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Final report

EFTA Surveillance Authority mission to

ICELAND

27 – 30 September 2004

regarding the application of EEA legislation related to measures for the control of certain fish diseases, and related to health conditions for the production and the placing on the market of fishery products

Comments from the Icelandic Competent Authorities to the content of the report have been included in *underlined italic*. The comments are also annexed to the report. Additional general information on action already taken has also been annexed to the report. However, detailed information on action already taken, which identifies the establishments visited, has not been included in the report.

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List of abbreviations and terms used in the report

AMAP	Arctic Monitoring and Assessment Programme of the Nordic Council of Ministers
Authority	EFTA Surveillance Authority
BKD	Bacterial Kidney Disease
CA	Competent Authority
CCP	Critical Control Point
CVO	Chief Veterinary Officer of the Chief Veterinary Office
CRL	Community Reference Laboratory
DFVF	Danish Institute for Food and Veterinary Research, Århus, Denmark.
DG SANCO	Health and Consumer Protection Directorate General of the European Commission
DVO	District Veterinary Officer
EC	European Community
EEA Agreement	Agreement on the European Economic Area
EFA	Environment and Food Agency of Iceland/Umhverfisstofnun
Fiskistofa	Directorate of Fisheries
FVO	Food and Veterinary Office of DG SANCO
HACCP	Hazard Analysis and Critical Control Points
IB	Inspection Body/Skoðunarstofa
IFL	Icelandic Fisheries Laboratories/Rannsóknastofnun Fiskiðnaðarins
IHN	Infectious Haematopoietic Necrosis
IHNV	Infectious Haematopoietic Necrosis Virus
IPN	Infectious Pancreatic Necrosis
IPNV	Infectious Pancreatic Necrosis Virus
ISA	Infectious Salmon Anaemia
ISAV	Infectious Salmon Anaemia Virus
Keldur	Institute for Experimental Pathology of the University of Iceland at Keldur/ Tilraunastöð H.Í. Í meinafræði, Keldur
Löggildingarstofa	Icelandic Accreditation Body
NNV	Nervous Necrosis Virus
NRL	National Reference Laboratory
OIE	World Organisation for Animal Health
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
OV	Official Veterinarian for fish diseases
SOP	Standard of Operational Procedures
Surveillance and Court Agreement	Agreement Between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice
SWEDAC	The Swedish Board for Accreditation and Conformity Assessment
VHS	Viral Haemorrhagic Septicaemia
VHSV	Viral Haemorrhagic Septicaemia Virus
Veterinærinstituttet	Norwegian National Veterinary Institute, Oslo, Norway

1 Introduction

The mission took place in Iceland from 27 to 30 September 2004. The inspection team comprised 2 inspectors from the EFTA Surveillance Authority (the Authority), and one inspector from the Food and Veterinary Office (FVO) of the Health and Consumer Protection Directorate General (DG SANCO) of the European Commission, participating as an observer.

An opening meeting was held on Monday 27 September 2004 at the Icelandic Directorate of Fisheries (Fiskistofa). At this meeting representatives of the relevant Icelandic Ministries and Competent Authorities (CAs) added information to their reply to the Authority's pre-mission questionnaire. Throughout the mission two representatives from Fiskistofa accompanied the inspection team. An inspector from the relevant Inspection Body (IB) participated in two of the three establishments visited. The Official Veterinarian for fish diseases (OV) participated during the visit to the National Reference Laboratory (NRL) and to the aquaculture farm visited.

A final meeting was held at Fiskistofa on 30 September 2004 at which the inspection team orally presented the main findings and some preliminary conclusions from the mission.

2 Objectives of the mission

The main objectives of the mission was to assess the Icelandic CAs application of the requirements laid down in Council Directive 91/493/EC, Council Directive 93/53/EEC and related legislation (see Chapter 3 and 4).

A particular focus was put on the CAs' follow-up of findings during the last missions in this field, the control and monitoring of the relevant fish diseases, the functionality of the NRL and official inspections of fishery products establishments.

The meetings with the CAs and the different establishments and laboratories visited during the mission are listed in Figure 1.

Figure 1: Competent Authorities, laboratories and establishments visited during the mission

		Comments
Competent Authorities	4	Central level (incl. the opening and closing meeting)
National Reference Laboratory	1	Designated as the national reference laboratory for certain fish diseases
Fish farms	1	Smolt and ongrowing farm
Establishments	3	Processing of fishery products, two also processing farmed fish

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) The Act referred to at Point 6.1.7 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, and in particular Article 8 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*.

It should be noted that, although incorporated into the EEA Agreement, this Decision has not been made applicable to Iceland.

4 Other relevant legislation

The main European Community (EC) Acts in the field of live aquaculture animals and production of fishery products incorporated into the EEA Agreement and applicable to Iceland are:

a) 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.

b) *EFTA Surveillance Authority Decision No 227/04/COL of 9 September 2004 concerning the status of Iceland with regard to the fish diseases viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN*).

c) The Act referred to at Point 6.1.9 of Chapter I of Annex I to the EEA Agreement, *Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC.*

d) The Act referred to at Point 18 of Chapter XII of Annex II to the EEA Agreement, *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs*.

e) The Act referred to at Point 7a of Chapter II 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.*

f) The Act referred to at Point 6.2.47 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2003/774/EC of 30 October 2003 approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods.*

g) The Act referred to at Point 6.2.13 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 93/51/EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish.*

h) The Act referred to at Point 6.2.14 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 94/140/EC of 19 January 1993 laying down the detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products*.

i) The Act referred to at Point 6.2.21 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 94/356/EC of 20 May 1994 laying down the detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products.*

j) The Act referred to at Point 6.2.28 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 95/149/EC of 8 March 1995 fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used.*

k) The Act referred to at Point 6.2.42 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/225/EC of 15 March 2002 laying down detailed rules for the implementation of Council Directive 91/492/EEC as regards the maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods*.

l) The Act referred to at Point 6.2.43 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/226/EC of 15 March 2002 establishing special health checks for the harvesting and processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) exceeding the limit laid down by Council Directive 91/492/EEC.*

m) The Act referred to at Point 54zn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs*, as amended.

n) The Act referred to at Point 54zj of Chapter XII of Annex II to the EEA Agreement, *Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs*, as amended.

o) The Act referred to at Point 54zzc of Chapter XII of Annex II to the EEA Agreement, *Commission Directive 2002/69/EC of 26 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs*, as amended.

It should be noted that the Act referred to at point 4.2.63 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2001/183/EC laying down the sampling plan and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC*, has not been made applicable to Iceland.

5 National legislation

The main Acts creating the legal basis for the Chief Veterinary Office's application of Council Directive 93/53/EEC related to the control of certain fish diseases are *Act No 25/1993 on animal diseases*, *Act No 66/1998 on veterinarians*, *Act No 54/1990 on the import of live animals*, and *Regulation No 665/2001 on action to be taken in the case of contagious diseases*. The latter entered into force 4 September 2001. All these legal texts are adopted by the Ministry of Agriculture.

The main Act creating the legal basis for Fiskistofa's application of the EEA legislation in the field of fishery products is the *Act No 55/1998 regarding the handling, processing and distribution of marine products*. This Act implements, *inter alia*, Directives 91/492/EEC, 91/493/EEC and 92/48/EEC, and it gives the legal basis for a number of regulations of which the two most important are *Regulation No 849/1999 on control of import of fishery products* and *Regulation No 233/1999 regarding the handling, processing and distribution of marine- and fishery products*, as amended by Regulation No 387/2000 and Regulation No 367/2001.

In addition to these legal texts, a number of regulations regulate the handling, processing and distribution of marine products. The following list is not exhaustive but contains the main Icelandic legal texts incorporating the EEA legislation related to fish diseases and the production and the placing on the market of fishery products.

a) Council Directive 91/67/EEC is implemented in *Regulation No 526/2003 concerning the animal health conditions governing the placing on the market of aquaculture animals and products* (date of entry into force was 16 July 2003). This regulation was issued by the Ministry of Agriculture. Furthermore, the Directive is also implemented into *Regulation No 485/2003 amending Regulation No 238/2003 on farming of marine species* (date of entry into force was 2 July 2003). This Regulation was issued by the Ministry of Fisheries.

b) Council Directive 91/493/EEC, Council Directive 92/48/EEC, Commission Decision 94/140/EEC, Commission Decision 94/356/EEC and Commission Decision 95/149/EEC are implemented into *Regulation No 233/1999 on fishing, handling, processing and distribution of fishery products* (date of entry into force was 30 March 1999). The Regulation was issued by the Ministry of Fisheries.

c) Council Directive 98/83/EC is implemented into *Regulation No 536/2001 on water intended for human consumption* (date of entry into force was 28 June 2001). The Regulation was issued by the Ministry for the Environment.

d) Commission Decision 93/25/EEC is implemented into *Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs*. The Regulation was issued by the Ministry of Fisheries. No information was made available to the inspection team regarding the national measures implementing Commission Decision 2003/774/EC for which the date of entry into force was 25 September 2004.

e) Commission Decision 93/51/EEC is implemented into *Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs* and *Regulation No 233/1999 on health conditions for the handling, processing and distribution of fishery products*.

f) Commission Regulation (EC) No 466/2001 is implemented in *Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs, Regulation No 233/1999 on health conditions for the handling, processing and distribution of fishery products* and *Regulations No 502/2003, 661/2003 and 662/2003 on the entry into force of several EC Acts on contaminants in foodstuffs.* The two first regulations are issued by the Ministry of Fisheries while the three last ones are issued by the Ministry for the Environment.

The Authority is currently in the process of carrying out a conformity assessment of the Icelandic measures notified to it as implementing, *inter alia*, Directives 91/67/EEC and 93/53/EEC.

6 Information on production and export

The number of aquaculture farms registered by the CA in accordance with the requirements of Article 3 of Directive 93/53/EEC is given in Figure 1. In Iceland only four on-growing farms (out of six) for production of Atlantic salmon and 14 small on-growing farms (out of 17) for cod are sea-cage farms. The rest of the farms are land based.

Figure 1: Number of aquaculture farms registered by the CA

Type of farm	Species						
	Salmon	**Arctic char**	**Cod**	**Halibut**	**Rainbow trout**	**Other***	**Total**
1. Broodstock							
- farmed	2	3	1	1	1	4	12
- wild	6	-	-	-	-	2	8
2. Hatcheries	3	4	2	1	-	1	11
3. Ongrowing	6	17	18	2	3	7	53
Total	17	24	21	4	4	14	84

* Sea trout, haddock, turbot, spotted wolfish, freshwater prawns, blue mussels and abalone.

The number of factory vessels, freezer vessels, auction markets and fishery production establishments approved by Fiskistofa in accordance with Directive 91/492/EEC and Directive 91/493/EEC, the number of fishing vessels complying with the requirements of Directive 92/48/EEC, and the number of landing sites are given in Figure 2.

