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Final report

EFTA Surveillance Authority mission to

NORWAY

25 – 30 April 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 Norway have been included in the report in *underlined italic* or annexed to the report.

Contents **Page**

List of abbreviations and terms used in the report

AOAC	Association of Analytical Communities
ASP	Amnesic Shellfish Poison
Authority	EFTA Surveillance Authority
AZA	Azaspiracid
Bonamiosis	A disease in oysters caused by the parasite *Bonamia ostrea*
CA	Competent Authority
CEFAS	The Centre for Environment, Fisheries & Aquaculture
CODEX	Codex Alimentarius Commission of the Food and Agriculture Organisation and the World Health Organisation.
CRL	Community Reference Laboratory
DSP	Diarrhetic Shellfish Poison
EC	European Community
EEA Agreement	Agreement on the European Economic Area
FEPAS	Food Examination Performance Assessment Scheme
FIDIR	Directorate of Fisheries/Fiskeridirektoratet
HPLC-FLD	High Performance Liquid Chromatography – Fluorescence Detection
HPLC-UV	High Performance Liquid Chromatography – Ultra Violet Detection
IFREMER	French Research Institute for Exploitation of the Sea
ISO	International Organisation for Standardisation
KNT	Municipal Food Authority/Kommunalt næringsmiddeltilsyn
LC-MS	Liquid Chromatography – Mass Spectrometry
Marteiliosis	A disease in oysters caused by the parasite *Marteilia refringens*
NFSA	Norwegian Food Safety Authority/Mattilsynet
NIFES	National Institute of Nutrition and Seafood Research/Nasjonalt Institutt for Ernærings- og sjømatforskning
NMKL	Nordic Committee on Food Analysis/Nordisk Metodikkomité for Næringsmidler
NRL	National Reference Laboratory
NS	Norwegian Standard/Norsk standard
NVH	Norwegian School of Veterinary Science/Norges Veterinærhøgskole
OIE	World Organisation for Animal Health
PBDEs	Polybrominated Diphenyl Ethers
PCBs	Polychlorinated Biphenyls
PCDD/F	Polychlorinated dibenzo-p-dioxins and dibenzofurans
PSP	Paralytic Shellfish Poison
SDT	Norwegian Animal Health Authority/Statens dyrehelsetilsyn
SLT	Norwegian Agricultural Inspection Service/Statens landbrukstilsyn
SNT	Norwegian Food Control Authority/Statens næringsmiddeltilsyn
SOP	Standard Operation Procedure
UTM	Universal Transverse Mercator Grid
VI	National Veterinary Institute/Veterinærinstituttet
YTX	Yessotoxins

1 Introduction

The mission took place in Norway from 25 to 30 April 2004. The inspection team comprised 2 inspectors from the EFTA Surveillance Authority (the Authority).

An opening meeting was held on Monday 25 April at the Norwegian Food Safety Authority (NFSA)/Mattilsynet in Oslo. At this meeting representatives of the NFSA added information to the reply to the Authority's pre-mission questionnaire. Throughout the mission two representatives from the NFSA accompanied the inspection team.

A final meeting was held at the NFSA on 30 April 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 Norwegian Competent Authority's (CA) 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	Including opening and final meetings, one meeting with a regional office and one with a local office of the NFSA
National reference laboratories	3	NRLs for marine biotoxins, bacterial and viral contamination, and for diseases affecting live bivalve molluscs
Other laboratories	2	One laboratory analysing water samples for algae and one local laboratory preparing samples for analyses for marine biotoxins
Establishments/vessels	2	One approved dispatch centre and one vessel harvesting and transporting live bivalve molluscs

A particular focus was put on the CA's 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 CA.

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.

