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Final report

EFTA Surveillance Authority mission to

ICELAND

1 – 5 March 2004

regarding the application of EEA legislation related to the production and the placing on the market of live bivalve molluscs

Please note that comments from Iceland have been included in the report in *underlined italic* or annexed to the report.

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List of abbreviations and terms used in the report

ASP	Amnesic Shellfish Poison
Authority	EFTA Surveillance Authority
Bonamiosis	A disease in oysters caused by the parasite *Bonamia ostrea*
CA	Competent Authority
CRL	Community Reference Laboratory
CVO	Chief Veterinary Officer
DSP	Diarrhetic Shellfish Poison
EC	European Community
EEA Agreement	Agreement on the European Economic Area
EFA	Environment and Food Agency of Iceland/Umhverfisstofnun
Fiskistofa	Icelandic Directorate of Fisheries
IB	Inspection body/Skoðunarstofa
IFL	Icelandic Fisheries Laboratories/Rannsóknastofnun Fiskiðnaðarins
Keldur	Institute for Experimental Pathology of the University of Iceland at Keldur
Marteiliosis	A disease in oysters caused by the parasite *Marteilia refringens*
MRI	Icelandic Marine Research Institute/Hafrannsóknarstofnun
NRL	National Reference Laboratory
PCBs	Polychlorinated Biphenyls
PCDDs	Polychlorinated Dibenzo-p-dioxins
PCDFs	Polychlorinated Dibenzofurans
PSP	Paralytic Shellfish Poison
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
UTM	Universal Transverse Mercator Grid

1 Introduction

The mission took place in Iceland from 1 to 5 March 2004. The inspection team comprised 2 inspectors from the EFTA Surveillance Authority (the Authority).

An opening meeting was held on Monday 1 March at the Icelandic Directorate of Fisheries (Fiskistofa). The meeting continued on Tuesday 2 March, both in the morning and in the afternoon. At these meetings representatives of Fiskistofa added information to the reply to the Authority's pre-mission questionnaire. Throughout the mission two representatives from Fiskistofa accompanied the inspection team.

A final meeting was held at Fiskistofa on 4 March 2004 at which the inspection team orally presented the main findings and conclusions of the mission.

2 Objectives of the mission

The main objective of the mission was to assess the Icelandic Competent Authorities' (CAs) application of the requirements laid down in Council Directive 91/492/EC, Council Directive 95/70/EC and related legislation (see Chapter 3 and 4).

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

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

		Comments
Competent Authority	4	Central (incl. the opening and closing meeting)
National reference laboratories	1	Designated as national reference laboratory for certain diseases affecting live bivalve molluscs
Other laboratories	3	Laboratories analysing samples for algae, bacteria, marine biotoxins, dioxins and heavy metals
Establishments	1	Mussel farm

A particular focus was put on the CAs' procedures for classification of production areas, the control and monitoring of production of bivalve molluscs, the laboratory network and the laboratories co-operation and communication with the CAs.

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 6.1.10 of Chapter I of Annex I to the EEA Agreement, *Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs*, as amended, and in particular Article 6 thereof.

d) The Act referred to at Point 3.1.8 of Chapter I of Annex I to the EEA Agreement, *Council Directive 95/70/EC of 22 December 1995 introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs*, as amended, and in particular Article 8 thereof.

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

4 Other relevant legislation

The main European Community (EC) acts in the field of bivalve molluscs, incorporated into the EEA Agreement and applicable to Iceland are:

a) 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 relevant application texts.

b) The Act referred to at Point 54n of Chapter XII of Annex II to the EEA Agreement, *Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs*.

c) 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*.

d) 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*.

e) The Act referred to at Point 6.1.10a of Chapter I of Annex I to the EEA Agreement, *Council Decision 1999/313/EC of 29 April 1999 on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs*.

f) The Act referred to at Point 6.2.12 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 93/25/EEC of 11 December 1992 approving certain treatments to inhibit the development of pathogenic micro-organisms in*

bivalve molluscs and marine gastropods, as amended.

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 6.2.17 of Chapter I of Annex I to the EEA Agreement, *Council Decision 93/383/EEC of 14 June 1993 on reference laboratories for the monitoring of marine biotoxins*, as amended.

i) 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*.

j) 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*.

k) 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*.

l) The Act referred to at Point 54 zzc 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*.

5 National legislation

The main Act creating the legal basis for Fiskistofa's application of the EEA legislation in the field of bivalve molluscs is the *Act No 55 of 10 June 1998 regarding the handling, processing and distribution of marine products (Lög nr. 55/1998, um meðferð, vinnslu og dreifingu sjávarafurða)*. This Act implements, *inter alia*, Directives 91/492/EEC and 91/493/EEC and it gives the legal basis for a number of regulations of which the two most important are *Regulation No 849 of 14 December 1999 on control of import of fishery products* and *Regulation No 233 of 30 March 1999 regarding the handling, processing and distribution of marine- and fishery products*, as amended by Regulation No 387 of 29 May 2000 and Regulation No 367 of 7 May 2001.

In addition to these legal texts a number of regulations regulate the handling, processing and distribution of marine products. The following list of acts (adopted by the Ministry of Fisheries unless otherwise stated) is not exhaustive but contains the main legal texts

incorporating the EEA legislation related to bivalve molluscs in Iceland. The information in the list was a part of the Icelandic reply to the Authority's pre-mission questionnaire and was handed over to the inspection team during the mission.

a) Council Directive 91/492/EEC is implemented into the *Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs*.

b) Council Directive 91/493/EEC is implemented into *Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs*, *Regulation 233/1999 on health conditions for the handling, processing and distribution of fishery products* and *Regulation 558/1997 on own checks*.

c) Commission Regulation (EC) No 466/2001 is implemented in *Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs* and *Regulation 233/1999 on health conditions for the handling, processing and distribution of fishery products*[1].

d) Commission Decision 93/51/EEC is implemented in *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*.