Figure 2: Number of landing sites and approved fishing vessels, factory vessels, freezer vessels, auction markets and establishments

	Year	
	2002	**2004**
Fishing vessels	1690	1756
Factory vessels	40	41
Freezer vessels	22	21
Landing sites	68	68
Auction markets	31	30
Establishments*	748	647

* The total number of approvals issued by Fiskistofa. According to Fiskistofa the approval numbers are linked to each establishment as a legal entity, to the location of the production facility and to the type of products produced. Consequently, one establishment can have more than one approval number linked to the same production facilities.

The quantity of the different aquaculture species produced in Iceland is included in Figure 3.

Figure 3: Production volume (in tons) of different species of aquaculture animals

	Year			
Species	**2000**	**2001**	**2002**	**2003***
Atlantic salmon	2.602	2.645	1.471	3.700
Arctic char	925	1.320	1.540	1.950
Rainbow trout	30	105	248	80
Halibut	34	93	120	120
Turbot	-	3	9	25
Seabass	20	20	40	40
Cod	11	70	205	300
Abalone	15	22	24	8

* Estimates

The statistical information provided by the Icelandic CAs related to production and placing on the market of live aquaculture animals and products did not contain information related to the placing on the market of live aquaculture animals. However, out of a total of approximately 6000 tons of slaughtered aquaculture animals in 2003, 60% was Atlantic salmon and 31% was arctic char.

Figure 4 contains information on the quantity and value of fishery products exported from Iceland. The information is split on the main species.

Figure 4: Export quantities (tons) and value (million ISK) by species

	Year*			
	2001		2002	
Species	**Quantity**	**Value**	**Quantity**	**Value**
Cod	116.181	51.223	112.789	48.546
Capelin	330.423	15.403	349.575	20.467
Shrimps	27.708	12.668	31.918	12.714
Redfish	48.339	9.876	56.462	10.724
Haddock	17.016	7.328	17.913	8.198
Greenland halibut	11.300	3.648	13.959	4.169
Herring	71.303	4.864	48.307	4.161
Coalfish	15.330	3.199	17.457	3.683
Shellfish, crustaceans, and molluscs	13.629	729	25.629	1.454
Other	127.792	13.107	130.186	14.475
Marine products (total)	**779.021**	**122.045**	**804.195**	**128.591**

* Figures for 2003 were not available at the time of the mission.

7 Previous missions[1]

7.1 General comments

The Authority has carried out a number of inspections to Icelandic fishery products establishments since 1995. In the missions carried out since 2000 in the field of fishery products and live bivalve molluscs, the Authority has had a particular focus on the performance of the Icelandic Competent Authorities.

Since 2000, the Authority has carried out three missions in this field, one in October 2000, one in September 2002 and one in March 2004. During these missions the Authority has assessed the CA's application of both Directive 91/492/EEC (September 2002 and March 2004) and Directive 91/493/EEC (October 2000 and September 2002).

The final reports from these missions are available at the Authority's homepage: http://www.eftasurv.int/.

It follows from these reports that the Authority revealed non-compliances related to, *inter alia*, the official control (including approval) of establishments, documentation of the water supply, the size, design and layout of the establishments, maintenance of the establishments and the equipment, and to the production of fishery products.

Finally, in the report from the mission in September 2002, the Authority also concluded that the routines for follow-up of conclusions of visits by the Authority and of findings of official inspections needed improvements.

[1] *In chapter 7 ESA addresses some points raised in previous missions. Several of these points were minor deficiencies and they have all been addressed by the Icelandic Competent Authority.*

7.2 Mission carried out in October 2000

In the report from the mission in 2000, the Authority concluded that, *inter alia*, the routines for approval of establishments should be improved in order to comply with the requirements of Article 7 of Directive 91/493/EEC, since production/activity had been initiated in one the establishments and one auction market visited before being approved by the CA.

As a follow-up of the conclusions and recommendations of the final report from the mission, Fiskistofa sent a letter to the Authority on 31 May 2001 in which it was stated, *inter alia*, that […] "In those cases were the Directorate of Fisheries has received information that a company has started production without approval, actions have been taken. These actions have included intensive laboratory testing on products produced without approval, closure of premises, etc."

Furthermore, the Authority concluded that the own checks system, including Hazard Analysis and Critical Control Points (HACCP) in the establishments was not fully in compliance with the requirements of Directive 91/493/EEC and Decision 94/356/EEC, since verification of the systems was missing and also not commented on by the IBs.

As a follow-up, Fiskistofa informed the Authority in its letter of 31 May 2001 that "The Directorate of Fisheries will revise the chapter on own checks system in the Inspection manual, with a special focus on verification procedures. The Directorate of Fisheries has reaffirmed with the inspection bodies the demands that are placed on the establishments regarding own checks system."

7.3 Mission carried out in September 2002

In the report from the mission carried out in September 2002, the Authority concluded that, *inter alia*, the routines for approval of establishments were not always in accordance with the requirements of Directive 91/493/EEC since some of the approval documents did not reflect the establishments' compliance with the requirements of the Directive.

As a follow-up of the conclusions and recommendations of the final report from the mission, Fiskistofa sent a letter to the Authority on 10 April 2003, in which it stated that "Approving of establishments is the Directorate's responsibility and the routines are quite clear and understandable. In one of the establishments visited an old certificate for the working approval was handed over to the ESA representatives. In 1998 the Directorate replaced all the approval certificates. The establishments were not asked to return the old documents. The document itself has no meaning as such as the list of the approved establishments is valid as it is shown on the Directorate's web site at all times."

Furthermore, the Authority concluded that the own-checks systems (including HACCP) in the establishments visited were not in compliance with the requirements of Directive 91/493/EEC and Decision 94/356/EEC, since identification of hazards was incomplete or missing in all establishments visited. Additionally, relevant information such as a description of the products, identification of the intended use of the products, analysis of risks and procedures for corrective action and verification were not always available.

In the letter of 10 April 2003 Fiskistofa stated that "The Directorate does not agree with the statement that the identification of hazards were incomplete in all the establishments. The establishments are supposed to evaluate the risk of biological, chemical and physical

hazards and identify if there is a critical point in the processing and handling. The biological hazards are understood to be the microorganisms that can be dangerous for human health, like e-coli, salmonella etc. it is also common knowledge that those microorganisms are killed during the cooking process of the fish before consumption. Therefore simply listing "bacteria" as the biological hazard is sufficient in the Directorate's opinion.

In establishments producing "ready-to-eat" food the control is more intensive and product samples are taken for laboratory testing according to a sampling plan. These samples are tested for listeria, salmonella, e-coli and total count as a minimum. It is the understanding of the Directorate that ESA and the Directorate were in agreement about the chemical and physical hazards."

Additionally, in the reply to the Authority's pre-mission questionnaire for this mission Fiskistofa added information to some of the Authority's conclusions included in the report from the mission in September 2002. Here Fiskistofa informs that all establishments visited by the Authority during that mission were visited during the first half of 2003. Based on the non-compliances revealed by the mission team, each of the establishments had to prepare a plan for corrective action which was approved by Fiskistofa. The relevant IBs were also informed. Most of the establishments have since been visited by inspectors from Fiskistofa.

In its letter of 10 April 2003 Fiskistofa states that "The Directorate admits that in some more difficult situations it is not sufficient to base the follow-up entirely on the notifications from the IBs. Therefore a reorganisation of the follow-up procedures has been planned to ensure more effectiveness. The reorganised procedures will be in force not later than January 1st, 2004."

In its reply Fiskistofa also informs that a plan for re-organisation of the inspection activities has been introduced to the Director of Fiskistofa. It is also stated that "The main aim with the plan is to increase the efficiency of the inspections, increase the producer's quality- and safety-awareness, reduce the bad influence of competition between the IBs as well as to improve the reporting of the inspections to the Directorate."

The plan contains information related to the way of carrying out inspections, follow-up of deficiencies and co-operation between the parties involved. Additionally, the plan also contains suggestions for changes in the procedures for registration and inspection of fishing vessels.

However, at the opening meeting a representative of Fiskistofa informed the inspection team that small and gradual changes had been done during the last two years, but the re-organised follow-up procedures are still on the drawing table. A date for entry into force of the revised procedures has not been agreed. A draft document related to the procedures for approval of establishments was handed over to the inspection team at the opening meeting.

On request from the inspection team, Fiskistofa provided information related to the follow-up of one of the establishments visited by the Authority in both 2000 and 2002. According to that information the establishment had taken into consideration the deficiencies revealed during the Authority's mission. However, inspection reports from

the relevant IB or from Fiskistofa were not available[2]. The CA's verification of the information provided by the establishment could therefore not be assessed.

8 Main findings

8.1 Competent Authorities

According to the Icelandic Foodstuffs Act No 93/1995, as amended, the responsibility for implementation and application of EEA Acts made applicable to Iceland and related to food safety is split between the Ministry for the Environment, the Ministry of Agriculture and the Ministry of Fisheries.

The Ministry for the Environment has the main responsibility for food legislation and control of domestic and imported retail food and enacts the Icelandic legislation implementing EEA Acts on, *inter alia*, water intended for human consumption and the monitoring of contaminants in foodstuffs.

The Ministry of Agriculture's main responsibilities comprises, *inter alia*, the Icelandic legislation implementing EEA Acts related to production and trade in live aquaculture animals, including control and monitoring of fish diseases.

The Ministry of Fisheries enacts the Icelandic legislation implementing EEA Acts related to, *inter alia*, harvesting, processing and distribution of marine products.

The following CAs have competence in the fields related to the production and the placing on the market of aquaculture animals and fishery products:

a) **The Environment and Food Agency (EFA)**, being organised under the Ministry for the Environment, is the CA with regard to application of Regulation (EC) No 466/2001 and other related EEA Acts in areas other than for fishery products and bivalve molluscs. The EFA is also involved in issuing of licences for fish farms and fishery products establishments.

b) **The Chief Veterinary Office**, being organised under the Ministry of Agriculture, is responsible for the application of Directives 91/67/EEC and 93/53/EEC and other EEA Acts related to trade and monitoring and control of fish diseases, including inspections of fish farms. Additionally, as part of the application of Directive 93/53/EEC, the Chief Veterinary Office is also involved in the issuing of licensing of fish farms.

c) **Fiskistofa**, being organised under the Ministry of Fisheries, is the CA for the application of Directive 91/493/EEC and other EEA Acts related to handling, processing and distribution of marine products. Additionally, Fiskistofa is the CA for the operation of the Icelandic border inspection posts controlling imports of fishery products into the EEA via Iceland.

   Fiskistofa is also the CA with regard to the application of the Icelandic measures

[2] *The reason for this is that they were not requested by ESA.*

implementing Regulation (EC) No 466/2001 for the parts related to the control and monitoring of contaminants in fishery products and bivalve molluscs.