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 Norway 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 the NFSA's application of the EEA legislation in the field of bivalve molluscs is the *Act of 19 December 2003 No 124 relating to Food Safety and Plant and Animal Health (Lov 19. desember 2003 nr 124 om Matproduksjon og mattrygghet mv.)*. This Act implements partly Council Directive 91/492/EEC and provides the legal basis for other national measures implementing this directive and other relevant EEA legislation. Council Directive 91/492/EEC is also implemented in the *Quality Regulation of 14 June 1996 No 667 relating to Fish and Fishery products as last amended by Regulation of 17 March 2004 No 536 (Kvalitetsforskrift 14. juni 1996 nr 667 for fisk og fiskevarer, sist endret ved forskrift av 17. mars 2004 nr 536)* (adopted by the Ministry of Fisheries).

In addition to these legal texts a number of regulations regulate the handling, processing and distribution of marine products. The following list of acts is not exhaustive but

contains the main legal texts incorporating the EEA legislation related to bivalve molluscs in Norway. The information in the list was part of the Norwegian reply to the Authority's pre-mission questionnaire. Additional information was provided during the mission.

a) Council Directive 95/70/EC is implemented into:
   i) *Regulation of 16 January 2004 No 279 relating to approval and enlargement of aquaculture establishments and registration of garden ponds.* (Adopted by the Ministry of Fisheries.)

   ii) *Regulation of 18 December 1998 No 1409 relating to the establishment and operation of fish farms, and measures to prevent disease at fish farms*. (Adopted by both the Ministry of Fisheries and the Ministry of Agriculture.)

   iii) *Regulation of 15 January 2004 No 278 about health inspections of aquaculture animals*. (Adopted by the Ministry of Fisheries.)

   iv) *Regulation of 5 February 1990 No 144 relating to instructions for A-, B-, and C-diseases*. (Adopted by the Ministry of Agriculture.)

   v) *Regulation of 1 January 1995 No 99 relating to list of diseases in fish and other aquatic animals applied to the Food Law*. (Adopted by the Ministry of Agriculture.)

   vi) *Regulation of 4 July 1991 No 509 relating to prevention, control and eradication of diseases in aquatic organisms.* (Adopted by the Ministry of Agriculture.)

b) Commission Regulation (EC) No 466/2001 is implemented into *Regulation of 27 September 2002 No 1028 relating to certain contaminants in foodstuffs*, as amended. (Adoptred by the Ministry of Health.)

c) Commission Directive 2001/22/EC is implemented into *Regulation 27 September 2002 No 1028 relating to certain contaminants in foodstuffs*, as amended.

d) Commission Directive 2002/69/EC is implemented into *Regulation of 23 May 2003 No 633 amending regulation of 27 September 2002 No 1028 regarding certain contaminants in foodstuffs*.

e) Commission Decisions 93/25/EEC, 93/51/EEC, 2002/225/EC and 2002/226/EC are all implemented into the *Quality Regulation of 14 June 1996 No 667 relating to Fish and Fishery products.*

6 Information on production and export

The production quantity of the different species is included in Figure 2 while export quantity and the value thereof split on the main markets are listed in Figure 3. The figures for the production volume in 2003 were not available at the time of the mission.

In Norway bivalve molluscs are mainly produced in the regions of Skagerak, Rogaland and Sør-Trøndelag. However, production areas are classified in most of the coastal counties.

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

	Year		
Species	**2001**	**2002**	**2003**
Blue mussels (*Mytilus edulis)*	920	2.557	n/a
Great scallop	22	5	n/a
Oysters	2,5	1,7	n/a