In its reply to the pre-mission questionnaire Fiskistofa informed the Authority that Council Directive 95/70/EC has not been implemented into Icelandic legislation, but the Directive is nevertheless applied by Fiskistofa. However, on 25 of February 2004 the Authority initiated the formal procedures referred to in Article 31 of the Surveillance and Court Agreement, by issuing a letter of formal notice to Iceland for failure to implement or to notify the Authority of the national measures considered by Iceland to implement Council Directive 95/70/EC.

Furthermore, according to the list of legislation handed over by representatives of Fiskistofa to the inspection team during the mission, Commission Decision 2002/225/EC, Commission Decision 2002/226/EC and Commission Directive 2001/22/EC[2] have not been implemented into Icelandic legislation. *This Directive has been implemented by Regulation 736/2003 (um sýnatökur og meðhöndlun sýna fyrir mælingar á aðskotaefnum í matvælum).* However, according to Fiskistofa these acts are nevertheless applied in Iceland.

Finally, the Authority has observed that the adaptation text to the Act referred to at Point 6.2.17 of Chapter I of Annex I to the EEA Agreement (Council Decision 93/383/EEC as amended) indicates that Fiskistofa is listed as the National Reference Laboratory (NRL)

[1] It should be noted that the Icelandic Ministry for the Environment has notified to the Authority the measures considered by it to implement Commission Regulation (EC) No 466/2001. However, there seem to be some discrepancies between the content of the measures notified by that Ministry and the content of the Icelandic Regulations 260/1999 and 233/1999.

[2] It should be noted that the Icelandic Ministry for the Environment has notified to the Authority the measures considered by it to implement Commission Directive 2001/22/EC.

for the monitoring of marine biotoxins. However, Fiskistofa has no facilities enabling it to function as a NRL as it is foreseen in that Decision.

6 Information on production and export

The production quantity of the different species is included in Figure 2 while the export quantity and the value thereof split on the main markets are listed in Figure 3.

Representatives of Fiskistofa informed the inspection team that the production of Red Abalone is only taking place at on-shore farms and that, apart from some test batches placed on the EU market, the vast majority is exported to Japan for further growth before harvested for human consumption. Fiskistofa is not considered as CA when it comes to the production of Red Abalone. *The Directorate is the CA for the production of Red Abalone.*

Figure 2: Production volume of different species (in tons)

	Year		
Species	**2001**	**2002**	**2003**
Scallops	6.499	5.192	789
Iceland cyprine	7.433	12.353	14.430
Red abalone[3]	-	-	-

Figure 3: Export quantities (tons) and value (thousand ISK) split in species and main markets

	Year					
	2001		**2002**		**2003[4]**	
Species and countries	**Quantity**	**Value**	**Quantity**	**Value**	**Quantity**	**Value**
Scallops, total	**630**	**595.508**	**617**	**523.996**	**171**	**123.135**
France	311	299.917	338	280.006	101	70.797
Netherlands	179	162.535	130	112.689	40	30.283
United States	79	76.702	81	75.154	5	4.253
United Kingdom	33	30.876	45	36.369	19	14.938
Denmark	8	7.597	12	8.265	-	-
Belgium	10	9.627	8	7.451	6	6.865
Sweden	2	1759	2	2.063	-	-
Iceland Cyprine, total	**312**	**80.413**	**798**	**181.022**		**164.650**
Faeroe Islands[5]	53	6.313	129	19.233	169	24.405
United States	368	74.100	669	161.789	617	140.245
Red Abalone, total	**-**	**-**	**25**	**69.535**	**6,5**	**13.077**
Japan	-	-	24	57.409	6	12.229

[3] No data was available at the time of the inspection.
[4] Preliminary figures.
[5] Representatives of Fiskistofa informed the inspection team that the export of Iceland Cyprine to the Faeroe Islands was bait and not for human consumption.

7 Previous mission

The Authority's last mission in this field to Iceland took place in September 2002. The final report from that mission is available at the Authority's homepage on the Internet: http://www.eftasurv.int/. During that mission the Authority assessed the application by the CAs of both Directive 91/493/EEC on fishery products and Directive 91/492/EEC on bivalve molluscs.

In the mission report it was concluded that, *inter alia*, the relevant parts of Directive 91/492/EEC were not applied to the production and harvesting of Scallops (*Clamys islandica*). Moreover NRLs for the monitoring of marine biotoxins and for viral and bacteriological contamination of bivalve molluscs were not designated and that the laboratories visited were not approved by the CA.

Furthermore, procedures for classification of production areas as foreseen in Directive 91/492/EEC were not established, the public health control and monitoring of production of bivalve molluscs were not fully in compliance with Directive 91/492/EEC, evaluation of methods for harvesting, transport and handling of live bivalve molluscs could not be documented and procedures related to transport documents and/or permanent transport authorisations were not established.

As a follow-up of the findings during that mission, Fiskistofa informed the Authority in a letter of November 2002 that although harvesting and other handling and distribution are covered by Icelandic regulations implementing Directive 91/492/EEC, areas where wild scallops are harvested have not been demarcated and classified.

Further to the conclusions contained in the report from that mission, Fiskistofa informed the Authority in a letter of April 2003 that the relevant NRLs would be designated before 31 December 2003 and that the laboratories visited had been approved as they were subsidiaries of an approved laboratory.

Finally, Fiskistofa informed that the procedures for classification of production areas should be in place before 1 June 2003, the public health control and monitoring of production of bivalve molluscs would be formalised no later than 1 July 2003 and that the necessary transport documents/authorisations would be in place no later that 1 October 2003. Regarding evaluation of methods for harvesting, transport and handling of live bivalve molluscs, a project was initiated late 2002 related to the harvesting of Iceland Cyprine.

