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**Final report**

# EFTA Surveillance Authority mission to

# ICELAND

# 19 – 22 September 2005

**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**

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## List of abbreviations and terms used in the report

| | |
|---|---|
| Authority | EFTA Surveillance Authority |
| BF | Bluegill Fry |
| CA | Competent Authority |
| CCP | Critical Control Point |
| CVO | Chief Veterinary Officer |
| CRL | Community Reference Laboratory |
| DVO | District Veterinary Officer |
| EEA Agreement | Agreement on the European Economic Area |
| EFA | Environment and Food Agency of Iceland/*Umhverfisstofnun* |
| EPC | Epithelioma Papulosum Cyprini |
| Fiskistofa | Directorate of Fisheries |
| GMP | Good Manufacturing Practice |
| 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 |
| ISA | Infectious Salmon Anaemia |
| NRL | National Reference Laboratory |
| OV | Official Veterinarian for fish diseases |
| Surveillance and Court Agreement | Agreement Between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice |
| VHS | Viral Haemorrhagic Septicaemia |
| VHSV | Viral Haemorrhagic Septicaemia Virus |

## 1 Introduction

The mission took place in Iceland from 19 to 22 September 2005. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority) and one national expert.

This mission was a follow-up mission of the one carried out in September 2004. The final report from that mission is available at http://www.eftasurv.int/.

The opening meeting was held at the Icelandic Directorate of Fisheries (Fiskistofa) on Monday 19 September 2005. 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. Representatives of Fiskistofa accompanied the mission team throughout the mission. The relevant Inspection Body (IB) was present in all the establishments visited. The Official Veterinarian for fish diseases (OV) also participated during the relevant parts of the mission.

The final meeting was held at Fiskistofa on 22 September 2005. At this meeting the mission team orally presented the main findings and some preliminary conclusions from the mission.

## 2 Mission objectives and proceeding

The scope of the mission was to assess the Icelandic CAs application of the requirements laid down in *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*, *Council Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases* and related legislation (see Chapter 3 and 4).

The main objectives of the mission were to assess the extent to which the Icelandic CAs have implemented the corrective actions notified to the Authority following the mission in September 2004, and to assess any other actions intended to address the recommendations in the report from the previous mission.

Consequently, the mission team focused in particular on the situation at the National Reference Laboratory (NRL), the contingency plan for certain fish diseases, and on Fiskistofa's procedures for approval of new establishments and its follow-up of the establishments visited last year.

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

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

| | | Comments |
|---|---|---|
| **Competent Authorities** | 4 | 3 at the central level (including the opening and closing meeting) and one with the local CA |
| **National Reference Laboratory** | 1 | Designated as the national reference laboratory for certain fish diseases |
| **Establishments** | 3 | Fishery product establishments, two also processing farmed fish |

A scheduled visit to one of the local CAs was cancelled because the District Veterinary Officer (DVO) was occupied with clinical duties.

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

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 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.*

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

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

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

j) 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.*

k) 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.*

l) 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.*

m) 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*.

n) 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*.

o) 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*.

p) 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*.

q) 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.

r) 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.

s) 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.

## 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, Regulation No 665/2001 on action to be taken in the case of contagious diseases*, and *Regulation No 447/2005 introducing minimum measures for the control of certain fish diseases within the EEA*. The latter entered into force 28 April 2005. 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*, 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. Furthermore, Council Directive 93/53/EEC is also implemented in *Regulation No 510/2005 introducing minimum measures for the control of certain fish diseases within the EEA*, which was adopted by the Ministry of Fisheries and entered into force on 26 May 2005.

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 and Commission Decision 2004/453/EEC are implemented in *Regulation No 446/2005 concerning the animal health conditions governing the placing on the market of aquaculture animals and products* (date of entry into force was 28 April 2005). This regulation was issued by the Ministry of Agriculture. Furthermore, the Directive and the Decision are also implemented into *Regulation No 511/2005 concerning the animal health conditions governing the placing on the market of aquaculture animals and products* (date of entry into force was 26 May 2005). 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 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.

