Brussels, 24 October 2005

Case No: 56380
Event No: 345601

Final report

EFTA Surveillance Authority mission to

NORWAY

27 June to 1 July 2005

concerning the application of EEA legislation related to the control of certain fish diseases

Comments from the Norwegian Competent Authority are at Annex 1. Some of the comments are also included in the report in *underlined italic*. Additional information on action already taken is at Annex 2.

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List of abbreviations and terms used in the report

ADNS	Animal Disease Notification System
Authority	EFTA Surveillance Authority
CA	Competent Authority
CRL	Community Reference Laboratory
DO	District Office of the NFSA/*Distriktskontor*
DVO	District Veterinary Officer/*Distriktsveterinær*
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EU	European Union
FHS	Fish Health Services
FIDIR	Directorate of Fisheries/*Fiskeridirektoratet*
HO	Head Office of the NFSA/*Mattilsynets hovedkontor*
IF	Immunoflourescence
IHC	Immunohistochemistry
IHN	Infectious haematopoietic necrosis/*infeksiøs hematopoietisk nekrose*
IPN	Infectious pancreatic necrosis/*infeksiøs pancreas nekrose*
ISA	Infectious salmon anaemia/*infeksiøs lakseanemi*
ISAV	ISA virus
MAF	Ministry of Agriculture and Food/*Landbruks- og matdepartementet*
MFCA	Ministry of Fisheries and Coastal Affairs/*Fiskeri- og kystdepartementet*
NFSA	Norwegian Food Safety Authority/*Mattilsynet*
NFSC	National Fish and Seafood Centre of the NFSA/*Nasjonalt senter for fisk og sjømat*
NIFES	National Institute of Nutrition and Seafood Research/*Nasjonalt Institutt for Ernærings- og sjømatforskning*
NOK	Norwegian Kroner/*Norske kroner*
NRL	National Reference Laboratory
NVI[1]	National Veterinary Institute/*Veterinærinstituttet*
OIE	Office International des Épizooties/World Organisation for Animal Health
RO	Regional Office of the NFSA/*Regionkontor*
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RVO	Regional Veterinary Officer/*Fylkesveterinær*
SDT	Norwegian Animal Health Authority/*Statens dyrehelsetilsyn*
SFD	Section for Fish Diseases of the NRL
SLT	Norwegian Agricultural Inspection Service/*Landbrukstilsynet*
SNT	Norwegian Food Authority/*Statens næringsmiddeltilsyn*
SOP	Standard Operational Procedure
SVS	Section for Virology and Serology of the NRL
VHS	Viral haemorrhagic septicaemia/*hemorrhagisk virusseptikemi*
VNN	Viral Nervous Necrosis

[1] *The English name of the laboratory is the National Veterinary Institute, abbreviated NVI.*

1 Introduction

The mission took place in Norway from 27 June to 1 July 2005. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority), one national expert and an observer from the Food and Veterinary Office of the European Commission.

The opening meeting was held on Monday 27 June 2005 at the Norwegian Food Safety Authority's (NFSA)/*Mattilsynet's* head office (HO) in Oslo. At that meeting the representatives of the Ministry of Fisheries and Coastal Affairs (MFCA) and of the Competent Authority (CA) added information to the Norwegian reply to the Authority's pre-mission questionnaire.

Throughout the mission four representatives of the NFSA (*two* from the HO, *one* from the Regional Office (RO) and one from the National Fish and Seafood Centre of the NFSA(NFSC)/*Nasjonalt senter for fish og sjømat*) accompanied the mission team. In addition, representatives from the relevant District Offices (DOs) participated during visits to the establishment, the laboratories, the different farms and the well boat visited.

A final meeting was held at the HO of the NFSA in Oslo on 1 July 2005, at which the mission team orally presented the main findings and some preliminary conclusions from the mission.

2 Objectives of the mission

The main objective of the mission was to assess the Norwegian CA's application of the requirements of Council Directive 91/67/EEC, Council Directive 93/53/EEC and related legislation (see Chapter 3 and 4). A particular focus was put on the co-operation between the CA and the laboratories involved in the control of the relevant fish diseases, the measures for the control of diseases affecting aquaculture animals and in particular the control of infectious salmon anaemia (ISA)/*infeksiøs lakseanemi*, and finally, monitoring of the diseases infectious haematopoietic necrosis (IHN)/*infeksiøs hematopoetisk nekrose* and viral haemorrhagic septicaemia (VHS)/*viral hemoragisk septikemi*.

The meetings with the CA and the visits to the establishment, laboratories, farms and well boat during the mission are listed in Figure 1.

Figure 1: Competent Authority, establishments, farms, vessels and laboratories visited during the mission

	Number	Comments
Competent Authority	5	Two with the HO (opening and closing meeting), one meeting with the RO and two meetings with two different DOs
Laboratories	2	The NRL and a laboratory analysing samples from aquaculture farms, fishery products establishments, etc.
Farms	2	One hatchery and one ongrowing farm
Establishment	1	Approved for slaughtering of fish from farms where ISA is diagnosed
Vessel	1	A well boat

3 Legal basis for the mission

The legal basis for the mission was:

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

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

c) The Act referred to at Point 4.1.5 of Chapter I of Annex I to the EEA Agreement, *Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products*, as amended, and particular Article 17 thereof.

d) The Act referred to at Point 3.1.7 of Chapter I of Annex I to the EEA Agreement, *Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases*, as amended, and in particular Article 16 thereof.

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

4 Other relevant legislation

a) The Act referred 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.

b) 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.

c) 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.

d) 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.*

e) The Act referred to at Point 4.2.73 to the EEA Agreement, *Commission Decision 2003/466/EC establishing criteria for zoning and official surveillance following*

suspicion or confirmation of the presence of infectious salmon anaemia (ISA).

f) The Act referred to at Point 7.1.9 of Chapter I of Annex I to the EEA Agreement, *Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC,* as amended[2].

g) The *EFTA Surveillance Authority Decision No 244/02/COL of 11 December 2002 amending the EFTA Surveillance Authority Decision No 71/94/COL of 27 June 1994 concerning the status of Norway with regard to infectious haematopoietic necrosis and viral haemorrhagic septicaemia and repealing the EFTA Surveillance Authority Decision No 159/98/COL of 25 June 1998.*

h) The *EFTA Surveillance Authority Decision No 226/04/COL of 9 September 2004 approving the scheme submitted by Norway for the withdrawal of all fish in Norwegian farms infected with infectious salmon anaemia (ISA).*

5 National legislation

The main Norwegian Act creating the general framework for the function of the NFSA is the *Act of 19 December 2003 No 124 relating to Food Safety and Plant and Animal Health (the Food Act).* This Act provides the legal basis for regulations in this field adopted by the Ministry of Agriculture and Food (MAF) and the MFCA.

The regulation that provides the legal basis for the NFSA's application of Council Directive 91/67/EEC is *Regulation of 14 October 2003 No 1239 concerning the animal health conditions governing the placing on the marked and the import of aquaculture animals and aquaculture products.* The regulation is adopted by the MFCA.

The Act that provides the legal basis for the NFSA's application of Council Directive 93/53/EEC is the *Act of 19 December 2003 No 124 relating to Food Safety and Plant and Animal Health (the Food Act).* In addition, this Directive is also implemented in a number of regulations, *inter alia, Regulation of 2 May 1990 No 144 concerning the instructions of the list A, B and C diseases, Regulation 4 July 1991 No 509 concerning prevention, control and eradication of diseases of aquatic animals,* and *Regulation 20 February 1997 No 193 concerning transportation of aquatic organisms*.

In Annex A of Directive 91/67/EEC contagious diseases are grouped in three different lists (List I, II and III), where List I contains the most serious contagious diseases. In Norway, contagious diseases are grouped in three different lists (List A, B and C) where List A contains the most serious contagious diseases.

[2] Council 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 is still to be incorporated into the EEA Agreement.

ISA is included in List I of Annex A to Directive 91/67/EEC while it is in List B in the Norwegian regulation implementing that Directive. Both IHN and VHS are included in List II of Directive 91/67/EEC, while they are in List A in the Norwegian regulation.

6 Background

6.1 ISA

ISA is a viral disease known to develop disease only in Atlantic salmon (*Salmo salar*). However, the ISA virus (ISAV) may survive and replicate in some species of trout, which thus may act as carriers of the virus for an unknown period of time.

The disease was first diagnosed in Norway in 1984. Since then, the disease has been diagnosed in Canada (1996), Scotland (1998), Chile (1999), the Faroe Islands (2000), USA (2001) and Ireland (2002).