8 Main findings

8.1 Competent Authorities

According to the Icelandic Foodstuffs Act No 93 of 28 June 1995, as amended, the responsibility for implementation and application of EEA acts related to food safety in Iceland 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*, control on import and export of animal origin and health inspections of aquaculture animals. Finally, the Ministry of Fisheries enacts the Icelandic legislation implementing EEA acts related to, *inter alia*, production, harvesting, processing and distribution of marine products.

The following CAs have competence in the field of control of bivalve molluscs:

a) **Fiskistofa** is the CA for the application of Directive 91/492/EEC including, *inter alia*, classification of production areas and public health control and monitoring of production of bivalve molluscs. Fiskistofa is also the CA with regard to the application of the Icelandic measures implementing Commission Regulation (EC) No 466/2001, as amended, and Directives 2001/22/EC and 2002/69/EC for the parts related to the control and monitoring of contaminants in fishery products and bivalve molluscs. Finally, Fiskistofa is also the CA with regard to the application of the Icelandic measures implementing Directive 95/70/EC.

b) **The Chief Veterinary Office** provides scientific competence in relation to diseases affecting bivalve molluscs.

c) **The Environment and Food Agency (EFA)** is the CA with regard to the implementation of Regulation (EC) No 466/2001, as amended, and Directives 2001/22/EC and 2002/69/EC, and for application of these acts in areas other than for fishery products, bivalve molluscs and products falling under the responsibility of the Chief Veterinary Office.

Fiskistofa is organised under the Ministry of Fisheries, while the Chief Veterinary Office is organised under the Ministry of Agriculture. The EFA is organised under the Ministry for the Environment.

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.

8.2 Control of diseases affecting bivalve molluscs

In the reply to the Authority’s pre-mission questionnaire Fiskistofa informed that although not being implemented into Icelandic legislation, the content of Directive 95/70/EC is nevertheless applied in Iceland.

However, during the mission the inspection team was informed by representatives of Fiskistofa that so far, establishments rearing bivalve molluscs had not been registered. Procedures for keeping records of live bivalve molluscs entering farms or leaving farms and procedures for on-farm registration of abnormal mortality were not in place.

Furthermore, during the mission representatives of Fiskistofa informed the inspection team that a programme for monitoring and sampling in bivalve molluscs farms, farming areas and harvested natural beds in order to observe whether there is an abnormal mortality and keep track of the health situation of stocks was not in place.

Moreover, procedures for notification to the CA by the shellfish farmers or any other persons, who suspect presence of any disease or observe abnormal mortality of bivalve molluscs in farms, farming areas, harvested natural beds etc, were not applied.

Finally, measures to be initiated by the CA in case of observation of any abnormal mortality or if the CA has information giving it reason to suspect the presence of a disease were not established.

The inspection team was informed that during the last few years a drastic decrease in the wild stock of Scallops has been observed in Breiðafjörður on the west coast of Iceland. As far as brought into the knowledge of the inspection team, Fiskistofa had so far not been involved in this situation. However, the relevant NRL had late 2002 been contacted by the Icelandic Marine Research Institute (MRI)/Hafrannsóknarstofnun. Additional information is to be found under Chapter 8.8.2 on the NRL for diseases affecting live bivalve molluscs.

8.3 Indication and classification of production areas for bivalve molluscs

8.3.1 Indication of production areas

The harvesting areas in Iceland are divided into five main areas each having its own number (x): Vestfirðir (1), Norðurland (2), Austfirðir (3), Suðurland (4) and Vesturland (5). Each of these main areas is divided into sub areas (yy) and a further subdivision (y) of the areas is also used. Consequently, each production area has a unique four-digit number. Additionally, each main area is identified by a two-letter code used as a prefix (VS = veiðisvæði/production area) to the unique four-digit identification number (VS xyyy).

Example:
VS 2041: Production area # 1 in area 04 (Skjálfandi) in the main area Norðurland.

According to information contained in Fiskistofa's reply to the pre-mission questionnaire, the boundaries of the classified production areas are given by *Lat/Lon or geographical references to indicate areas etc*.

Boundaries of production areas containing natural deposits of bivalve molluscs from which live bivalve molluscs are harvested, are not always indicated. However, during the mission representatives from Fiskistofa agreed to the fact that indication of location and boundaries is relevant for all areas from which bivalve molluscs are harvested. *Boundaries of areas harvested during 2003 and 2004 are always indicated.*

8.3.2 Classification of production areas

Up to the time of the mission three different production areas had been classified according to the requirements laid down in Chapter I of the Annex to Directive 91/492/EEC:

1) Skjálfandi VS 2041
2) Þistilfjorður VS 2061
3) Bakkaflói VS 3011

All these areas are classified as "A" areas as it is laid down in point 1(a) of Chapter I of that Annex.

In one of these classified production areas the sampling started in April 2001. A total of 9 sampling points were decided by Fiskistofa and indicated by UTM accuracy. During a period lasting until April 2002, approximately 30 water samples were collected at each of these sampling points. The samples were analysed for faecal coliform bacteria. Based on the results of these samples the production area was classified as "A" and opened for harvesting in May 2002.

The representatives from Fiskistofa informed the inspection team that when classifying production areas samples from live bivalve molluscs have only been taken since late 2002. However, samples are also taken from sea water. The representatives also informed that the period for which samples are taken for classification shall be at least four months and that seasonal variations are not relevant to take into account when classifying.

Furthermore, classification of other production areas than those complying with the requirements in point 1(a) of Chapter I of the Annex to Directive 91/492/EEC is not relevant in Iceland. As purification centres and relaying areas are not established or approved, harvesting will be stopped in production areas when the requirements in point 1(a) of Chapter I of that Annex can not be complied with.