Furthermore, Fiskistofa is issuing licences for farming of marine species and is also the CA with regard to the application of the Icelandic measures implementing Directive 93/53/EEC for marine species. However, the competence related to fish diseases and placing restrictions on farms for marine species has been delegated to the OV.

d) **The Directorate for Freshwater Fisheries**, being organised under the Ministry of Agriculture, is responsible for the issuing of licences for farming of freshwater and anadromous species.

Based on the Foodstuffs Act No 93/1995, a consultative committee, the Food Council, has been established in order to ensure the collaboration of the parties responsible for food safety on both national and local level. Members of the Council are nominated by the Director of the EFA, the Chief Veterinary Officer (CVO) of the Chief Veterinary Office and the Director General of Fiskistofa. Further duties of the Food Council are related to harmonisation of food legislation and food control, co-ordination of food control and of training of staff involved in such control.

Furthermore, a Fish Disease Committee has been established in order to provide advice for the Ministry and the Chief Veterinary Office in problems related to fish diseases. This Committee consists of the CVO, the Director of Fiskistofa, the Director of the Directorate of Freshwater Fisheries and the Director of the Institute for Experimental Pathology of the University of Iceland at Keldur (Keldur). The OV and the person responsible for the NRL at Keldur act as experts for the Committee.

However, at the opening meeting representatives of the Chief Veterinary Office and Fiskistofa recognised the needs for further clarification of the co-operation between the two Authorities with regard to the application of Directive 93/53/EEC.

8.2 Organisation of the Competent Authorities

8.2.1 The Chief Veterinary Office

The Official Veterinary Service in Iceland is organised within the Ministry of Agriculture. Being the chief executive of the Chief Veterinary Office, the CVO is reporting directly to the Minister of Agriculture.

In addition to the CVO, the Chief Veterinary Office consists of nine veterinary officers, of which one is appointed Deputy CVO, each responsible for different animal species and different surveillance duties.

On a local level, the Chief Veterinary Office consists of 15 District Veterinary Officers (DVOs).

8.2.2 Fiskistofa

Being located in Reykjavík, with no regional or local level, Fiskistofa operates on a national level. According to the organisation chart provided by Fiskistofa as a reply to the Authority's pre-mission questionnaire, eight Departments are organised directly under the Director of Fisheries.

It is the Department of Seafood Safety that is responsible for the enforcement of laws and regulations regarding handling, processing and distribution of fishery products. This Department consists of six senior staff members and four inspectors in addition to the Head of Department.

For carrying out routine inspections of fishing vessels, freezer vessels, factory vessels, auction markets and fishery products establishments Fiskistofa has approved two inspection bodies, Frumherji hf and Sýni skoðunarstofa ehf (see Chapter 8.9.2).

8.3 Monitoring of contaminants in foodstuffs

According to Fiskistofa's reply to the Authority's pre-mission questionnaire, heavy metals and organic pollutants are monitored every other year in the Icelandic waters. Heavy metals have been monitored since 1989 while organochlorine compounds have been monitored since 1991.

This monitoring programme is part of Iceland's commitments under the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) and the Arctic Monitoring and Assessment Programme (AMAP) of the Nordic Council of Ministers.

For analyses of dioxins and dioxin-like PCBs, a total of 69 samples are foreseen to be collected from fishery products during 2004.

All this activity is co-ordinated by the Icelandic Fisheries Laboratories (IFL). Additional information is included in the report from the Authority's mission regarding the application of EEA legislation related to the production and the placing on the market of live bivalve molluscs, carried out in March 2004 and available at its homepage: http://www.eftasurv.int/information/reportsdocuments/vetcontrolmatters/fishery/dbaFile5802.pdf.

8.4 Official control of aquaculture farms and monitoring of certain fish diseases

According to information provided by the Chief Veterinary Office as a reply to the Authority's pre-mission questionnaire, Iceland has for more than forty years applied national legislation specifically designed for the control of fish diseases. Since 1985 regular fish health surveillance has been obligatory for all fish farms.

The official control and monitoring of certain fish diseases in Iceland consists of both health inspections on the farms and analyses of samples at Keldur or laboratories abroad.

8.4.1 Official control of aquaculture farms

In Iceland it is the responsibility of the Directorate of Freshwater Fisheries to issue operating licences for aquaculture farms (freshwater and anadromous species). For marine species Fiskistofa is the CA for issuing such licences.

Before licences are issued, different authorities are involved in the assessment of the application. A planning agency organised under the Ministry for the Environment evaluates whether it is necessary to do an environmental impact assessment. Depending on the size of the farm an environmental licence is issued by either the local health authorities or the EFA.

An evaluation by the CVO of the consequences related to fish diseases is also obligatory before the Directorate of Freshwater Fisheries or Fiskistofa are issuing the operational licences.

In order to keep a register of all farms rearing or keeping fish susceptible to the diseases listed in the relevant EEA legislation, the Directorate of Freshwater Fisheries submits a copy of the issued licences to the Chief Veterinary Office. However, similar procedures are not established between Fiskistofa and the Chief Veterinary Office.

According to information provided by the OV during the mission, the general rule is that ongrowing farms are visited by the CA twice a year, other farms once a year and some small farms are visited every second year. However, farms exporting live fish or eggs can be visited as much as ten times per year.

It is the OV that co-ordinates all inspections and other activity related to the fish farms. Information on the activity for one year is normally distributed to the DVOs during September the preceding year.

The involvement of the DVOs is mainly related to on-farm sampling. Inspections on farms by the DVOs are under the supervision of the OV. However, the majority of official inspections on farms are carried out by the OV.

A checklist is used when inspections are carried out and written reports are sent to the farms following the inspections. Copies of the reports are also sent from the OV to the relevant DVOs. The reports create the basis for any relevant follow-up by the CA or by the farm. However, the OV informed the inspection team that inspection procedures did not contain requirements for checking the cleaning and disinfection of well boats and trucks used for transport of live fish.

The OV also informed the inspection team that, independent of the diseases possibly present, notification to the CA in cases of suspicion of presence of contagious fish diseases are done either to the DVO or the OV.

It is the OV that has the legal power to place restrictions on farms. This usually happens once or twice per year. The right of appeal is laid down in Icelandic law and it is the Ministry of Agriculture that is handling appeals of decisions adopted by the OV.

The inspection team observed that the Icelandic contingency plan for a number of contagious diseases, including infectious salmon anaemia (ISA), was not necessarily reflecting the actual procedures established and applied. Furthermore, the plan was not up-dated as, *inter alia*, the contingency plan contained official veterinarians that had not worked as such for at least one year.

Training programmes for persons included in the contingency plan had not been established and it was also admitted that not all persons included in the contingency plan were aware of their obligations and responsibilities. Moreover, the CVO had not organised any exercises related to fish diseases based on the contingency plan. However, one exercise (related to Foot and Mouth Disease) had been organised this year, the first in several years.

Finally, the OV also informed the inspection team that the local disease control centres were not properly equipped in order to co-ordinate the disease control measures on a local level as foreseen in Directive 93/53/EEC.

8.4.2 Monitoring of certain fish diseases

All samples are either collected by the OV or the DVOs, and since 1993 sampling procedures and analysing methods as referred to in the relevant EEA legislation have been applied.

Between 1985 and 1992 salmonids were screened for presence of virus causing, *inter alia*, infectious pancreatic necrosis (IPN), viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN). Between 60 and 150 samples were collected from all farms 2 to 4 times per year. Additionally, 60 samples for viral examination were collected annually from all broodstock farms. As of 1993 minimum 30 samples from each farm have been analysed for these viruses. None of these samples and the 736 samples analysed in 2003 were positive for the presence of the viruses causing the diseases IPN, VHS and IHN. These analyses are carried out at Keldur (see Chapter 8.5).

Samples have also been analysed for possible presences of infectious salmon anaemia virus (ISAV) and nervous necrosis virus (NNV). In 2003 a total of 58 samples were analysed for ISAV and 90 samples for NNV. None of these samples were positive for the viruses.

Analyses of the 58 samples for ISAV were performed at Keldur based on clinical signs and post mortem findings (macroscopic, histological and haematological) in accordance with the 2003 OIE Manual of Diagnostic Tests for Aquatic Animals. In the reply to the pre-mission questionnaire it was informed that confirmation of any findings indicating a possible presence of ISAV will be made on material sent to the Norwegian National Veterinary Institute in Oslo, Norway (Veterinærinstituttet).

Based on an agreement from 2000, samples collected from farmed juveniles of halibut are analysed for NNV at Veterinærinstituttet.

In the period between 1985 and 1992 the same amount of samples were screened for presence of a number of bacteriological diseases, in particular Furunculosis (*Aeromonas salmonicida* ssp. *salmonicida*), atypical Furunculosis (*Aeromonas salmonicida* ssp. *achromogenes*), Yersiniosis (*Yersinia ruckeri*) and Bacterial Kidney Disease (BKD) (*Renibacterium salmoninarum*). As of 1993 minimum 60 samples from each broodfish farm and all stripped fish from sea farms and wild broodfish have been collected annually and analysed for the presence of the bacteria causing Furunculosis, Yersiniosis and BKD.

According to the Icelandic reply to the Authority's pre-mission questionnaire 1.473 samples were analysed in 2003 for *Vibrio anguillarum*, *V. salmonicida* and *Moritella viscosa*, and 1.601 samples for *Renibacterium salmoninarum*. Finally, 150 samples of salmonids were analysed for the presence of *Gyrodactilus salaris*. However, the results of these analyses and similar analyses carried out earlier years were not made available to the inspection team.

8.5 Aquaculture farm visited

During the mission one aquaculture farm was visited. The farm had been approved by the EFA and an operating licence had been issued by the Directorate of Freshwater Fisheries. It should be recalled that an operating licence can only be issued if the approval by the EFA is valid. The EFA includes an expiry date in its approvals and they are normally valid for ten years. The approval in the establishment visited was issued in 2000.

According to the representative of the farm, the OV visits the farm minimum eight times per year and 2-3 of these visits are unannounced. In cases of increased mortality on the farm the persons responsible notify the OV directly. Furthermore, the limit for notifying the OV is 0,2 % mortality per day. However, in some cases and due to certain activity on the farm, a mortality of 1% can be accepted as normal and therefore not resulting in any notification to the OV.

The representative of the farm also informed that the OV issues reports following the visits and that the farm receives a copy of the reports. Invoices related to the inspections carried out by the OV are sent to the farm from the Chief Veterinary Office.

The OV informed the inspection team that restrictions on farms are very rare. The last two restrictions issued by the OV were because of BKD. The procedure to be followed for placing restrictions on farms is more or less the same, while the lifting of restrictions is different and depending on the disease present.

Deficiencies and restrictions noted in one report are followed-up during subsequent visits and the necessary actions taken were informed to be included in the reports from these visits.