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

	Year					
	2001		**2002**		**2003**	
Species and countries	**Quantity**	**Value**	**Quantity**	**Value**	**Quantity**	**Value**
Blue mussels, total	**694**	**8448**	**1482**	**8671**	**1966**	**7717**
EU, total	**617**	**6762**	**1443**	**7523**	**1942**	**7087**
Germany	34	184	221	510	837	1750
Denmark	146	342	363	880	336	766
Ireland					218	662
France			84	553	179	1351
The Netherlands	287	3952	675	3566	142	403
Sweden	29	292	14	308	138	646
Belgium	28	619	58	1008	64	904
Third countries, total	**77**	**1686**	**39**	**1148**	**24**	**630**
Great scallop, total	**425**	**15702**	**429**	**16875**	**323**	**12757**
EU, total	**420**	**15258**	**415**	**16264**	**314**	**12382**
Italy	148	5502	70	2648	66	2153
Belgium	125	4372	156	5359	63	2260
Germany	40	1520	51	1935	61	2433
The Netherlands	69	2435	65	2366	54	2119
Spain	15	608	24	1033	49	2005
France	1	43	0	32	2	460
Sweden	2	109	5	361	5	367
Denmark	10	345	31	2002	9	461
Luxemburg			2	72	0	11
Great Britain	10	324	9	408	4	213
Third countries, total	**5**	**444**	**14**	**611**	**9**	**375**
Oysters, total	**2**	**220**	**2**	**121**	**21**	**700**
EU, total	**1**	**134**	**1**	**66**	**20**	**662**
Third countries, total	**1**	**86**	**1**	**55**	**1**	**38**

7 Previous mission

The Authority's last mission in this field to Norway took place in March 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 report from that mission it was concluded that, *inter alia*, Directive 91/492/EEC was not applied on production of marine gastropods. It was also concluded that a national reference laboratory (NRL) for the monitoring of viral and bacteriological contamination of bivalve molluscs had not been designated and that the Authority had not been notified of the designation of the NRL for the monitoring of marine biotoxins.

Furthermore, it was concluded that although a procedure for classification of production areas had been established, evidence of compliance with the requirements, including indication of location and boundaries of the production areas, as laid down in Article 5(2)(a) and Chapter I of the Annex to Directive 91/492/EEC could not be demonstrated. The procedures for approval of establishments, including dispatch centres, were not always in compliance with the requirements of Directive 91/492/EEC since temporary approvals were issued by the CA.

Finally, it was concluded that methods for harvesting, transport and handling of bivalve molluscs had not been evaluated and procedures for collecting samples for laboratory tests (public health control and monitoring of production) had not been established.

As a follow-up of findings and conclusions of that mission the Norwegian CA, by a letter of 8 August 2002, informed the Authority that the requirements of Directive 91/492/EEC related to marine gastropods were foreseen to be applied as of September 2002. However, the necessary amendments to the Norwegian regulation did not enter into force until 17 March 2004.

With regard to NRLs Norway notified the Authority of the two relevant laboratories late 2002. Procedures for classification of production areas were distributed to the regional offices during 2002. However, necessary updates of the Norwegian legislation were not finalised until March 2004.

In the letter of August 2002 the Authority was also informed that procedures for evaluation of harvesting methods would be prepared before the end of 2002. However, following a request for information Norway informed in a letter of 23 April 2003 that these procedures were still to be finalised and that the process would continue after the NFSA had been established. Finally, in the same letter the Authority was informed that the revised procedures for approval of establishments would be applied as of July 2003.

8 Main findings

8.1 Competent Authorities

In Norway the Ministry of Agriculture, the Ministry of Fisheries and the Ministry of Health have the legal competence to enact regulations in the field of food safety. The legal basis for such regulations is the Act of 19 December 2003 No 124 relating to Food Safety and Plant and Animal Health.

According to Article 23 of that Act, the NFSA is the CA with regard to application of Norwegian legislation implementing EEA legislation in the field of bivalve molluscs. Additionally, the NFSA has the legal power to adopt national measures implementing safeguard decisions adopted by the EC Commission and applicable to Norway through the EEA Agreement.

The NFSA, established 1 January 2004, consists of the former Norwegian Agricultural Inspection Service/Landbrukstilsynet (SLT), the Norwegian Animal Health Authority (SDT), the Norwegian Food Control Authority/Statens næringsmiddeltilsyn (SNT), the Municipal Food Control Authorities (KNTs) and the Seafood Inspectorate of the Norwegian Directorate of Fisheries/Fiskeridirektoratet (FIDIR).