Finally, according to the representatives from Fiskistofa, procedures for re-classification of production areas are still to be formalised.

8.4 Health control and monitoring of production of bivalve molluscs

According to Fiskistofa's reply to the Authority's pre-mission questionnaire, procedures for re-opening of temporarily closed production areas are under review. It is foreseen that these procedures will be in place and applied as of May 2004. However, in general a production area might be re-opened if two consecutive tests show that the production area is within the limits.

8.4.1 Monitoring of the microbiological quality of bivalve molluscs

Monitoring of production areas is only done during harvesting. It is foreseen that four samples of bivalve molluscs should be analysed per year for coliform bacteria or E. coli. The samples have to be taken by the farmers. However, the costs for transport of the samples and analyses are covered by Fiskistofa. *Contracted rescue officers so far have in most instances taken the samples and in one case a contracted local fisherman took samples. However, in the case of farms, of which two are in the process of being opened, the samples may be taken by the farmers and/or by officers of Fiskistofa.*

8.4.2 Monitoring of the plankton situation in seawater

The phytoplankton species registered in Icelandic waters and known to produce shellfish toxins are listed in Figure 4 on page 14.

In its reply to the Authority's pre-mission questionnaire related to the mission carried out in September 2002, Fiskistofa informed the Authority that for monitoring of the phytoplankton situation in Icelandic waters, samples were taken monthly from May to October. Both sampling and analyses were carried out by the MRI, which also evaluated the results and sent reports to Fiskistofa.

In the reply to the Authority's pre-mission questionnaire related to the mission comprised by this report, Fiskistofa informed that monitoring of the phytoplankton situation in Icelandic waters has not been performed during the last two years. Furthermore, it informed that the procedure for monitoring of algae is under construction and that the procedure has not been applied to harvesting areas.

During the mission representatives of Fiskistofa informed the inspection team that some monitoring of algae had been carried out until 1995. However, a project for monitoring of algae in Icelandic waters has been outlined, but not initiated. This project is foreseen to start up some time during 2005 and last for approximately five years.

Finally, a representative of the MRI informed the inspection team that phytoplankton samples are collected once a year (during May) at between 20 and 25 sampling stations around Iceland. Moreover, these samples are only irregularly analysed for species identification.

Figure 4: Phytoplankton species registered in Icelandic waters and known to produce shellfish toxins

Dinoflagellates		**Diatoms**
Alexandrium minutum		Pseudo-nitzschia delicatissima
Alexandrium ostendfeldii		Pseudo-nitzschia fraudulenta
Alexandrium tamarense		Pseudo-nitzschia pseudodelicatissima
Dinophysis acuminate		Pseudo-nitzschia pungens
Dinophysis acuta		Pseudo-nitzschia seriata
Dinophysis norvegica		
Gonyaulax grindley		
Gymnodinium spp.		**Other**
Gyrodinium spp.		Heterosigma akashiwo
Phalachroma rotundatum		
Prorocentrum lima		
Prorocentrum minimum		

8.4.3 Monitoring of biotoxins in bivalve molluscs

A plan for monitoring biotoxins in bivalve molluscs has been applied since February 2003. According to this plan samples are to be taken only by producers/gatherers. However, Fiskistofa intends to include sampling for verification of these results in the future.

The species sampled as a part of the monitoring are Blue Mussel (*Mytilus edulis*) and Iceland Cyprine (*Arctica icelandica*). Fiskistofa and the Icelandic Fisheries Laboratories (IFL)/Rannsóknastofnun Fiskiðnaðarins (RF) have agreed that samples of bivalve molluscs shall be analysed for biotoxins by the IFL. However, the agreement has not been formalised.

Samples to be analysed for Paralytic Shellfish Poison (PSP) are taken throughout the year, while samples to be analysed for ASP and Diarrhetic Shellfish Poison (DSP) are taken from June to October. From May to October samples are taken every week. In November and December samples are taken every second week and analysed for PSP. If the samples analysed in November and in December are negative, samples from January to April are only collected once a month. It should be noted that samples are only taken according to this programme when harvesting is taking place.

As a follow-up of the Authority's mission in 2002 a letter was sent to Iceland in October 2002 requesting information regarding, *inter alia*, official sampling related to monitoring the harvesting of wild Scallops. In its reply of November 2002 Fiskistofa stated that "Since the only scallop product is a frozen muscle, testing for algal poison has not been performed as this is not relevant". Representatives of Fiskistofa confirmed this opinion during this mission.

During 2003 a total of 38 samples of bivalve molluscs were collected and analysed for a possible presence of marine biotoxins. The samples were collected from all three classified production areas and three areas in the process of being classified. One of the 38 samples analysed was positive for DSP. This sample had been collected in October 2003 from one of the areas in the process of being classified. Approximately four weeks later one sample was taken from two other production areas close to the one that was positive for DSP. Both of the two last samples showed negative results.

Representatives of Fiskistofa informed the inspection team that during 2003 the distribution of results from the analysing laboratories via the IFL had not been functioning. It had normally taken more than one month to receive the results of the analyses. The positive result of the sample collected in October 2003 had been notified to Fiskistofa 14 days after the sample had been collected.

8.4.4 Monitoring of contaminants in foodstuffs

According to information provided by Fiskistofa heavy metals and organic pollutants are monitored every other year and once prior to opening of a new production area.

Furthermore, there is an ongoing programme for monitoring pollution in and around Iceland. The programme is a part of Iceland's commitments under the Convention for the Protection of the Marine Environment of the North-east Atlantic (OSPAR) and the Artic Monitoring and Assessment Programme (AMAP) of the Nordic Council of Ministers. Additionally, the IFL is regularly analysing for heavy metals in fishery products.