At the farm a special computerised system is used for registration of all relevant information related to production, mortality, feeding and information related to fish entering and leaving the farm.

The only contact between the farm and veterinarians was with the OV. No contact had been established with a private practitioner. During the visit to the farm, the OV informed the inspection team that some DVOs involved in aquaculture farming also can act as private practitioners.

The OV informed the inspection team that although the DVOs have the legal power to issue health certificates and transport documents for transport of live aquatic animals, such documents are only issued by the OV.

Furthermore, the OV monitors all prescriptions of antibiotics prescribed by private practitioners for the use in aquaculture farms. At the farm visited it is the OV that is issuing prescriptions for the use of antibiotics. Representatives of the farm visited informed the inspection team that antibiotics are only used to a limited extend, and only during the smolt stage. Last time antibiotics were used at the farm was against winter ulcers (*Moritella viscosa*), three months before the visit.

The OV also provided information related to procedures applied when aquaculture animals are imported to Iceland from other countries (other EEA-Countries and third countries). The importer must submit an application to the Chief Veterinary Office.

Following a positive outcome of the assessment of the application by the CA, all consignments imported to Iceland are subject to veterinary control at the point of entry into Iceland. The OV accompanies the consignments to the farm of destination where the animals are kept isolated for one month.

This might not be fully in compliance with the relevant control directives[3]. However, since this was not comprised by the objectives of the mission, the information will be followed up separately by the Authority.

Finally, the inspection team observed that feed and formalin were stored in the same room on the farm, and vaccines having exceeded the expiry date were not properly disposed of.

8.6 National reference laboratory for certain fish diseases

According to the adaptation text to Council Directive 93/53/EEC as referred to at Point 3.1.7 of Chapter I of Annex I to the EEA Agreement, the Icelandic NRL for certain fish diseases is Tilraunastöð H.Í. Meinafræði, Keldur, 112 Reykjavík (Institute for Experimental Pathology of the University of Iceland at Keldur (Keldur).

In the Icelandic reply to the Authority's pre-mission questionnaire it is informed that the Institute for Experimental Pathology consists of several sections, and that the Fish Disease Laboratory, being one of these sections, is the NRL for certain fish diseases.

Representatives of the CA informed the inspection team that a process for a total revision of the laboratory structure in Iceland had been initiated by the Food Council. A report describing the current situation was foreseen to be delivered by an external expert in October 2004. The content of this report will create the basis for recommendations to be issued by the Food Council.

The laboratory is organised under the Ministry of Education. The main tasks of the NRL, as they are laid down in the Act No 50/1986, are to conduct research in the field of fish diseases, to diagnose fish diseases and to regularly perform screening of samples of fish in order to ensure safe trade of products from aquaculture facilities.

In its reply to the pre-mission questionnaire, the Icelandic CA stated that the laboratories organised under the Institute and the analysing methods applied are not accredited. Furthermore, during the visit to the NRL the inspection team was informed that a complete quality system/Standard of Operational Procedure (SOP) was not in place.

However, a process for establishing a SOP was initiated in 2002 in the Section for Bacteriology. This manual has been applied for approximately 2 years. The Institute foresees to send an application for accreditation of the Section for Bacteriology to the Icelandic accreditation body (Löggildingarstofa) before 1 May 2005. The general procedures established are also to be applied by the NRL.

[3] Council Directive 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, and Council Directive of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC.

A representative of the NRL informed the inspection team that the NRL has applied an internal manual for many years. However, this manual has not been based on any international recognised standard. A SOP is in the process of being finalised, but a date for which the manual will be applied was still to be agreed. A representative of the NRL informed the inspection team that 1 May 2006 had been agreed as a time limit for which an application for accreditation of the NRL should be submitted to Löggildingarstofa.
Furthermore, it follows from the Icelandic reply to the Authority's pre-mission questionnaire, that screening and diagnosis related to viral haemorrhagic septicaemia virus (VHSV), infectious haematopoietic necrosis virus (IHNV) and infectious pancreatic necrosis virus (IPNV) is based on a methodology provided by the Community Reference Laboratory (CRL) at the Danish Institute for Food and Veterinary Research (DFVF), Århus, Denmark. The protocol has been applied since 1999. A written procedure has also been prepared for methods related to BKD.

The inspection team observed that verification of results of samples analysed at the laboratory were not carried out. Moreover, the NRL had not participated in any inter-comparison test or similar tests.

During the visit to the NRL the inspection team was informed that the NRL is not involved in the planning of the programme for sampling related to the monitoring of the diseases IHN and VHS. Furthermore, the NRL had not been involved in the preparation of the contingency plan for ISA.

The majority of the samples related to monitoring of, *inter alia*, the diseases IHN and VHS are collected from broodfish during October, November and December. These samples are collected by the OV and the DVOs, and either brought directly to the laboratory by them or sent by express delivery. The samples brought to the laboratory by the OV are identified upon arrival at the laboratory. Procedures related to traceability of samples were not included in the manual.

The time from collection of samples until distribution of results is normally minimum two weeks. Although it was informed that official samples can be given priority, procedures for handling of such samples had not been formalised. Some parameters are analysed at laboratories abroad, mainly in Denmark and Norway. However, procedures related to subcontracted laboratories were not in place or incomplete, and routines for distribution of positive results from these laboratories were not formalised.

Results of official samples and samples collected by the farms are all distributed to the farmer and to the Chief Veterinary Office. However, procedures for distribution of positive results were not formalised.

At the NRL the number of staff seemed to be sufficient for the amount of samples currently being analysed. Additionally, a representative of the NRL informed the inspection team that, although not formalised, procedures for replacement of staff during absence were applied.

The inspection team observed that procedures for calibration of thermometers and weights were not in place and that such equipment used in the NRL had not been calibrated. Moreover, samples, analysed samples, ingredients (also those where the expiry date had

been exceeded) and media used in the laboratory were stored together in the same fridge and freezer.

Finally, the inspection team also observed that procedures for checking whether incoming samples were adequate for the analyses to be carried out were not in place and that the owners of the samples were known to the analysing personnel during the analysing process.

Based on the observations made during the visit to the NRL, a meeting was arranged between the inspection team and representatives of the Ministry of Agriculture, the Chief Veterinary Office and the NRL before the final meeting.

At this meeting the Icelandic Authorities informed the inspection team that immediate action would be taken in order to verify the results of the samples to be analysed this autumn as part of the monitoring of the diseases IHN and VHS. Additional information from the Icelandic Competent Authorities is included in Chapter 10 on page 31.

8.7 Approval and suspension/withdrawal of approval of vessels, auction markets and fishery products establishments

8.7.1 Approval of vessels, landing sites, auction markets and fishery products establishments

According to the Icelandic reply to the Authority's pre-mission questionnaire, the approval procedure is normally initiated by the signing of a contract between the company/person in charge and one of the approved IB.

Following such a contract the IB sends the application on behalf of the other part to Fiskistofa. Fiskistofa then sends the relevant information, by way of checklists, to the company/person in charge. Following a request from the company/person in charge, an inspector from Fiskistofa inspects the premises/factory vessel. Fiskistofa issues the approval document when the inspector has concluded that the premises/factory vessel is in compliance with the Icelandic requirements.

The list of approved establishments is updated and the relevant IB is informed about the new approved establishment. Following such notification the IB initiate the regular inspections. However, for freezer vessels and fishing vessels, the inspections carried out prior to Fiskistofa's approval are also carried out by the contracted IB.

In Iceland approval numbers are linked to each establishment as a legal entity, to the location of the production facilities and to the type of products produced. Consequently, one establishment can have more than one approval number linked to the same production facilities.

For landing sites Fiskistofa requires that adequate weighing facilities and an accredited weighing person are available at the harbour. Additional requirements for harbours are under the responsibility of the Icelandic Maritime Administration.

8.7.2 Suspension/withdrawal of approval of vessels, auction markets and fishery products establishments

Fiskistofa's suspension/withdrawal of approvals of vessels, auction markets and fishery products establishments can be based on a report from the IB, a report from Fiskistofa's own inspectors and/or a notification from the management of the establishment.

According to information included in the Icelandic reply to the Authority's pre-mission questionnaire, inspectors from Fiskistofa visit establishments in which inspections carried out by the IB have revealed a serious deficiency. If the situation is verified by the inspectors from Fiskistofa, a written warning is issued. If the deficiencies have not been rectified within the time limit set out in the written warning and verified on-the-spot by inspectors from Fiskistofa, the approval is withdrawn. Fiskistofa can, following a declaration from the establishment, inspect the facilities and allow production to be resumed, if no deficiencies are present or at least when a corrective plan has been presented and approved.

Furthermore, establishments are only withdrawn from the list of approved establishments if the approval is permanently withdrawn.

8.8 Official inspections of vessels, auction markets and fishery products establishments

8.8.1 General information

In Iceland accredited IBs, acting on behalf of the Directorate, perform inspections of vessels, auction markets and fishery products establishments. The activities of the IBs are regulated in the Icelandic Regulation No 450/1997 on surveillance framework and working methods of accredited inspection bodies in the fish industry.

According to the Icelandic reply to the Authority's pre-mission questionnaire, fishery products establishment and factory vessels with all year production are inspected four times per year, i.e. once every three months. Other vessels (including freezer vessels) are inspected once or twice per year depending on the size.

Furthermore, the inspection team was informed that all inspections carried out, both by Fiskistofa and the IBs, are pre-notified[4]. According to the inspection manual, inspections can only be carried out if the person responsible for the establishment is present. Inspections of establishments are not carried out during temporary stops in the production.

In order to verify the performance of the IBs, Fiskistofa is performing common visits, comparison visits or checking the reports from the inspections carried out by the IBs. Common visits to an establishment are carried out simultaneously by inspectors from the IBs and Fiskistofa. During these inspections the inspectors discuss their findings and assessment in order to harmonise the results. Four such visits per IB inspector are scheduled per year.

Comparison visits are carried out by Fiskistofa in an establishment shortly after it has been inspected by the IB. The results of these visits are discussed in meetings between Fiskistofa and the IBs. Four such visits are also scheduled per IB inspector per year.

[4] *This is not correct as most inspections by Fiskistofa are not pre-notified. It should also be noted that most inspections by Fiskistofa are follow up inspections and visits.*

Statistical material from the reports stored in the database at Fiskistofa is produced and evaluated once a year.

In addition to these visits, Fiskistofa also uses the findings during its follow-up visits to establishments where serious deficiencies have been revealed, to verify the performance of the inspectors of the IBs.

Results from such verifications were not assessed by the inspection team during the mission.

8.8.2 Inspections carried out by Fiskistofa

According to the Icelandic reply to the Authority's pre-mission questionnaire, Fiskistofa is, *inter alia*, responsible for approval of vessels, auction markets and fishery products establishments and for the official inspections of these premises.