Since ISA is classified in List I of Annex A to Council Directive 91/67/EEC, the control measures prescribed in Council Directive 93/53/EEC aim at eradicating the disease. The measures include amongst others withdrawal of the fish from infected farms in accordance with a scheme established by the CA and, for the EFTA EEA States, approved by the Authority. The Norwegian scheme for the withdrawal of all fish in Norwegian farms infected with ISA was approved by the Authority on 9 September 2004[3].

In March 1993 the European Commission adopted a decision on certain protective measures in respect of ISA in Norway. This ban on import to the European Union (EU) of live fish, eggs and gamets of fish belonging to the family *Salmonidae* was upheld until 2003, when live gamets could be imported to the EU on certain criteria.

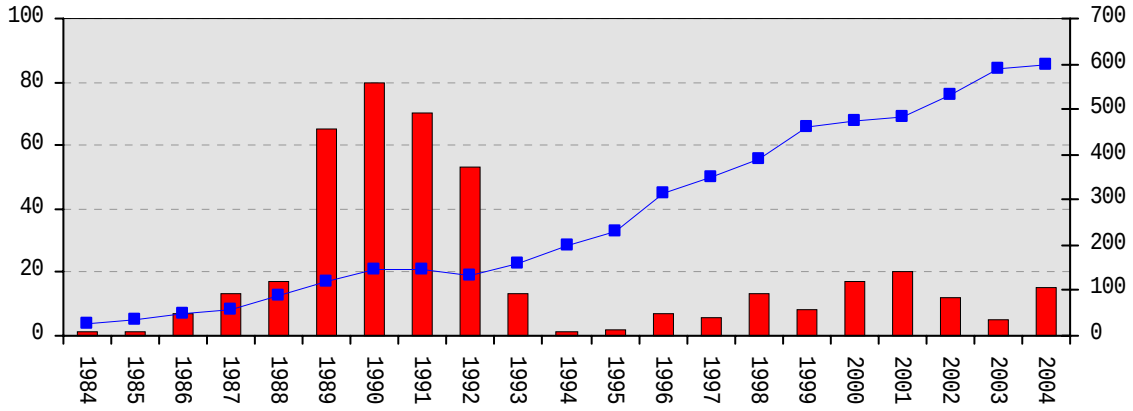
6.2 Evolution of ISA in Norway

From the time ISA was first diagnosed in 1984 and up to 2004 a total of 441 outbreaks have been reported in Norway. The yearly number of outbreaks peaked in 1990 with a total of 80 outbreaks. Since 1993 the annual incidence of ISA has varied between 1 and 20.

Figure 2 shows the number of verified outbreaks and the salmon production in tons per year from 1984 to 2004. In the figure, the read columns indicates the number of outbreaks and follows the left scale, while the blue line indicates the production and follows the right scale.

[3] The Authority Decision No 226/04/COL, OJ C 319 23.12.2004, p. 65

Figure 2: **Number of verified outbreaks of ISA in Norway and the salmon production in tons per year** *(Summary of epidemiological reports regarding outbreaks of ISA in Norway 2004, Veterinary Institute)*



6.3 IHN and VHS

IHN and VHS are two important virus infections in *Salmonids*. IHN has caused serious economic losses in farmed rainbow trout and salmon, and the disease has also had an impact on wild populations of Pacific salmon. The disease was first described in Europe in 1985 (France and Italy). The disease has been diagnosed in several countries in Europe, but so far not in Norway. VHS was reported for the first time in Norway in 1964 and until 1974, several clinical disease outbreaks were diagnosed.

Because of the disease status the Authority adopted Decision No 71/94/COL in which Norway was recognised as approved continental zone and as approved coastal zone for fish with regard to IHN and VHS. By Decision No 220/96/COL the Authority established a buffer zone towards Russia. Norway has applied a surveillance and control programme for these two diseases since 1994.

6.4 Other diseases

The parasite *Gyrodactylus salaries* was observed in Norwegian rivers for the first time in 1975. Since then the parasite has been observed in 45 Norwegian rivers, 13 hatcheries/ farms with Atlantic salmon and 26 hatcheries/farms with rainbow trout.

The disease Viral Nervous Necrosis (VNN) has been diagnosed twice in Norway, in turbot in 1991 and in halibut in 1995, while the presence of *Anguillicola* spp. in Norwegian fauna can not be excluded. Finally, the protozoan parasites *Bonamia ostreae* and *Marteilia refringens* have never been diagnosed in Norway.

The number of fish diseases diagnosed by the National Veterinary Institute (NVI) since 1997 are included in Figure 3.

Figure 3: Fish diseases diagnosed by the NVI

	1997	1998	1999	2000	2001	2002	2003	2004
ISA	6	13	14	23	21	12	7 [4]	17 [5, 6]
IPN [7]						174	178	172
PD	7	7	10	11	15	13	23	44
HSMB (HSMI)								54
Piscirickettsiosis	1	0	6	0	1	17	5	0
Furunkulosis	4	1	2	6	3	0	2	3 [8]
BKD	15	0	3	3	3	1	1	1

6.5 Aquaculture production in Norway

A total of 112 establishments are approved for handling (slaughtering and/or further processing) of salmon and rainbow trout. *Five* establishments are approved according to Directive 90/667/EEC for handling high risk materials while *four* establishments are approved for handling low risk materials.

The amounts of aquaculture production of salmon, rainbow trout, char, cod and halbut in Norway from 2001 to 2004 are included in Figure 4.

Figure 4: Aquaculture production in Norway from 2001 to 2004 in tons.

	Salmon	Rainbow trout	Char	Cod	Halibut	Other fish species
2001	436 106	71 764	317	864	377	
2002	462 495	83 559	319	1253	424	377
2003	507 412	69 128	269	2181	427	663
2004	544 027	65 026				1 229

7 Main findings

7.1 Competent Authority

7.1.1 General information

It follows from a Royal Decree of 19 December 2003 that the authority to instruct the NFSA is split between the MAF, the MFCA and the Ministry of Health and Care Services.

The MAF is responsible for the budgetary allocations to the NFSA, for the co-ordination of the Ministries' activities towards the NFSA, and for legislation covering, *inter alia*, terrestrial production.

The MFCA is responsible for legislation related to aquatic production, *inter alia*, the national legislation implementing Council Directive 91/67/EEC, Council Directive

[4] Two adjacent farms were situated in the same control zone.
[5] Two adjacent farms were situated in the same control zone.
[6] The number includes one seawater farm around which a control zone was established as ISA was detected in one fish by pathology and immunohistochemistry.
[7] Statistics for the years 1997-2001 are not included due to uncertain registration during this period.
[8] Comprised one outbreak on a marine production site, one outbreak in wild salmon population, and one freshwater brown trout hatchery.

93/53/EEC, and for Council Directive 91/493/EEC related to the production and the placing on the market of fishery products.

The Ministry of Health and Care Services is, *inter alia*, responsible for national legislation implementing the Act referred to at Point 7a of Annex XX to the EEA Agreement, *Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption*, and the food legislation in Chapter XII of Annex II to the EEA Agreement (e.g. contaminants, food additives and labelling).

7.1.2 Organisation, legal powers and budgetary allocations

The NFSA is the Competent Authority and consists of the former Norwegian Agricultural Inspection Service/*Statens landbrukstilsyn* (SLT), the Norwegian Animal Health Authority/*Statens dyrehelsetilsyn* (SDT), the Norwegian Food Authority/*Statens næringsmiddelstilsyn* (SNT), the Municipal Food Control Authorities/*Kommunale næringsmiddeltilsyn* (KNT) and the Seafood Inspectorate of the Directorate of Fisheries/ *Fiskeridirektoratet* (FIDIR).

The NFSA is organised in three administrative levels, the central level with the HO, a regional level with eight ROs, and a local level with 64 DOs. The HO, being located in Oslo, is responsible for co-ordinating the organisation's activities including, *inter alia*, inspections, surveillance and eradication of animal diseases, and preparation of new legislation. Out of a total of 1300 employees in the NFSA, the HO has approximately 130, the ROs have 230, and the DOs have 940 employees.

Five different national centres, having been assigned special tasks, are located at different ROs. The national centres have no legal power, take instructions only from the HO, but are administratively organised under the respective ROs. Being located at the RO in Bergen, the NFSC is the national centre related to fish diseases and seafood production.

According to information provided by representatives of the NFSA, it is the principal rule that administrative decisions shall be adopted at the local level. Any appeal following these decisions shall be considered at the regional level.

The HO sets out the scope of the budget to the ROs. This is followed by a budgetary process at the RO and in co-operation with the DOs. Within the framework agreed with the RO, the DOs can allocate the budget as most suitable for the respective districts.

