Final report

EFTA Surveillance Authority mission to

NORWAY

from 26 April to 7 May 2010

regarding the application of EEA legislation related to

fish health

Please note that the comments from the Norwegian competent authorities to the factual content of the report, if any, have been included in the body of the report in *underlined italic* print. Comments and information on the corrective actions taken and planned are included in Annexes 4 and 5 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 Norway from 26 April to 7 May 2010.

The objective of the mission was to verify that official controls related to fish health are carried out in compliance with the European Economic Area legislation.

The mission team found that the situation was, from a general point of view, satisfactory concerning the official controls carried out by the Norwegian Food Safety Authority. The epidemiological situation concerning fish diseases listed in Directive 2006/88/EC is in principle under control despite the recent outbreaks of infectious salmon anaemia. Relevant activities were mainly in conformity with the EEA requirements laid down in Directive 2006/88/EC and related legislation. However, the targeted surveillance for infectious haematopoietic necrosis had been discontinued.

The official and the private laboratories dealing with fish health diagnosis were well organised with only minor discrepancies observed.

Some inconsistencies were observed in the authorisation of processing establishments slaughtering aquaculture animals for disease control purposes and some information was missing in the registers of authorised aquaculture production businesses and processing establishments. In Norway fish health biologists (and not only registered veterinarians) are allowed to prescribe medicated feedingstuffs to aquaculture animals.

Finally, based on shortcomings identified in the system in place for the approval of establishments processing fishery products and deficiencies observed on the spot by the mission team particularly in one establishment visited, the mission team cannot exclude that fishery products which were not in conformity with the EEA Agreement requirements were being placed on the market of the EEA.

The report includes a number of recommendations addressed to the Norwegian 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 Norway from 26 April to 7 May 2010, as part of the EFTA Surveillance Authority's (the Authority) planned mission programme. The mission team comprised two inspectors from the Authority and a national expert.

The opening meeting was held with representatives of the Norwegian Food Safety Authority (NFSA) on 26 April at the NFSA's head office in Bergen. A video-link with the NFSA's head office in Oslo was also provided allowing other representatives of the NFSA and of the Ministry of Fisheries and Coastal Affairs to participate. At the meeting, the representatives of the NFSA added information to its reply to the Authority's pre-mission questionnaire.

Throughout the mission, a representative of the head office in Bergen accompanied the mission team. In addition, representatives of the relevant regional offices and district offices of the NFSA participated during meetings at the district offices and visits to the different farms and establishments.

A final meeting was held at the NFSA's head office in Oslo on 7 May 2010, where, 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. The meetings with the competent authorities and the visits to premises during the mission are listed in Table 1.

Table 1: Competent authorities and premises visited

	Number	Comments
Competent authorities	5	Including the opening meeting in Bergen, the final meeting in Oslo and meetings at district offices where representatives of the regional and district offices participated.
Hatcheries	2	One brood stock farm supplying mainly eggs and some fry to other hatcheries and one hatchery supplying smolt to grow-out farms.
Aquaculture farms	3	Grow-out farms.
Establishments slaughtering and processing fishery products	4	One establishment processing category 2 and category 3 animal by-products of aquaculture origin not intended for human consumption, three establishments processing aquaculture animals for placing on the market for human consumption (one of these was not in operation at the time of the visit).
Well boats	2	Transporting live fish from hatcheries to grow-out farms or from grow-out farms to slaughtering facilities.
Laboratories	5	The National Veterinary Institute main laboratory based in Oslo and two regional laboratories. Two private laboratories.

2 Scope and objective of the mission

The following main European Economic Area (EEA) acts and related EEA legislation fall within the scope of the mission:

a) The Act referred to at Point 4.1.5a of Chapter I 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 corrected.

b) The Act referred to at Point 4.2.63 of Chapter I 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.*

c) The Act referred to at Point 4.2.68 of Chapter I 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).*

d) The Act referred to at Point 4.2.73 of Chapter I 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).*

The main objective of the mission was to assess the application by the Norwegian competent authorities of the above-mentioned legislation and other legislation referred to under Annex 2 to this document. A particular focus was put 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*.

3 Legal basis for the mission

The legal basis for the mission was:

a) 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);

b) Point 4 of the Introductory Part of Chapter I of Annex I to the Agreement on the European Economic Area (EEA Agreement);

c) Article 58 of *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*;

d) *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.*

e) Article 45 of *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.*

Other legislation relevant for the mission is listed in Annex 2.

4 Background

4.1 Background

The previous mission concerning fish health was carried out in Norway from 27 June to 1 July 2005. The final report from that mission is accessible on the website of the Authority, www.eftasurv.int. The Authority concluded on a number of issues in the report from the mission in 2005 and subsequently the NFSA informed the Authority of corrective measures taken, or to be taken.

In relation to the status of Norway with regard to IHN and VHS, the Authority has adopted Decision No 02/10/COL of 5 January 2010 concerning the status of Norway with regard to infectious haematopoietic necrosis and viral haemorrhagic septicemia and repealing Decision No 302/08/COL of 21 May 2008. Decision No 02/10/COL recognises Norway, with the exemption of the areas referred to in the Annex to the Decision, as approved continental zone and as approved coastal zone for fish with regard to IHN and VHS (see details in table 2).

In relation to the status of Norway with regard to ISA (details are also provided in table 2), the NFSA has the authority to declare the Norwegian zones or compartments as free of the disease in accordance with Article 50 and Part II of Annex V to Directive 2006/88/EC.

The information on the ISA free zones or compartments is available on the website of the NFSA.

In relation to non-exotic diseases, the epidemiological situation in Norway is summarised in table 2.

Table 2: Non-exotic diseases (*)

Spring viraemia of carp (SVC)	Never recorded in Norway
Viral haemorrhagic septicaemia (VHS)	Last disease outbreak in July 2008. Last virus detection in May 2009. The samples of this last detection were from fish before slaughtering tested positive using real time reverse transcriptase PCR (RT-PCR). The VHS virus related to the outbreaks in Norway was identified as genotype 3 in rainbow trout within the same fjord area (Storfjord, Sunnmøre). The following applies to Norway: Disease-free status– All of Norway except buffer zone (border to Russia) and Storfjord; Undetermined health status - Buffer zone (border to Russia); Eradication Programme – Storfjord.
Infectious haematopoietic necrosis (IHN)	Never recorded in Norway Disease-free status – All of Norway except buffer zone (border to Russia).
Koi herpes virus disease	Never recorded in Norway.
Infectious salmon anaemia (ISA)	ISA is considered to be endemic outside three zones and 17 compartments declared disease-free and listed as such by Norway. Last outbreak was in April 2010 in Troms. A zone was temporary suspended in Nordland following a suspected outbreak. At the time of the mission, the suspicion was still pending (Lofoten).
Infection with *Marteilia refringens*	Never recorded in Norway.
Infection with *Bonamia ostreae*	In 2009 a positive PCR test in wild European flat oysters (*Ostreae edulis L.*) was reported by the NFSA from one area close to Arendal in Aust- Agder County. No disease outbreak or increased mortality was reported.

(*) Source: NFSA - reply to the pre-mission questionnaire of the Authority and additional information received from representatives of the NFSA head office in Bergen.

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, exotic diseases as listed in Part II of Annex IV to Directive 2006/88/EC have never been recorded in Norway.

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, Norway has also established a list of diseases (so called "list 3" as mentioned in Annex 1 of the national Regulation of 17 June 2008 No. 819 concerning the animal health conditions governing the placing on the market and the import of aquaculture animals and aquaculture products) including diseases which assume a relevant importance at national level (*e.g.* pancreas disease (PD), salmon louse, *Gyrodactylus salaris* etc.).

The National Veterinary Institute (NVI) publishes annual reports on the fish health situation in Norway. The reports are available on its website.

4.2 Information on production and trade

Figures for the production and trade of fish in Norway provided by the NFSA in its reply to the pre-mission questionnaire of the Authority are given in Annex 3. According to additional information provided by representatives of the NFSA head office in Bergen, the main third countries of origin for import of trout (products thereof) were Peru and Russia.

5 Findings and Conclusions

5.1 Legislation and implementing measures

Legal requirements

Article 3 of Regulation (EC) No 882/2004; Chapter I of Directive 2006/88/EC.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, the main Norwegian Act creating the general framework for the functioning of the NFSA is Act No. 124 of 19 December 2003 relating to food safety and plant and animal health (the Food Act). The Food Act also provides the legal basis for regulations in the relevant fields (including aquatic animal health) adopted by the Ministry of Agriculture and Food, the Ministry of Health and Care Services and the Ministry of Fisheries and Coastal Affairs.

Directive 2006/88/EC is implemented in a number of national regulations, inter alia, Regulation of 17 June 2008 No. 819 concerning the animal health conditions governing the placing on the market and the import of aquaculture animals and aquaculture products, Regulation of 17 June 2008 No. 820 relating to transport of aquaculture animals, Regulation of 17 June 2008 No. 821 relating to approval an use of disinfectants in aquaculture farms and transport units, Regulation of 17 June 2008 No. 822 relating to operation of aquaculture farms, Regulation of 17 June 2008 No. 823 relating to establishment and expansion of aquaculture farms, pet shops, etc.