During 2003 a total of four samples had been collected by the CA and submitted to RF for analyses of heavy metals (cadmium, lead and mercury).[6]

Representatives of Fiskistofa informed the inspection team that procedures for sampling for analysis of contaminants in foodstuffs are under revision. It is foreseen that the new procedures will be applied as of 1 May 2004. The representatives also informed the inspection team that the current sampling procedures are not taking into account the requirement that sampling is only to be performed by authorised qualified persons.

8.4.5 Viral contamination

According to information contained in Fiskistofa's reply to the Authority's pre-mission questionnaire there is no surveillance of possible viral contamination of bivalve molluscs in Iceland.

8.5 Approval and withdrawal of approval of dispatch centres, purification centres etc.

According to the information in the reply to the pre-mission questionnaire Fiskistofa has so far not approved dispatch centres or purification centres. Approval of such centres will follow the same procedures as for approval of fishery products establishments.

Such centres must meet all relevant requirements in the legislation before being approved by Fiskistofa. Additionally, before Fiskistofa assesses an application for approval, a representative of the centre must have signed a contract with an accredited Inspection Body (IB)[7].

After having assessed the application and inspected the establishment with a favourable outcome, Fiskistofa issues an approval certificate with a unique approval number. The establishment is added to a list of approved establishments, which is continuously updated and available on Fiskistofa's homepage on the Internet. A letter is also sent to the contracted IB, which initiates regular inspections.

Suspension/withdrawal of approvals of dispatch centres and purification centres by Fiskistofa 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.

In cases where an inspection carried out by the IB reveals a serious deficiency, inspectors from Fiskistofa visit the establishment and if the situation is verified, a written warning is issued. If the deficiencies have not been rectified within the time limit set out in the written warning, the approval is withdrawn. Fiskistofa issues a new approval only after an inspection has revealed that the deficiencies have been rectified or at least a plan for corrective action has been approved by Fiskistofa.

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[6] *The analysis of contaminants comprises not only cadmium, lead and mercury but the trace elements arsenic, selenium, chromium, nickel, silver, copper and zinc and the organic contaminants PCBs and a series of organochlorine pesticides including chlordanes, toxaphenes, DDTs and endosulfanes. This is in accordance to the annex of Council Directive 79/923/EEC of 30 October 1979.*

[7] In Iceland accredited IBs recognised by Fiskistofa carry out inspections of bivalve molluscs and fishery products establishments, vessels and auction markets.

Following a permanent withdrawal of an approval, the establishment is deleted from the list of approved establishments.

8.6 Registration documents and permanent transport authorisation

A template for a registration document for the identification of batches of live bivalve molluscs during transport from the production areas to a processing plant has been prepared by Fiskistofa. This document is not used since gathering is carried out by the staff that is operating the processing plant. However, representatives from Fiskistofa informed the inspection team that in such a situation a permanent transport authorisation as a replacement for the registration document is not applied in Iceland.

8.7 Control system for end products

It follows from the Icelandic Regulation No 260/1999 on fishing, handling, processing and distribution of live bivalve molluscs that the CA is obliged to perform checks on end products.

However, according to information provided by Fiskistofa as a reply to the pre-mission questionnaire, official checks are not carried out on end products. In that reply Fiskistofa is also referring to that Regulation regarding requirements related to the establishments own checks system.

8.8 Laboratories

8.8.1 General comments

Representatives of Fiskistofa informed the inspection team that the Food Council recently had initiated a process for a total revision of the laboratory structure in Iceland.

According to Article 24 of the Icelandic Foodstuffs Act No 93 of 28 June 1995, as amended, "supervisory bodies and parties producing or distributing foodstuffs" are obliged to notify the relevant competent authority in case of suspicion of a health risk due to consumption of foodstuffs. Furthermore, laboratory staff must notify the relevant competent authority if certain microorganisms that are subject to notification obligations according to Icelandic law are discovered when testing and analysing foodstuffs. However, it seems from this legal text that this obligation does not cover, *inter alia*, toxins in bivalve molluscs.

In at least two of the laboratories visited the anonymity of samples could not always be guaranteed, as the identity of the owner and/or the origin of the samples were available during the analysing process. This could raise a problem of confidentiality.

The number of staff at the laboratories visited seemed to be sufficient for the number of samples currently being analysed.

8.8.2 National reference laboratory for diseases affecting bivalve molluscs

Representatives of Fiskistofa and of the laboratory informed the inspection team that the Institute for Experimental Pathology of the University of Iceland at Keldur (Keldur) had been appointed as the NRL for diseases affecting bivalve molluscs. Keldur, being an independent University Institute under the Division of Medicine, is organised under the Ministry of Education.

The Fish Disesase Laboratory, a division of Keldur, has an independent financial budget. The laboratory is, *inter alia*, responsible for diseases affecting bivalve molluscs. Its duties are laid down in a special Law, the Law about the Fish Disease Laboratory No 50 of 6 May 1986 as amended. The representatives of Fiskistofa and of the laboratory informed the inspection team that the laboratory had been appointed by the Ministry of Agriculture, but only by way of what is laid down in the Law. However, the obligations falling from Directive 95/70/EC, as it was incorporated into the EEA Agreement, are not reflected in that Law.

The main activity of the Fish Disease Laboratory is related to fish diseases affecting aquaculture animals. Apart from a project on investigation of a drastic decrease in the wild stock of Scallops in Breiðafjörður, initiated late 2002, no emphasis has been put on diseases affecting bivalve molluscs. The laboratory is the only laboratory in Iceland working in the field of diseases affecting bivalve molluscs.

Although being appointed as a NRL for diseases affecting bivalve molluscs, no contact has been established with the relevant CAs. The representative of the NRL informed the inspection team that, so far, the laboratory has not established any contact with the Community Reference Laboratory (CRL) regarding diseases affecting bivalve molluscs. Furthermore, the inspection team was informed that the laboratory had not established any contact with relevant NRLs in other EEA countries.