7.1.3 Training of staff

In the reply to the Authority's pre-mission questionnaire the NFSA informed that the training programme established shall ensure that all relevant personnel are able to develop and maintain the necessary skills related to handling (both fieldwork and administration) of outbreaks of ISA. The ROs are responsible for ensuring that all key persons have participated in the courses.

Further to the Norwegian reply to the pre-mission questionnaire, the programme includes a three hour presentation of ISA, the Norwegian strategy for controlling ISA, and a two days training course on the contingency plan for control of ISA.

As part of the training programme, the NVI has prepared an illustrated presentation of ISA which is used in courses and information meetings within the NFSA. Another presentation available at the NFSA's website is primarily for the aquaculture industry.

In addition to the training organised by the HO of the NFSA, the different ROs arrange regular meetings with the staff of the DOs responsible for fish diseases. Finally, on a district level, contact groups for staff involved in fish diseases have been established.

7.1.4 Regional Office visited

During the mission one RO was visited. The region consists of 14 DOs and has a total of 221 staff members, out of which 17 are at the RO. According to information provided at the RO, the region has budgetary allocations for 207 staff members. Furthermore, the number of staff at the RO was assumed to be sufficient for its duties. However, according to information from a representative of the RO the number of staff at the district level has to be increased by about 60 in order to cope with the duties assigned to the 14 districts.

The shortage of staff at the district level was in particular visible in the field related to fish and fishery products. Apparently, this was mainly because of the transfer of duties from the FIDIR following the re-organisation of the CAs, without transferring a sufficient number of staff.

The region had one lawyer at the RO and none at the district level. A representative of the RO informed the mission team that the number of staff with legal competence was insufficient at the regional level.

Regular meetings are held both between the HO and the ROs and between the ROs and the DOs. Although contact with the NFSC should go through the RO, direct contact between the DOs and the NFSC occurs.

A representative from one of the DOs informed the mission team that, at least in that district, the surveillance and control programmes were given highest possible priority within the budget.

However, representatives of the RO visited informed the mission team that for 2005, the budgetary allocations were not sufficient for carrying out all the duties assigned to it. Moreover, it could not be excluded that the lack of staff and insufficient budgetary allocations could be in conflict with some of the obligations falling from the EEA Agreement.[9]

During the mission, representatives of the NFSA informed the mission team that procedures for HO audits of the ROs were not established. At the RO visited discussions on plans for audits of the DOs had been initiated, but it was not foreseen that these plans could be applied as of 2006. However, major decisions adopted on the district level are assessed by the RO in order to ensure a correct and harmonised application within the region.

[9] *See "Footnote 9" of Annex 1.*

7.1.5 District Offices visited

During the mission two DOs were visited, both within the same region and both having outbreaks of ISA in 2005[10].

In one of the districts visited (having two ISA outbreaks so far this year) representatives of the DO informed the mission team that a study had revealed a shortage of more than 3 man labour years, which equals almost 50% of the total workload within the district. A similar situation was also described in the second district visited.[11]

Although in process of being established, representatives of the NFSA in the region visited informed the mission team that, not all DOs have facilities that can ensure rapid and efficient eradication of an outbreak of a contagious disease. However, it is foreseen that all DOs will have sufficient facilities in the early autumn 2005[12].

7.2 Laboratory services

7.2.1 General information

In Norway only the NVI is involved in analyses of official samples related to fish diseases. The NVI is a governmental agency *owned by the MAF and* funded by the MAF, the MFCA, the NFSA[13] and the Research Council *of Norway*. The NVI consists of a central laboratory in Oslo and five regional laboratories located in Sandnes, Bergen, Trondheim, Harstad and Tromsø.

For 2005 the total budget for the NVI is 205 million NOK. The basic funding is 105 million NOK from the MAF and the MFCA, out of which 33 million NOK is received from the MFCA. The 33 million NOK is covering activities related to aquatic animals, one third covering running expenses and two third covering salaries, corresponding to approximately 45 full time positions.

The remaining 100 million NOK is received from the Research Council, the EU and from the NFSA. 25 % of these fundings (corresponding to approximately 20 full time positions) are related to fish and seafood activities. Consequently, out of a total number of 250 full time positions within the NVI (the central laboratory and the five regional laboratories) 65 are involved in activities related to aquatic animals, safety of seafood etc.

The NVI and the NFSA have signed an agreement on co-operation related to administrative support. According to this agreement the support from the NVI comprises emergency preparedness, surveillance, advisory services, duties related to references, diagnostics and risk evaluation.

The mission team observed that the agreement for the period 1 January to 31 December 2005 was signed in March 2005. Furthermore, the annex to the agreement containing details on the NVI's duties, including procedures for notification, had still to be finalised at the time of the mission.

The NVI has also established its own emergency plan. In this plan reference is made to, *inter alia*, the Norwegian regulation related to List A, List B and List C diseases, in which it

[10] *See "Footnote 10" of Annex I.*
[11] *See "Footnote 9" of Annex I.*
[12] *See "Footnote 12" of Annex I.*
[13] *See "Footnote 13" of Annex 1.*

is stated that the central laboratory of the NVI shall always confirm the diagnosis of a List A disease.

In addition, the emergency plan also contains information related to co-operation with the NFSA, references to EEA legislation and to the Office International des Épizooties (OIE). Finally, the plan contains both general and specific information related to organisation of the NVI during crisis and on crisis management.

According to information included in the Norwegian reply to the Authority's pre-mission questionnaire, the NFSA established in 2004 procedures for approval/recognition of laboratories performing analyses of both official and private samples, including analyses of samples related to aquaculture animals and products. The basic criteria for approval were that the laboratories should be accredited according to ISO 17025 in addition to accreditation of the actual methods used. Other criteria for approval were quality, service and price.

It follows from the Norwegian reply to the Authority's pre-mission questionnaire, that the NVI (both the central laboratory and the regional laboratories) have a general quality assurance programme equal to ISO/IEC 17025. The NVI has a number of accredited analyses, but not in the field related to aquaculture animals and fish diseases. However, a process for accreditation of the different laboratories has been initiated.[14]

Finally, some other universities/research institutions analyse samples related to fish diseases, but all samples from the local fish health services (FHS) are analysed at the NVI.

The information contained in Chapter 7.2.2 to 7.2.4 is related to the fish diseases ISA, IHN and VHS.

7.2.2 Division of tasks between the regional laboratories and the central laboratory

Samples related to the monitoring programme for IHN and VHS are sent directly to the central laboratory[15] in Oslo, where all the samples are analysed. Samples related to suspicion of ISA are sent to the regional laboratories, apart from samples from the county of Møre and Romsdal, which are sent to the central laboratory in Oslo.

The NVI receives both private samples from the FHS and official samples from the NFSA. However, most regional laboratories only perform histopathological analyses on samples related to suspicion of ISA. Other analyses and verification of diagnosis are carried out at the central laboratory in Oslo.

The central laboratory is responsible for development of new methods, for co-ordinating the work within the NVI and for being the link to the Community Reference Laboratory (CRLs). For example, ISA diagnostic methods, which are also applied internationally, have been developed by the central laboratory. Furthermore, the diagnostic activity is harmonised through two annual meetings between diagnosticians from the regional laboratories and the central laboratory. At these meetings training in new methods is also provided by the central laboratory.

[14] *See "Footnote 14" of Annex 1.*
[15] *See "Footnote 15" of Annex 1*.

All the laboratories use a common, online register system for samples and results. A quality assurance system covers all the laboratories with online access to method descriptions and procedures for reporting etc.

Procedures for compilation, preparation and distribution of results of analyses carried out have been prepared, and are applied at both the central laboratory and the regional laboratories. According to these procedures, information on results shall always be in writing. Results can also be provided by e-mail following a written agreement, and by phone based on certain criteria. However, oral information can only be given as an addition to written information.

In general, information shall only be given to the owner of the sample, apart from when the presence of a List A or List B disease is either suspected or verified. It follows from the reporting procedures that, in case of suspicion or verified presence of a List A or List B disease, the guidelines in the NVI's emergency plan are to be applied. According to this plan, the NVI (the regional laboratory or the central laboratory) shall notify the relevant DO of the NFSA in case of suspected presence of any of these diseases. In case of verified presence of any of these diseases, the relevant Director of Department shall notify the HO of the NFSA by phone and e-mail in accordance with the procedures agreed.

Representatives of the NVI informed the mission team that information on suspicion and following verification of presence of, *inter alia*, ISA, the central laboratory or the relevant regional laboratory notifies the DO of the NFSA by e-mail with copies to the respective RO and to the HO. However, in the written information following verification of ISA the mission team observed in one case that the central laboratory sent the results to the DO of the NFSA and a copy to the relevant regional laboratory. In another case, based on a private sample, the central laboratory sent the result to the local fish health service with a copy to the relevant DO[16].