Decision 2001/183/EC is implemented in a series of administrative procedures for surveillance programmes and chapters on VHS and IHN. Decision 2002/878/EC is implemented in a series of administrative procedures for surveillance programmes and chapters on *Bonamia ostreae* and *Marteilia refringens* and Decision 2003/466/EC is implemented in the contingency plan for control of ISA in Norway.

The mission team noted that the following requirements are laid down in the Norwegian legislation and implemented in Norway: weekly reporting of mortality from aquaculture

production businesses during an outbreak of ISA and synchronized fallowing period of two months after all fish in affected farms have been removed.

Conclusions

The national legislation in place fulfilled the relevant EEA requirements in the field of fish health. In some instances, Norway has laid down and implemented stricter requirements than in the EEA legislation regarding fish health.

5.2 Competent Authorities

5.2.1 Organisation and responsibilities

Legal requirements

Article 4(1) of Regulation (EC) No 882/2004.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, the Norwegian Act of 17 June 2005 No. 79 relating to aquaculture (the Aquaculture Act) lays down the requirements for establishing aquaculture farms in Norway. The application form is available on the Directorate of Fisheries website and must be submitted to the county in which the farm will be located. The county will distribute the application for further case handling by the sectoral competent authorities (*inter alia* the environmental competent authorities, the Directorate of Fisheries, the Norwegian Coastal Administration and the NFSA). The permit to establish an aquaculture farm will be issued by the county if the different sectoral competent authorities give favourable decisions and/or opinions. The register of aquaculture business operators in Norway is administered by the Directorate of Fisheries.

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, the NFSA is the competent authority carrying out official controls and monitoring related to fish health. The NFSA has three administrative levels. The head office is located in Oslo, Bergen, Sortland, Ås, Sandnes and Brumunddal. There are eight regional offices and 54 district offices. The NFSA has approximately 1,300 employees. All coastal district offices have inspectors trained for fish health inspections. All regional offices have qualified personnel dedicated to work with fish health.

The division of power between the different levels of the Authority is described in a letter of delegation (Regulation of 9 February 2005 No. 115), which was under revision at the time of the mission. According to the letter of delegation, the district offices of the NFSA have the competence to make decisions in the first instance within their districts. The regional offices have the authority to make decisions within their respective geographical areas, and will, *inter alia*, handle appeals to decisions adopted at district level. Furthermore, the letter of delegation outlines exemptions from the general rule, *e.g.* when a national contingency team is established at a regional office, the Head of Department for controls in the NFSA may give the office the competence to adopt decisions related to events outside its geographical area as well.

According to the version of the letter of delegation available at the time of the mission, the competence to give permission to use vaccines for fish diseases was given to two regional offices. However, according to additional information provided by representatives of NFSA during the opening meeting, following the outbreaks of ISA in Troms county in 2007, the permission to vaccinate had been given by the head office of the NFSA. According to the same information, it would be the head office of the NFSA that would give such permission also in the future.

The mission team was informed by representatives of the NFSA that, also the Directorate of Fisheries carries out inspection of fish farms in Norway. The scope of the inspections carried out by the Directorate of Fisheries covers issues such as the technical equipment, *e.g.* the equipment's ability to sustain the weather conditions on the location where it is situated in such a way that no farmed fish may escape.

Conclusions

During the meetings with the different levels of the competent authorities involved in the control of fish diseases, the mission team confirmed that responsibilities were well defined, as required by Art. 4.1 of Regulation (EC) No 882/2004.

5.2.2 Cooperation and coordination

Legal requirements

Article 4(3 and 5) of Regulation (EC) No 882/2004.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, the NFSA is cooperating with the Directorate of Fisheries by means of joint inspections and audit teams. These audits cover issues related to the internal control systems in place with regard to *e.g.* fish health and welfare and technical equipment and procedures in place to prevent fish from escaping.

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority , the NFSA fish health staff at regional level are assembled to regular telephone meetings, normally two to three times per year. The telephone meetings are conducted by the fish health personnel of the head office. In addition, at least annually, the personnel of the head office organise a two days assembly, for the regional staff, *Fiskehelseforum* (Fish Health Forum). Furthermore, corresponding assemblies are regularly arranged at regional level with the NFSA fish health inspectors from the district offices.

According to additional information provided by representatives of the NFSA during the opening meeting, a strategic forum (a formal meeting between the feed and aquaculture industry and the NFSA) takes place twice a year, in particular for the fish health area.

The mission team observed that joint inspections with the Directorate of Fisheries took place in a district office visited; it also observed the documented effective coordination and communication of information during the outbreaks of ISA from 2007 to date in two districts affected. The mission team was also informed by a NFSA regional officer that as a pilot project, "experience teams", comprising a mentor and trainees were established in one region, allowing newly recruited staff to join more experienced staff during inspections of farms and other premises as part of their training.

Conclusions

The mission team observed the effective communication and coordination between the competent authorities involved in the fish health control in compliance with Article 4(3 and 5) of Regulation (EC) No 882/2004.

5.2.3 Delegation of specific tasks related to official controls

Legal requirements

Article 5 of Regulation (EC) No 882/2004

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, fish health and food safety is under the full responsibility of the NFSA and no specific tasks have been delegated to other control bodies.

Conclusions

There are no control bodies in Norway within the meaning of Article 5 of Regulation (EC) No 882/2004

5.2.4 Staff performing official controls

Legal requirements

Article 6 of Regulation (EC) No 882/2004.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, a fish health training course for NFSA officials, both from regional and district offices, was arranged twice in 2008. The training courses were aimed at increasing the number of personnel qualified to work in the fish health field. The training courses covered, *inter alia*, the following topics: fish health regulations, administrative law, important fish diseases, diagnostic criteria, fish epidemiology, control of fish diseases, water quality and fish welfare.

All employees carrying out control duties related in the area of fish health at all levels in the NFSA, are either qualified veterinarians or fish health biologists. In addition, the NFSA has lawyers employed specifically in this sector.

The fish health training programme for NFSA officials planned for 2010 includes one course covering fish health and welfare and production of food from fish farmed in inland waters, the establishment of experience teams in other regions based on the feed back from the pilot run in the region of Trøndelag, Møre and Romsdal in 2009, and a course on fish health and fish welfare (5 days course in cooperation with the NVI).

Conclusions

Staff met by the mission team were suitably qualified, trained and experienced to carry out official controls related to fish diseases in line with the requirements of Article 6 of Regulation (EC) No 882/2004.

5.2.5 Internal audits

Legal requirements

Article 4(6) of Regulation (EC) No 882/2004.

Findings

The NFSA head office and a regional officer explained to the mission team that a system for internal audits had been established and audits are carried out each year on specific topics of the organisation as a whole. Central audit teams are appointed by the head office

of the NFSA. The audit teams are comprised by NFSA staff of different professional background and from different parts of the organisation according to the scope of the audits to be carried out. In 2009 the "Case handling" was the topic taken into consideration. Reports of the audits carried out are published on the website of the NFSA. The NFSA representatives of one district office informed the mission team that no written feed back summarising findings and conclusions valid specifically for that unit had been received. In another district visited audits have been carried out by the central audit team, in addition this district office had been audited by the regional office and the report from the last was available.

At the time of the mission, no specific internal audits related to fish health had been organised at different levels of the NFSA.

Conclusions

The NFSA carried out some internal audits in conformity with the requirements of Article 4(6) of Regulation (EC) No 882/2004. However, no specific internal audits related to fish health had been organised at different levels of the NFSA

5.3 Points related to Chapter II of Directive 2006/88/EC, Aquaculture production businesses and authorised processing establishments

Legal requirements

From Article 4 to Article 10 of Directive 2006/88/EC (including Annexes II and III) concerning authorisation and relevant requirements of aquaculture production businesses and processing establishments slaughtering aquaculture animals for disease control purposes.

Article 31 of Regulation (EC) No 882/2004 and Article 4 of Regulation (EC) No 854/2004 concerning approval of food business establishments.

Article 8(1) of Directive 90/167/EEC requires that, medicated feedingstuffs are supplied to stock farmers or holders of animals only on presentation of a prescription from a registered veterinarian.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, for a licence to be granted, the aquaculture production businesses must not pose an unacceptable risk for infection being spread, including the risk of infection entering the aquaculture production businesses and their surrounding environment. The same principle applies to processing establishments slaughtering aquaculture animals for disease control purposes. Guidelines regarding fish processing establishments including authorisation of those slaughtering aquaculture animals for disease control purposes have been established by the NFSA.

The district offices have the power to issue and withdraw the authorisation of the aquaculture production businesses and the approval of processing establishments slaughtering aquaculture animals.