In one of the establishments visited representatives from Fiskistofa informed the inspection team that, when going on inspections for follow-up of major deficiencies revealed during inspections done by the IBs, only the major deficiencies revealed are checked. This is contrary to the information that other representatives of Fiskistofa provided at a meeting with the inspection team. At this meeting the inspection team was informed that when deficiencies are revealed during follow-up inspections, the inspectors from Fiskistofa check the whole establishment[5].

In the reply to the Authority's pre-mission questionnaire, the Icelandic CAs informed that official samples are not collected for analysis of biological, chemical and physical parameters in relation to production of fishery products. Fiskistofa does not perform microbiological checks on a regular basis. However, in some cases Fiskistofa uses microbiological analyses to support an action taken against an establishment. Official sampling of products for analyses of a possible presence of virus and parasites is not performed and chemical checks are not performed on a regular basis.

However, in this context the CA referred to the obligations on the establishments to perform such checks as it is laid down in the Icelandic Regulation No 233/1999 on health conditions for the handling, processing and distribution of fishery products. Furthermore, Fiskistofa also referred to the legal obligations on surveillance bodies or agencies and those that produce food, to notify Fiskistofa if samples collected from fishery products are positive for certain pathogenic bacteria[6].

8.8.3 Inspection Bodies and inspections carried out by the Inspection Bodies

In Iceland currently two accredited IBs perform inspections of vessels, auction markets and fishery products establishments. In order to carry out such inspections, the IBs must be accredited and operate in accordance with the European Standard ÍST EN 45004:1995 on General criteria for the operation of various types of bodies performing inspections. Additionally, the IB's must be recognised by Fiskistofa.

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[5] *This is a misunderstanding as the inspectors evaluate on site if it is necessary to check the whole establishment or if it is only necessary to address the serious deficiencies.*

[6] *In this discussion ESA omits to mention the role of the testing laboratories. They are obliged by the Food law to notify the relevant Competent Authority if certain pathogenic micro organisms are found. This is of an immense importance for the whole inspection system in Iceland and is unique for the EEA.*

The IBs currently active in Iceland are accredited by both Löggildingarstofa and the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) as Type A Inspection Bodies (providing "third party" services as defined in Point 4.2.1 of the ÍST EN 45004:1995). According to the Icelandic reply to the Authority's pre-mission questionnaire, Fiskistofa assists Löggildingarstofa in the accreditation of IBs. However, during the mission representatives of Fiskistofa stressed that the inspectors from Fiskistofa acted as private consultants (technical assessors) when assisting Löggildingarstofa and SWEDAC in the accreditation of the IBs.

Moreover, it should be noted that the inspection manual used by the IBs during their inspections of establishments and vessels, and also creating the basis for the accreditation of the IBs, has been prepared by Fiskistofa.

The inspections carried out by the IBs are in accordance with a predefined procedure laid down in the inspection manual. Based on this manual the IBs have prepared forms which are used during the inspections. These forms are approved by Fiskistofa. The findings are either rated as 0 (no deficiency), A (serious deficiency) or F (regular/minor deficiency).

The IBs send the inspection reports to Fiskistofa once a week by e-mail or by fax within 24 hours in cases where serious deficiencies have been revealed. Further follow-up of the latter is done by Fiskistofa since the IBs have no legal power.

Finally, regular/minor deficiencies revealed during one inspection and not rectified at the time of the next regular inspection carried out by the IB, are automatically classified as serious deficiencies and followed-up by Fiskistofa[7].

8.9 Fishery products establishments visited

8.9.1 General comments

When visiting one of the establishments, the inspection team observed that several pallets of fish frozen at sea had been unloaded from a freezer vessel and left on the quayside under ambient temperature. The content of several of the boxes were thawed. The inspection team did not observe any action initiated by Fiskistofa and no information of any action taken by Fiskistofa was made available to the inspection team during the mission.

It should be noted that although requested in the first establishment visited, all documents related to the official control were not made available to the inspection team in the two other establishments visited[8].

[7] *It should however be noted that this does not mean that all minor deficiencies not corrected become major deficiencies. The establishment only gets one major deficiency for not correcting deficiencies found in a previous inspection.*

[8] *In the first establishment visited inspectors from ESA requested documents related to that establishment. This was not understood by representatives from Fiskistofa to indicate more than a request for documents related to that establishment. Had it been understood to include more documentation related to other establishments this would of course have been supplied. Unfortunately this was not mentioned again by the inspectors from ESA until at the final meeting, when it was too late to do anything about it.*

Based on the observations in one of the establishments visited the inspection team invited the representatives of Fiskistofa to provide information before the final meeting of any action taken against the establishment. Before the final meeting the inspection team was informed that a representative of the establishment had been contacted and invited to provide an action plan based on the findings during the visit. Additional information is included in Chapter 10 on page 31.

8.9.2 Official inspections

In one of the establishments visited the inspection team was informed that one of the accredited IBs is offering employees of establishments a discount on official checks of their cars if the establishment is signing a contract with that IB.

Moreover, inspection fees charged by the different IBs are paid directly by the establishments to the IBs. The inspection team was also informed that the fees charged by the different IBs were not known to Fiskistofa.

Additionally, identification of the location of the production facilities and the type of products concerned were not evident on the approval certificates presented to the inspection team during the mission. In one establishment visited the address on the approval document was different from the one where the actual production was taking place.

Furthermore, in one of the establishments visited the types of processing comprised by the approval document were not clear to the persons responsible for production. Processing of one type of products had therefore been initiated although that process was not covered by the approval document issued by Fiskistofa. According to a representative from Fiskistofa, the types of processes covered by the different approvals were not clearly defined.

The approval certificates issued by Fiskistofa contain the date of first approval. However, the date of issue of the certificates is not included. Some of the inspection reports issued by Fiskistofa and presented to the inspection team during the mission did not bear a date of issue.

The inspection team also observed that two major deficiencies included in an inspection report from the IB were followed-up by way of a letter from Fiskistofa 14 days later. Following a letter from the establishment stating that the deficiencies had been rectified, the case was closed without any inspection carried out by Fiskistofa.

In one of the establishments visited, the equipment and machinery had been moved to new renovated facilities in 2000, and production had been initiated without any inspection by Fiskistofa. The HACCP plan had not been assessed by the CA and a revised and updated approval corresponding to the new premises had not been issued before start-up of production.

In the same establishment the IB had performed an inspection late August 2004. During that inspection four minor deficiencies had been revealed. During the Authority's visit approximately one month later, a large number of deficiencies, some of them major according to the inspection manual used by the IB, were revealed. Moreover, the inspector of the IB informed the inspection team that this establishment is visited four times per year

unless seasonal stops had been notified. During all these inspections, which normally last for three to four hours, the IB checks all points in the manual.

In the reports issued by the IB following inspections in this establishment, the inspection team observed that it could not be documented whether the inspector from the IB had verified that deficiencies revealed during previous inspections had been rectified. The inspection team also observed that the inspection reports normally contained observations from two or three processes taking place in different parts of the establishment for which Fiskistofa had issued different approval numbers.

In the second establishment visited the inspector from the IB was not present during the visit. In this establishment information was not available enabling the inspection team to verify whether deficiencies revealed during an inspection in September 2002 had been rectified, and verified by Fiskistofa, before the approval was issued one month later.

Samples collected by representatives of this establishment indicated that the establishment had started up production without having been approved by Fiskistofa. This was confirmed in a report issued by the IB on 17 September 2002. Representatives of the establishment informed that they had the opinion that the already existing approval also covered the new product.

One representative of the establishment also informed the inspection team that fish fillets produced before having received the approval document from Fiskistofa, had been sent to another establishment with the same owner. There the fillets had been further processed before being placed on the market.

Moreover, in the report from the inspection carried out by inspectors from Fiskistofa in September 2002, nine deficiencies related to the establishment's own checks system, including the HACCP plan, were identified. During the Authority's visit to this establishment, the inspection team observed that at least three of these deficiencies were still either only partially rectified or not rectified.

During the last 21 months the IB had inspected the establishment five times, although no stop in the production had taken place[9]. According to the information provided by Fiskistofa, this establishment should have been inspected seven times. Evidence of any action taken by Fiskistofa regarding this deviation from the inspection frequency was not made available to the inspection team.

Furthermore, during an inspection by the IB in June 2004 seven minor and three major deficiencies had been registered. It was, *inter alia*, indicated that the monthly sampling of seawater had not bee carried out (major deficiency). The inspection team observed that samples of seawater had also not been collected in July and August 2004.

[9] *This is a misunderstanding by ESA as it came out during the visit to the establishment mentioned that there had been production stops.*

Concerning the discussion in this paragraph it should be noted that Fiskistofa does not necessarily address each individual discrepancy observed in the work of the inspection bodies but chooses to address more issues at once. It should also be noted that it is not possible to correct deficiencies retroactively.

During an inspection by Fiskistofa in August 2004 some of the major deficiencies revealed by the IB in June 2004 had still not been rectified. Fiskistofa had given a new deadline of 1 September 2004 for rectification of the still outstanding deficiencies. The establishment had applied for a further prolongation of the deadline until February-March 2005. However, any reply to the latter from Fiskistofa was not made available to the inspection team during the mission[10].

In the last establishment visited the inspection team compared the findings of the inspection team with simultaneously registered deficiencies in the inspection report used by the inspector from the IB. Seven deficiencies were registered in the inspection report while the inspection team and the inspector from the IB registered in total more than 20 deficiencies.

8.9.3 Conditions related to the own-checks system including HACCP

In the first establishments visited the inspection team observed that not all the processes carried out in the premises had been evaluated according to the general principles of the own-checks system, HACCP included. For example, all processes were not included in the flowchart, all relevant hazards had not been identified and the intended use of the final products had not been indicated. Furthermore, procedures for verification and review of the HACCP plan had not been established.

Additionally, procedures for monitoring some of the prerequisites were not in writing and the procedures for pest control described in the own-checks system were not applied. The information related to training of staff was not up-dated.

In the second establishment visited, more than one version of some of the documents in the HACCP plan existed. However, because none of the documents were dated, the validity of the different documents could not be established. Additionally, the procedures for sampling and for cleaning of facilities and equipment, and the procedures for verification and review of the own-checks system were incomplete.

This establishment, *inter alia*, slaughtering and processing farmed salmon, had not identified any critical control points (CCPs). According to the Icelandic legislation sampling of products once a year is sufficient if no CCP has been identified. The inspection team observed that a number of samples had been analysed for, *inter alia*, *Listeria* spp. in 2002 and 2003, but analyses had not been carried out since February 2004. Representatives of the establishment informed the inspection team that this was because the current buyer did not require such analyses to be carried out.

In this establishment procedures for registration of temperature were not established. The representative of the establishment informed the inspection team that the temperature of the fillets was checked three times per day. However, this information could not be verified as nothing was registered.