7.2.3 The National Reference Laboratory for fish diseases

The Norwegian National Reference Laboratory (NRL) for fish diseases is part of the central laboratory of the NVI. In addition, for fish diseases caused by ISAV and by the parasite *Gyrodactylus salaries*, the central laboratory also has the status of OIE reference laboratory.

The laboratory was well equipped and the facilities were clean and of sufficient size. The personnel involved in diagnosis of ISA were highly qualified, and are internationally recognised as the leading experts in this field. However, the mission team observed that the laboratory was not accredited according to ISO 17025 or other accreditation system.[17]

At the NRL, the mission team visited both the Section for Fish Diseases (SFD) and the Section for Virology and Serology (SVS).

It is the SFD that is responsible for the receipt and registration of incoming samples. After examination, the samples are distributed to the relevant analysing sections. Standard Operational Procedure (SOP) for handling of incoming samples was demonstrated during the visit. The procedures seemed correctly applied apart from traceability of checks of the

[16] *See "Footnote 16" of Annex 1.*
[17] *See "Footnote 14" of Annex 1.*

incoming samples, since that was only applied when deviations were registered. Furthermore, the person responsible for carrying out the checks could not be identified on the analysing sheets.[18]

The mission team observed that when carrying out Immunoflourescence (IF) on imprints, traceability of the use of positive controls, quality/acceptance criteria for imprints and batch numbering of antiserum were insufficient or absent. Furthermore, one or two scientists were reading the slides. In one case, with ISA susceptible samples, signing and dating were not done, and conclusions were not written on the working sheet.[19]

In another case the mission team observed that outgoing letters with results of analyses carried out were not available. Representatives of the laboratory informed the mission team that this was because the regional laboratory had been responsible for finalising the letter.

For Immunohistochemistry (IHC) a non-registered SOP was demonstrated. However, any procedure describing the ISA IHC specifically was not made available to the mission team. According to the reply to the pre-mission questionnaire, a specific procedure has been prepared. Moreover, relevant working sheets could not be demonstrated and the traceability of the samples was insufficient[20].[21]

It was observed that information was often provided to the DO of the NFSA when the results of the different analyses carried out was available. However, the mission team observed that, in one case, the histology carried out could not be documented.[22]

In another recent case the mission team observed that reading of imprints could not be documented. It was not possible to trace back the analysing process and no conclusion was available[23]. Information on the results of the analyses was sent by e-mail to the relevant DO of the NFSA, with a copy to the regional laboratory. Results from the histopathology and Reverse Transcription-Polymerase Chain Reaction (RT-PCR) analyses carried out had been sent to the relevant regional laboratory, which was responsible for issuing the final letter.

Representatives of the SFD informed the mission team that the Section had participated in two recent ISA proficiency tests. However, the reports from the tests had not been filed.[24]

At the SVS the mission team observed adequate procedures for handling of samples upon arrival, separation of different samples, disinfection procedures, homogenisation and registration.

The SOP for cell cultivation was demonstrated. However, the registered document was still to be approved. The mission team observed that the traceability during cell cultivation was sufficient, since it was possible to trace back the sample to the original preparation of the plates. Furthermore, the reading of results had been registered and dated, and the person

[18] *See "Footnote 18" of Annex 1.*
[19] *See "Footnote 19" of Annex 1.*
[20] *See "Footnote 19" of Annex 1.*
[21] *See "Footnote 21" of Annex 1.*
[22] *See "Footnote 22" of Annex 1.*
[23] *See "Footnote 19" of Annex 1.*
[24] *See "Footnote24" of Annex 1.*

responsible was indicated by its initials. All inoculated trays were tested separately by IF. Positive controls were only included at this stage of the procedures.

The mission team observed that the diagnostic methods used for the detection and confirmation of ISA and for IHN and VHS were in accordance with the methods laid down in Commission Decision 2003/466/EC and in Commission Decision 2001/183/EC, respectively.

The first approved and registered version of the SOP for RT-PCR for ISAV was demonstrated to the mission team. A second version was in the process of being approved. Traceability for this procedure was satisfactory. Information on the handling of weak positive or false positive reactions was described, *inter alia*, sequencing, re-examination and another RT-PCR. This procedure was activated when other evidence of ISAV was absent.

Documentation of participation in proficiency tests was provided. The SVS has participated in two recent ISA tests. The SVS also participates in the annual proficiency test organised by the CRL. The performance of this was examined. However, any follow-up of the results of this test could not be documented.[25]

7.2.4 Regional laboratory

The laboratory visited receives approximately 400 submissions of samples per year from the 70-80 aquaculture farms in its region. Most of the samples consist of organ materials in formalin or blood plates for bacteriological analysis.

The laboratory performs histopathology, but for the time being not any specific tests for ISAV. The laboratory was not accredited for diagnosis of any of the relevant fish diseases. Approximately one man labour year is affiliated to analyses related to aquaculture. Histopathology was performed by two experienced veterinarians.

Methods such as RT-PCR, IF and IHC are being considered, but not yet implemented. The regional laboratory is generally responsible for providing test reports and collates the necessary diagnostic documentation.

During 2004 the laboratory was involved in diagnosis of five outbreaks of ISA. The mission team observed that in one case it took three weeks from the first suspicion of ISA until a negative diagnosis was made.

The mission team examined one case where ISA was suspected following histopathological analyses of a sample of Atlantic salmon submitted by a private veterinarian. No clinical signs of ISA had been observed. The regional laboratory informed the DO and the central laboratory. The material was sent to the central laboratory for further examination and additional samples were provided by the DO. The suspicion of ISA was ruled out after three weeks. Involvement by the RO or the HO of the NFSA could not be documented.

[25] *See "Footnote 25" of Annex 1.*

7.3 General observations related to licencing of aquaculture farms, approval of slaughterhouses and incineration plants, disease status, and prevention and control of fish diseases

7.3.1 Licencing of aquaculture farms[26]

It follows from the Norwegian reply to the Authority's pre-mission questionnaire, that the FIDIR is co-ordinating the process for assessment of applications, and the issuing of licences for fish farming. In addition to the FIDIR, the applications are assessed by the relevant DO of the NFSA, the Coastal Administration and the Environmental Authorities (part of the County Administration), in light of the legislation they enforce.

The licences are issued by the FIDIR which is also responsible for withdrawing licences when the conditions are violated. It is rare that licences are withdrawn, but during 2003 the production in one farm was stopped because the licence was not valid. The number of aquaculture licences in Norway is listed in Figure 5.

Due to the production cycle, each aquaculture farm has often more than one location, normally two or three. A separate licence must be issued for each location. However, more than one farm can have licences for the same location.

Normally the licences are permanent. However, in some cases, in particular due to environmental and animal health issues, a licence can be temporary.

Figure 5: Number of aquaculture licences in Norway

	Salmon and Rainbow trout	Other fish species
Broodstock licences	27	
Hatcheries [27]	270	
Ongrowing licences	967	745[28]

Approvals of sea farms for production of salmon and rainbow trout contain restrictions on the amount of live fish to be kept at any given time, normally 780 metric tons per production cycle.

Apart from the restrictions on production volume, the issuing of licences for other species than salmon and rainbow trout follow the procedures described above. All licences are registered in a register administered by the FIDIR.

7.3.2 Approval of slaughterhouses and incineration plants[29]

In order to be approved, establishments slaughtering aquaculture animals must comply with, *inter alia*, one regulation containing requirements related to facilities, handling of aquaculture animals and products, and one related to treatment of influent and effluent water.

[26] *See "Footnote 26" of Annex 1.*
[27] The number of hatcheries is not specified for other species than salmon and rainbow trout.
[28] All licences including those for broodstock farms and hatcheries.
[29] *See "Footnote 29" of Annex 1.*

Issuing of approvals and withdrawals of approvals are the responsibility of the DOs. However, the evaluation of methods for treatment of effluent water from slaughterhouses etc. and the approval of such methods is the responsibility of the NVI in Oslo. Representatives of the NFSA informed the mission team that the capacity for evaluation and approval of such methods is insufficient.

According to information provided by the NFSA, five establishments are approved for handling of high risk materials, while four establishments are approved for handling of low risk materials.

7.3.3 Contingency plans and withdrawal schemes

The Norwegian guidelines for handling of outbreaks of ISA were in 2002 replaced by a contingency plan and special instructions. The current version of the contingency plan and the instructions are from July 2004.

As part of the contingency plan for ISA the NFSA has prepared procedures for withdrawal of fish in farms infected with ISA. Following an application from Norway, and after having assessed the scheme in close co-operation with the European Commission, the Authority, by its Decision No 226/04/COL of 9 September 2004 approved the Norwegian scheme for withdrawal of all fish in Norwegian farms infected with ISA.