The NFSA is organised in three administrative levels; one central office, eight regional offices and 64 district offices. The central office, being located in Oslo, is responsible for co-ordinating the organisation's activities including, *inter alia*, inspections, disease surveillance and eradication, and preparation of legislation. Three of the regional offices, having the status of national centres, have been assigned tasks related to specific fields. One of these three is the regional office in Bergen which is the national centre related to fish and seafood.

The national centre related to fish and seafood has been, *inter alia*, allocated the responsibility for drafting instructions related to official control in the field of bivalve molluscs. The instructions are distributed to all regional offices by the central office. Furthermore, the national centre is also involved in preparation of control and surveillance programs and represents the NFSA in meetings organised by, *inter alia*, the Codex Alimentarius Commission of the Food and Agriculture Organisation and the World Health Organisation (CODEX) and the EC Commission.

The number of staff of the NFSA is approximately 130 at the central level, 230 at the regional level and 940 at the local level. The number of staff at the different regional offices varies between 10 and 50, while the number of staff at the local offices varies between less than 10 and up to 70.

Laboratory services are not a part of the CA. At the time of the inspection procedures for purchasing of analyses and laboratory support were about to be established. The establishment of these procedures were co-ordinated at the central level. However, following invitations for tender contracts are foreseen to be entered between the regional offices and the relevant laboratories.

From the documents received during the mission regarding contracts with laboratories it is not clear whether there is a requirement that the analysing laboratories shall be accredited.

Although all three Ministries are financing the activities of the NFSA, it is the Ministry of Agriculture, being the co-ordinating Ministry, that allocates the resources.

8.2 Control of diseases affecting bivalve molluscs

In July and October 1994 Norway submitted to the Authority two programs concerning monitoring of the bivalve molluscs diseases Bonamiosis and Marteiliosis. By Decision 191/94/COL of 30 November 1994 the Authority approved the programs.

Based on the results of this monitoring Norway sent in November 2000 an application to the Authority for approval of Norway as one coastal zone free of Bonamiosis and Marteiliosis. The Authority is in the process of finalising the assessment of the application.

A copy of a licence for growing live bivalve molluscs issued by the SDT contains a reference to the relevant national legislation regarding the obligation of the holder of the licence to observe and report to the CA any abnormal mortality on the farm.

A register containing information of all licensed farms is administered by the FIDIR and up-dated at the regional offices.

8.3 Classification of production areas for live bivalve molluscs

Classification of production areas according to the present procedures was initiated in 2000. Until the end of 2003 the classification of production areas was carried out by the regional offices of the FIDIR. As of 2004, the local offices of the NFSA are classifying the production areas.

As a part of the transfer of duties from the regional offices of the FIDIR to the local offices of the NFSA, a course was arranged in March 2004 where staff of the relevant local offices participated. Classification of production areas, sampling and traceability, algae toxins and legal aspects related to issuing of harvesting permissions were items on the agenda.

During the inspection representatives of the NFSA informed the inspection team that although there is a legal basis in the Norwegian regulation for classifying production areas complying with point 1(b) of Chapter I of the Annex to Directive 91/492/EEC, such production areas are still to be classified. Classification according to point 1(c) of Chapter I of the Annex is not foreseen to be carried out in Norway.

According to the list of production areas, one area has been classified as "B", complying with the requirements in point 1(b) of Chapter I of the Annex to Directive 91/492/EEC. Relaying areas are not approved in Norway. However, one dispatch centre is also approved as a purification centre.

According to 2003 figures some 250 production areas were classified in the counties Østfold, Rogaland, Agder, Hordaland, Sogn og Fjordane, Møre og Romsdal, Sør- and Nord-Trøndelag, Nordland, Troms and Finmark. The majority (approximately 160) of the classified production areas are in the counties of Hordaland, Sogn og Fjordane, Møre og Romsdal, and Sør- and Nord-Trøndelag.