The laboratory is not accredited. However, it is foreseen that the accreditation process of the division working in the field of diseases affecting bivalve molluscs will be initiated during 2005 in order to receive an accreditation in 2006. The representative of the laboratory informed the inspection team that a complete Standard of Operational Procedures (SOP) is still to be prepared. For example, written procedures for handling of samples and preparing samples for analyses were not established.

However, the representative of the laboratory was aware of the methods and procedures referred to in the Annex to Commission Decision 2002/878/EC. In the project regarding the decrease in the stock of wild scallops, diagnostic methods used were wet screening, histopathology and electron microscopy. Based on the samples analysed at the laboratory in December 2002, a parasite was identified as a possible causative agent. However, at the time of the mission confirmatory identification of the parasite was still pending.

The representative of the laboratory informed the inspection team that, so far, no contact had been established between the relevant competent authorities and the laboratory in order to participate in the preparation of a programme for monitoring and sampling with regard to diseases affecting bivalve molluscs.

However, co-operation had been established between the NRL and the MRI regarding sampling in relation to the investigation of the decrease of the wild stock of scallops in Breiðafjörður.

8.8.3 Laboratory involved in monitoring the plankton situation in seawater

In Iceland the MRI is the national laboratory for analysing seawater samples for phytoplankton. Being an official laboratory organised under the Ministry of Fisheries and located in Reykjavík, the laboratory comprises five branches in Iceland and three research

vessels. The total number of staff is approximately 150 out of which 1-3 persons are located at each of the branches. The main activity of the laboratory is the monitoring of the fish stocks in Icelandic waters.

Analyses of samples for species identification are only carried out at the main laboratory in Reykjavik. At this laboratory a total of four persons are working in the section relevant for analysing seawater samples for plankton. Out of this four, two are involved in the preparation and analysis of the samples. Seawater samples are mostly checked for salinity, temperature, zooplankton and phytoplankton. Samples to be analysed for phytoplankton are normally collected once a year (in May) at 20 to 25 sampling stations around Iceland. These samples are only irregularly analysed for species identification.

The representatives of the laboratory informed the inspection team that the laboratory has not been approved by Fiskistofa for the relevant analyses carried out and the laboratory is not accredited. Some guidelines, *inter alia*, for how to take samples, are in place. However, a written SOP is in the process of being prepared. According to the representatives of the laboratory this manual will be finalised before the end of the first half of 2004.

The laboratory has not formalised co-operation with other institutes or universities with regard to identification of phytoplankton species etc in seawater samples. However, samples are occasionally sent to other countries for further identification.

Representatives of the laboratory have participated in meetings with Fiskistofa related to the planning of a programme for the monitoring of algae activity in Icelandic waters. However, the project is in the initial stage and details related to sampling frequency, sampling procedures, designation of sampling points, reporting procedures etc. is still to be decided and formalised.

Finally, the laboratory's participation in preparation of the programme and its involvement in the application of the programme are still to be formalised.

8.8.4 Laboratories involved in monitoring of marine biotoxins and viral and bacteriological contamination of bivalve molluscs

The only Icelandic laboratory involved in the official monitoring of marine biotoxins and viral and bacteriological contamination is the IFL.

The IFL has its main office in Reykjavik and a total of four branches in Iceland. However, representatives of the laboratory informed the inspection team that all analytical activity will be terminated in three of the four branches (in Akureyri, Ísafjörður and Vestmannaeyjar) as of May 2004.

The laboratory, which is organised under the Ministry of Fisheries, is divided into three divisions: Division of Research and Development, the Analytical Service Division and the Operational Division. The IFL has since 1997 been accredited according to ISO 17025 on General requirements for the competence of testing and calibration laboratories. The Icelandic Metrology and Accreditation Service/Löggildingarstofa and the Swedish Board for Accreditation and Conformity Assessment (SWEDAC) are the responsible accreditation bodies.

The current accreditation comprises the quality system, eight microbiological test methods and six chemical test methods mainly related to shellfish, fish, fish meal and water.

During the Authority's mission in 2002, Fiskistofa issued a letter for approval of the laboratory. However, that letter was not fully taking into account the principles of Directive 93/99/EC.

The laboratory is involved in Fiskistofa's planning of the monitoring programme. However, this co-operation is not formalised.

As the IFL has not sufficient competence and capacity for performing analyses for marine biotoxins, the laboratory has agreed with laboratories outside Iceland for these analyses[8]. Samples are sent to a laboratory in Denmark to be analysed for ASP and to a laboratory in Ireland to be analysed for DSP and PSP[9]. These routines have been applied since February 2003. However, IFL has not formalised agreements with these laboratories.

8.8.5 Laboratories involved in monitoring of contaminants in foodstuffs

8.8.5.1 The Research and Development Division of the Icelandic Fisheries Laboratory

The analyses of the contaminants cadmium, lead and mercury are carried out at the laboratory organised under the Research and Development Division of the IFL laboratory in Reykjavik.

The quality system of the laboratory is accredited, but methods related to analysing the relevant contaminants[10] (cadmium, lead and mercury) in foodstuffs are not. Representatives of the laboratory informed the inspection team that due to the high number of methods and the cost of achieving and maintaining an accreditation, it is not foreseen that the relevant methods will be accredited. However, the laboratory participates regularly in internationally organised ring tests and co-operates with laboratories in other countries on a case by case basis.

The laboratory is involved in Fiskistofa's planning of sampling related to monitoring of contaminants in foodstuffs. However, the co-operation is not formalised.