[10] *The reply is in the Directorates files and would have been made available if ESA had asked for it during the mission. As regards the long time given to correct the deficiency it should be noted that this is a seasonal production, going on for a few weeks in February and/or March so there was no reason to give a shorter time limit.*

The third establishment visited had been approved by Fiskistofa in 2001 for handling of fresh fish, and for handling of salted fish in the beginning of 2004. However, any assessment of the establishments HACCP system by Fiskistofa could not be documented. The HACCP plan had been prepared by an external laboratory with limited involvement by the quality manager of the establishment. The inspection team observed that the quality manager was not familiar with the HACCP plan, and was not aware of some relevant legal requirements (i.e. temperature requirements for raw materials).

8.9.4 Conditions related to premises

There was not a clear separation between clean and contaminated parts of the buildings in any of the three establishments visited. The design and layout could not always preclude contamination of the products.

Forklifts were observed used both outside and inside in the presumed clean parts of the premises. Doors to the outside were often kept open during production or not closing tightly.

In at least one establishment visited the walls and the ceiling in the production area did not have smooth surfaces that were easy to clean. Wooden walls were observed in the freezer store in one of the establishments visited. Parts of the walls were damaged and sawdust had accumulated on the floor. Additionally, considerable amounts of ice were accumulating in the store and condense was observed in the ceiling in the processing area in one of the establishments visited.

In one establishment visited, the staff had to go through the processing area to get to the changing room. The changing room was not separated from the production area and had no facilities for hand washing. In another of the establishments visited working clothes were kept in direct contact with the walls in a poorly maintained and very dirty room.

In at least one of the establishments visited the facilities for washing and disinfecting hands were insufficient. The wash basins were either not accessible due to storage of packaging materials or used for storage of rusty tools and working equipment. In another establishment one of the taps did not have any water supply.

Some parts of the premises in all the establishments visited were poorly maintained, and in one of the establishments visited the room for storage of waste was very poorly maintained and cleaned.

Although to a varying degree, waste water was accumulating in the processing area in all the establishments visited.

8.9.5 Conditions related to equipment

Generally, the equipment in the establishments visited was in an acceptable state of repair.

However, in one of the establishments visited the engine for the conveyer belt was rusty. The forks on the forklift used in the production area was rusty resulting in contamination of the tubs were unprotected fishery products were stored.

Some of the tubs used for storage of raw materials and products for further processing were poorly maintained.

Wooden working tools and wooden pallets were observed in the processing area in two of the establishments visited.

8.9.6 Conditions related to hygiene and production

In all the establishments visited contaminated ice used in the production was observed. In the first establishment visited, containers used for transport and storage of ice were filled under open air at the quayside and transported and stored outside under open air without any protection. In this establishment the inspection team was informed that checking of ice production plants is not included in the inspection manual used by the IBs. Consequently, such plants have not been checked by the IBs.

In the first establishment visited the water supply was from a municipal borehole. Representatives of the establishment informed the inspection team that the water was not treated before being distributed to the users and no equipment was available for treatment of the water in case of changes in the quality.

In this establishment the inspection team observed that the temperature in both raw materials and in the products during processing was above the limits required in the Icelandic legislation. In the raw material (whole cod) the temperature was measured several places to be above + 4°C, cod filets were during processing temporarily kept in trays with stagnant water at a temperature of + 10°C, and the temperature in the mechanically recovered fish flesh was measured to be up to + 14°C.

A representative of the establishment informed the inspection team that the temperature reading devices were not calibrated. When demonstrated by the responsible staff, the inspection team observed that the temperature was no always measured in the most critical parts of the products. In the second establishment visited evidence of registration and control of the temperature in the freezer store could not be provided.

The inspection team observed that fish fillets were accumulating on the conveyer belts during processing, and that mechanically recovered fish flesh and fish fillets were left in trolleys and on the production tables respectively, both during short breaks and during the lunch break. The representative of the establishment informed the inspection team that the machinery for mechanical recovery of fish flesh was cleaned only once a day.

The inspection team also observed that after gutting, the salmon were kept in stagnant bloody water. The tank used for bleeding of salmon did not have a direct water supply, but used water from the stunning tank. Water was pumped from one tank to the other when the temperature was exceeding + 0,5°C or when too much blood had accumulated in the bleeding tank. In this establishment the inspection team was informed that, according to the inspection manual used by the IB, gutting was considered to be an operation to be carried out in the contaminated parts of the facilities. However, this was contrary to what was observed in another establishment visited, where gutting and filleting were carried out in the presumed clean parts of the facilities[11].

[11] *There is some misunderstanding in this observation as the inspection manual does not address gutting in the way stated in the report.*

Fish skin for further processing in other establishments and intended for gelatine production was frozen in the machine that was also used for freezing of salmon guts.

Packaging materials were de-wrapped in the production area close to exposed products. Packaging materials were stored on the table where fish fillets were handled. Moreover, products intended for further processing in another establishment and intended for human consumption were partly handled as waste. However, it was labelled as for human consumption.

One person was observed eating in the production area, high pressure hosing was observed in the processing area during production, and waste was accumulating in the production area. In the processing area a waste container without lid was placed close to exposed fish flesh. Cleaned and dirty plastic tubs were stored outside around the establishment together with spare parts and machinery.

In the second establishment visited it was observed that gutted salmon were stored on ice in plastic sacks and plastic tubs without drainage of melt water. Additionally, in the third establishment visited the inspection team observed that frozen products were thawed in stagnant water. According to the inspection manual this is not a deficiency. However, a Fiskistofa representative informed the inspection team that this is considered to be a minor deficiency and only if the temperature in the product kept in stagnant water is above + 8°C[12].

In the third establishment visited the inspection team observed that water from the filleting table was contaminating fillets and presumable clean knifes used for filleting. Knifes used for filleting etc. were not always kept hygienically during processing.

In two of the establishments visited, products during processing (both fillets and fish flesh), packaging materials, unclean working tables and other surfaces in the production area were handled without any cleaning of hands between the different operations.

Finally, in two of the establishments visited cleaning of tubs was carried out so that already cleaned tubs were contaminated and the risk of contamination of ice could not be excluded.

8.9.7 Conditions related to labelling and storage

In the first establishment visited it was observed that raw materials were stored exposed in the same room as waste and products intended for further processing. In this establishment it was also observed that exposed products, unlabelled products and products where the expiry date had been exceeded, were stored in the freezer store for final products. Moreover, block frozen cod skins intended for further processing and for human consumption were stored exposed and in direct contact with wooden pallets.

In this establishment the inspection team also observed that packaging materials were not stored protected from dust and contamination, and together with final products, bait, spare parts and machinery. Partly damaged packaging materials intended for use on board a fishing vessel were stored unprotected in a corridor in the establishment.

[12] *Thawing fish in water is not a deficiency. However if the temperature of the product rises above 4°C this becomes the deficiency.*

In the second establishment visited the representative of the establishment informed the inspection team that packaging materials were transported from the producer to the establishment only wrapped in thin plastic film. The inspection team observed that the packaging materials were not sufficiently protected from dust and contamination, both during transport to, and during storage in the establishment.

In the same establishment it was observed that final products were stored in the freezer store without any labelling, thus tracing the products back to its origin and date of production was impossible. In this establishment it was also observed that products exceeding the expiry date were considered as waste and stored in the waste storage. However, the original packaging and the labelling had not been removed.

9 Final meeting

A final meeting was held in the afternoon on Thursday 30 September 2004 at Fiskistofa with representatives from the Ministry of Agriculture, the Ministry of Education, the Ministry of Fisheries, the Chief Veterinary Office, Fiskistofa, the NRL and the Directorate of Freshwater Fisheries. At this meeting the inspection team orally presented the main findings and some preliminary conclusions of the mission.

At the meeting the inspection 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 CAs took note of the findings and the preliminary conclusions presented at the final meeting. The CAs did not indicate any major disagreement with the main findings and the preliminary conclusions presented. However, representatives of Fiskistofa indicated that, if necessary, comments to the conclusions would be included in its reply to the draft report. The CAs also provided some additional information for clarification. This information has been taken into account in the report.

10 Additional information provided by the Icelandic Competent Authorities

Before the Authority had finalised the draft report, the Chief Veterinary Office submitted to it additional information related to the observations made at the NRL. According to this information the Chief Veterinary Office has claimed that all working procedures necessary in conducting analyses of specific pathogens to ensure safe trade of products from aquaculture facilities must be in line with Council Directive 93/53/EEC.

According to the information received, it has also been decided, in co-operation with the NRL and the CRL for VHSV and IHNV in Århus, that a representative number of samples (approximately 14 %) will be sent to the CRL for analyses this winter. An agreement has also been signed between the NRL and the CRL to ensure rapid diagnostic service concerning serious viral diseases. Finally, the CA has claimed by a formal letter that the NRL must fulfil various demands related to accreditation of relevant test methods according to Council Directive 93/53/EEC, at the latest on 1 January 2006.

Furthermore, Fiskistofa has also submitted to the Authority additional information related to the follow-up of the findings in two of the establishments visited during the mission.

According to this information the establishments in question had been visited by inspectors from Fiskistofa on 5 and 6 October 2004. Reports from the inspections were sent to the establishments and the establishments were requested to send an action plan to Fiskistofa before 15 November 2004. Furthermore, "From the beginning, in all contacts with the companies, it has been emphasised that they must start immediately on the good housekeeping, cleanliness and hygiene issues already pointed out and mentioned."

Finally, one of the establishments has been visited a second time in order to put emphasis on the seriousness of the situation and to get an update on the status. This establishment has already taken some corrective action. Further action against the establishments is pending the content of their action plans.

11 Conclusions[13]

11.1 Official control related to certain fish diseases

11.1.1 The co-operation between the Chief Veterinary Office and Fiskistofa must be clarified in order to ensure compliance with the requirements of Directive 93/53/EEC.

11.1.2 The content and the application of the contingency plan related to List I diseases (see Annex A to Directive 91/67/EEC) could not ensure compliance with Directive 93/53/EEC and in particular Article 15 and Annex D thereof.

11.2 National reference laboratory for certain fish diseases

11.2.1 Compliance with the requirements of Directive 91/67/EEC, Directive 93/53/EEC and in particular Article 12 thereof, related to the NRL for certain fish diseases, and the verification of the status foreseen in the Authority's Decision No 227/04/COL could not be assured.

11.3 Official control related to production of fishery products

The Icelandic system for official control of fishery products establishments can not ensure that the production of fishery products and that the fishery products placed on the market are in compliance with Directive 91/493/EEC.

11.3.1 The requirements of Directive 91/493/EEC and in particular Article 6 thereof were not complied with since the CA could not ensure that the persons responsible for establishments had taken all necessary measures so that, at all stages of the production of fishery products, the specifications of the Directive were complied with.

[13] *The Icelandic Competent Authorities' comments to the conclusions are at Annex I.*

11.3.2 Compliance with the requirements of Directive 91/493/EEC and in particular Article 7 thereof could not be assured since establishments had been approved

although they did not meet the requirements of the Directive.