In the list the name of the production area and the municipality in which it is located, the owner of the production area, the licence number and the UTM reference are indicated. Additionally, the status with regard to classification and the species produced are also indicated.

However, the inspection team observed that the list was not updated as the status of the production area, the licence number and the UTM reference were not always included.

The inspection team was informed that it is the respective local offices that are responsible for the classification of production areas, by issuing classification documents. In order to be classified four samples of molluscs must be collected during 12 months representing the different seasons of the year. *During and after classification, shellfish farmers must sample molluscs from the production area for microbiological examination four times per year (own-checks). The CA can use the results from these examinations for re-classification.*

Additionally, information related to currents and topography and results from one sample of molluscs collected in February or beginning of March and analysed for heavy metals (Cadmium, Lead and Mercury) shall also create the basis for issuing a classification document. *Areas for growing and harvesting will not be approved when located close to industrial and sewage outlets, or other contamination sources where the water may contain for instance chemical and/or microbiological contamination in unacceptable amount or in amounts which may cause danger to health.*

Samples used in the classification process can be collected by the growers, but they must be analysed at a laboratory approved by the NFSA. The CA also informed the inspection team that official samples from classified production areas shall be collected at least every four years.

Procedures for re-classification have not been established since the CA considers the procedures described above and the results of the samples collected during production of molluscs sufficient for maintaining the status as classified. Population centres, location of significant sewage systems and effluent discharge point(s) are factors that are not considered once the production areas have been classified. Such points are also not included in the maps indicating the production areas.

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

In its reply to the Authority's pre-mission questionnaire the NFSA informed that 15 dispatch centres are approved in Norway. One of these has also been approved as a purification centre.

In the reply the NFSA also informed that criteria or administrative procedures for approval of vessels harvesting live bivalve molluscs have not been prepared. During the inspection representatives of the NFSA confirmed that procedures for checking that equipment for harvesting, transport and handling of live bivalve molluscs do not cause excessive damage to the shells or tissues or result in additional contamination of the product are not established.

When approving dispatch centres and purification centres the local inspectors are using the same guidelines as used when approving fishery products establishments complying with the requirements of Directive 91/493/EEC. During the mission the inspection team received a copy of a check list used during such inspections. That check list did not contain all the relevant requirements listed in point III and IV of Chapter IV of the Annex to Directive 91/492/EEC.

It is the local offices of the NFSA that are issuing approval documents for establishments considered to comply with the requirements of Directive 91/492/EEC. The right of appeal of any decision adopted by the local offices is included in the Norwegian Quality Regulation and it is the respective regional offices that consider the appeals. At a meeting with representatives of a regional office of the NFSA the inspection team was informed that the number of staff at the regional level having legal competence is increasing. At the time of the inspection staff having legal competence was available at approximately 60% of the regional offices.

8.5 Public health control and monitoring of production of bivalve molluscs[1]

The NFSA has prepared a program for monitoring of production of bivalve molluscs. Representatives of the CA informed the inspection team that the control program for 2004 covers the months from March through November. However, the inspection team was also informed that, if all official requirements are complied with, harvesting can take place throughout the year.

At the beginning of every year the producers/owners of classified production areas notify the CA of all production areas from which harvesting will take place during the coming 12 months. At the beginning of 2004 it was foreseen that harvesting would take place from approximately 200 out of the 250 classified areas. This information created the basis for the extent of the 2004 monitoring program.

During the mission the inspection team received an updated copy of the program for 2004. The majority of the 50 classified production areas included in the 2004 program are in the counties of Hordaland, Sogn og Fjordane, Trøndelag and Møre and Romsdal.

According to the program, it is for each of the regional offices of the NFSA to decide on whether the production areas are to be included in the program, but 25% of the classified production areas from which harvesting is carried out shall be included in the program. Consequently, during a four year period all classified production areas are covered by the program.