In the reply to the Authority's pre-mission questionnaire, the Icelandic CA informed the Authority that, although not implemented, Commission Decision 2003/390/EC and Commission Decision 2003/466/EC are applied in Iceland.

A conformity assessment will be carried out on the amended Icelandic measures recently notified to it as implementing, *inter alia*, Council Directive 91/67/EEC and Council Directive 93/53/EEC.

## 6 Previous missions

Since 2000, the Authority has carried out four missions to Iceland in the field of fishery products and live bivalve molluscs: one in October 2000, one in September 2002, one in March 2004 and one in September 2004. During these missions the Authority has assessed the CAs' application of both Council Directive 91/492/EEC (September 2002 and March 2004) and Council Directive 91/493/EEC (October 2000, September 2002 and September 2004). During the mission carried out in September 2004 the Authority also assessed the application of Council Directive 91/67/EEC and Council Directive 93/53/EEC.

The final reports from these missions, including information provided by the Icelandic CAs on action taken, are available at the Authority's homepage: http://www.eftasurv.int/. It follows from these reports that the Authority has revealed non-compliances related to, *inter alia*, documentation of the quality of the water used, including production and handling of ice, related to the size, design and layout of establishments, to maintenance of establishments and equipment, and to the production of fishery products.

During the mission carried out in September 2004 the Authority had a particular focus on the performance of the Icelandic CAs. Therefore, the report from that mission contains more detailed conclusions on the official control related to the production of fishery products. The Authority concluded, *inter alia*, that establishments had been approved although they did not meet the requirements of Council Directive 91/493/EEC and that the CA had not taken the necessary measures where it had been revealed that establishments were not complying with the requirements of that Directive.

## 7 Main findings

In addition to information on the organisation of the Icelandic CAs, this chapter contains some of the conclusions included in the report from the mission carried out in September 2004, information provided by the Icelandic CAs as a follow-up to those conclusions, and the observations made during this mission.

### 7.1 Competent Authorities

In Iceland, three Ministries are responsible for implementation and application of EEA Acts comprised by this mission. The Ministry of Agriculture is responsible for, *inter alia*, the Icelandic legislation implementing EEA Acts related to production and trade in live aquaculture animals (freshwater species), including control and monitoring of fish diseases.

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

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 Chief Veterinary Office, Fiskistofa and the Environment and Food Agency, respectively, are responsible for the enforcement of the Icelandic legislation adopted by these Ministries.

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 at both the national and local level. Members of the Council are nominated by the Director of the Environment and Food Agency (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 of Agriculture and for 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. The OV and the person responsible for the NRL act as experts for the Committee.

### 7.1.1 The Chief Veterinary Office

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

The Chief Veterinary Office is responsible for the application of Council Directive 91/67/EEC and Council Directive 93/53/EEC and other EEA Acts related to trade, and for the monitoring and control of fish diseases, including inspections of fish farms. Additionally, as part of the application of Council Directive 93/53/EEC, the Chief Veterinary Office is also involved in the issuing of licenses for fish farms.

In addition to the CVO, the Chief Veterinary Office consists of nine veterinary officers, each responsible for different animal species and different surveillance duties. One of the veterinary officers is appointed Deputy CVO and another has the position of OV. The duties assigned to this position vary from, *inter alia*, import control of live aquatic animals for either human consumption or for ongrowing, inspections of all aquaculture farms in Iceland, sampling in the majority of the farms, issuing of prescriptions for use of veterinary medicinal products in the aquaculture industry, placing restrictions on farms and issuing of licences, certificates etc.. In addition, the person having this position should also provide advice to the Fish Disease Committee.

On a local level, the Chief Veterinary Office consists of 15 DVOs, some involved in both official and clinical duties.

A new CA, *Landbúnaðarstofnun*, will be established as of 1 January 2006. This will arise from the different CAs currently organised under the Ministry of Agriculture. CAs constituting the new authority will be the Chief Veterinary Office, the Feed, Seed and Fertilizer Directorate, the Icelandic Meat Classification Board, the Plant Protection Service, and the Directorate of Fresh Water Fisheries.