According to additional information provided by representatives of the NFSA during the mission, the effluent water treatment system and/or method used in processing establishments slaughtering farmed fish should be approved by the NVI in order for the establishment to get an approval from the NFSA. In its reply to the pre-mission questionnaire of the Authority, the NFSA stated that in Norway the processing establishments slaughtering aquaculture animals are in principle authorised for disease

control harvesting purposes. Additional *ad hoc* requirements might be required in some cases (*e.g*. disinfection of transport water and prohibition of intermediate storage of fish in slaughter cages by the processing establishments slaughtering aquaculture animals). However, a list of authorised processing establishments slaughtering aquaculture animals for disease control purposes was not available; furthermore, a representative of a district office of the NFSA informed the mission team that one of the two slaughterhouses in the district was authorised for slaughtering of diseased fish. The other slaughterhouse was not authorised for sanitary slaughter because it did not have a proper system for treatment of the transport water.

In a processing establishment authorised for slaughtering aquaculture animals for disease control purposes visited by the mission team, the method for the effluent water treatment was approved by the NVI in May 1999. The approval was issued to the company that developed the method and installed the equipment. A specific approval of the system of treatment of water/effluents for this slaughterhouse was not available.

The mission team visited a processing establishment that was involved in the slaughtering of fish from the control zone for VHS; the last slaughtering activities took place on 30 March 2010 and the next was planned for 19 July 2010. The establishment had been approved by the former competent authority (Directorate of Fisheries) for the following production codes (as reported in the list of production codes of approved establishments available at the NFSA website):

- April 2001; temporarily approved for code 26 (handling of farmed fish) until March 2006. Approved for slaughtering of farmed fish.
- April 2001; approved for code 01 (packing of fresh fish) and 03 (freezing), no time limit
- November 2003; approved for code 02 (filleting) and code 60 (fish oil), no time limit.

Several inspection reports on official controls carried out by the NFSA were available, however no audits had been carried out by the NFSA in this establishment. Furthermore, at the time of the mission, the NFSA had not issued an authorisation allowing this establishment to slaughter aquaculture animals for disease control purposes (nor extended or renewed the approval for processing fishery products issued by the previous competent authority expired in March 2006).

This establishment had to deal with the emergency slaughtering following outbreaks of VHS[1] in the region during 2008. However, the authorisation of the system for treatment of water/effluents from the slaughterhouse, issued by the NVI, expired in 2006. The establishment was inspected by the NFSA prior to the emergency slaughtering and additional requirements were laid down; following this, the system for effluent water treatment in the establishment was inspected by the NVI in January 2008. The inspection report from the NVI described problems with the automatic registration, pre-filtering and the mixers. The establishment got a derogation from the NFSA for the automatic registration and established an additional water treatment system for the transport water of the well boat prior to slaughtering of the diseased fish. The mission team found that the automatic registration was in place at the time of the visit.

The mission team visited another establishment slaughtering and processing farmed Atlantic salmon and found several inconsistencies in the approval process (see details at section 5.10 of this report).

[1] *The Norwegian Food Safety Authority stated in its reply to the draft report that "there were outbreaks of VHS (not IHN) during 2007 and 2008 in the eastern part of Storfjorden. IHN has never been detected in Norway".*

In relation to the register of aquaculture production businesses and authorised processing establishments and according to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority and to additional information provided by representatives of the NFSA during the opening meeting, the updated national register for authorised aquaculture production business is available on the website of the Directorate of Fisheries and the one for authorised processing establishments is available on the website of the NFSA. However, the mission team noted that not all the required information related to the aquaculture business operators and to the processing establishments were available in the registers. In particular the following were missing: contact details, dates for specific authorisation, identification codes or numbers, capacity (not understandable whether the figure available is specifying the total capacity or the capacity for each category of fish), register of susceptible species and updated information on the health status.

In the legend list available at the NFSA website, code 26 is used for establishments "handling farmed fish". The mission team noted that this code was used for all establishments processing aquaculture animals, without specifying which establishments were slaughtering and processing and which were only processing.

The mission team noted that the authorisation of aquaculture business operators was given according to the purpose of the business, *e.g.* commercial, research or slaughter cage. According to additional information provided by representatives of the NFSA in the opening meeting, authorisation for slaughter cages was given to business operators with a processing establishment for slaughtering farmed fish. The mission team noted that, not all aquaculture business operators with authorisation for slaughter cage listed by the Directorate of Fisheries appeared in the list of establishments approved by the NFSA for code 26.

In relation to official controls and according to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, the official controls carried out by the NFSA on fish health are risk based and establishments with higher probability for spreading disease (*e.g*. hatcheries) are inspected more frequently than others according to the procedures laid out in the surveillance programmes[2].

The NFSA also cooperate with private fish health services in control and monitoring of fish diseases at the fish farm level. Fish farms have since the late 1980's been obliged to have a private risk based surveillance programme, carried out by fish health services/companies. The aquaculture business operators either employ fish health professionals directly or have a contract with a private company that provides fish health services to the aquaculture business. The individuals have license to work in the field of fish health as authorised veterinarians or authorised fish health biologists. The mission team was informed by representatives of the NFSA head office that fish health biologists are authorised in Norway to prescribe medicated feedingstuffs to aquaculture animals.

The private fish health services can collect and send samples related to fish health control to laboratories but, in case of any sample positive for a listed disease, samples will be collected and sent for confirmation by the NFSA.

The mission team met skilled and motivated fish health professionals working in private fish health services.

[2] Surveillance programs related to fish health in 2010 included: *Gyrodactylus salaries;* salmon lice in the national salmon fjords and salmon rivers; Brood stock programme (tested for ISA and PD), VHS/IHN programme, BKD programme, resistance of salmon lice, crayfish plague, and *Bonamia spp*. and *Marteilia spp* programme. See also Point 5.7.

The official surveillance programmes also have a priority to the more susceptible species (*e.g.* priority of rainbow trout in the VHS/IHN programme). The mission team observed that in the VHS/IHN programme, facilities keeping brood stock are inspected at least two times per year. According to the general contingency plan for fish diseases and the ISA control plan, farms within a control zone and aquaculture production businesses and processing establishments receiving fish infected with listed diseases shall be more frequently inspected and sampled. The mission team observed that farms with ISA confirmed diagnosis are inspected by the NFSA minimum once per month until all fish is slaughtered. Farms within the control zone are inspected, by the NFSA or the fish health service, at least 12 times in total the first year and 6 times in total the second year following an outbreak of ISA.

In relation to recording obligations and traceability the mission team found consistent documentation available on the spot apart from one farm where the mission team noted that not all movements of fish were registered from November 2009 to April 2010. Mortality records at farm level and during transport was available apart in a well boat where the journal log did not include this; the operator informed the mission team that data were available at the office, as the mortality was registered upon arrival in the processing establishment and not by the well boat.

In relation to good hygiene practice, the mission team found that good hygiene practices were in place in all aquaculture farms visited. In one processing establishment the tank storing ensilaged animal by-products not intended for human consumption (fish slaughter waste) was not fully tight.

In relation to animal health surveillance scheme, the national Regulation of 17 June 2008 No. 822, stipulates that a risk based fish health check shall be performed without unnecessary delay when increased mortality occurs, and that the NFSA shall be notified if the increased mortality is due to a listed disease or if the reason for the increased mortality is not clarified. The tasks of the fish health services including examinations and sampling are laid down in this regulation. It is also mandatory to have more frequent fish health checks in hatcheries and smolt producing farms than in grow-out farms. The mandatory fish health inspection rate is also related to the extent of production.

The mission team observed that the inspection frequency by fish health services was at minimum four times per year in grow-out farms with more than 3000 and less than 50,000 fish. Grow-out farms with more than 50,000 fish, should have at least 6 routine health checks per year, with a maximum of 3 months between each health check.

Conclusions

Some establishments, slaughtering fish originating from control zones or processing fishery products did not have proper and updated authorisation issued by the NFSA as required by Article 4 and 5 of Council Directive 2006/88/EC.

The approval process of establishments processing fishery products was found inconsistent with the requirements laid down in Article 31 of Regulation (EC) No 882/2004 and Article 4 of Regulation (EC) No 854/2004.

The national registers for authorised aquaculture production business and of authorised processing establishments were available. However, not all information required as laid down in Article 6 of Directive 2006/88/EC and Part I and Part II of Annex II to the Directive was included. A list of authorised processing establishments slaughtering aquaculture animals for disease control purposes was not available. The frequency of routine inspections for official controls and for animal health surveillance scheme was higher than requested by the EEA legislation. Recording obligations, traceability and good

hygiene practices were found satisfactory in the establishments visited, apart from minor exceptions.

The system in place with private fish health services (veterinarians or fish health biologists) was positively evaluated by the mission team. However, compliance with Article 8(1) of Directive 90/167/EEC on medicated feed can not be ensured since in Norway not only registered veterinarians are permitted to prescribe medicated feedingstuffs to aquaculture animals but also fish health biologists.

5.4 Points related to Chapter III of Directive 2006/88/EC, Animal health requirements for placing on the market of aquaculture animals and products thereof

Legal requirements

From Article 11 to Article 21 of Directive 2006/88/EC.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, in order to be authorised as means of transport used for transporting aquaculture animals, the vessels must comply with the national Regulation of 17 June 2008 No. 820 containing requirements related to fish health and fish welfare during transport. The district office has the competence to authorise and withdraw authorisation of the means of transport. In general, the authorisations are valid for five years. The NFSA has made the list of authorised means of transport available on its website.