Additional prioritised criteria for including harvesting areas in the 2004 program are:

a) harvesting areas that intend to harvest but are still to be classified
b) harvesting areas that most probably will harvest during 2004
c) harvesting areas that intend to harvest in 2005, but are still to be classified

The program also contains guidelines for collection of samples, packaging and labelling, and sending of samples to the analysing laboratory. The costs related to official sampling

[1] Additional information related to procedures and methods is included in Chapter 8.8 Laboratories.

and analyses are covered by the NFSA. However, the producers are not reimbursed the value of molluscs collected.

Generally, the 2004 program has a particular focus on mapping of possible presence of *Vibrio* spp. in water and shell from classified production areas, monitoring of bacteria, heavy metals and contaminants in live bivalve molluscs, and finally, monitoring of algae in seawater and control of the presence of algae toxins in live bivalve molluscs.

From the list of production areas it seems that during 2003 bivalve molluscs were harvested for placing on the market for direct human consumption from production areas still to be classified according to Chapter I of the Annex to Directive 91/492/EEC.

8.5.1 Monitoring of the microbiological quality of bivalve molluscs

According to the 2004 control program four samples shall be collected from each of the predefined locations/production areas.

One sample must be collected before 15 March. Thereafter samples must be collected once between April and June, once between July and September and, finally, once during the months of October and November. Each time at least four kilos of shells must be collected. The shells must be representative for the production area and, if relevant, be collected from different water depths.

All samples shall be analysed for *E. coli* and enterococci. One sample from each production area, collected in August, shall be analysed for *Salmonella*.

According to the control program it is for the local offices to decide on a local laboratory for analyses of samples collected. However, the laboratory must be located reasonably close to the production area where the samples have been collected.

8.5.2 Monitoring of viral contamination

Sampling for monitoring of presence of virus in bivalve molluscs is also included in the control program for 2004. The current project will be terminated in September 2004. At the time of the inspection, the NFSA had not decided on any checks to be carried out as of 2005.

Samples are collected at the predefined production areas. In order to establish some historical data the sampling points in the 2004 plan are more or less the same, or close to the areas where samples were collected in 2003.

From January through September 2004 one sample shall be collected every month from each of the predefined production areas. 45 to 50 mussels, 10 oysters or approximately 4 scallops shall be collected from each area. All samples are analysed at the Norwegian School of Veterinary Science/Norges Veterinærhøgskole (NVH).

8.5.3 Monitoring of the plankton situation in seawater

According to the 2004 control program official samples must be collected on a monthly basis from March through November from the 50 predefined production areas.

Two samples (one for quantitative and one for qualitative analysis) are collected from each production area each time. One of the samples contains water collected from different depths (0.5, 3 and 6 meters) or, if necessary, adjusted according to the depths where shells are growing. The other sample contains the content of a water sample collected with net from 10 meters depth and up to the surface.

Depending on the origin the samples shall be sent to one of the four different laboratories in Norway analysing water samples for the presence of algae.

The program comprises registrations of dominating algae species in the samples in addition to monitoring of potential toxin producing algae such as *Alexandrum* spp. (*A. tamarense, A. ostenfeldii* and *A. minutum*), *Dinophysis* spp. (*inter alia*, *D. acuminata*, *D. acuta*, *D. norvegica*, *D. rotundata* and *D. dens*), *Pseudo-nitzchia* spp., *Protoperidinium crassipes* and *P. curtipes*, and *Protoceratium reticulatum*.

8.5.4 Monitoring of marine biotoxins in bivalve molluscs

Two control programs are currently in place for the monitoring of marine biotoxins in bivalve molluscs. One of the programs, earlier under the responsibility of the SNT, has been running for some 15 years and includes approximately 26 sampling points along the Norwegian coast. The aim of this program has been to collect information regarding possible presence of toxins in molluscs and provide advices for those who collect wild mussels for own consumption.

The other program is applied on commercial production and placing on the market of bivalve molluscs. This program follows similar sampling procedures as those described under Chapter 8.5.1.

