk analysis as set out in the Aquatic Animal Health Code, mainly taking notice of the animal health status of the exporting country.

All imported live aquaculture animals from third countries are placed in quarantine for up to six months. Meanwhile all effluent water has to be disinfected with chlorine. The quarantine is under supervision of the official fish health veterinarian that can perform sampling and disease testing if necessary.

The mission team noted that:

- Ornamental fish are imported only with individual import approvals from MAST (in 2012 about 25 consignments) and must after import stay in quarantine for four weeks in the retail shop selling them. The retail shops are not specifically authorised by MAST.

- In Iceland two quarantines are approved by MAST specifically for imported live fish for aquaculture purposes. In general imported live fish/animals for aquaculture must stay in quarantine for six months before they can be released.

5.5.2 Certification: Placing of aquaculture animals on the market

According to information provided in the reply to the pre-mission questionnaire MAST is considering the whole territory of Iceland as one zone (with the exception of the ISA approved farms) with the same health status for fish and mollusc diseases, as referred to in Part A of Annex III to the said Directive. This conclusion is based on active surveillance and regular disease testing in Iceland since 1985 (see also section 5.3.2).

All shipments of live fish and eggs (also within Iceland) must be notified beforehand to the official fish health veterinarian. Notifications must be submitted to the official fish health veterinarian who will issue a health and transport certificate if the farm fulfils the requirements. If the consignment is destined for placing on the market outside of Iceland (in EEA countries or third countries) the official fish health veterinarian is responsible for contacting the competent authorities in the receiving country beforehand. If the placing on the market in the receiving country is accepted, the official fish health veterinarian can issue a health certificate in line with Annex II, Part A of Commission Regulation (EC) No 1251/2008, if the aquaculture production business fulfils the requirements. Each certificate contains serial number (individual series for each receiving country), stamp and signature given by the official fish health veterinarian.

The mission team noted that:

- MAST has decided to issue certificates for all movements of live fish or eggs also within Iceland.
- It was confirmed that inspections were carried out by the official fish health veterinarians 72 hours before loading of live fish or eggs at the place of dispatch in connection with the certification when exporting for third countries or for intra-union trade.
- Certificates that were checked for smolt to the Faeroe Islands stated that they were coming from ISA free zone, which is not correct although outbreaks of ISA have never been detected (see also section 4.3.1). Certificates that were checked for salmon eggs sent from a brood stock farm from Iceland to other EEA states and Chile stated that they were coming from ISA free zone which is not correct (see also section 4.3.1. regarding current declaration from MAST for disease-free status concerning ISA for three farms in Iceland).

Conclusions

The competent authorities of Iceland has set up an effective import control system in order to ensure compliance with animal health conditions and animal health certification requirements for import into the EEA of aquaculture animals and products thereof, including those intended for human consumption, and ornamental aquatic animals intended for closed ornamental facilities in line with the requirements of Chapter IV of Regulation (EC) No 1251/2008.

The competent authorities of Iceland can 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) No 1251/2008. Nevertheless, some shortcomings were detected in the issuing of health certificates for aquaculture animals and products regarding status for ISA.

6 Final meeting

A final meeting was held on 20 March 2013 at the MAST Headquarters in Selfoss with representatives from MAST, the Ministry of Industries and Innovation and the Directorate of Fisheries. At this meeting, the mission team presented its main findings and preliminary conclusions of the mission.

At the meeting the mission team also explained that, based on a more detailed assessment of the information received during the mission, additional conclusions could be included in the report.

7 Recommendations

Iceland should notify the Authority, within two months of receiving the final report, by way of written evidence, of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding, relevant to all the recommendations hereunder. The Authority should also be kept informed of the completion of the measures included in the timetable.