7.3.4 Vaccination

In the reply to the pre-mission questionnaire the NFSA informed that, according to the Norwegian *Regulation of 20 December 1999 No 1310 relating to vaccination of domestic animals, wildlife, fish and other animals*, vaccination against List A and List B diseases is not allowed and vaccination against diseases on List I and List II in Annex A to Council Directive 91/67/EEC is not taking place.

Furthermore, vaccination against diseases not classified as List A or List B diseases is only allowed when the Norwegian Medicine Agency has granted an exemption for the relevant vaccine and an application for the use of the vaccine has been approved by the NFSA. Vaccination against the fish diseases furunculosis and infectious pancreatic necrosis (IPN) (List B diseases in Norway) is allowed when these conditions are fulfilled.

In the reply to the pre-mission questionnaire the NFSA also stated that vaccination of farmed Atlantic salmon in Norway against the diseases furunculosis, vibriosis and cold water vibriosis has been of great importance for the control of these diseases. Almost all farmed Atlantic salmon in Norway is vaccinated against furunculosis.

7.3.5 Routine animal health controls

During the mission representatives of the NFSA informed the mission team that within at least one region it has been agreed to have revisions of farms every three years. However, this has not been harmonised on a national level.[30]

In the region visited it was observed that the RO had not formalised procedures for verification of the monitoring of the aquaculture farms carried out by the DOs. However, the RO is comparing the DOs' annual plans and reports in order to check whether the goals have been achieved.

[30] *See "Footnote 30" of Annex 1.*

According to the reply to the pre-mission questionnaire checklists for use during routine animal health controls were prepared and used by the DVOs of the SDT. However, following the establishment of the NFSA, these checklists have not been used and checklists based on the current legislation are still to be prepared.[31]

Since 1 January 2005, all visits to farms and establishments by the DO shall be documented. Reports etc. are normally issued after the visits and sent to the farms and the establishments.

The DOs plan their inspections based on a programme from the RO. In the two districts visited the representatives of the NFSA informed the mission team that reports are always issued when aquaculture farms are inspected. The reports are normally issued after the visits and sent to the farms. Since it is impossible to take samples without assistance from farm representatives, visits are normally notified a few days in beforehand. Visits for taking samples as part of the IHN and VHS programme can be notified up to one month in advance.

During the inspections on farms the inspectors of the DOs also check the work carried out by the local fish health service. In one of the districts visited, a representative of the DO provided details on two cases of improper follow-up of increased mortality. In one case the farm had not notified the fish health service and in the other case, the fish health service had taken samples for laboratory analyses, but not notified the DO.

Representatives of the NFSA also informed the mission team of the obligations on the owners of the farms to report mortality, feeding, growth, temperature etc. to the FIDIR. The information is sent electronically to a database administered by the FIDIR, but accessible for the staff of the NFSA.[32]

7.3.6 Economic compensation

In the reply to the Authority's pre-mission questionnaire, the NFSA stated that related to aquatic animals, financial losses following actions in accordance with the legislation in force are not to be compensated by the Norwegian Authorities. This is also regulated in the *Regulation of 4 July 1991 No 509 relating to prevention, control and eradication of diseases in aquatic organisms*. In Article 16 of that Regulation it is stated that "[e]conomic losses due to measures imposed according to these regulations are not compensated by the authorities."

7.3.7 Monitoring programmes

According to information provided as a reply to the pre-mission questionnaire, Norway has five monitoring programmes related to aquatic animals. In addition to the surveillance programme for bonamiosis and marteiliosis in European flat oysters, one programme is related to surveillance and control of the nematode *Anguillicola* spp. in eel, one programme is related to surveillance and control of VNN in halibut, turbot and cod, and one programme related to *Gyrodactylus salaries* in Atlantic salmon.

[31] *See "Footnote 31" of Annex 1.*
[32] *See "Footnote 32" of Annex 1.*

While *Gyrodactylus salaries* was first observed in Norway in *1975*, the current programme started in 2000. In addition to the surveillance programme, actions have been taken to eradicate the parasite from rivers and fish farms. By January 2005 *Gyrodactylus salaris* had known occurrence in 19 rivers, while 11 rivers were under observation after treatment. A total of 15 rivers have been declared free of the parasite after treatment with Rotenone.

7.4 Monitoring of IHN and VHS

After the establishment of the NFSA, it has been the responsibility of the NFSC in Bergen to co-ordinate the monitoring programme and to prepare the instruction for the programme. The instruction must be approved by the HO.

According to the programme, all farms shall be inspected at least once a year. However, broodstock farms shall be inspected at least twice a year. It is the responsibility of the ROs to prepare a sampling plan for each region. Samples are taken during inspection on the farms by inspectors from the DO. Samples are taken from 50% of the locations every year in order to ensure that during a two year period (approximately one production cycle) samples shall have been taken from all locations. All samples taken as part of the surveillance programme for IHN and VHS are analysed at the NVI in Oslo.

The mission team observed that results from the viral examination were neither communicated directly to the DOs, nor to the fish farms, but distributed through monthly reports to the ROs.[33]

During the mission the surveillance programme was explained in detail. The mission team did not observe discrepancies between Commission Decision 2001/183/EEC and the inspections and sampling carried out.

7.5 Measures taken by the NFSA to control ISA

7.5.1 General observations to the outbreaks in 2003, 2004 and 2005

During the mission the NFSA provided information on the outbreaks in 2003, 2004 and 2005. A total of 7 outbreaks of ISA were verified during 2003[34], but information was provided for 6 of these outbreaks. In addition, for two of the outbreaks information related to dates for sampling, confirmation of diagnosis, initiation of slaughter and the date for completion of destruction/slaughter was not made available to the mission team. For all outbreaks increased mortality had been observed in periods prior to the first sampling for ISA analyses. In one case it took approximately eight months from the first samples analysed for ISA had been taken until the location was empty. For two other outbreaks the slaughtering was finalised within 80 working days.

For the three outbreaks where the relevant information was available, it took 14, 8 and 6 days, respectively, from the first samples were collected and until the diagnosis was confirmed. In one of the outbreaks restrictions were put on the location seven days before the first ISA sample was taken, while in another outbreak restrictions were put on the location at the same time as the first samples were taken. In two other outbreaks restrictions were put on the locations seven and 15 days, respectively, after the first targeted samplings.

[33] *See "Footnote 33" of Annex 1.*
[34] *See "Footnote 34" of Annex 1.*

The mission team received information for 15 of the outbreaks in 2004. However, the information was incomplete for three of the outbreaks. For two of the outbreaks in 2004 the ISA diagnosis was received at the HO approximately two weeks after they had been confirmed.

In a report from the NVI (*Summary of epidemiological reports regarding outbreaks of ISA in Norway 2004*) it is stated that "[r]eports from locations where ISA has been verified, demonstrate that the disease may appear with acute symptoms or after a prolonged period of (moderately) increased mortality due to various specific or non-specific problems. ISA may appear alone or in combination with other diseases. The clinical picture is complex, and it is currently impossible to tell how long the infection has been present on the site before the ISA suspicion occurs."

For the last four outbreaks in the autumn of 2004 slaughtering was initiated almost on the same day as ISA was confirmed. However, for five of the outbreaks in 2004 slaughtering had been initiated from six days up to more than two months after the diagnosis had been confirmed. Furthermore, for seven of the outbreaks slaughtering was finalised within 80 days, but for two outbreaks it took approximately 95 days from the verified diagnosis until the locations were empty.

For five of the outbreaks in 2005, the information provided by the NFSA was insufficient. The information also indicates that for four of the outbreaks, the ISA diagnoses were received at the HO between three and 13 days after they had been confirmed. In three of the outbreaks information on the date when restrictions were put on the farm was not available. For one of the other outbreaks restrictions were put on the farm at the same time as samples for ISA analyses were taken. In three outbreaks restrictions were put on the farm between five and 12 days after the first ISA samples were collected. In two other cases, samples for ISA analyses were taken six and 39 days, respectively, after restrictions had been put on the locations.

For the outbreaks in 2005, where information was made available to the mission team, the time from confirmation of diagnosis until start-up of slaughtering was maximum five days.

7.5.2 Measures taken in case of suspicion

During the mission the NFSA's application of the ISA contingency plan during the first outbreak of ISA this year was assessed. The mission team observed that, although not fully functioning, local and regional diseases control centres had been established. However, at the HO the establishment of a national crisis centre could not be demonstrated. The documentation of co-ordination of the control measures on a national level and documentation of action taken were insufficient, and the involvement by the management of the HO was not evident.