The mission team observed that movements into free zones and movements between infected and non-infected farms are regulated by procedures to reduce the probability for spreading disease. *E.g.* according to the contingency plan for control of ISA in Norway, the transport route shall be authorised by the NFSA when transporting fish from farms with confirmed ISA.

The mission team found that the NFSA and the operators pay special attention to the epidemiological status of the areas sailed through when transporting fish on well boats. The mission team visited one well boat with a sufficient well capacity to run with closed valves for a prolonged period of time, minimising the exchange of water from the vessel and the surrounding waters. This procedure is used *e.g.* when transporting diseased fish through a disease free zone. Transport routes of live fish have to be authorised by the NFSA. Strict rules applied for the disinfection of ballast- and transport water, and the operators illustrated the procedures to the mission team.

The mission team observed that fish could be pumped directly from the well boat to the slaughterhouse in order to avoid keeping diseased fish in slaughtering cages and thereby reducing the probability of spreading disease.

In relation to animal health certification, the NFSA head office explained to the mission team that trade within the EEA is registered in the common European database TRACES. If trade with live animals and certain animal products is to take place, the first part of the health certificate can be filled in by the operator in TRACES and then sent electronically to the relevant district office of the NFSA for approval. The mission team checked health certificates in a hatchery, for incoming eggs and smolt, and for delivery of eggs from a brood stock farm, and found them consistent with the EEA requirements.

Conclusions

The system in place and verified by the mission team contained adequate provisions to fulfil the animal health requirements for placing on the market of aquaculture animals and products thereof as laid down by Chapter III of Directive 2006/88/EC.

5.5 Points related to Chapter IV of Directive 2006/88/EC, Introduction of aquaculture animals and products thereof into the Community from third countries

Legal requirements

From Article 22 to Article 25 of Directive 2006/88/EC.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, imports are allowed only from EEA approved third countries and a health certificate should accompany such imports.

According to additional information provided by representatives of the NFSA during the opening meeting, Regulation (EC) No 1251/2008 of 12 December 2008 implementing 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, not yet implemented in the EEA agreement, is already incorporated into national legislation to ensure that all requirements are fulfilled.

Conclusions

The system in place and verified by the mission team contained adequate provisions to fulfil the requirements for introduction of aquaculture animals and products thereof from third countries as laid down in Chapter IV of Directive 2006/88/EC.

5.6 Points related to Chapter V of Directive 2006/88/EC, Notification and minimum measures for control of diseases of aquatic animals

Legal requirements

From Article 26 to Article 43 of Directive 2006/88/EC.

Articles 5, 6 and 7 of Regulation (EC) No 1774/2002.

Findings

The mission team verified that requirements related to disease notification are fulfilled, and that in case of suspicion of a listed disease, control measures have been regularly applied and epizootic investigations carried out. In particular, the mission team was informed in details of the actions taken at district level when outbreaks of VHS and ISA occurred. All aquaculture farms and processing establishments visited had a system in place to ensile separately category 2 and 3 material of fish origin. The farms visited handled all animal by-products as category 2 material (*e.g.* dead fish collected from the cages). The establishments visited distinguished between, and handled separately, category 2 (*e.g.* slaughter waste from diseased fish) and category 3 material (slaughter waste from clinically healthy fish). The material was grinded, acid added, and stored in tanks at pH 4 or less.

An establishment receiving and processing only animal by-products of aquaculture origin was visited by the mission team. The mission team noted that the company had a good

management system in place and that the NFSA had issued several consistent reports. The traceability for the animal by-products was ensured by the use of commercial documents, of which the mission team found copies both at farm level and at the processing establishment.

Representatives of the NFSA informed the mission team that no fish disease in Norway is considered to be an emerging disease. A list of criteria to be met in order to be classified as an emerging disease had not been established, *e.g.* a set level of mortality caused by a not previously listed aetiological agent. Representatives of the head office of the NFSA informed the mission team that the World Organisation for Animal Health (OIE) criteria will be followed in relation to classification of a disease as an emerging disease and that a mortality rate of 20% might be considered appropriate in order to evaluate the status of a new disease as being an emerging disease. According to the annual fish health reports from the NVI, increased mortality, close to 20 %, in addition to reduced growth, was observed in some farms in the fall of 2008 and 2009. No cause for this increased mortality had been identified. It was at the time of the mission called the "fall disease" ascribed to an unknown aetiological agent. The NFSA had not classified or evaluated the disease with regard to whether it should be notified as an emerging disease.

Conclusions

All relevant requirements concerning the notification and minimum measures for control of diseases of aquatic animals as laid down in Chapter V of Directive 2006/88/EC were applied promptly and effectively.

Dead fish were removed and disposed from aquaculture farms in accordance with Article 34 of Directive 2006/88/EC and Regulation (EC) No 1774/2002.

The NFSA head office did not consider a disease reaching 20% of mortality as an emerging disease.

5.7 Points related to Chapter VI of Directive 2006/88/EC, Control programmes and vaccination

Legal requirements

From Article 43 to Article 48 of Directive 2006/88/EC.

Findings

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, the NFSA runs several annual official surveillance and eradication programmes in the context of aquatic animal health and particularly on VHS, IHN, bonamiosis and marteiliosis, bacterial kidney disease (BKD), *Gyrodactylus salaris* and salmon louse (surveillance only). The purpose of the majority of the programmes is twofold, combining prevention of introduction of diseases to new sites from infected premises, and the documentation of disease-free status to benefit for the export of aquaculture products. Annual reports on the individual programmes were issued and were made available to the mission team.

The surveillance programme for 2010 was provided to the mission team by representatives of the head office of the NFSA. The programme contained instructions on the surveillance to be carried out during the year for:

- *Gyrodactylus salaries*
- salmon lice in the national salmon fjords and salmon rivers
- tests of brood stock for ISA and PD

- VHS/IHN
- BKD
- resistance of salmon lice
- crayfish plague
- *Bonamia spp*. and *Marteilia spp*.

With regard to VHS/IHN, two programmes are established in Norway for 2010: one at national level and one in the area of Storfjord, where the VHS outbreaks occurred in 2008. The programmes specify that for 2010 no farms with brood stock should be sampled and that for VHS the active surveillance and sampling in Storfjord should be carried out for a period of minimum two years.

In relation to the *Bonamia ostreae* outbreak in 2008, the representatives of the NFSA provided in the opening meeting the mission team with a copy of a letter addressed to the Authority confirming that the NFSA will not withdraw the restrictions implemented in the area. The NFSA head office informed the mission team that they were considering to reduce the control zone.

The NFSA head office also explained to the mission team that surveillance in the whole country would be more risk based in the future. Risk categorisation was at the time of the mission according to the type of farm (*e.g*. hatcheries and brood stock farms have a higher risk than grow-out farms). According to additional information provided by the NFSA in the opening meeting, the plan was to categorise each farm location with regard to the risk of spreading disease.

The mission team was informed by a district officer of the NFSA that following several cases of ISA, vaccination against the disease is carried out, on a voluntary basis, with an approved vaccine in the control and surveillance zones established in his district.

In relation to exotic and emerging diseases the contingency plan had at the time of the mission not yet been finalised. The mission team observed that a draft contingency plan for exotic and emerging diseases was at the time of the mission under internal evaluation in the NFSA. The mission team noted that the draft contingency plan did not comprise up-to-date operations manuals and real-time alert exercises.

The mission team noted furthermore, that no training on exotic diseases had been organised by the NFSA.

Conclusions

Surveillance and eradication programmes have been established by the NFSA, covering the whole of Norway.

The contingency plan for emerging and exotic diseases, as requested in Article 47 of Directive 2006/88/EC, was not yet finalised. The draft plan did not include up-to-date operations manuals and organisation of real-time alert exercise, as requested by points 7 and 9 of Annex VII to Directive 2006/88/EC.

5.8 Points related to Chapter VII of Directive 2006/88/EC, Disease free status

Legal requirements

From Article 49 to Article 53 of Directive 2006/88/EC.

Article 52 of Directive 2006/88/EC states that, "*A Member State that is declared free from one or more non-exotic diseases listed in Part II of Annex IV in accordance with Article 49 may discontinue targeted surveillance and maintain its disease-free status.…*"

The EFTA Surveillance Authority Decision 02/10/COL of 5 January 2010 repealing Decision No 302/08/COL of 21 May 2008 recognising Norway, with the exemption of the areas referred to in the Annex, as approved continental zone and as approved coastal zone for fish with regard to IHN and VHS. The Decision makes reference to Article 50 of Directive 2006/88/EC related to disease free zones (and not a State as for in Article 49 of the Directive.

Findings

According to representatives of the NFSA, it was of the NFSA's opinion that, Norway is not obliged to carry out targeted surveillance for VHS and IHN in disease free zones. Due to the outbreaks of VHS in 2007 and 2008, the surveillance of VHS is ongoing, and the surveillance programme for VHS/IHN covered only farms rearing rainbow trout.