No	Recommendation
1	The competent authorities should ensure that all the relevant legislation concerning aquatic animal health is made part of its legal order.
2	The competent authorities should ensure that official veterinarians who carry out official controls on use of veterinary medicinal products are free from any conflict of interest when simultaneously carrying out private practice work as required by Article 4 (2.b) of Regulation (EC) No 882/2004.
3	The competent authorities should ensure that internal or external audits are carried out in the area of aquatic animal health to ensure that the objectives of Regulation (EC) No 882/2004 are achieved in line with Article 4(6) of that regulation.
4	The competent authorities should ensure that the national reference laboratory has accredited methods for all diseases of fish, molluscs and crustaceans or has agreements with other accredited laboratories in order to comply with Articles 56 and 57 of Directive 2006/88/EC.
5	The competent authorities should review the authorisation procedure to ensure that all conditions of Article 5 of Directive 2006/88/EC are fulfilled before granting approvals to aquaculture production businesses in line with Article 4 of the same Directive.
6	The competent authorities should review the register of authorised aquaculture production businesses to include all relevant information in line with Article 4 and 5 of Directive 2006/88/EC and Commission Decision 2008/392/EC.
7	The competent authorities should submit the contingency plan for fish diseases for approval to the Authority in line with paragraph 4 of Article 47 of Directive 2006/88/EC.
8	The competent authorities should ensure that there are facilities equipped or authorised for slaughtering fish for disease control purposes or alternative methods for culling and disposal of diseased fish in order to ensure that disposal of carcasses will be done in line with point 12 of Annex VII of Directive 2006/88/EC.

Annex 1 - List of abbreviations and terms used in the report

The Authority	EFTA Surveillance Authority
BIP	Border inspection post
BKD	Bacterial Kidney Disease
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EHN	Epizootic haematopoietic necrosis
EU	European Union
EURL	EU Reference Laboratory
FVO	Food and Veterinary Office of the European Commission
IHN	Infectious haematopoietic necrosis
IPN	Infectious pancreatic necrosis virus
ISA	Infectious salmon anaemia
KHV	Koi herpes virus disease
MAST	The Food and Veterinary Authority of Iceland
NRL	National reference laboratory
OIE	Office International Epizootic (World Animal Health Organisation)
PCR	Polymerase chain reaction
PD	Pancreas disease
SOP	Standard operating procedures
SVC	Spring viraemia of carp
VHS	Viral haemorrhagic septicaemia
VNN/VER	Viral nervous necrosis/viral encephalopathy and retinopathy

Annex 2 - Other relevant legislation

The following EEA legislation was also taken into account in the context of this mission:

a) The Act referred to at Point 3.1.8a of Chapter 1 of Annex I to the EEA Agreement, *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*, as amended;

b) The Act referred to at Point 3.2.42 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/896/EC of 20 November 2008 on guidelines for the purpose of the risk-based animal health surveillance schemes provided for in Council Directive 2006/88/EC;*

c) The Act referred to at Point 4.2.63 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2001/183/EC 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*;

d) The Act referred to at Point 4.2.68 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2002/878/EC of 6 November 2002 establishing the sampling plans and diagnostic methods for the detection and confirmation of the presence of the mollusc diseases Bonamiosis (Bonamia ostreae) and Marteiliosis (Marteilia refringens);*

e) The Act referred to at Point 4.2.73 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2003/466/EC of 13 June 2003 establishing criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA);*

f) The Act referred to at point 4.2.86 of Chapter 1 of Annex I to the EEA Agreement, *Regulation (EC) No 1251/2008 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*, as amended*;*

g) The Act referred to at Point 4.2.87 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/392/EC 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;*

h) The Act referred to at Point 4.2.88 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2008/946/EC of 12 December 2008 implementing Council Directive 2006/88/EC as regards requirements for quarantine of aquaculture animals;*

i) The Act referred to at Point 4.2.89 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2009/177/EC 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 (notified under document number C(2008) 6264) (Text with EEA relevance)*;

j) The Act referred to at Point 4.2.94 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2010/221/EU 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 (OJ L 98, 20.4.2010, p. 7)*, as amended*;*