Samples to be analysed for dioxins and dioxin-like PCBs are collected by the staff from the MRI and sent to the IFL for further preparation and distribution to relevant laboratories. The IFL forwards samples to the Department of Pharmacology and Toxicology of the University of Iceland for analysing some of the dioxin-like PCBs (some of the mono-ortho PCBs), while other parameters (as referred to in the Annex to Directive

[8] *It is right that IFL together with the Institute of Pathology of the University of Iceland at Keldur did not have the capacity to perform the analysis of biotoxins during 2003. However, these institutes have the competence to analyse ASP (HPLC/UV at IFL) and together as regards PSP and DSP (extractions and purification of extracts at IFL and the mouse bioassay at Keldur) as evidenced by a FDA-approval of all these three groups of toxins.*

[9] *Furthermore, the ASP was analysed for at a laboratory in Ireland (obtaining accreditation for that analysis in December 2003 from the Irish National Accreditation Board (INAB)) while the assays of DSP and PSP were carried out by an accredited laboratory in Denmark.*

[10] *The relevant contaminants are the trace elements arsenic, selenium, chromium, nickel, silver, cadmium, copper and sinc in addition to cadmium, lead and mercury.*

2002/69/EC) are mainly analysed at a laboratory in Germany and sometimes at a laboratory in Norway[11].

8.8.5.2 The Department of Pharmacology and Toxicology of the University of Iceland

The laboratory at the Department of Pharmacology and Toxicology, being part of the University of Iceland and organised under the Ministry of Education, is the only laboratory in Iceland analysing organic pollutants. In addition to the mono-ortho PCBs determined in samples from the IFL, the laboratory is also analysing other PCBs, organochlorids and insecticides.

Due to, *inter alia*, the small amount of samples analysed per year, the laboratory is not accredited and it is not foreseen that an accreditation process will be initiated. Furthermore, although a written operational manual is in place, a quality system has not been established. However, the laboratory participates twice a year in ring tests organised by the QUASIMEME Project Office at the FRS Marine Laboratory in Aberdeen, UK.

The laboratory annually receives approximately 70 samples from the IFL. The laboratory is notified by the IFL one to two weeks upon arrival of the samples. All samples are homogenised by the IFL before being sent to the analysing laboratory. The origins of the samples are not known to the staff analysing the samples. Results are notified back to the IFL normally within two months after arrival. However, co-operation with the IFL is not formalised nor are procedures for notification of results.

Finally, the laboratory is not involved in Fiskistofa's planning of the sampling programme.

8.9 Mussel farm and establishment visited

8.9.1 General comments

Farming of mussels is in its initial face in Iceland. At the time of the mission Fiskistofa had not approved any farms according to Directive 91/492/EEC. However, one farm, which was visited during the mission, had initiated the construction of facilities, and the CA's classification process of the relevant production areas was in its final stages.

8.9.2 Production areas and on shore facilities

The owner of the farm visited informed the inspection team that, pending the necessary approvals by the CA, the placing of processed mussels on the EEA market and the placing on the domestic market of live mussels for direct human consumption, will be initiated later this year.

When in full operation, the farm will consist of mussel lines located in three different production areas and on-shore facilities for handling of both live mussels for direct human consumption and for further processing. Additionally, a specially equipped boat will be used for harvesting of mussels and for transport to the on-shore facilities. Areas/facilities for relaying or purification are not foreseen.

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[11] *IFL forwards samples for the analysis of PCBs and the organochlorine pesticides including chlordanes, toxaphenes, DDTs, and endosulfanes to the Department of Pharmacology and Toxicology of the University of Iceland as well to a laboratory in Germany while the dioxins and the dioxinlike PCBs are mainly analysed at accredited laboratories in especially Germany but also in the Netherlands and Norway.*

Furthermore, it is foreseen that harvesting will take place on a daily basis and throughout the year, except for the spawning season (during the month of August). The total production capacity is calculated to be approximately 300 tons of live mussels per year.

Co-operation with Fiskistofa was established in 2001 and the classification process was initiated in 2002. However, the final classification of the production areas is still pending.

Informal contact had been established with the CA regarding layout of the facilities, but at the time of the visit none of the facilities had been approved. According to information provided to the inspection team during the visit, the CA had so far not evaluated the equipment intended for harvesting, transport, landing and handling of the mussels and the necessary approvals were still to be issued.

The representative of the farm also informed the inspection team that the own checks system, sampling programme included, was still to be prepared.

8.9.3 Sampling

The representative of the establishment informed the inspection team that samples from the different production areas had only been collected by the staff of the farm, none had been collected by the CA or representatives of the CA.

According to information provided by Fiskistofa during the mission, samples had been collected since October 2002 from two of the three (non-classified) production areas. In one of the areas three seawater samples had been collected in the fourth quarter of 2002 for analyses of faecal coliform bacteria. Three samples of mussels were taken in the fourth quarter of 2002, out of which one was analysed for heavy metals, one for organic pollutants, two for salmonella and three for faecal coliform bacteria. Additionally, five samples of live mussels had been collected during 2003 and analysed for algae toxins. Out of the five samples one had been positive for DSP.

In the other production area two seawater samples, one collected late 2003 and the other early 2004, were analysed for E. coli. Furthermore, two samples of mussels were collected during 2002, two during 2003 and one early 2004. All these samples were analysed for faecal coliform bacteria and Salmonella. Finally, two samples were analysed for PSP and one for DSP during the second half of 2003.

The inspection team was also informed that a programme for the monitoring of, *inter alia*, the possible presence of toxin-producing algae in the production areas and biotoxins in live mussels, after the classification of the areas, is still to be prepared.

9 Final meeting

A final meeting was held in the afternoon on Thursday 4 March 2004 at Fiskistofa with representatives of Fiskistofa and from one of the laboratories visited. At this meeting the inspection team orally presented the main findings and preliminary conclusions of the mission.

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

The CA agreed to the findings and the conclusions[12] and provided some additional information for clarification. This information has been taken into account in the report.