The surveillance programme for VHS was carried out in conformity with the requirements for maintaining disease-free status in the coastal zone of Norway with the exception of a buffer zone to Russia (no active surveillance) and in the control zone established following outbreaks of VHS in 2007 and 2008 (active surveillance in order to regain the disease-free status).

The mission team noted that the established surveillance programme for IHN did not cover all the susceptible species since salmon farms was not included in the program in 2009 and 2010. Salmon farms were last included in the surveillance programme in 2008 when 444 (approximately 50 % of registered farms in Norway) farms were inspected and sampled. Following the decision to include only farms rearing trout, the number of inspected and sampled farms was reduced to 51 in 2009. The number of farms inspected and sampled during 2010 was expected to be at the same level as for 2009.

In relation to ISA, 17 compartments/zones are officially declared free by the NFSA and the list is publicly available on its website. The surveillance in these compartments/zones, as observed by the mission team, was carried out with higher frequency than in areas of different status, both by the NFSA and the fish health inspectors.

Conclusions

The procedures applied in Norway for VHS were in conformity with Decision 2001/183/EC and with the Authority Decision 02/10/COL of 5 January 2010. However for IHN, the NFSA decision to discontinue targeted surveillance is not in conformity with Article 52 of Directive 2006/88/EC. Furthermore, the fact that Atlantic salmon is not amongst species to be sampled in order to maintain approved free status for IHN is not consistent with the requirements in Part I, 1 of the Annex to Decision 2001/183/EC.

5.9 Points related to Chapter VIII of Directive 2006/88/EC, laboratories

Legal requirements

Article 4(2c), Article 12 and Article 33 of Regulation (EC) No 882/2004; Articles 56 and 57 and Part II and III of Annex VI of Directive 2006/88/EC.

Findings

The mission team visited the main laboratory in Oslo and two regional laboratories of the NVI. The NVI is designated by the NFSA to carry out analysis of official samples. Two private laboratories were also visited by the mission team. All the NVI laboratories were accredited in accordance with the National Accreditation System of Norway, in compliance with the standard ISO/IEC 17025.

According to information provided by the NFSA in its reply to the pre-mission questionnaire of the Authority, an agreement has been signed between the NFSA and the NVI in order to provide diagnostic services. However, the mission team observed that the agreement with the NVI had not been updated since established in 2006 and that the annex to it referred to, *inter alia,* the repealed Directive 93/53/EEC.

The NVI is owned by the Ministry of Agriculture and Food, and the main supporting funds originate from that Ministry and the Ministry of Fisheries and Coastal affairs. Private funding is very limited, in order to keep the independence. However, a head of department of the NVI informed the mission team that some tasks and diagnostic work ordered by the private sector is needed in order to know the trends in the field. Main activities related to diseases of list 1 and 2 were carried out in Oslo, except for molluscs diseases.

The NVI in Oslo was designated as the National Reference Laboratory (NRL) for fish diseases and as the OIE reference laboratory for ISA and for infection with *Gyrodactilus salaris.* Virus isolation and Polymerase Chain Reaction (PCR) to detect ISA virus (ISAV) are both in process to be accredited. Samples are mainly sent to the NVI by personnel of the NFSA and sometimes by the fish health services, through the regional laboratories. Samples arriving at the NVI in Oslo are mainly tissues in transport medium or fixed tissues for PCR or histology and immunohistochemistry (IHC).

The mission team noted that the section for fish diseases of the NVI had participated in the proficiency test organised every year by the Community Reference Laboratory with good results.

In the last years many resources had been used on developing an IHC test for detection of ISAV antigens in tissues of affected fish. The method, validated in Oslo, was distributed to all the regional laboratories. No proficiency test of this method had at the time of the mission been organised. According to representatives of the NVI a new procedure would be adopted very soon, introducing a more specific, purified antibody to avoid risk of false positives due to the presence of *Vibrio spp*. and *Parvicapsula spp*. infections[3].

The mission team visited the cell culture laboratory of the NVI. The laboratory was equipped for the purpose and bio-safety measures were applied for entrance. An updated register, including information, like origin, date of replication, medium used, split ratio, number and type of plates/flasks produced etc was available.

The procedures adopted to detect ISAV, IHN virus (IHNV) and VHS virus (VHSV) on cell cultures relied on approved methods, including the neutralization of the infectious pancreatic necrosis virus (IPNV) immediately after tissue homogenization.

The sensitivity of the cell cultures was tested regularly every 6 months. The mission team observed that, particularly for VHS-IHN samples, no temperature control was performed at the arrival of the samples in the laboratory[4].

In one of the regional laboratories of the NVI visited, the mission team noted that the laboratory was accredited according to ISO/IEC 17025 for histopathology of *Bonamia spp.* and *Marteilia spp*. and it was appointed by the NFSA as NRL for the two above mentioned diseases. Other methods applied in this laboratory were not accredited. However, a quality control system was implemented. The laboratory received samples

[3] *The Norwegian Food Safety Authority stated in its reply to the draft report that "the NVI has mentioned that this method is in process to be accredited".*

[4] *The Norwegian Food Safety Authority stated in its reply to the draft report that "the NVI has mentioned that temperature was controlled at opening of sendings by checking if the cooler brick was still partly frozen, but not with a thermometer".*

with suspicion of ISA, PD and other diseases; these samples were formalin fixed tissues and examined with histopathology method here but forwarded to the main laboratory in Oslo for PCR and virus isolation. IHC was performed for ISA and IPN and had been validated by the NVI in Oslo.

The mission team visited the histopathology section and noted that out of twelve staining procedures available to the laboratory staff and hung up on the wall, only one corresponded exactly (photocopy) to the one detailed in the standard operating procedures manual of the laboratory. All the other procedures available to the staff (including those accredited for molluscs) were presented in basic sheets often amended without any official reference and with hand written instructions (*e.g.* significant changes in the staining time). Furthermore, the general procedure on how to deal with samples (paraffin embedding, tissue section, tissue staining and microscope observation), was not available on-the-spot.

In the other regional laboratory of the NVI visited, the mission team observed that 1000-1200 samples were received annually for diagnostic and surveillance purposes concerning the most important diseases: PD, ISA, IPN, *Moritella viscosa* infection, *Pseudomonas spp.* infection, etc. Particular attention was given during the last years to diagnosis of ISA by IHC. A protocol, originally validated from the NVI in Oslo, had been adopted since 2005 and was still in use but a new one was expected to be forwarded very soon and would be used in all the regional laboratories in order to harmonize the adoption of this technique.

The IHC procedure applied for the detection of ISA antigens had been checked in the laboratory; the method was clearly reported in the manual available in the laboratory, well detailed and exhaustive in all parts except the interpretation of the results which was not completely clear in order to avoid false positive results.

The mission team also visited a well organised and equipped private laboratory established in 2005. The mission team noted that a real time PCR screening was performed for: ISA, IPN, VHS and IHN. The ISA protocol was based on the OIE manual and the VHS based on other published protocols. The screening method was accredited by the Norwegian Accreditation Body one year ago according to ISO/IEC 17025.

In relation to ISAV the laboratory was working on the validation of a diagnostic method to differentiate between pathogenic and non-pathogenic strains of the ISAV; the method was, however, not accredited at the time of the mission. According to the timeframe set out by the laboratory, the accreditation of the method should be in place within a year. The differentiation of pathogenic and non-pathogenic strains was considered important with regard to the management of the status of ISA free compartments.

The NFSA had issued two import licenses to the laboratory to allow import of:
- a one time licence for VHS /IHN and different others reference samples (active viruses used in validation of the method. IHN from US, VHS from Denmark)
- a general commercial import licence - to import samples from abroad (EEA and third countries, especially Chile)

The NFSA district office had meetings with the person responsible for the laboratory prior to issuing the import licenses to discuss handling and storage of reference material and waste treatment. The mission team noted that a protocol for the above mentioned material had been signed with the NFSA district office which imposes the laboratory to keep records and notify the district office of what is received, what is used, when run out etc.

The mission team observed that a positive result of a sample was not recorded in the electronic file reporting all the results obtained in the laboratory. The manager informed that this was because she forgot to transfer the information from the hard copy paper to the electronic sheet.

Another private laboratory was visited by the mission team. Two years prior to the mission the laboratory started the reverse transcriptase (RT)-PCR which was the only method used in the laboratory for diagnosis of fish diseases. In particular, the following tests were available for salmonids: IPNV, ISAV, VHSV, BKD, salmonid alpha virus and *Flavobacterium.* For marine fish (Atlantic cod and halibut) the analysis were carried out to detect IPNV, nodavirus and *Francisella spp.*

The laboratory had been temporarily approved by the NFSA. The first temporary approval was valid from 30/9/2008 to 10/6/2009 and the last dated 30/11/2009 was valid until 30/6/2010. A standard operating procedures manual was available since March 2008. Validation of internal methods was ongoing and accreditation according to ISO/IEC 170251 was planned for June 2010.