One sample must be collected from each of the predefined production areas and transported to the local laboratories. The local laboratories are, when relevant, preparing the samples before they are forwarded to the NVH.

The NFSA foresees that the two programs will be co-ordinated during 2004.

8.5.5 Monitoring of contaminants in foodstuffs

It follows from the control program that samples to be analysed for heavy metals and dioxins shall be collected twice per year, the first time before 15 March (before spawning) and the second sample in August (after spawning). Each sample shall contain at least four kilos of molluscs. The shells, apart from scallops, can be frozen before transport to the laboratory. Scallops must be packed and sent on the day of collection in order to arrive fresh at the laboratory. All samples are sent directly from the local offices of the NFSA to the laboratory.

One laboratory, the National Institute of Nutrition and Seafood Research (NIFES) in Bergen, is analysing all samples related to contaminants in bivalve molluscs.

The heavy metals analysed are Cadmium, Lead, Mercury, Silver, Chromium, Zink, Copper and Arsenic. Furthermore, samples are analysed for dioxins (PCDD/F), dioxin-like Polychlorinated Biphenyls (PCBs) (non-ortho and mono-ortho), PCB and Polybrominated Diphenyl Ethers (PBDEs). During 2003 84 samples out of a scheduled 100 were collected

for analyses of heavy metals, while for dioxin, dioxin-like PCBs and PCB 16 samples out of a scheduled 50 were analysed.

Results of the analyses are sent to NFSA. According to documentation received during the mission, all samples collected during 2003 for determination of the relevant contaminants were below the limits set out in Commission Regulation (EC) No 466/2001.

The inspection team noted that results from samples collected in March 2003 and in the autumn 2003 for analysis of heavy metals were received at the NFSA in the beginning of March 2004 and the results from samples collected in August – September 2003 for analysis of dioxin and dioxin-like PCBs were finalised late December 2003.

According to the annual report for 2002 from the NIFES regarding the surveillance program for bivalve molluscs, Cadmium levels in wild stock of *Chlamys opercularis* from one location in 2000 and 2001 were 1,2 and 2,1 mg/kg wet weight, respectively and 0,93 mg/kg wet weight in 2002. Concentration of Lead in mussels collected from one location in 2002 were 2,2 mg/kg wet weight, i.e. above the limits laid down in Commission Regulation (EC) No 466/2001. The annual report did not contain any additional information regarding these values apart from the recommendation from the NIFES to include collection of samples from the same location in the 2003 program. Figures for 2003 were not available at the time of the mission.

8.5.6 Official checks on end products

At the local office of the NFSA visited, the inspection team was informed that during 2002 and 2003 random sampling of end products for checking compliance with the requirements of the bivalve molluscs legislation had not been carried out. However, internal meetings in order to prepare procedures for such checks had been held recently and such sampling was foreseen to be initiated in the near future.

8.5.7 Inspections of establishments, equipment for harvesting and transport of live bivalve molluscs etc.

The NFSA has issued an instruction to the local offices on official control related to production and placing on the market of bivalve molluscs. According to this instruction the local inspectors shall inspect the producers, the production areas and establishments involved in the production and placing on the market of bivalve molluscs.

The instruction lists the main control points to be checked during such inspections, including, *inter alia*, the location of the production areas, correct use of transport documents, documentation on toxins and contaminants, facilities and equipment, and where relevant, results of purification of molluscs.

In addition to the sampling and analyses carried out according to the program described above, samples shall be collected for verification of the different establishments own-checks system. According to the NFSA's instruction to the local offices on official control related to production and placing on the market of bivalve molluscs, official sampling for verification is of particular importance where purification is taking place. In general, the type of production and volume are factors that should be taken into account when deciding the frequency.

The instruction contains no information related to inspection or checks to be carried out on equipment for harvesting and transport of live bivalve molluscs to establishments on shore. However, representatives of the CA informed the inspection team that procedures for such checks are in the process of being prepared.