### 7.1.2 Fiskistofa

Fiskistofa is the CA responsible for the enforcement of legislation adopted by the Ministry of Fisheries. Furthermore, Fiskistofa issues licences for farming of marine species and is also the CA with regard to the application of the Icelandic measures implementing Council 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. Additionally, Fiskistofa is the CA for the Icelandic border inspection posts where fishery products imported into the EEA via Iceland are controlled.

According to the reply to the pre-mission questionnaire, Fiskistofa is divided into eight Departments, all organised directly under the Directorate of Fisheries. Fiskistofa has no regional or local level. 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.*. As of June 2005, Fiskistofa has been registering fishing vessels smaller than 15 gross registered tons without prior inspections. Fiskistofa is also responsible for carrying out inspections of these vessels.

### 7.1.3 Environment and Food Agency

According to the Foodstuffs Act No 93/1995, the EFA shall advise the Minister for the Environment and supervise the local control authorities, which are under the responsibility of the local Environmental and Public Health Committees.

The EFA is the CA with regard to application of EEA Acts, such as the Commission Regulation (EC) No 466/2001. However, Fiskistofa is the CA regarding application of this Act in the fields of fishery products and bivalve molluscs. The EFA is also involved in issuing of licences for fish farms and fishery products establishments.

During the mission a representative of the EFA provided information on the involvement of the local food control authorities in the inspection of fishery products establishments. According to this information, the mentioned local authorities are inspecting establishments producing fishery products only for the domestic market. Legal basis for such inspections are the Icelandic Regulation 522/1994 implementing Council Directive 93/43/EEC.

### 7.1.4 The Directorate for Freshwater Fisheries

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

## 7.2 Official control related to certain fish diseases

Following the mission to Iceland, in September 2004, the Authority concluded that the co-operation between the Chief Veterinary Office and Fiskistofa had to be clarified in order to ensure compliance with the requirements of Council Directive 93/53/EEC.

In its follow-up Fiskistofa informed the Authority that after a conformity assessment of the Icelandic legislation implementing the relevant EEA legislation, it had been decided to issue some new national regulations by both the Ministry of Fisheries, with regard to marine species, and by the Ministry of Agriculture, with regard to fresh water species. Fiskistofa also informed the Authority that these new Icelandic regulations would enter into force before 1 March 2005. It was also foreseen that the revision of the Icelandic legislation would define more clearly the co-operation between the Chief Veterinary Office and Fiskistofa.

The new Icelandic regulations entered into force late April and late May 2005. A general agreement between the Chief Veterinary Office and Fiskistofa on their co-operation was signed late July 2005.

Representatives of the CAs informed the mission team that the establishment of the new CA as of 1 January 2006 had been considered not to alter, at least for the time being, the co-operation already established between the Chief Veterinary Office and Fiskistofa.

Following the mission in 2004 the Authority concluded that the content and the application of the contingency plan related to the fish diseases in List I of Annex A to Council Directive 91/67/EEC could not ensure compliance with Council Directive 93/53/EEC and in particular Article 15 and Annex D thereof.

To this conclusion the Chief Veterinary Office informed the Authority in January 2005 that work had already started on updating the Icelandic contingency plan for certain fish diseases.

During the mission the Authority observed that some amendments had been done to the contingency plan. However, representatives of the Chief Veterinary Office informed the mission team that, in case of suspicion or an outbreak of a List I disease, the OV would be more involved in the activity on a local level than indicated in the plan. Representatives of the Chief Veterinary Office also informed the mission team that the plan could have contained more details on actions to be taken at the local level in case of suspicion and or confirmation of a List I disease.

Moreover, the mission team observed only sparsely or incomplete information related to competence and responsibilities for the staff expected to be involved in disease outbreaks. The mission team also observed that some general training related to outbreaks of serious contagious diseases had been carried out in the spring of 2004. However, a training programme for relevant staff had not been established and training related to a possible outbreak of a serious contagious fish disease had not been planned for the near future.

Furthermore, representatives of the Chief Veterinary Office informed the inspection team that the equipment and materials considered relevant for carrying out disease control measures properly was insufficient in most of the local disease centres.