The laboratory had, at the time of the mission, not received samples for diseases listed in Part II of Annex IV of Directive 2006/88/EC (including samples for ISA originating from officially free zones or compartments). Samples were only received from private customers. The mission team was informed that the laboratory had not participated in any comparative tests at the time of the mission.

The person responsible for the laboratory informed the mission team that no studies on relative sensitivity had been carried out compared to using virus isolation on cell culture. In order to define the sensitivity of the applied method, positive samples had been diluted and tested to a certain value considered enough to detect carrier fish.

Conclusions

The NFSA has designated NRLs and laboratories to support the official control in the fish health sector in accordance with Article 4(2)(c), Article 12 and Article 33 of Regulation (EC) No 882/2004 and Article 56 and 57 of Directive 2006/88/EC. Not all methods used for diagnostic purposes of diseases listed in Part II of Annex IV of Directive 2006/88/EC had been accredited. Furthermore, not all laboratories visited had participated in comparative tests organised by the NRL in line with the requirements laid down in Annex VI of Directive 2006/88/EC.

In relation to the laboratories visited a general positive conclusion can be drawn on the competences of the personnel dealing with fish diseases. The mission team identified some inconsistencies, particularly in the histopathology section of one of the regional laboratories of the NVI on written procedures and in one private laboratory on studies of relative sensitivity.

5.10 Miscellaneous related to food hygiene

Legal requirements

Article 31 (2) of Regulation (EC) No 882/2004; Articles 3 and 4 of Regulation (EC) No 854/2004; Article 4 of Regulation (EC) No 853/2004,; Chapter VII of Annex II of Regulation (EC) No 882/2004; Articles 4, 6 and 7 of Directive 98/83/EC.

Findings

The mission team visited an establishment slaughtering and processing farmed Atlantic salmon (already mentioned at point 5.3). This establishment had an initial approval issued by the Directorate of Fisheries in March 2003. The mission team noted that, the operator had applied for approval by the NFSA for code 01 (packing of fishery products) in November 2007. The application template used by the operator did not include code 26

(handling of farmed fish). The mission team also noted that no evidence of follow-up by the NFSA to this application was available at the establishment.

In October 2008, a completely new establishment, located nearby the previously authorised and in the meantime dismantled establishment, started its activity without any formal approval issued by the NFSA. This new establishment was allowed to use the same approval number as the dismantled establishment without having received any formal inspection confirming that, the establishment fulfilled the requirements laid down in the relevant legislation in relation to the different activities for processing fishery products.

The NFSA had issued at least two declarations to whom it may concern (5 February 2009 and 21 April 2010) certifying the approval of this new establishment. In the declaration of April 2010, production codes 1 and 26 were mentioned specifically. Two reports from inspections carried out in January and April 2010 were available.

In relation to potable water, the mission team was informed that the establishment received untreated water from a dam (surface water) belonging to a private entrepreneur. The water was treated by ultra violet light at the establishment. However, the operator confirmed to the mission team that this aspect was not yet duly considered in their HACCP plan and that they were still working on its correct implementation. Furthermore, the few parameters analysed by the operator included only bacterial parameters, however, not *Clostridium perfringens.* No chemical parameters had been analysed since the new establishment started its activity in October 2008.

The mission team noted that the only critical control point identified in the HACCP manual was the reception of live fish where a declaration from the farmer of origin was requested stating that the fish had not been treated with veterinary medicinal products in the last twelve months. However, the mission team verified that a prescription for *Deltamethrine* was issued in September 2009 for a site from where live fish had been delivered in February 2010 to this establishment. The accompanying form clearly stated that the fish had not received any drug treatment the last 12 months. The farmer, contacted on the spot by the operator, had not considered *Deltamethrine* as being a medication.

Conclusions

Severe inconsistencies in the implementation of the requirements listed in Article 31 (2) of Regulation (EC) No 882/2004; Articles 3 and 4 of Regulation (EC) No 854/2004; Article 4 of Regulation (EC) No 853/2004,; Chapter VII of Annex II of Regulation (EC) No 852/2004; Articles 4, 6 and 7 of Directive 98/83/EC were observed by the mission team in the establishment visited.

6 Overall conclusion

The mission team found that the situation was, from a general point of view, satisfactory concerning the official controls carried out by the Norwegian Food Safety Authority. The epidemiological situation concerning fish diseases listed in Directive 2006/88/EC is in principle under control despite the recent outbreaks of infectious salmon anaemia. Relevant activities were mainly in conformity with the EEA requirements laid down in Directive 2006/88/EC and related legislation. However, the targeted surveillance for infectious haematopoietic necrosis had been discontinued.

The official and the private laboratories dealing with fish health diagnosis were well organised with only minor discrepancies observed.

Some inconsistencies were observed in the authorisation of processing establishments slaughtering aquaculture animals for disease control purposes and some information was

missing in the registers of authorised aquaculture production businesses and processing establishments. In Norway fish health biologists (and not only registered veterinarians) are allowed to prescribe medicated feedingstuffs to aquaculture animals.

Based on shortcomings identified in the system in place for the approval of establishments processing fishery products and deficiencies observed on the spot by the mission team particularly in one establishment visited, the mission team cannot exclude that fishery products which were not in conformity with the EEA Agreement requirements were being placed on the market of the EEA.

7 Final meeting

A final meeting was held on 7 May 2010 at the NFSA's head office in Oslo with representatives from the Ministry of Fisheries and Coastal Affairs and the NFSA. At this meeting, the mission team presented its main findings and some 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 and recommendations could be included in the report.

The representatives of the NFSA and the Ministry did not have any objections to the observations made and the preliminary conclusions presented.

The Head of Department for controls of the NFSA informed the mission team of actions already taken related to the serious shortcomings identified in one establishment slaughtering farmed salmon were confirmed to the mission team. Actions already taken were in particular related to the creation of an emergency inspection team and the collection of water samples.

8 Recommendations

The Norwegian Food Safety Authority should inform the Authority in its reply to the draft 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. This information will be annexed to the final report. The Authority should also be kept informed of the completion of the measures included in the timetable.

No	Recommendation
1	The competent authority should ensure that only registered veterinarians should be allowed to prescribe medicated feedingstuffs as required by Article 8(1) of Directive 90/167.
2	The competent authority should ensure that processing establishments, slaughtering aquaculture animals for disease control purposes are authorised in accordance with the requirements laid down in Article 4 and 5 of Directive 2006/88/EC.
3	The national registers for authorised aquaculture production business and of authorised processing establishments should include all relevant information as set out in Article 6 and Annex II to Council Directive 2006/88/EC.
4	The competent authority should draw up a contingency plan for emerging and exotic diseases in conformity with the requirements laid down in Article 47 of Directive

	2006/88/EC.
5	In order to maintain disease-free status for infectious haematopoietic necrosis, the competent authority should ensure that sampling is carried out in conformity with the requirements laid down in Article 52 of Directive 2006/88/EC and the Annex to Decision 2001/183/EC.
6	On the basis of Article 31(2)(c) of Regulation (EC) No 882/2004, the competent authority should ensure that only food business establishments in compliance with the EEA legislation are approved.
7	In order to comply with the requirements of Articles 3 and 4 of Regulation (EC) No 854/2004; Article 4 of Regulation (EC) No 853/2004,; Chapter VII of Annex II of Regulation (EC) No 852/2004; Articles 4, 6 and 7 of Council Directive 98/83/EC, the competent authority should ensure that the deficiencies observed by the mission team are corrected in the establishments visited and are not present in other approved establishments.
8	The competent authority should ensure that the NRL organises, and that, the official laboratories analysing official samples participate in comparative tests to ensure confidence and reliability of the laboratory performance in line with the requirements laid down in Article 12 of Regulation (EC) No 882/2004, and in Articles 56 and 57 and Annex VI of Directive 2006/88/EC.