k) *Commission Decision 2007/240/EC of 16 April 2007 laying down new veterinary certificates for importing live animals, semen, embryos, ova and products of animal origin into the Community pursuant to Decisions 79/542/EEC, 92/260/EEC, 93/195/EEC, 93/196/EEC, 93/197/EEC, 95/328/EC, 96/333/EC, 96/539/EC, 96/540/EC, 2000/572/EC, 2000/585/EC, 2000/666/EC, 2002/613/EC, 2003/56/EC, 2003/779/EC, 2003/804/EC, 2003/858/EC, 2003/863/EC, 2003/881/EC, 2004/407/EC, 2004/438/EC, 2004/595/EC, 2004/639/EC and 2006/168/EC*, as made applicable to the EFTA States through the procedures referred to at Point 7 of the Introductory Part of Chapter I of Annex I to the EEA Agreement*;*

l) The *EFTA Surveillance Authority Decision No 277/04/COL of 9 September 2004 concerning the status of Iceland with regard to the fish diseases viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN).*

Annex 3 – Reply to the draft report

ESA mission on fish health 2013				
	Recommendation	**Action**	**Time aspect**	**Enclosures**
1	The competent authorities should ensure that all the relevant legislation concerning aquatic animal health is made part of its legal order.	The point is taken notice of and the procedure is ongoing. Since the mission took place additional acts have been implemented. Decision 2009/177 (IS 221/2013), Decision 2008/392 (IS 271/2013), Decision 2008/896 (IS 272/2013), Decision 2008/946 (IS 273/2013, Directive 2012/31 (IS 367/2013).		
2	The competent authorities should ensure that official veterinarians who carry out official controls on use of veterinary medicinal products are free from any conflict of interest when simultaneously carrying out private practice work as required by Article 4 (2.b) of Regulation (EC) No 882/2004.	The competent authorities find it necessary to present correction to some misunderstanding regarding conflict of interest. The two important and different tasks; 1) the responsibility of prescription and use of veterinary medicine in aquaculture and 2) the control on use of veterinary medicine, are under the official control of two separate offices in MAST. Both official fish health veterinarians are responsible for the first task; prescription of veterinary medicines for preventive measures and treatments against diseases. The senior official fish health veterinarian, as a member of the Fish		

ESA mission on fish health 2013				
		Disease Committee, is involved in deciding when and which medicine may be used in aquaculture animals. The second task, of official controls of use of veterinary medicinal products in animals, including aquaculture animals, is carried out by another inspector. In addition to this, a third veterinary official, belonging to a different division in MAST, is responsible for the national residue control plan, sampling and testing (office of food safety and consumer affairs.)		
3	The competent authorities should ensure that internal or external audits are carried out in the area of aquatic animal health to ensure that the objectives of Regulation (EC) No 882/2004 are achieved in line with Article 4(6) of that regulation.	MAST intends to carry out audits on its own procedures and preparation has commenced. The organization of the audits and ideas for the structure of such an audit system have been drafted and sent to the MoII for implementation. The draft is currently under revision at MAST.		
4	The competent authorities should ensure that the national reference laboratory has accredited methods for all diseases of fish, molluscs and crustaceans or has agreements with other accredited laboratories in order to comply with Articles 56 and 57 of Directive 2006/88/EC.	As confirmed in the draft report the Laboratory of Experimental Pathology at Keldur has been appointed as national reference laboratory (NRL) for fish, crustacean and molluscs diseases by the competent authorities. NRL at Keldur has not accredited methods to identify EC listed pathogens	November 30th 2013	