Finally, the mission team observed that procedures for international notification of outbreaks of List I diseases were not referred to in the contingency plan.

### 7.3 National reference laboratory for certain fish diseases

The Icelandic NRL for certain fish diseases operates from the laboratories of the Institute for Experimental Pathology, University of Iceland, Keldur, 112 Reykjavik. A diverse range of activities are performed at the Institute of Experimental Pathology, including applied veterinary research and diagnostic services.

Under the Authority's Decision No 227/04/COL of 9 September 2004 concerning the status of Iceland with regard to the fish diseases IHN and VHS, Iceland has the status of approved zone. The NRL is responsible for the screening of fish samples for Infectious Haematopoietic Necrosis Virus (IHNV) and Viral Haemorrhagic Septicaemia Virus (VHSV) as part of the surveillance programme required for maintenance of approved zone status under Commission Decision 2001/183/EC.

In the report from the mission in 2004 the Authority concluded that compliance with the requirements of Council Directive 91/67/EEC and Council Directive 93/53/EEC, in particular Article 12 of the latter, related to the NRL for certain fish diseases could not be assured. Furthermore, it was concluded that verification of the status foreseen in the Authority's Decision No 227/04/COL could not be assured.

In its follow-up to the recommendations from that mission the Chief Veterinary Office informed the Authority that, during November 2004, a number of samples had been analysed for IHNV and VHSV at the Community Reference Laboratory (CRL). This was in accordance with the agreement established between the Icelandic NRL and the CRL following the Authority’s mission in 2004. A total of 88 samples (approximately 15% of the total number of samples collected in Iceland in 2004) had been analysed and neither IHNV nor VHSV were diagnosed in the samples.

During this mission the inspection team observed certain deficiencies with regard to the layout of the laboratory. In particular, the sample reception area and processing area were in the same room. Immediately adjacent to this room was an aquarium facility for experimental work involving live fish. At the time of the visit, tanks in the aquarium contained juvenile cod undergoing a passive immunisation trial. The inspection team was informed that research involving live viruses was not conducted in the aquarium. However, the provenance of the cod could not be determined at the time of the visit.

Bacteriology and parasitology research and diagnostic work was conducted in the same room where samples of fish tissues were received and processed. Also immediately adjacent to this room was a cold store and freezer store, where cell culture media were stored along side research materials, and a small laboratory where cell culture medium was prepared and dispensed and where cell cultures were inoculated and incubated.

The layout of the laboratories poses a risk with regard to cross contamination of diagnostic and research samples. A member of staff of the NRL informed the inspection team that a reorganisation of the layout of the laboratory facilities to improve the separation of different functions was planned before the end of 2005 and that a new building had recently been proposed.

The NLR supplies equipment for collection of fish tissue and ovarian fluid samples and for packaging of these samples during transportation to the NRL. The sampling schedule is devised by the OV and is in part dependent on the time of maturation of brood fish. A

total of 700-800 fish may be sampled in one year, usually in pools of five fish. The NRL occasionally receives samples of live fish which have to be processed immediately as there are no biosecure holding facilities available.

Routine samples are collected by the OV or DVOs and either brought directly to the NRL by the OV or sent by express delivery. The NRL supplies a car as necessary to collect the samples on arrival at the depot in Reykjavik. The samples are transported in insulated plastic tubs with one or two freezer blocks. The insulated plastic tubs and other reusable materials used for packaging and transport of samples are disinfected after use. The NRL was unable to verify that the temperature of the samples during transportation was lower than 10 °C but not frozen, and the temperature of the samples is not measured on arrival at the NRL, although the inspection team was informed that the samples are always found to be cool on arrival.

Samples are usually received by the NRL the day after sampling has taken place but on rare occasions the samples can arrive on the second day. Samples are logged and assigned a unique batch number on arrival. The time of sampling is not noted on the documentation accompanying the samples. The NRL was, therefore, unable to confirm that the samples are processed within 48 hours.