The majority of the communication between the NFSA and the NRL were observed to be between the DOs and the laboratory. Information related to laboratory findings for single samples were often distributed by several e-mails to the DOs with copies to RO and HO. Confirmation on receipt of e-mails was documented in one case. Furthermore, communication of results varied from case to case.

Standardised procedures for communication or a clear chain of information could not be demonstrated. A number of activities and actions, in particular related to phone calls, e-mails and meetings could not be documented.

However, at one of the DOs visited representatives of the NFSA informed the mission team that the case handling programme available was used for documentation of tasks performed, including minutes and notes from telephone conversations and e-mail correspondence. Copies of registrations documenting the use of the system were provided.

On 4 March 2005 the HO was notified by the RO and the NRL of the suspicion of presence of ISA in the samples taken on 24 February. Confirmation of the receipt of the notification could not be documented. However, representatives of the NFSA informed the mission team that routines for such confirmation and also for filing of e-mails were not included in their procedures. Upon receipt of the notification information was filed in as separate case, and the Ministry of Fisheries and a particular "fish group" was notified of the suspicion. Information was also placed on the NFSA's website.

In the period between the notification of suspicion and 10 March 2005, when the HO was notified of the confirmed presence of ISA, the HO was in contact with the NRL and with the RO. However, this activity could not be documented.

The DO notified the RO both by phone and by e-mail on 28 February 2005 of the suspicion of ISA in one farm. At the RO the head of the department for disease control and the fish specialist had a meeting in which the information from the DO was discussed. However, minutes from that meeting were not available. Due to the staff situation at the DO in the district where the suspected farm was located, the RO established contact with the neighbouring DO, and it was agreed that staff from this DO should provide the necessary competence to handle the possible outbreak.[35]

On 3 March preliminary restrictions were put on the farm in question and four other farms in the same area. Preliminary information on the contact with the farm in question was sent to the RO.

7.5.3 Measures taken in case of confirmation

Following the notification from the RO and the NRL to the HO of the confirmed outbreak of ISA, the HO notified the Authority, the European Commission and the EU Member States via the Animal Disease Notification System (ADNS), and the OIE.

During the spring of 2005 the HO held one meeting to discuss the situation with regard to ISA in Norway, and in particular about two outbreaks in a region that had been free from the disease for several years. Minutes from that meeting were not available.

On 9 March 2005 the DO notified the RO by e-mail of the confirmed presence of ISA on the farm. The same day the representatives of the farm were also notified (orally) of the confirmed presence of ISA. Although the RO did not confirm to the DO that the information had been received, such procedure is included in the RO's administrative safeguard plan. However, the same day the RO sent a letter to the HO with a copy to the DO, notifying the HO of the confirmed presence of ISA on the farm.

[35] *See "Footnote 35" of Annex 1.*

On *11* March 2005 the RO and the DO arranged a meeting where further action was discussed. In addition to representatives of the RO and the DO, representatives of two other DOs, the local fish health service and the farm were present. The permanent restrictions on the farm were confirmed on 17 March 2005. Following confirmations of ISA, the HO adopts Regulations containing detailed requirements on actions in the control zones and in the surveillance zones. For this outbreak such a Regulation was adopted on 17 March 2005.

Late April 2005 a second outbreak of ISA was confirmed within the eradication zone. This did not trigger any extra action at the RO. However, the mission team observed that, although the second farm was included in the eradication zone established in the beginning of March, samples were not taken at the second farm before 12 April 2005.

7.5.4 Disposal of fish in infected farms[36]

In the Norwegian regulation on establishment of aquaculture farms it is required that all locations shall have an emergency plan containing, *inter alia*, details for slaughtering of infected fish, including agreements with well boats and slaughterhouses. Guidelines for the NFSA's assessment of the applications are in the process of being finalised and it is foreseen that they will be applied as of the autumn of 2005.

All locations with infected fish must have a plan for slaughtering and hygiene approved by the DO before slaughtering can commence. As part of the plan for the location visited, the mission team observed that the well boat used for transport of infected fish had to use a particular route between the location and the slaughterhouse.

The mission team observed that the boat had not been inspected more than twice by the DO in approximately three months. Furthermore, it could not be documented that the inspection frequencies and routine surveillance of movement, transport and slaughtering of infected fish could ensure that the activity was in compliance with the plan approved by the DO.

7.5.5 Disinfection, fallowing and repopulation of farms

In the farm visited the cage where the fish with symptoms had been kept was, at the time of the visit, still not taken out for disinfection.

Fallowing of any of the locations comprised by the first outbreak in 2005 was still to be initiated.

It was observed that nets from cages with infected fish were not removed, washed and disinfected after destruction of the infected fish. These findings/non-compliances were documented in a report from the DO to the farm. However, any additional follow-up by the DO was not evident.

7.5.6 Epizootic investigation

Before the establishment of the NFSA, the regional veterinary officer (RVO) of the SDT was responsible for carrying out epizootic investigations based on information provided

[36] *See "Footnote 36" of Annex 1.*

by the DVOs. Guidelines for the DVOs and RVOs were established, but applied to a variable extent.

Procedures for the DOs and the ROs of the NFSA have been established and applied since February 2005. The carrying out of epizootic investigations is the responsibility of the ROs. However, it is the DOs that are carrying out the investigations.

In one of the districts visited the mission team observed that the epizootic investigation was incomplete. At the regional office visited it was not evident that the investigations were followed-up and involvement of the HO could not be documented. Evidence of sampling as part of the epizootic investigation was not provided.

However, representatives of the NFSA informed the mission team that together with the NVI the NFSA had initiated, in the spring of 2005, both a project on evaluation of the strategy and the plan for eradication of ISA in Norway. An epidemiological investigation was also part of this project.

At the time of the visit a report based on the information made available to the NVI had been prepared for the outbreaks in 2003 and 2004. In addition, the NFSA and the NVI had prepared a checklist to be used by the DOs during their investigations.

The project should be finalised before the summer of 2005. However, at the time of the mission any other information than the reports from the outbreaks in 2003 and 2004 were not available.

7.6 Aquaculture farms, well boat and establishment visited[37]

The aquaculture farm visited seemed well organised, clean and tidy. The information registered regarding movements into and out of the different locations was not easily accessible. However, the necessary information seemed to have been registered.

It was observed that the plan for slaughtering and hygiene in the farm visited, was incomplete with regard to, *inter alia*, details related to slaughtering of fish and procedures and methods for disinfection of equipment.

The well boat visited was six years old, well maintained, clean and tidy. A detailed captain's logbook was provided. Chloride and Virkon S was used as disinfectant. However, the efficiency of the chloride concentration used for disinfection of pipes and pumps (300 g chloride per 80 m^3 seawater) could not be documented. Furthermore, the efficiency of this disinfection had not been addressed by the DO.

The slaughterhouse visited was approved according to Council Directive 91/493/EEC. In addition, the system of handling of waste water had been approved by the NVI.

Although not part of the scope of the mission it should be mentioned that during the visit to the slaughterhouse the mission team observed several deficiencies related to Council Directive 91/493/EEC. This was pointed out to the DO representative, which informed the mission team that the DO was aware of the situation, and that it was agreed with

[37] *See "Footnote 37" of Annex 1.*

representatives of the establishment that when the slaughtering of the fish from ISA infected locations had been finalised, extensive maintenance would be initiated.

8 Final meeting[38]

A final meeting was held on Friday 1 July 2005 at the HO of the NFSA in Oslo with representatives from the MFCA, the NFSA and from the NRL. At this meeting the mission team orally presented the main findings and some preliminary conclusions of the mission.

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

The Norwegian representatives took note of the findings and the preliminary conclusions presented. The representatives of the NFSA did not indicate any major disagreement with the main findings and the preliminary conclusions presented. The CA also provided some additional information for clarification. This information has been taken into account in the report.

9 Conclusions

9.1 Application of Council Directive 91/67/EEC[39]

Compliance with Council Directive 91/67/EEC, and in particular Annex A thereof, and Council Directive 93/53/EEC, and in particular Chapter II thereof, could not be assured, since ISA is not considered as a List I disease in Norway.

9.2 Contingency plan[40]

The contingency plan was not in full compliance with Council Directive 93/53/EEC, and in particular Article 15 and Annex D thereof, *inter alia*, since requirements on the establishment and operation of a national crisis centre were missing.

9.3 National crisis centre[41]

Full compliance with Council Directive 93/53/EEC, and in particular Article 8(4), Article 15 and Point 1 of Annex D thereof could not be assured, since, *inter alia*, the co-ordination of the control measures on a national level was not evident.

9.4 Epizootic investigation

Full compliance with Council Directive 93/53/EEC, and in particular Article 5(2)(h), Article 6(a) and Annex D thereof could not be assured, since the epizootic investigations were not sufficiently carried out or followed up.