11.3.3 Compliance with Article 7 of Directive 91/493/EEC could not be assured since the CA had not taken the necessary measures where inspections by the CA or the IBs had revealed that establishments were not complying with the requirements of the Directive.

11.3.4 Compliance with Article 7 of Directive 91/493/EEC could not be assured since the CA had not taken the necessary measures where the inspections referred to in Article 8 of Directive 91/493/EEC had revealed non-compliances with the content of that Directive.

11.3.5 Compliance with Directive 91/493/EEC and in particular Article 7 and Chapter V of the Annex thereof could not be assured since inspections are normally not carried out without prior warning, and inspections carried out by Fiskistofa and the IBs do not comprise sampling and analysis.

11.4 Conditions related to fishery products establishments

11.4.1 Conditions related to own-checks systems including HACCP

Deficiencies related to the own-checks systems were observed in all establishments visited. For example, identification of hazards was incomplete, processes had not been included in the flowcharts, the intended use of the products had not been indicated, procedures for verification and review, and monitoring procedures for some prerequisites where either not prepared or not applied. Compliance with the requirements of Article 6 of Directive 91/493/EEC and with Decision 94/356/EEC could therefore not be assured.

11.4.2 Conditions related to facilities and equipment.

There was not a clear separation between clean and contaminated parts of the facilities in any of the establishments visited. Walls were some places not easy to clean, doors to the outside were not closing properly and facilities for storage of working clothes were sometimes insufficient. Maintenance was poor in one of the establishments visited. Wooden pallets and wooden working tools were observed in two of the establishments visited. Compliance with the requirements in Point I and II(A) of Chapter III of the Annex to Directive 91/493/EEC could therefore not be assured.

11.4.3 Conditions related to hygiene and production

Processing and handling of fishery products were not always carried out in such a way as to avoid contamination or spoilage. This is not in compliance with the requirements of, *inter alia*, II(B) of Chapter III and Points I, II, III and IV of Chapter IV of the Annex to Directive 91/493/EEC.

11.4.4 Conditions related to labelling

Unlabelled products were observed in the freezer stores in two of the establishments visited. This is not in compliance with the requirements of Chapter VII of the Annex to Directive 91/493/EEC and Directive 2000/13/EC.

11.4.5 Conditions related to storage

Final products stored outside at the quayside were not in compliance with the requirements of Chapter VIII of the Annex to Directive 91/493/EEC.

In two of the establishments visited packaging materials were not stored protected from dust and contamination. This is not in compliance with the requirements of Chapter VI of the Annex to Directive 91/493/EEC.

12 Recommendations to the Competent Authorities of Iceland

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

Iceland should notify to the Authority within two months after receiving the draft 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 11 of this report. The Authority should also be kept informed of the completion of the measures included in the timetable.

12.2 Official control related to certain fish diseases

The CA should make sure that the contingency plan for certain fish diseases is updated so that it complies with the requirements of Directive 93/53/EEC. Equipment and training should be given a particular focus.

12.3 National reference laboratory

The CAs should make sure that immediate action is taken so that the NRL involved in the monitoring of certain fish diseases can ensure the intentions and obligations laid down in Directive 93/53/EEC and other related EEA legislation.

12.4 Official control of production of fishery products

The CAs should in particular take note of the conclusions under point 11.3 and take immediate and proper action in order to ensure that the Icelandic system for official control of production of fishery products complies with the intentions and requirements of Directive 91/493/EEC.

12.5 Fishery products establishments

The CA should take the necessary action to make sure that approved establishments comply with the requirements of Directive 91/493/EEC. In this process the Authority would like to reiterate the importance of equal treatment of establishments.

Annex I Letter to the EFTA Surveillance Authority from the Icelandic Directorate of Fisheries on behalf of the Icelandic Competent Authorities

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussels,
Belgium

21 January 2005

Reference is made to a letter from ESA dated 19 November 2004, containing a draft report of a mission to Iceland 27 - 30 September 2004 regarding official control of certain fish diseases and of production and the placing on the market of fishery products.

In ESA letter *"Iceland is invited to comment on the factual content or other elements of the report, preferably within 25 working days of the receipt of the draft report,,* and it is reccommended that *"Iceland should notify the Authority within two months after receiving the draft report, written evidence of any corrective action already taken."*

This letter will address the factual content and other elements of the draft report and also give account of corrective actions already taken. In the first part of this reply issues arising from the conclusions and recommendations in the ESA report will be addressed whereas factual content will be addressed in the second part.

11 Conclusions

11.1 Official control related to certain fish diseases

11.1.1 Here ESA concludes in the draft report that: *"The co-operation between the Chief Veterinary Office and Fiskistofa must be clarified in order to ensure compliance with the requirements of Directive 93/53/EEC."*

As ESA is already aware of, following a conformity assessment initiated by ESA, Iceland has decided to issue new regulations implementing inter alia Directive 93/53/EEC. This will be done with a regulation from the Ministry of Fisheries as regards marine species and by the Ministry of Agriculture as regards fresh water species. These measures will enter into force before 1 March 2005. ESA was informed about Icelands intention in this regard at the package meeting in Reykjavik on the 25th of November 2004. As for the co-ordination between the Chief Veterinary Office and Fiskistofa in this field, it will be defined more clearly following this revision of the Icelandic regulatory framework.

See also attached letter from the Veterinary Officer for Fish Diseases, dated January 7th 2005.

11.1.2
See the attached letter from the Veterinary Officer for Fish Diseases.

11.2 National reference laboratory for certain fish diseases
11.2.1
See the attached letter from the Veterinary Officer for Fish Diseases.
See also attached letter from the Institute for Experimental Pathology, dated January 17th 2005.

11.3 Official control related to production of fishery products
In the draft report it is stated that "*The Icelandic system for official control of fishery products establishments can not ensure that the production of fishery products and that the fishery products placed on the market are in compliance with Directive 91/493 /EEC* "

This conclusion is drawn from the fact that during the visit ESA found some deficiencies both in relation to official control and the own-checks systems, facilities and equipment, hygiene etc. in the establishments visited. The Directorate of Fisheries, being responsible for the official control of fishery products, strongly objects to this conclusion. The language ESA repeatedly uses in support of the above conclusion; namely that compliance with various provisions of the Directive could not be assured because some deficiency was found somewhere, is very misleading. A deficiencyiy is understood to mean a case or a condition that is not in conformity with specific provisions of the Directive. Such cases are usually an exception from the rule and they can certainly not be taken as proof or even an indication that the Directive is not complied with generally.

11.3.1 is a good example of how ESA arrives at the above conclusion. **11.3.1** states that *"The requirements of Directive 91/493 /EEC and in particular Article 6 thereof were not complied with since the CA could not ensure that the persons responsible for establishments had taken all necessary measures so that, at all stages of the production of fishery products, the specifications of the Directive were complied with"*

The Directorate of Fisheries, being the CA, wonders what surveillance authority on earth can ensure that all persons responsible for all establishments take all necessary measures so that, at all stages of the production all relevant specifications are complied with at all times?

This of course is not possible. Some deficiencies will always be found during thorough inspections of any fisheries products establishment in any country and the deficiencies found by ESA during this visit and accounted for in this draft report, cannot in any way justify the conclusions in **11.3** and **11.3.1.** The production of Icelandic fisheries products is strictly controled by responsible persons in the establishments, by sales organizations, by foreign inspections bodies on behalf of the buyers, by the inspection bodies on behalf of the Icelandic CA and by the CA itself.

The buyers within the EEC are the ones making the highest demands for safe quality products and the Icelandic fisheries products have a long record of meeting those demands and as a result obtaining the highest prices.

Food surveillance authorities bear responsibilities not only to protect the health of the consumers but also towards the food producers. The failure of one producer to comply with one or more specifications of Directive 91/493/EEC calls for actions aimed at that particular producer. When ESA concludes that one or more deficiencies found in one establishment is a proof of an incompetent official control system and goes on indicating that this means that all producers and products then must be considered not to comply, this is unfair both to the producers and the CA.

11.3.2. The rule is that all establishments must be inspected and approved by the CA before starting up new production or before moving into new premises and there is a procedure in place for this approval work. (See annexes 4 and 5). It has, however, happened that a producer starts up production without notifying the CA beforehand as he should. In most cases these are well established producers with valid production licences who are moving the production into new and better premises. The CA will nevertheless highlight the rule on it's homepage as well as in a printed leaflet.

11.3.3. and **11.3.4.** Where inspections by the inspection bodies, the CA or ESA reveal non-compliances with Directive 91/493, the CA has a system in place to ensure that the necessary action is taken. In the year 2004 inspectors from the CA visited 772 fish processing establishments. 427 of these visits were follow up inspections because of serious deficiencies, 192 visits were inspections due to applications for new approvals, 39 visits were made to improve and control the harmonization between the inspectors from the IBs and 114 visits were due to other reasons. 16 warnings were issued and 3 establishments were closed temporarily.

As regards the follow up from ESA inspections, the CA has always taken the actions it has found appropriate and necessary as accounted for in replies to previous mission reports from ESA. The ESA comments in this last draft report relating to Article 7 of Dir.91/493 have been thoroughly discussed within the CA and with the IBs. The CA has looked into its own work and procedures in this regard and is assured that these provisions are generally complied with. ESA comments, however, will be used to make further improvements to these procedures.

11.3.5. Pre notified inspections can in the Directorate of Fisheries opinion not be considered a non compliance of Dir. 91/493. It is not required that inspections of the CA are unanounced and attention is also drawn to the fact that full inspections include an audit that requires the person or persons responsible in the inspected establishment to be present.

No official samples are taken by the CA as stated in the answers to the PMQ in August 2004. It is the producers responsibility to take samples for organoleptic checks, parasite cheks and bacteriological and chemical cheks when necessary. The results of sampling are always available for the inspectors of the IBs and the CA. Heavy metals are monitored yearly (since 1991) in marine biota around Iceland. (See Rf - report: "Vöktun á óæskilegum efnum í sjávarafurðlum 2003", http://www.rf.is/media/utgafa//SKYRSLA06-04.pdf)

11.4 Conditions related to fishery products establishments
11.4.1 - 11.4.5 In the inspections of the three establishments that ESA visited during this mission, several defiencies were observed, both regarding the own check systems as well as facilities, equipment and production. In short the CA agrees mostly with the ESA findings and will act accordingly. As previously emphasized in this letter there is a system in place that ensures appropriate and necessary actions when the outcome of inspections call for measures to be taken. And it is maintained that the CA is indeed very competent.