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

Authority	EFTA Surveillance Authority
BKD(V)	Bacterial kidney disease (Virus)
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
HACCP	Hazard Analysis and Critical Control Point
IHN(V)	Infectious haematopoietic necrosis (Virus)
IPN(V)	Infectious pancreatic necrosis (Virus)
ISA(V)	Infectious salmon anaemia (Virus)
NFSA	Norwegian Food Safety Authority
NRL	National Reference Laboratory
NVI	National Veterinary Institute of Norway
OIE	World Organisation for Animal Health
PD	Pancreas disease
RT-PCR	reverse transcriptase Polymerase Chain Reaction
TRACES	Trade Control and Expert System
VHS(V)	Viral haemorrhagic septicaemia (Virus)

Annex 2 - Relevant legislation

The following legislation has also to be taken into account in the context of this mission:

a) The Act referred to at Point 4.1.5a of Chapter I 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 corrected.

b) The Act referred to at point 1.1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market*, as amended and as adapted.

c) The Act refereed to at point 7.1.10 of Chapter I of Annex I to the EEA Agreement, *Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community*.

d) The Act referred to at Point 1.1.2 of Chapter I of Annex I to the EEA Agreement, *Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market*, as amended and as adapted.

e) The Act referred to at Point 4.2.51 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 1999/567/EC of 27 July 1999 laying down the model of the certificate referred to in Article 16(1) of Council Directive 91/67/EEC*.

f) The Act referred to at Point 4.2.63 of Chapter I 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*.

g) The Act referred to at Point 4.2.65 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/300/EC of 18 April 2002 establishing the list of approved zones with regard to Bonamia ostreae and/or Marteilia refringens*, as amended.

h) The Act referred to at Point 4.2.66 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/308/EC of 22 April 2002 establishing lists of approved zones and approved farms with regard to one or more of the fish diseases viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN)*, as amended.

i) The Act referred to at Point 4.2.68 of Chapter I 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).*

j) The Act referred to at Point 4.2.72 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2003/390/EC of 23 May 2003 establishing special conditions for placing on the market of aquaculture animals species considered not susceptible to certain diseases and the products thereof.*

k) The Act referred to at Point 4.2.73 of Chapter I 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)*.

l) The Act referred to at Point 4.2.79 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2004/453/EC of 29 April 2004 implementing Council Directive 91/67/EEC as regards measures against certain fish diseases in aquaculture animals*, as corrected and amended.

m) The Act referred to at Point 6.1.8 of Chapter I of Annex I to the EEA Agreement, *Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products*, as amended.

n) The Act referred to at Point 7.1.9b of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption*, as corrected and amended.

o) *Commission Decision 2003/804/EC of 14 November 2003 laying down the animal health conditions and certification requirements for imports of molluscs, their eggs and gametes for further growth, fattening, relaying or human consumption*, as amended and 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..

p) *Commission Decision 2003/858/EC of 21 November 2003 laying down the animal health conditions and certification requirements for import of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption*, as amended and 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.

q) *Commission Decision 2006/656/EC of 20 September 2006 laying down the animal health conditions and certification requirements for imports of fish for ornamental purpose*, 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.

r) *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.

s) *Commission Regulation (EC) No 1252/2008 of 12 December 2008 derogating from Regulation (EC) No 1251/2008 and suspending imports into the Community from Malaysia of consignments of certain aquaculture animals*, 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.

t) The *EFTA Surveillance Authority Decision No 394/06/COL of 13 December 2006 approving the up-dated scheme submitted by Norway for the withdrawal of all fish in Norwegian farms infected with infectious salmon anaemia (ISA).*

u) The *EFTA Surveillance Authority Decision No 02/10/COL of 5 January 2010 concerning the status of Norway with regard to infectious haematopoietic necrosis and viral haemorrhagic septicaemia and repealing Decision No 302/08/COL of 21 May 2008.*

v) The *EFTA Surveillance Authority Decision No 225/04/COL of 9 September 2004 recognising the entire coastline of Norway as an approved zone with regard to Bonamia ostreae and Marteilia refringens.*

ACTS OF WHICH THE EFTA STATES AND THE EFTA SURVEILLANCE AUTHORITY SHALL TAKE DUE ACCOUNT

w) The Act referred to at Point 55 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2003/634/EC of 28 August 2003 approving programmes for the purpose of obtaining the status of approved zones and of approved farms in non-approved zones with regard to viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) in fish,* as amended.

x) The Act referred to at Point 56 of Chapter 1 of Annex I to the EEA Agreement, *Commission Decision 2003/904/EC of 15 December 2003 approving programmes for the purpose of obtaining the status of approved zones and of approved farms in non-approved zones with regard to viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) in fish, and amending Annexes I and II to Decision 2003/634/EC.*

Annex 3 – Information on production and trade[5]

3.1 Total production

Species Common and scientific name	**Total Production**		
2009	**For human consumption (tonnes)**	**Restocking (fish x 1000 less the 250 gram)**	**Other Aquaculture purposes**
Atlantic Salmon *Salmo Salar*	857 053	233 495	
Atlantic Salmon, eggs *Salmo Salar*		350 000	
Rainbow trout *Oncorhynchus mykiss*	75 954	16 403	
2008	**For human consumption (tonnes)**	**Restocking (fish less the 250 gram)**	**Other Aquaculture purposes**
Atlantic Salmon *Salmo Salar*	735 966	231 538	
Rainbow trout *Oncorhynchus mykiss*	81 246	17 704	
Atlantic Cod *Gadus morhua*	5341		
2007	For human consumption (tonnes)	Restocking (fish less the 250 gram)	Other Aquaculture purposes
Atlantic Salmon *Salmo Salar*	744 222	262 959	
Rainbow trout *Oncorhynchus mykiss*	77 381	34 312	
Trout *Salmo Trutta*	85	323	
Atlantic Cod *Gadus morhua*	6067		

3.2 Trade of live aquaculture animals

Species Common and scientific name	**Placed on the market in other EEA member states**		
2008	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
Atlantic Salmon *Salmo Salar*	530 039		
Rainbow trout *Oncorhynchus mykiss*	10 445		
Atlantic Cod *Gadus morhua*	9907		
2007	For human consumption (tonnes)	Restocking (tonnes)	Other Aquaculture purposes
Atlantic Salmon *Salmo Salar*	502 746		
Rainbow trout *Oncorhynchus mykiss*	7 510		
Atlantic Cod *Gadus morhua*	6789		

Species - Common and scientific name	**Introduced from other EEA member states**		
2009	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
03019100 Trout, live	2,000		
03019901 Salmon (e.g. fingerlings, smolt), live	0,150		
03019902 Turbot (e.g. fingerlings, smolt), live		1,079	
03019909 Live fish ex. trout, eel, carpe, tuna, salmon, turbot and aquarium fish	1,114		

[5] Sources: The Directorate of Fisheries, Norway Statistics, SalmoBreed AS, Norwegian Seafood Export Council

Species - Common and scientific name	**Introduced from other EEA member states**		
03021102 Trout farmed incl. head, fresh or cooled	89,875		
03021103 Trout farmed ex head, fresh or cooled	4,830		
03021201 Pacific Salmon, Atlantic salmon and Donau salmon, farmed incl. Head, fresh or cooled	20,582		
03021901 Arctic Charr, fresh or cooled	0,538		
03032102 Trout farmed incl. Head, frozen	19,193		
03032103 Trout farmed ex. head, frozen	4,797		
03032202 Pacific Salmon, Atlantic salmon and Donau salmon, ex. Head, frozen	7,200		
03052009 Liver, row, and milt ex salted lumpfish, dried, smoked, salted	2,477		
2008	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
03019100 Trout, live	1,100		
03019902 Turbot (e.g. fingerlings, smolt), live		2,351	
03019909 Live fish ex. trout, eel, carpe, tuna, salmon, turbot and aquarium fish	3,924		
03021102 Trout farmed incl. head, fresh or cooled	114,940		
03021103 Trout farmed ex head, fresh or cooled	10,311		
03021201 Pacific Salmon, Atlantic salmon and Donau salmon, farmed incl. Head, fresh or cooled	30,774		
03021901 Arctic Charr, fresh or cooled	5,499		
03032102 Trout farmed incl. Head, frozen	21,219		
03032201 Pacific Salmon, Atlantic salmon and Donau salmon, incl. Head, frozen	2,828		
03052009 Liver, row, and milt ex salted lumpfish, dried, smoked, salted	26,603		
2007	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
03019100 Trout, live	1,500		
03019901 Salmon (e.g. fingerlings, smolt), live			32,500
03019902 Turbot (e.g. fingerlings, smolt), live		2,308	
03019909 Live fish ex. trout, eel, carpe, tuna, salmon, turbot and aquarium fish	3,778		
03021102 Trout farmed incl. head, fresh or cooled	117,023		
03021103 Trout farmed ex head, fresh or cooled	4,714		
03021201 Pacific Salmon, Atlantic salmon and Donau salmon, farmed incl. Head, fresh or cooled	55,608		
03021901 Arctic Charr, fresh or cooled	2,843		
03032102 Trout farmed incl. Head, frozen	29,471		
03032103 Trout farmed ex. head, frozen	68,232		
03032201 Pacific Salmon, Atlantic salmon and Donau salmon, incl. Head, frozen	43,010		
03032202 Pacific Salmon, Atlantic salmon and Donau salmon, ex. Head, frozen	7,685		
03052009 Liver, row, and milt ex salted lumpfish, dried, smoked, salted	19,953		

3.3 Trade with third countries of live aquaculture animals and products hereof:

Species Common and scientific name	**Exported to third countries**		
2008	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
Atlantic Salmon *Salmo Salar*	177787		
Rainbow trout *Oncorhynchus mykiss*	79716		
Atlantic Cod *Gadus morhua*	109		
2007	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
Atlantic Salmon *Salmo Salar*	186282		
Rainbow trout *Oncorhynchus mykiss*	49151		
Atlantic Cod *Gadus morhua*	56		