[38] *See "Footnote 38" of Annex 1.*
[39] *See "Footnote 39" of Annex 1.*
[40] *See "Footnote 40" of Annex 1.*
[41] *See "Footnote 40" of Annex 1.*

9.5 Measures in case of outbreaks of ISA

The measures taken in case of confirmed outbreaks of ISA, including, *inter alia*, destruction or slaughtering of fish from infected farms, disinfection of cages and materials, and increased surveillance, were not always fully complying with Council Directive 93/53/EEC, and in particular Article 5(1) and Article 6(a) thereof.

9.6 Laboratories

The laboratories were mostly in compliance with Directive 93/53/EEC and in particular Article 12 thereof. However, discrepancies were observed, *inter alia*, incomplete SOPs and/or the insufficient application of established SOPs.

10 Recommendations to the Norwegian Competent Authority

10.1 Notification of corrective action and a plan for completion of measures

Norway should notify to the Authority within two months after receiving the final report, written evidence of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding at that time, relevant to all the conclusions under Chapter 9 of this report. The Authority should also be kept informed of the completion of the measures included in the timetable.

10.2 Competent Authority

The NFSA should ensure that a sufficient number of staff is available and with relevant competence enabling the CA to take all the necessary actions foreseen in Directive 93/53/EEC in case of outbreaks of ISA.[42]

The NFSA should take the actions necessary to ensure an optimal involvement (both related to competence and communication) by the NRL in the handling of outbreaks of ISA.

Furthermore, wherever relevant, procedures for documentation should be improved in order to facilitate the handling of outbreaks of ISA and eradication of the disease.

10.3 Infectious salmon anaemia

The NFSA should take the necessary action to make sure that outbreaks of ISA in Norway are handled as a List I disease, as foreseen in Directive 91/67/EEC and Directive 93/53/EEC.

10.4 Laboratories

All necessary action related to establishment and application of systems and procedures should be taken in order to improve the laboratories' (both the NRL and other laboratories involved in analyses of samples from the aquaculture industry) documentation of handling of samples in general and related to ISA in particular.

[42] *See "Footnote 9" of Annex I.*

Annex 1 The Norwegian Food Safety Authority's comments to the draft report

Comments to the factual content or other elements of the draft report

1 Introduction
Third paragraph
The mission team were accompanied by two (not one) representatives from the head office of the NFSA and one (not two) from the Regional Office.

5 National legislation, paragraph one and three
Act of 19 December 2003 No 124 relating to Food Safety and Plant and Animal Health is to be named the Food Act, not the Food Law.

6.5 Aquaculture production in Norway
Five establishments (not four) are approved according to Directive 90/667/EEC for handling high risk materials while four (not two) establishments are approved for handling low risk materials. This information is also available in the revised answer to the Pre-mission questionnaire sent to the Authority 7 July 2005.

Footnote 9

7.1.4 Regional Office visited – sixth paragraph,
7.1.5 Districts offices visited – second paragraph and
10.2 Competent Authority- first paragraph
All the above mentioned paragraphs regard budgetary allocations. We would like to emphasize that possible non- compliances in our opinion are not due to the budgetary situation for 2005. On the contrary; in despite of the budgetary situation for 2005 the NFSA has, on a general basis, improved the follow-up of ISA, in our opinion.

Footnote 10

7.1.5 District Offices visited
First paragraph
Only one of the two DOs visited had outbreaks of ISA in 2005, but the observation zone reaches in to the other DOs area.

Footnote 12

Last paragraph
In case a DO does not have adequate facilities, they will cooperate with neighbouring DOs to ensure rapid and effective eradication of an outbreak of a contagious disease.

7.2 Laboratory services
The NFSA has invited The National Veterinary Institute to comment on the draft report number 7.2 and its comments are as follows:

General: The English name of the laboratory is the National Veterinary Institute, abbreviated NVI.

7.2.1 General information
1. Paragraph: The NVI is a governmental agency owned by the MAF and funded by the MAF, the MCFA and the Research Council of Norway.

Footnote 13

Comment: In connection with the establishment of the NFSA, this institution also contributes with some basic funding of NVI for a limited period of time. However, in the future all funding from the NFSA will be connected to contract work.

Footnote 14

Page 13, 2 paragraph (and page 14, second paragraph under **7.3.2**): Diagnostic work is based on anamnestic information, evaluation of clinical signs and pathological changes, and analyses for microorganisms etc. The investigational character of this work involves evaluations, decision-making regarding following steps in the examination, and modifications of standard procedures due to variation in quality of diagnostic material and preliminary findings in early stages of the diagnostic process. These characteristics of diagnostic work limits the possibilities of accreditation of the analyses involved. However, a process aiming at the accreditation of analyses which are suitable will be initiated this autumn (2005). This process will also include the implementation of the general quality assurance program of the NVI. (Comment page 14, **7.2.3** 2. paragraph).

Footnote 15

7.2.2 Division of tasks between the regional laboratories and the central laboratory

1 paragraph: The central laboratory is the “regional laboratory” even for the Agder-counties and the eastern part of Norway.

Footnote 16

Page 14, end of second paragraph: We would like to underline, that in both the examples given by the mission team, the DO of NFSA in the relevant district was notified, in one case directly, in the other by receiving copy of the outgoing letter. In general, the outgoing letters with the results of the analyses and conclusions from diagnostic investigations are addressed to the person or organisation submitting the samples, in many cases the DO, if the material is submitted in connection with the suspicion of a modifiable disease. If others (i.e. local fish health services or regional laboratories of the NVI) have submitted the samples, and notifiable diseases are suspected or diagnosed, copies of outgoing letters are sent to the relevant level of NFSA. Hence, it is crucial to distinguish between notification and report to submitter.

Copies of outgoing letters are also sent to the relevant regional laboratory of NVI when samples originating from their region have been analysed at the central

laboratory. The central laboratory may receive samples directly from other counties than those served directly, when this is wanted either in the field or at the otherwise relevant regional laboratory. The central laboratory has a supportive function to all the regional laboratories. If samples are received by the regional laboratories and forwarded to the central laboratory for specific analyses or diagnostic investigations, the regional laboratory will be the submitter of the final outgoing letter. This may explain deviations pointed at by the mission team.

7.2.3 The National Reference Laboratory for fish diseases
2 paragraph, last sentence: Comments have been given earlier.

Footnote 18

4 paragraph: Side 14 (7.2.3), 6 paragraph: It is the SFH that is responsible for the receipt and registration of incoming samples to the central laboratory.

It has been considered sufficient to note deviations from the normal for incoming samples. To note normality is redundant, and can not be applied in general, only on. However, a check box for control of critical points will be added on our main journal to ensure compliance. The person responsible for the check is clearly identifiable to the top left on our main journal print outs. It is not written by hand, but an active input in our PJS is required, rendering the computer file and date the basis of traceability. The main journal will in the future also be signed and dated by hand.

Footnote 19

5 paragraph and last sentence paragraph 7, two first sentences paragraph 9: The laboratory described is where both the IF and IHC tests originate. The notes are done in the same way as during the development of the tests. All information is available to the scientists, but in a format never intended for external documentation. Thus the worksheet for noting IF results may only quote pos/neg controls, while these specimens themselves have full traceability through a journal number. The individual reagent tubes may not be labelled in full, but are kept in a system of boxes with overview of content. The quality/acceptance criteria for IF are described in detail in a course document distributed along with specimen examples to all the regional laboratories (and are available upon request). The course is based upon experiences with approximately 2200 specimens from all ISA outbreaks and numerous differential diagnostic investigations from 1997-2001. In our disease diagnostics, the IF and IHC tests have been continuously under evaluation using all other available information from the clinical, pathological, bacteriological and virological-investigations performed. The procedures for the tests are under revision to achieve external documentation for audits.

Footnote 21

7 paragraph: The IHC procedure shown was the original used when the test was developed. There is an official version of this procedure which has been distributed to the regional laboratories using the method. However, this version is still to be

finalized in our QA system. It is available, also to the ESA, on request. It was not asked for during the visit and was thus not given.

Footnote 22

8 paragraph: Histology is always carried out, the descriptions are available in our computer file system, the sections and blocks are archived and available for retesting. The written report is made available as soon as possible. Delays may be due to complex disease conditions where additional work is done and the information already given is sufficient for a definitive, official diagnosis.

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9 paragraph: Comments regarding final letters from regional laboratories has been given previously.

Footnote 24

10 paragraph: A system for filing and following up ring tests is described in the VI QA manual and will be followed for future tests. The tests participated in were only filed as ordinary submissions in the PJS system, and thus not specifically documented as ring tests.