The NRL encourages the OV and DVOs to collect routine samples during the early part of the week but any samples received late in the week are processed immediately. Samples are not frozen prior to processing. The NRL claimed that there had never been any problem with contamination of the samples, but the NRL does not supply transport medium to the OV or DVOs. The inspection team was advised that transport medium containing antibiotics would be supplied in future. At present, a known volume of cell culture medium is added to the samples on arrival at the NRL. The quantity of fish tissue in each sample is assessed against tubes containing known volumes of fluid and additional medium is added as required to obtain a ratio of tissue to cell culture medium of 1:10.

Maintenance of cell lines and inoculation of cell cultures are conducted in the same laminar flow cabinet. This cabinet is not used for research work. Individual batches of samples are processed separately. Negative controls are included but positive controls are not. The inspection team was informed that positive controls will be included in the future.

During the previous mission of September 2004, it was established that the NRL had not participated in any inter-laboratory proficiency tests. Subsequently, in autumn 2004, the NRL participated in a ring test in which it achieved a 100% success rate in identification of the virus samples supplied. The principal member of staff involved in reading results of virus culture tests at the NRL and another member of staff who occasionally reads virus culture test results when the principal reader is absent, both participated in the ring test.

Antibodies used in virus identification tests are supplied by the CRL in Århus, Denmark. No antibody validation work is done in-house. There is a formal agreement with the CRL whereby the NRL will participate in ring tests on a regular basis in the future. In addition, the CRL will be consulted in the event of a positive cell culture test for IHN or VHS in order to confirm the identity of the agent.

Bluegill Fry (BF) and Epithelioma Papulosum Cyprini (EPC) cell lines are supplied at low passage number and with certification that they are mycoplasma-free by the CRL. The

continued susceptibility of the cell lines to IHN and VHS is not determined by the NRL at six monthly intervals and the interval between batches of new cell lines supplied by the CRL may be more than 12 months. The NRL does keep a back-up of the cell lines in liquid nitrogen.

At present, the NRL has no cell lines or other reagents, such as antibodies, for the isolation and identification of ISA virus. A representative of the NRL informed the mission team that the OV and DVOs have formol saline available so they can take fish tissue samples for histology should they observe clinical signs of disease during a fish farm inspection. A pathologist is available on site at the NRL although his experience in relation to pathology associated with ISA could not be determined at the time of the visit.

The NRL was in possession of copies of methods supplied by the CRL but at present there was no formal documentation of the operating procedures carried out at the NRL. A representative of the NRL informed the mission team that the initial deadline of end December 2005 for submission of documentation for the purpose of accreditation of the procedures for IHN and VHS testing was unrealistic. No new deadline had been set.

### 7.4 Official control related to production of fishery products

Following the mission in 2004 the Authority concluded that the Icelandic system for official control of fishery products establishments could not ensure that the production of fishery products and the fishery products placed on the market were in compliance with Council Directive 91/493/EEC.

Fiskistofa commented that: "[t]his conclusion is drawn from the fact that during the visit the Authority found some deficiencies both in relation to official control and the own-checks system, 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 the Authority 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 deficiency 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."

In the report from the mission in 2004 the Authority also concluded that the requirements of Council 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.

Additionally, the Authority concluded that compliance with the requirements of Council 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.

In the final report the following comments from Fiskistofa were included: "[t]he 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 controlled 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 Council 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."

Furthermore, Fiskistofa stated, *inter alia*, that: "[t]he 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 work."

Additionally, Fiskistofa stated in its reply to the Authority's pre-mission questionnaire for this mission that instructions explaining the procedure on how to apply for a new approval have been placed on Fiskistofa's webpage, together with a checklist containing the most significant requirements for a fish processing establishment.

Fiskistofa has also informed the Authority that the Minister of Fisheries, in 2004, established a committee that should assess matters related to the working environment for entities in the fishing industry. This committee has had several meetings and discussed, *inter alia*, matters related to approved establishments, to IB and to quality issues related to production of fishery products. The committee makes its recommendations to the Minister of Fisheries, and Fiskistofa was at the time of the mission assessing the committee’s report concerning quality issues related to production of fishery products.