Species Common and scientific name	**Imported from third countries**		
2009	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
03019909 Live fish ex. trout, eel, carpe, tuna, salmon, turbot and aquarium fish	0,015		
03032103 Trout farmed incl. head, frozen	134,410		
03052009 Liver, row, and milt ex salted lumpfish, dried, smoked, salted	0,811		
2008	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
03019909 Live fish ex. trout, eel, carpe, tuna, salmon, turbot and aquarium fish	2,310		
03032102 Trout farmed incl. Head, frozen	59,068		
03032102 Trout farmed ex. Head, frozen	56,747		
03032201 Pacific Salmon, Atlantic salmon and Donau salmon, incl. Head, frozen	20,312		
2007	**For human consumption (tonnes)**	**Restocking (tonnes)**	**Other Aquaculture purposes**
03019909 Live fish ex. trout, eel, carpe, tuna, salmon, turbot and aquarium fish	0,028		
03032103 Trout farmed incl. head, frozen	80,420		
03032103 Trout farmed ex. head, frozen	4,010		
03032201 Pacific Salmon, Atlantic salmon and Donau salmon, incl. Head, frozen	5,631		
03032202 Pacific Salmon, Atlantic salmon and Donau salmon, ex. Head, frozen	21,514		

Annex 4 – Comments from the Norwegian Food Safety Authority to the draft report

DET KONGELIGE
FISKERI- OG KYSTDEPARTEMENT

Royal Ministry of Fisheries and Coastal Affairs

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussels
Belgium

Your ref. | Our ref. 200601556- /MHA-1 | Date 27 JULI 2010

EFTA Surveillance Authority mission to Norway regarding the application of EEA legislation related to fish health - draft report

Please find enclosed the response from the Norwegian Food Safety Authority on the EFTA draft report based on the mission to Norway from 26 April to 7 May 2010.

Yours sincerely,

Yngve Torgersen
Deputy Director General

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EFTA SURVEILLANCE AUTHORITY

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussels
Belgium

Your ref: Case No: 66746
Our ref: 2010/59368
Date: 23.07.10
Org.no: 985 399 077

Norwegian Food Safety Authority

Mattilsynet

Dear Sir/Madam

Subject: EFTA Surveillance Authority mission to Norway from 26 April to 7 May 2010 regarding the application of EEA legislation related to fish health - draft report.

Referring to the draft report we are pleased to be informed that the mission team found the situation satisfactory concerning control carried out by the Norwegian Food Safety Authority.

We can agree with the conclusions that the epidemiological situation concerning fish diseases listed diseases in Directive 2006/88/EC is in principle under control, that the official and private laboratories dealing with fish health diagnosis are well organised, and that the mission team met skilled and motivated professionals working in private fish health services.

We have not discovered essential mistakes of facts in the report, but some minor corrections and clarifications are enclosed.

Comments on corrective measures taken and planned in response to the recommendations are also enclosed.

Yours faithfully

Kristina Landsverk
Director

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Norwegian Food Safety Authority

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Clarifications and corrections

- **Draft report text point 5.3 (page 12):** - *This establishment had to deal with the emergency slaughtering following outbreaks of VHS/IHN in the region during 2008.*

  A correction:
  There were outbreaks of VHS (not IHN) during 2007 and 2008 in the eastern part of Storfjorden. IHN has never been detected in Norway.

- **Draft report text in point 5.9 (page 20):** - *In the last years many resources had been used on developing an IHC test for detection of ISAV antigens in tissues of affected fish. The method, validated in Oslo, was distributed to all the regional laboratories. No proficiency test of this method had at the time of the mission been organised. According to representatives of the NVI a new procedure would be adopted very soon, introducing a more specific, purified antibody to avoid risk of false positives due to the presence of Vibrio spp. and Parvicapsula spp. infections*

  A clarification:
  The NVI has mentioned that this method is in process to be accredited

- **Draft report text in point 5.9 (page 20):** - *The sensitivity of the cell cultures was tested regularly every 6 months. The mission team observed that, particularly for VHS-IHN samples, no temperature control was performed at the arrival of the samples in the laboratory.*

  A clarification:
  The NVI has mentioned that temperature was controlled at opening of sendings by checking if the cooler brick was still partly frozen, but not with a thermometer.

Annex 5 – Corrective action taken and planned by the Norwegian Food Safety Authority

Information on corrective actions taken and planned by the Norwegian competent authority

Reccommendation no 1
The competent authority should ensure that only registered veterinarians should be allowed to prescribe medicated feedingstuffs as required by Article 8(1) of Directive 90/167.

Comment:
This recommendation has previously been annotated by the Norwegian Ministry of Fisheries and Coastal Affairs.

Reccommendation no 2
The competent authority should ensure that processing establishments, slaughtering aquaculture animals for disease control purposes are authorised in accordance with the requirements laid down in Article 4 and 5 of Directive 2006/88/EC.

Measures:
Although all authorized establishments slaughtering farmed fish in Norway shall fulfil a minimum standard for disease control harvesting purposes e.g. related to disinfection of water/effluents, harvesting of diseased fish also has to be handled on a case to case basis taking into account the risk of spreading disease to other populations of aquatic animals. This recommendation therefore requires continuous attention and action from the competent authority.

Information on action taken against the establishment slaughtering fish from an ISA control zone referred to in point 5.10 in the report, is given in our comments to recommendation no 6 and 7.

Recommendation no 3
The national registers for authorised aquaculture production business and of authorised processing establishments should include all relevant information as set out in Article 6 and Annex II to Council Directive 2006/88/EC.

Measures:
The national register for processing establisments is now in process for updating in Norway, in constistency with the requirements laid down in article 6 of Directive 2006/88/EC and Annex II to the Directive. This updating process is planned to be finished this year.

The national register for authorised production business production has been established and is maintained by the Directorate of Fisheries. An updating process to include all information required as laid down in Article 6 of Directive 2006/88/EC and Part I and II of Annex II to the Directive has to be carried out in a cooperation between The Directorate of Fisheries and the Norwegian Food Safety Authority. The time aspect of a revision of the national register for authorised aquaculture production business has to be decided later.

Recommedations no 4
The competent authority should draw up a contingency plan for emerging and exotic diseases in conformity with the requirements laid down in Article 47 of Directive 2006/88/EC.

Measures:
A general contingency plan draft for list 1 and list 2 diseases as requested in Article 47 of Directive 2006/88/EC is under intern evaluation in the NFSA. The draft shall be updated according to the recommendations from the Authority this year.
A contingency plan for emerging diseases is in preparation and is planned to be completed this year

Recommendation no 5
In order to maintain disease-free status for infectious haematopoietic necrosis, the competent authority should ensure that sampling is carried out in conformity with the requirements laid down in Article 52 of Directive 2006/88/EC and the Annex to Decision 2001/183/EC.

Measures:
The ongoing VHS/IHN surveillance and eradication programmes in Norway are now being revised. From the next year it shall be ensured that sampling for IHN will be carried out in conformity with the requirements laid down in Article 52 of Directive 2006/88/EC and the Annex to Decision 2001/183/EC

Reccommendation no 6
On the basis of Article 31(2)(c) of Regulation (EC) No 882/2004, the competent authority should ensure that only food business establishments in compliance with the EEA legislation are approved.

Measures:
NFSA have looked into the missing process for finalizing the application for approval of the, in the establishment mentioned in the draft report point 5.10. The establishment has now been granted a conditional approval for three months, and this will be followed up by the district office (DO)

New routines for considering applications for approval are implemented in our new control system (MATS), and this system will ensure that applications are being considered by NFSA.

All establishments supervised by NFSA (for food of animal origin) have to be approved or re-approved based on our new legislation. Application for approval under Regulation (EC) No. 853/2004 is organised for in our new control system (MATS). The evaluation of establishments based on their application, is performed by the district offices, and a certificate of Full approval or Conditional approval is issued by the DO.
Approval or re-approval of establishments according to the new legislation will be a continuously process taking place from mid-June 2010 and onwards. Development of guidelines for this process is in progress.

Recommendation no 7
In order to comply with the requirements of Articles 3 and 4 of Regulation (EC) No 854/2004; Article 4 of Regulation (EC) No 853/2004,; Chapter VII of Annex II of Regulation (EC) No 852/2004; Articles 4, 6 and 7 of Council Directive 98/83/EC, the competent authority should ensure that the deficiencies observed by the mission team are corrected in the establishments visited and are not present in other approved establishments.

Measures:
Action is taken against the specific mentioned establishment, for deficiencies observed by the mission team.

Official controls on fish and fishery products from fishing ground, first landing, to movement, processing, wholesale and distribution is carried out by the DO. Directions for frequency and focus areas of official controls are given annually to the regional offices. NFSA are through our controls, in focus of ensuring that establishments fulfils the requirements in the food hygiene regulations.

Recommendation 8
The competent authority should ensure that the NRL organises, and that, the official laboratories analysing official samples participate in comparative tests to ensure confidence and reliability of the laboratory performance in line with the requirements laid down in Article 12 of Regulation (EC) No 882/2004, and in Articles 56 and 57 and Annex VI of Directive 2006/88/EC.

Measures:
The agreement between NFSA and NVI has to be updated this year, and the revised agreement shall ensure that the official laboratories analysing official samples participate in comparative tests to ensure confidence and reliability of the laboratory performance in line with the requirements laid down in Article 12 of Regulation (EC) No 882/2004, and in Articles 56 and 57 and Annex VI of Directive 2006/88/EC.