12 Recommendations to the Competent Authorities of Iceland
12.1 Notification of corrective action and a plan for completion of measures

Referring to point 11.3.2 above:
The CA will nevertheless highlight the rule on it's homepage as well as in a printed leaflet....
The CA will have finished this before end of April 2005

Referring to the point 12.4 below.
Point 2.
Before end of April 2005 the final decisions should have been taken.
Point 3.
The revision is taking place and the aim is to complete the revision before end of February 2005 and introduce the revised inspection manual to the IBs and the fishing industry before March 15, 2005.

Referring to the point 12.5 below.
The two day seminar that the CA will organize for inspectors and the responsible persons in fishery products establishments will be prepared and held not later than in April 2005.
The Authority will receive written notifications when these measures have been completed.

12.2 Official control related to certain fish diseases

See the attached letter from the Veterinary Officer for Fish Diseases.

12.3 National reference laboratory

See the attached letter from the Veterinary Officer for Fish Diseases.
See also the attached letter from the Institute for Experimental Pathology.

12.4 Official control of production of fishery products
The Icelandic inspection system is constantly under revision with the aim of improving it and making it more effective. Below, account is given of measures that have been taken towards this end since the ESA visit:

1. The inspection bodies were called to a meeting with the CA on the 8th of October 2004 to discuss the results of the comparison inspections made by the CA and the main findings and preliminary conclusions of the ESA mission. The main issue of the meeting was the big difference in the number of findings of the CA and ESA on one hand and the IBs on the other.
2. The CA sent a formal warning to the IBs in a letter dated 18.11.2004 (see annex 6 and 7) pointing out that the low number of findings in the inspections made by the IBs are unacceptable. This warning will be followed up by comparison inspections in January - March 2005. If the results require further actions to be taken, it will be done according to regulation no. 450/1997 (Regulation for the operation of inspection bodies in the fishing industry).
3. Some of the requirements in the inspection manual are being revised. Notice has been taken of the remarks in the ESA draft report. The main object in this revision is to clarify the requirements regarding the own check system including the HACCP and the documentation of the corrective actions taken. Requirements regarding hygiene, good housekeeping and product handling will also be looked at in this revision.

12.5 Fishery products establishments
The revised inspection manual will be introduced to the establishments in March 2005. The rule explained in **11.3.2** will be highlighted as explained, and in April 2005 the CA will organize a two day seminar for inspectors and the responsible persons in fishery products establishments in order to improve their knowledge and understanding of the inspection system. In the planning and preparation of the seminar, comments received from ESA in this draft report, and in previous reports, will be taken into account as appropriate.

As regards the establishments dealt with in this draft report, the following corrective actions have been taken:

As written in the draft report (ch. 10) action has been taken against two of the establishments.
These establishments were inspected by the CA inspectors. Reports with the findings from the inspections were sent to the establishments with a request to have their correction plans sent to the CA for approval.
Both establishments have sent their correction plans to the CA. The establishments are working on the corrections and the CA has made some follow up visits in both establishments. (See annexes 8 and 9).
Regarding the third establisment visited during the ESA visit, the CA has not taken any action. The reasons for that are firstly that ESA did not finish their visit there with a final meeting, after the representative from the CA pointed out that the way of questioning the responsible person in this establishment was unfair due to language difficulties and secondly that the CA was informed that the establishment would move their production to other premises, which has now occured.

Factual content

In chapter 7 ESA addresses some points raised in previous missions. Several of these points were minor deficiencies and they have all been addressed by the Icelandic Competent Authority.

At the bottom of page 13 ESA states that "... *inspection reports from the relevant IB or from Fiskistofa were not available."* The reason for this is that they were not requested by ESA.

On page 23 of the report it is stated that "... *all inspections carried out ... are pre-notified."* This is not correct as most inspections by Fiskistofa are not pre-notified. It should also be noted that most inspections by Fiskistofa are follow up inspections and visits.

On page 24 it is stated that "... *the inspectors from Fiskistofa check the whole establishment."* This is a misunderstanding as the inspectors evaluate on site if it is necessary to check the whole establishment or if it is only necessary to address the serious deficiencies.

Further down on the same page there is a discussion of legal obligations to notify the relevant authorities if certain pathogenic micro organisms are found. In this discussion ESA omits to mention the role of the testing laboratories. They are obliged by the Food law to notify the relevant Competent Authority if certain pathogenic micro organisms are found. This is of an immense importance for the whole inspection system in Iceland and is unique for the EEA.

On page 25 it is discussed how minor deficiencies that are not corrected become major deficiencies. It should however be noted that this does not mean that all minor deficiencies not corrected become major deficiencies. The establishment only gets one major deficiency for not correcting deficiencies found in a previous inspection.

In chapter 8.9 on page 25 ESA states" *It should be noted that although requested in the first establishment visited, all documents related to the official control were not made available to the inspection team in the two other establishments visited."* In the first establishment visited inspectors from ESA requested documents related to that establishment. This was not understood by representatives from Fiskistofa to indicate more than a request for documents related to that establishment. Had it been understood to include more documentation related to other

establishments this would of course have been supplied. Unfortunately this was not mentioned again by the inspectors from ESA until at the final meeting, when it was to late to do anything about it.

On page 27 ESA states "*although no stop in production had taken place"*. This is a misunderstanding by ESA as it came out during the visit to the establishment mentioned that there had been production stops.

Concerning the discussion in this paragraph it should be noted that Fiskistofa does not necessarily address each individual discrepancy observed in the work of the inspection bodies but chooses to address more issues at once. It should also be noted that it is not possible to correct deficiencies retroactively.

On the same page it is stated by ESA *"However, any reply to the latter from Fiskistofa was not made available to the inspection team during the mission."* The reply is in the Directorates files and would have been made available if ESA had asked for it during the mission. As regards the long time given to correct the deficiency it should be noted that this is a seasonal production, going on for a few weeks in February and/or March so there was no reason to give a shorter time limit.

At the top of page 30 there is a discussion of gutting and the inspection manual. There is some misunderstanding in this observation as the inspection manual does not address gutting in the way stated in the report.

Further down the page there is a discussion of thawing of fish. Thawing fish in water is not a deficiency. However if the temperature of the product rises above 4°C this becomes the deficiency.

On behalf of the Icelandic competent authorities

Þórður Ásgeirsson
Director of Fisheries

Annex II **Letter to the EFTA Surveillance Authority from the Icelandic Veterinary Officer for Fish Diseases, the Chief Veterinary Office, annexed to the letter from the Director of Fisheries**

DÝRALÆKNIR FISKSJÚKDÓMA
VETERINARY OFFICER FOR FISH DISEASES
INSTITUTE FOR EXPERIMENTAL PATHOLOGY
KELDUR, 112 REYKJAVIK
ICELAND

EMBÆTTI YFIRDÝRALÆKNIS
CHIEF VETERINARY OFFICER

Reykjavik, January 7th 2005

EFTA Surveillance Authority
Rue Belliard 35
B-l 040 Brussels
Belgium

SUBJECT: COMMENTS ON DRAFT REPORT - EVENT NO: 295058

Reference is made to the draft report due to the mission carried out by the EFTA Surveillance Authority (ESA) in Iceland from Sept. 27th to Sept. 30th 2004 to assess the Icelandic Competent Authorities (CA) application of relevant EEA legislation related to production and placing on the market of fishery products and control of certain fish diseases.

As pointed out in Chapters 11 and 12 in the draft report there are some remarks that I undersigned, as an official veterinarian for fish diseases, should make some comments on. I will just respond on those subjects which connects to my duties, with reference to above mentioned chapters as follows:

11.1.1 Effort has been made to clarify the co-operation between the Chief Veterinary Office and Fiskistofa. A working group has been established, leaded by the lawyers of the Ministry of Fisheries and Ministry of Agriculture, to solve that problem. As discussed at a package meeting in Reykjavik on November 25th 2004, a new regulation has been worked out to implement the Council Directive 93/53/EEC and this will be notified to ESA before March 1st 2005. The lawyers will give more detailed answer on that matter in a separate paper.

11.1.2 As pointed out in Chapter 12 (12.2) regarding recommendations to the CA work has already started to update the contingency plan for certain fish diseases so that it complies with the requirements of Directive 93/53/EEC. This work will also be given especial

focus when the new regulation will be implemented later this winter.

11.2.1 I can also confirm that the CA, in co-operation with the NRL and the Communitiy Reference Laboratory (CRL) for VHSV and IHNV in Århus, have sent a representative number of samples to the CRL for analysis during November 2004. This action was taken in line of the agreement made at a meeting prior to the final meeting on September 30th, as informed by letter from the CVO to ESA dated on October 13th 2004. Totally we sent 88 samples from brood fish, out of tot. 567 samples (approx. 15,5%). The results of these tests will be ruled out by Mr. Sigurður Helgason, Head of the Fish Disease Laboratoy, in a separate answer, in addition to other relevant information asked for in point 11.2.1.

Yours sincerely;

Gisli Jonsson
Veterinary Officer for Fish Diseases

Annex III Letter to the EFTA Surveillance Authority from the Icelandic National Reference Laboratory on fish and shellfish diseases, annexed to the letter from the Director of Fisheries

TILRAUNASTOO HASKOLA **ISLANDS I** MEINAFR/EDI ao Keldum

Reykjavik, January 17th 2005

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussels
Belgium

SUBJECT:
Comments / additional notes with reference to **Draft Report - Event No: 295058**

11.2.1 Agreement between Danish Institute for Food and Veterinary Research (DFVF) and Institute for Experimental Pathology (IEP) Keldur v/Vesturlandsveg, IS-112 Reykjavik, Iceland, on services provided by the DFVF for IEP (signed and dated 11-10-2004) (Annex 1).

Written replies from Danmarks Fødevareforskning, Afdeling for Fjerkræ, Fisk og Pelsdyr, Århus, dated 30. November and 15. December, 2004. Regarding the screening of organ material from Atlantic salmon broodfish of Icelandic origin. Organ samples from a total of 60 brood fish of fanned origin and 28 fish of wild origin were sampled and screened for viral infection with emphasis on VHS and IHN viruses (material from five fish were pooled to form a sample). This counts for 15.5% of brood fish screened during the 2004 spawning season. - Samples from each fish were analysed both in Århus and at the NRL, Keldur, in Iceland. No viruses were detected (Annex 2).

The NRL at Keldur participated in an Inter-laboratory proficiency Test on the isolation and identification of fish viruses. The proficiency test was organised by the Community Reference Laboratory (CRL) at Århus, during the autumn of 2004. The test consisted of five ampoules containing lyophilized cell culture supernatant and the participating laboratories (approximately 30) were asked to examine the content of each ampoule virologically by performing a titration followed by identification, in case of virus isolation. Part of the examination was to assess the sensitivity of virus detection in the participating laboratories as an addition to virus titration. The NRL at Keldur identified correctly viruses from all five ampoules (a full report from the CRL will be received later this month) (Annex 3).

Yours sincerely

Sigurður Helgason
Head of Fish Disease Laboratory
National Reference Laboratory on fish and shellfish diseases