Finally, in its reply to the Authority’s pre-mission questionnaire, Fiskistofa informed the Authority that a revised inspection manual (used by both the CA and the IBs) entered into force in March 2005. The manual is available at Fiskistofa’s webpage.

Representatives of two of the establishments also visited during the mission in 2004 informed the mission team that Fiskistofa's follow-up inspections had been more detailed and carried out more often than usual. Additionally, the frequency of the inspections carried out by the IBs was the same, but, on average, more comments had been made per visit.

Representatives of both the IBs informed the mission team that following the 2004 mission, some changes were made to the inspection procedures. Firstly, the HACCP

systems are now assessed in more detail. Secondly, the checklists were changed so that it is possible to register whether a point in the list has been checked or not, a column for deadlines was included, and the corresponding procedures were updated accordingly. Thirdly, the procedures were clarified in order to ensure that representatives of the establishments were available so that inspections could be carried out.

Representatives of Fiskistofa informed the mission team that checks of the establishments' temperature controls on the production line and checks of corrective actions had been included in the inspection manual. Furthermore, representatives of Fiskistofa also stated that they had established procedures in order to improve traceability of their documents.

In one of the establishments visited the inspection team observed that the establishment had not respected the deadlines set by the establishment itself or by Fiskistofa. Additionally, in this establishment it could not be documented that the CA had verified that all the deficiencies listed in the report from its inspection in October 2004 had been complied with.

In another establishment visited a new owner had taken over the premises and parts of the equipment. Fiskistofa had issued an approval in January 2005 following an application of mid December 2004. In this period the establishment had been inspected twice, and the owner had prepared an own checks system, including a HACCP plan, which had been assessed by Fiskistofa during one of the inspections. The mission team observed certain deficiencies with regard to, *inter alia*, the identification of hazards and the flow diagram. The deficiencies observed had not been identified by Fiskistofa.

Moreover, the mission team observed that the new approval had been issued for the premises although the deficiencies related to structure, layout etc., identified during the visit in 2004, had not been rectified.

The mission team did not observe that the CA had taken any action with regard to the insufficient separation between clean and contaminated parts of the production facilities and with regard to the production, transport and storage of ice.

In the report from the mission in 2004 the Authority concluded that compliance with Article 7 of Council 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.

To this conclusion Fiskistofa informed the Authority in its follow-up letter of January 2005 that a system is in place which shall ensure that the necessary action is taken when inspections by the IB, the CA or the Authority have revealed non-compliances. A number of establishments had been visited during 2004. These visits had, *inter alia*, resulted in the issuing of 16 written warnings and a temporary stop in the production in three establishments.

Furthermore, Fiskistofa added that regarding the follow up from the Authority's missions, the CA has always taken the actions it has found appropriate and necessary as accounted for in replies to previous reports. The Authority's comments in the report from the mission in 2004 and relating to Article 7 of Council Directive 91/493/EEC have been thoroughly discussed within the CA and with the IBs. Fiskistofa has also assessed its own procedures

and is assured that these provisions are generally complied with. However, Fiskistofa will use the Authority's comments in order to further improve the procedures.

During the mission Fiskistofa also elaborated on the procedures used for follow-up of findings during official inspections. These procedures have recently been amended in order to describe the actual steps carried out by the CA.

In the establishment approved by the CA early in 2005, the mission team observed that the IB had registered a number of both major and minor deficiencies during an inspection recently carried out. Representatives of Fiskistofa informed the mission team that it was in the process of following-up the content of that report. Additional information from Fiskistofa related to the mission team's observations in this establishment is included in Chapter 9.

In the 2004 report, the Authority concluded that compliance with Council Directive 91/493/EEC and in particular Article 7 and Chapter V of the Annex thereof could not be assured since inspections were normally not carried out without prior warning, and inspections carried out by Fiskistofa and the IBs did not comprise sampling and analysis.

To this conclusion Fiskistofa stated that: "[p]re 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 unannounced 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 responsibility of the producers to take samples for organoleptic checks, parasite checks and bacteriological and chemical checks 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."