Footnote 25

Last paragraph: It was commented that the results of the annual profiency test organised by the CRL had not been followed up. However, this will be implemented as soon as possible.

Footnote 26

7.3.1 Licencing of aquaculture farms

The number of licences is as follows:

Total number of:

Licenses for the production of salmon and trout:

Ongrowing licenses: Total 967, active 919[1]
Broodstock licenses: 27[1]
Hatcheries licenses: Total 270, active 202[2]

Approved aquaculture farms for the production of salmon and trout:

Ongrowing farms: 1300[3]
Broodstock farms: 90[3]
Hatcheries: 202[2]

Approved aquaculture farms for salmon and trout *with fish*:

[1] Fiskeridirektoratets konsesjonsregister, pr. juni 2005
[2] Fiskeridirektoratets statistikk for oppdrett, 2004
[3] Fiskeridirektoratets lokalitetsregister, pr. juni 2005

Ongrowing farms: 863[4]
Broodstock farms: 80[4]
Hatcheries: 202[2]

	Other fish species (31.12.04)	Shell species (31.12.04)
1.1.1. Broodstock licences [5]		
1.1.2. Hatcheries[6]		
1.1.3. Ongrowing farms	745[7]	916[8]

This information is also available in the revised answer to the Pre-mission questionnaire sent to the Authority 7 July 2005.

It seems to still bee some misunderstanding concerning routines for licensing and approval of aquaculture farms.

The production of salmon and rainbow trout on a national level is, among other things, regulated through limited number of licenses. A license ("konsesjon") for production of salmon and rainbow trout in sea contains restrictions on the amount of live fish to be kept at any given time, normally 780 metric tons, independent of production cycle.

Due to the production cycle and regularly fallowing, each license for production of salmon and rainbow trout is often designated to more than one aquaculture farm (location), normally two or three. All aquaculture farms designated to the same license are specified in the license with a unique number, geographical position and maximum allowed biomass for each aquaculture farm. On each aquaculture farm there might be several license holders ("konsesjonsinnehavere"), maximum 6 license holders. License holders on the same aquaculture farm are often owned by the same company. When there is more than one license holder on the same aquaculture farm, identical licenses are issued to each license holder.

In order to simplify the process for the user, FIDIR is co-ordinating the process for assessment of applications, and the issuing of licenses. Please note that all establishment and enlargement of aquaculture farms has to be approved the relevant DO of the NFSA. Approval issued by DO is an absolute condition for issuing of license by FIDIR.

In case of violation of conditions for approval issued by DO, or rules or regulations in pursuance of the Food Law, the DO of the NFSA has independent authority to withdraw approval of aquaculture farm. Since approval issued by DO is an absolute

[4] Anistat, april 2005
[5] The number of broodstock farms is not specified in the statistical rapports for 2003.
[6] The number of hatcheries is not specified for other species than salmon and rainbow trout.
[7] All licences including those for broodstock farms and hatcheries.
[8] All licences including those for broodstock farms and hatcheries.

condition for the license issued by FIDIR, the license issued by FIDIR becomes invalid if approval issued by DO is withdrawn. In practise the DO of the NFSA and FIDIR would coordinate their decisions.

The approval of each aquaculture farm also contains restrictions on the amount of live fish to be kept at any given time, but there might be several license holders on the same farm. 1560 – 2340 metric tons are common sizes on aquaculture farms.

The number of licenses for production of other species than salmon and rainbow trout are not limited in the same way on a national basis. Each license is designated to one approved aquaculture farm with restrictions on the amount of live fish to be kept at any given time. Licenses for production of marine fish species are often smaller than 780 metric tons.

All approved farms are also registered in a register administrated by the NFSA.

Footnote 29

7.3.2 Approval of slaughterhouses and incineration plants

HO of the NFSA will contact VI in Oslo in order to survey the situation and status regarding the capacity for evaluation and approval of methods for treatment of effluent water. Actions will be considered depending on the result of the survey.

Footnote 30

7.3.5 Routine animal health controls

First paragraph

The frequency of revision of farms is now harmonised on a national level, cf. letter dated 29.6.2005 from HO of the NFSA addressed to RO. The aim is to have annual revisions of 20 % of the license holders for production of salmon and rainbow trout.

Footnote 31

Third paragraph

NFSA and FIDIR have in cooperation, and in order to make sure that the system is flexible, decided not to establish detailed checklist for use during audits. The written procedure concerning audits of farms gives the audit team the possibilities of making their own checklist depending on the issue of the audit.

Footnote 32

Seventh paragraph

When report on mortality, feeding, growth, temperature, etc. is sent electronically it is also sent electronically to a database administered by the NFSA. The owners of the farms may also send report manually. To simplify reporting routines for the farmer, manual reports are sent to the FIDIR. FIDIR must forward copy of the report to relevant DO of the NFSA, cf. “Merknader til Forskrift 22. desember 2004 nr. 1785 om drift av akvakulturanlegg” paragraph 40.

7.3.6 Monitoring programmes – second paragraph
Gyrodactylus salaries was first observed in Norway in 1975, not 1995.

Footnote 33

7.4 Monitoring of IHN and VHS – third paragraph
It is important to emphasise that **negative** results from viral examinations are only distributed to the DOs and fish farmers once a month. All positive results are reported immediately to the NFSA and the fish farmer.

Footnote 34

7.5 Measures taken by the NFSA to control ISA
The NFSA officially operates with six verified outbreaks of ISA in 2003.

Footnote 35

7.5.2 Measures taken in case of suspicion – paragraph seven
The reason for involving the neighbouring DO was that the DO had no practical experience with an ISA-outbreak. There have been few disease-problems in this district the last years. However, the personnel have adequate theoretical experience. To make it clear that the neighbouring DOs involvement only was of supportive character and that the outbreak was handled by the DO where the outbreak occurred, the text in paragraph seven, last sentence, should be adjusted.

7.5.3 Measures taken in case of confirmation
The meeting mentioned in fourth paragraph was held on 11. March 2005.

Footnote 36

7.5.4 Disposal of fish in infected farms
Emergency plan is required when approval of aquaculture farm is applied for. It is also required in “Forskrift 22. desember 2004 nr. 1785 om drift av akvakulturanlegg”, cf. Paragraph 7. However, applications for approval of the emergency plan it self is not required. Further guidelines for the content of emergency plans are given in “Merknader til Forskrift 22. desember 2004 nr. 1785 om drift av akvakulturanlegg” paragraph 7. These guidelines will, as of the autumn of 2005, also be included in the existing “Veileder til forskrift 16.1.2004 nr. 279 om godkjenning av etablering og utvidelse av akvakulturanlegg og registrering av pryddammer”.

Footnote 37

7.6 Aquaculture farms, well boat and establishment visited
Guidelines for transport of aquaculture animals, including cleaning and disinfection of transport means, was applied 17.6.2005, cf. enclosure. Choice of disinfectants is mentioned in these guidelines, cf. section 4.1. This will be followed up by the HO in meeting with the RO by autumn 2005.

Footnote 38

8 Final meeting

The representatives of the NFSA did not indicate any major disagreement with the main findings and the preliminary conclusions mentioned. However, one representative underlined that answers to direct questions about budgetary allocations on a general basis should be assessed in a balanced way, due to general difficulties with exact calculations in this area and due to the fact that most organisations will overestimate rather than underestimate their workload and the budgetary allocations needed.

Footnote 39

9.1 Application of Council Directive 91/67/EEC

Even though ISA is in list B in the Norwegian legislation the disease is treated as a list I disease according to Directive 91/67/EEC. The listing is a result of how often ISA occurs and not the degree of the measures taken to control and eradicate the disease.

The conclusion concerning application of Council Directive 91/67/EEC seems to have been drawn based on listing and not how Norway deals with an ISA outbreak. The main question is whether outbreaks of ISA is handled according to *the approved scheme submitted by Norway for withdrawal of all fish in Norwegian farms infected with infectious salmon anaemia (ISA)* or not. There are no indications in the conclusion that the disease is not handled according to the scheme, thus compliance with Council Directive 91/67/EEC and Council Directive 93/53/EEC should be assured.

Footnote 40

9.2 Contingency plan and 9.3 National crisis centre

The NFSA define crisis unit as being the line of command from the HO through the RO to the DO. All activity connected to an outbreak is coordinated at the HO according to an action plan of which the inspection team has received a copy. We therefore disagree to the conclusion that a national crisis centre is missing.

Annex 2 The Norwegian Food Safety Authority's comments to the draft report

Actions already taken in response to recommendations from the EFTA Surveillance Authority

7.2 Laboratory services

7.2.1 General information

The annex to the signed agreement on co-operation between the NVI and the NFSA which was not finalised at the time of the inspection is now completed.