10 Conclusions

10.1 Application of Council Directive 95/70/EC

10.1.1 Compliance with the requirements of Council Directive 95/70/EC, and in particular Articles 4, 5 and 6 thereof, related to on-farm registrations, monitoring and sampling, notification to the CA in cases where presence of any diseases is suspected and procedures for follow-up in such cases, sampling included, could not be assured.

10.1.2 Although an NRL for certain diseases affecting bivalve molluscs has been designated, the role, responsibilities and obligations foreseen in Directive 95/70/EC and in particular Article 5 and 6 thereof could not be assured.

10.2 Application of other relevant EEA Acts

10.2.1 Commission Directive 2001/22/EC and Commission Directive 2002/69/EC on sampling and analysis of certain contaminants are not fully applied in Iceland[13].

10.3 NRLs for bacteriological and viral contamination and for algae toxins

Compliance with the requirements laid down in Directive 91/492/EEC and Decisions 1999/313/EC and 93/383/EEC, as amended, in particular with regard to designation of NRLs and the carrying out of the duties assigned to such laboratories, could not be assured.

10.4 Council Directive 93/99/EEC on the subject of additional measures concerning the official control of foodstuffs

Compliance with the requirements of Directive 93/99/EC, and in particular with regard to approval, and assessment of laboratories as laid down in Article 3 thereof, could not be assured.

10.5 Council Directive 91/492/EEC on health conditions for the production and the placing on the market of live bivalve molluscs

10.5.1 Follow-up of conclusions of visits by the Authority

The follow-up by Fiskistofa of the conclusions of visits by the Authority needs further improvements in order to be in accordance with the requirements of Directive 91/492/EEC and in particular Article 5(1)(a) thereof since conclusions

[12] *It should be noted that the nature of the final meetings is such that they are an opportunity for ESA to present its findings and for the Directorate to clarify some issues. The conclusions, as presented in Chapter 10 are only arrived after the ESA team has left Iceland so that the Directorate can not comment on these until the final report has been received. The Directorate therefore reserves the right to address these points and other in the draft report, at a later stage.*

[13] *Sampling and analysis performed at the Icelandic Fisheries laboratories are conducted according to Commission Directives 2001/22/EC and 2002/69/EC.*

related to, *inter alia*, public health control and monitoring of production and the use of transport authorisations in order to ensure traceability of consignments, were still not remedied. Furthermore, the location and the boundaries of production areas are not fixed for all areas from which bivalve molluscs are harvested, in accordance with the requirements in Chapter I of the Annex to the Directive.

10.5.2 Checks for possible presence of marine biotoxins in scallops

Compliance with the relevant requirements in Chapter V and VI of the Annex to Directive 91/492/EEC could not be assured since products of scallops are not checked for a possible presence of marine biotoxins.

10.5.3 Registration document/permanent transport autorisation

Compliance with the requirement in the last paragraph of point 6 of Chapter II to the Annex to Directive 91/492/EEC with regard to the granting of a permanent transport authorisation could not be assured.

10.5.4 Public health control and monitoring of production

Compliance with point 1(C) and 2 of Chapter VI of the Annex to Directive 91/492/EEC with regard to checks of possible presence of toxin-producing algae in production waters, including the laboratory involvement, could not be assured.

10.5.5 Public health control and monitoring of production

Sampling and analyses as foreseen in point 3 of Chapter VI of the Annex to Directive 91/492/EEC in order to verify that the level of marine biotoxins does not exceed safety limits could not be fully assured.

10.6 Application texts related to monitoring of contaminants in foodstuffs

10.6.1 Procedures for assuring that sampling is performed by authorised qualified persons such as laid down in point 3.1 of Annex I to Commission Directive 2001/22/EC could not be documented.

10.6.2 Procedures for sampling such as described in Annex I to Commission Directive 2002/69/EC and 2001/22/EC could not be documented.

11 Recommendations to the Competent Authorities of Iceland

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

Iceland 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 Laboratories

The CAs should make sure that proper action is taken so that NRLs and other laboratories involved in the monitoring of the production and placing on the

market of live bivalve molluscs are complying with the requirements laid down in the relevant legislation, such as Directives 91/492/EEC, 93/99/EEC and 95/70/EC.

11.3 Public health control and monitoring of production

The CAs should make sure that the obligations related to in particular public health monitoring and official sampling for laboratory analyses as foreseen in Directives 91/492/EEC and 95/70/EEC are complied with.

ANNEX

Additional comments contained in Fiskistofa's letter of 10 May 2004.

As has already been noted, in correspondance from the Directorate and in discussions during visits, improvements and development of inspection systems and action taken to ensure compliance with the relevant legislation is an ongoing process. The Directorate is grateful for comments made with the aim of improving the administration by the Directorate and takes into account the comments made by ESA, as applicable. It should further be noted that this field is very small in Iceland and therefore some processes are not fully developed as they have not yet been polished through use. This is reflected in several of the comments made by ESA and came regularly up during discussions throughout the visit.

Some changes have already been made since ESAs visit. Council Directive 95/70/EC introducing minimum Community measures for the control of certain diseases affecting bivalve mollusks has been applied in Iceland by the introduction of Regulation 345/2004 um lágmarksráðstafanir vegna eftirlits með tilteknum sjúkdómum sem herja á samlokur. Work has also begun on re-writing the Icelandic regulation on the production of bivalve molluscs to better reflect the relevant Community legislation. As stated earlier, work on reference and other laboratories is well under way in Iceland. As ESA noted there is also considerable work being done in strengthening the procedures and other tools in the control of the production and placing on the market of bivalve molluscs.

ESA will be informed of the progress of the work undertaken to improve the control in this area and the Directorate may avail itself of ESA's expertise by referring some matters to ESA for clarification, if this is deemed appropriate.