In the reply to the Authority's pre-mission questionnaire for this mission, Fiskistofa included a paper prepared by the Icelandic Fisheries Laboratories (IFL) regarding monitoring and research activities on contaminants at IFL. According to this document, the Ministry of Fisheries finances a project involving evaluation of the concentrations of various undesirable substances in the edible portion of marine catches. This is the first time that systematic collection of information has been carried out for a number of substances and many kinds of marine catches from Icelandic fishing grounds; in addition, information is being gathered on numerous substances that have not been previously examined. The substances being investigated are trace elements (mercury, cadmium, lead and the total concentration of arsenic as well as the concentration of inorganic arsenic), PAHs (17 substances), polychlorinated dibenzodioxins and dibenzofurans (17), dioxinlike PCBs (12), marker PCBs (6), polybrominated flame retardants (10 PBDEs ), organotins (10 substances), and numerous pesticides (HCB, DDTs, HCHs, aldrin/endrin/dieldrin, chlordanes, toxaphenes and endosulfan substances; altogether 29 chemical compounds).

### 7.5 Conditions related to fishery products establishments

In the report from the 2004 mission the Authority listed a number of deficiencies observed in the establishments visited related to the own-checks systems, including HACCP, to facilities and equipment, to hygiene and production and to labelling and storage.

In its follow-up letter of January 2005 Fiskistofa stated: "In the inspections of the three establishments that ESA visited during this mission, several deficiencies 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 outcomes of inspections call for measures to be taken. And it is maintained that the CA is indeed very competent."

In the reply to this mission's pre-mission questionnaire, Fiskistofa informed the Authority that a two-day seminar had been arranged for all inspectors within the inspection system in May 2005. All inspectors from the IBs as well as all relevant staff from Fiskistofa attended the seminar where HACCP was one of the main topics.

Furthermore, Fiskistofa informed the mission team that two of the establishments had been visited by inspectors from Fiskistofa in addition to the regular visits by the IBs. The establishments had been working on improvements in accordance with corrections plans sent to Fiskistofa. Additional follow-up visits had been planned to the establishments in order to verify that the deadlines had been complied with.

Two of the establishments visited in 2004 were also visited during this mission. The third establishment visited during this mission was operating in the building/facilities of one of the establishments visited in 2004. At the time of the visits, one of the establishments visited was slaughtering and packing salmon (also approved for processing white fish), one establishment was producing fish fillets and one establishment was not in production.

In one establishment the mission team observed some deficiencies related to the own-checks system including HACCP. It could not be established whether sufficient expertise had been involved in the preparation of the HACCP plan. Furthermore, the relevant hazards had not been indicated and listed, the flow diagram did not fully describe the processes taking place and the method used for identification of possible critical control points (CCPs) could not be produced.

In two of the establishments visited the majority of the deficiencies observed during the mission in 2004 had been rectified. In these establishments the level of maintenance and order had been improved. In the third establishment visited the facilities had been taken over by a new owner and a new approval had been issued by Fiskistofa in January 2005. In this establishment a number of deficiencies related to both facilities and production were observed.

There was no clear separation between clean and contaminated parts of the facilities in two of the establishments visited. In one of the establishments the mission team observed that outside, adjacent to the production area, with the door to the production area open and with fishery products exposed on the working tables, one staff member in working clothes was washing a car. In the same establishment some of the staff members entered the processing area before changing into working clothes, wooden pallets were observed in the production area and two mezzanines, which were not easy to clean, were used for storage of machinery and spare parts.

In all three establishments visited doors to the outside were either not closing properly or kept open during production. In a presumably clean area in one establishment visited, the

mission team observed both forklifts which were also used outside and dirt on the floor. In the same establishment it was observed, *inter alia*, that ice in plastic tubs without lids was transported outside, some of these tubs were dirty and contaminated ice was observed in some tubs. In another establishment the mission team was not given access to the ice machine.

Furthermore, the mission team observed that slaughtered fish for further processing was stored on ice in tubs without drainage of melt water. Products for further processing and intended for human consumption were stored directly on wooden pallets without sufficient protection from contamination.