ESA mission on fish health 2013				
		of molluscs and crustaceans. As the procedure for accreditation is costly and the number of Icelandic samples for screening will be limited in the foreseeable future the laboratory will seek for an agreement with relevant EC reference laboratories in order to comply with Articles 56 and 57 of Directive 2006/88/EC. The head of Fish disease section of Institute for Experimental Pathology, Keldur, will contact the EC reference laboratories in June 2013, asking for such an agreement. Subsequently a formal agreement would be signed on behalf of Keldur institute by the head of the Institute for Experimental Pathology, Keldur, Iceland. The EC laboratories are: **IFREMER:** European Union Reference Laboratory for mollusc diseases Av. de Mus de Loup, 17390 La Tremblade, France. **CEFAS:** European Union Reference Laboratory for crustacean diseases Barrack Road, Weymouth, Dorset DT4 8UB, United Kingdom.		

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		Also, the NRL at Keldur will seek for an update on the present agreement with the Community reference laboratory for fish diseases in Århus, Denmark, dated 06-10-2004 (DFVF J. nr 11021-00017). This would include support from ECRL in identifying listed EC viral pathogens and other viruses of concern.		
5	The competent authorities should review the authorisation procedure to ensure that all conditions of Article 5 of Directive 2006/88/EC are fulfilled before granting approvals to aquaculture production businesses in line with Article 4 of the same Directive.	The legal departments of the Directorate of Fisheries and MAST are cooperating to find a harmonized solution for this issue with the main goal being simplification of procedures that fulfill the provisions of Directive 2006/88/EC. This will probably call for an amendment of the national legislation. The goal of this work is also the harmonisation and combination of procedures for granting authorisations as stated in the directive. See attached memorandum.	January 1st 2014	 Memorandum_approvals.docx
6	The competent authorities should review the register of authorised aquaculture production businesses to include all relevant information in line with Article 4 and 5 of Directive 2006/88/EC and Commission Decision 2008/392/EC.	As noted in the draft report there is an official register in place of all aquaculture production businesses in Iceland which has been publicly abailable at the homepage of MAST for	November 30th 2013	

ESA mission on fish health 2013				
		some years (one correction should be made to the content of the draft report; the register was made and has been kept up to date by MAST, not the Directorate of Fisheries. See paragr. 2on page 16). The register is in line with the information set out in Annex II of Directive 2008/66/EC but has not been updated in accordance with the Commission Decision 2008/392/EC. This work will start as soon as possible.		
7	The competent authorities should submit the contingency plan for fish diseases for approval to the Authority in line with paragraph 4 of Article 47 of Directive 2006/88/EC.	MAST is preparing a comprehensive review of the existing contingency plan, parallel with a practical simulation exercise and training with focus on Viral haemorrhagic septicaemia (VHS), to be held in Bergen in Norway in December 2013 carried out by the NMDD's Nordic-Baltic Veterinary Contingency Group. Following this session the contigency plan will be submitted to ESA for approval as soon as possible.	February 28th 2014	
8	The competent authorities should ensure that there are facilities equipped or authorised for slaughtering fish for disease control purposes or alternative methods for culling and disposal of diseased fish in order to ensure that disposal of carcasses will be done in line with point 12 of Annex VII of Directive	The competent authorities have not seen it necessary to demand treatment of effluent water from aquaculture processing establishments, based on risk assessment of the establishments currently operating and with regard to		

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	2006/88/EC.	point 2 of Article 5 of Directive 2006/88/EC on risk-mitigation measures. Hence there are no facilities specifically equipped or authorised for slaughtering fish for disease control purposes in Iceland. MAST has not yet based its authorisation of fish processing facilities on Directive 2006/88/EC. In the event of an outbreak of a fish disease the contingency plan for fish diseases includes guidelines on the chain of command and communication between the environmental authorities, local municipal health authorities and MAST with regards to disposal of diseased fish, contaminated fish waste and carcasses. Further demands on disease prevention and mitigation are given by the veterinary officer for fish diseases at MAST to the aquaculture production business in question and other operators concerned. The burial sites for carcasses are not determined in advance (not listed in the contingency plan) because of different circumstances in the municipalities.		