In one of the establishments visited the mission team observed, *inter alia*, waste kept in the production area in tubs without lids, waste and wastewater accumulating on the floor, cooler bricks on the floor in the freezer and hosing of working tables while fish fillets were kept on the tables. Moreover, working gloves were stored in the area mainly used for maintenance of equipment and thereafter rinsed in a sink with hand operable taps.

In one of the establishments visited the freezer was not well organised, not sufficiently maintained and ice was accumulating in the ceiling and on packed products. In addition, some unlabelled products were also observed in the freezer.

In two of the establishments visited the storage of wrapping and packaging materials had improved since the visit in 2004. However, damaged packaging materials containing frozen products packed at sea were observed in the freezer in one of the establishments visited. In the room for storage of packaging materials and in the production area in another of the establishments visited, wrapping and packaging materials were stored exposed and in direct contact with the walls.

## 8 Final meeting

In the afternoon on Thursday 22 September 2005 the final meeting was held at Fiskistofa with representatives of 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 the Icelandic representatives 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.

## 9 Additional information provided by the Icelandic Competent Authorities

Before the Authority had finalised the draft report, Fiskistofa submitted to it additional information related to the follow-up of the findings in one of the establishments visited during the mission.

According to this information Fiskistofa sent a letter to the establishment in question on 23 September 2005 pointing out, *inter alia*, the seriousness of the obvious lack of Good Manufacturing Practice (GMP) observed during the visit. Fiskistofa visited the establishment on 26 September 2005 and a report from that visit was finalised on 28 September 2005. Following this report the establishment has sent a plan for corrective action to Fiskistofa and informed that most of the deficiencies have been corrected. Those still outstanding will be corrected before the end of October 2005.

## 10 Conclusions

### 10.1 Official control related to certain fish diseases

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

### 10.2 National reference laboratory for certain fish diseases

Compliance with the requirements of Council Directive 91/67/EEC, Council Directive 93/53/EEC, and in particular Article 12 thereof, related to the NRL for certain fish diseases could not be assured.

### 10.3 Official control related to production of fishery products

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. Furthermore, one of the establishments had been approved although it did not comply with the requirements of Council Directive 91/493/EEC. Full compliance with the requirements of Council Directive 91/493/EEC and in particular Point (c) of Article 3.1, Article 6, Article 7 and Chapter III of the Annex thereof could not be assured.

### 10.4 Conditions related to fishery products establishments

#### 10.4.1 Own-checks systems including HACCP

Some deficiencies, such as construction of flow diagram, listing of hazards and identification of CCPs, related to the HACCP system were observed in one establishment. Compliance with the requirements of Article 6 of Council Directive 91/493/EEC and with Commission Decision 94/356/EEC could therefore not be assured.

#### 10.4.2 Facilities and equipment

There was not a clear separation between clean and contaminated parts of the facilities in at least two of the establishments visited. Doors to the outside were not closing properly or kept open during processing. Compliance with the

requirements in Point I and II(A) of Chapter III of the Annex to Council Directive 91/493/EEC could therefore not be assured.

#### 10.4.3 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 Council Directive 91/493/EEC.

#### 10.4.4 Labelling of products

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 Council Directive 91/493/EEC and Council Directive 2000/13/EC.

#### 10.4.5 Storage

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

## 11 Recommendations to the Competent Authorities of Iceland

### 11.1 Notification of corrective action and a plan for completion of measures

The CAs should notify to the Authority within two months after receiving the final report, written evidence of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding at that time, relevant to all the conclusions under Chapter 10 of this report. The Authority should also be kept informed of the completion of the measures included in the timetable.

### 11.2 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 Council Directive 93/53/EEC. Equipment, training and division of tasks should be given a particular focus.

### 11.3 National reference laboratory

The CAs should make sure that the action necessary is taken in order to ensure that the NRL complies with Council Directive 93/53/EEC.

### 11.4 Official control of production of fishery products

The CAs should take proper action in order to ensure that the Icelandic system for official control of fishery products establishments, including the procedures for their approval, complies with the requirements of Council Directive 91/493/EEC.

### 11.5 Fishery products establishments

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