At the local office visited, the inspection team was informed that bivalve molluscs establishments are normally checked 6-7 times per year. Based on, *inter alia*, the production taking place and production volume, a plan has been established by the local CA outlining the number of inspections to be carried out annually.

After each inspection a report containing findings and conclusions is handed over to the representative of the establishment. Checklists prepared on the central level of the CA are used by the inspectors during the inspections.

8.6 Harvesting authorisations, registration documents and permanent transport authorisation

8.6.1 Harvesting authorisations

Harvesting of molluscs is only allowed when the CA has issued a harvesting authorisation. Issuing of authorisation is based on the results of three water samples collected weekly during three consecutive weeks and analysed for the presence of algae. In addition, during the third week of sampling one sample of molluscs shall be collected from the production area and analysed for algae toxins.

If the results of the analyses are within the limits set by the NFSA, a harvesting authorisation valid for fourteen days, is issued by the local CA. Renewal of a harvesting authorisation is dependent on the results of analyses of samples of water collected every week and samples of molluscs collected every fourteen days.

Re-opening of a production area (issuing of a new harvest authorisation) where results have been documented outside the limits set by the NFSA, is only possible when the same sampling frequency as described for opening of production areas has been followed and the results of the analyses are within the same limits.

Due to the changes in the organisation of the CAs, harvesting authorisations were, at the time of the inspection, issued by the local office in Trondheim. However, withdrawals of harvesting authorisations are done by the respective local offices of the NFSA. Later during 2004, issuing of harvesting authorisations will also be carried out by the respective local offices.

8.6.2 Registration documents and permanent transport authorisations

The CA has prepared two documents relating to transport of molluscs from the production areas to approved dispatch centres. One of the documents is used when staff of the dispatch centre/purification centre/relaying area is the same as those carrying out the harvesting of the molluscs.

The other document is used for batches when the staff carrying out the harvesting is not from the establishment receiving the batches.

Copies of the documents annexed to the Norwegian reply to the Authority's pre-mission questionnaire were in compliance with the requirements of Directive 91/492/EEC.

8.7 Follow-up of positive results

During the mission the inspection team received from representatives of the NFSA a copy of results of one sample analysed for biotoxins in live bivalve molluscs. The sample was collected on 16 February 2004, received at the analysing laboratory on 17 February and the results were notified to the CA on 20 February.

On 19 February the sample had been analysed for possible presence of several toxins/toxin complexes by chemical methods. By a letter of 23 February 2004 the local office of the NFSA informed the producer that the sample contained an amount of azaspiracid (AZA) that could create a risk to human health.

By the letter of 23 February the local CA issued a ban on harvesting of mussels from the production area where the sample had been collected. The decision contains a reference to the production area (indication of geographical name and approval number).

However, the decision did not contain any information on the use of registration documents or health documents issued and any possible action to be initiated by the producer related to batches being harvested between the date of sampling and the date of the issuing of the ban.

8.8 Laboratories

8.8.1 General comments

On 1 January 2004, when the NFSA was established, all laboratories being part of the former KNTs and the regional offices of the FIDIR were separated from the CA. Some of these laboratories have reorganised as independent laboratories or as part of laboratory networks.

According to information provided by representatives of the NFSA, all laboratories providing services to the CA are accredited. However, not all relevant methods at some of the laboratories visited during the inspection were accredited.

Where relevant, all the NRLs had established contact with the respective Community Reference Laboratories (CRLs). Furthermore, it was a general opinion that co-operation between the NRLs and the CRLs were functioning well.

Representatives of all the NRLs visited requested either formalisation or up-dating of the agreements/contracts on co-operation with the NFSA.

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

In at least one of the laboratories visited the staff indicated that their competence was not fully utilised by the NFSA.

8.8.2 National reference laboratory for diseases affecting bivalve molluscs

The NRL for diseases affecting bivalve molluscs is the National Veterinary Institute in Bergen. The laboratory is one of four regional laboratories of the National Veterinary Institute/Veterinærinstituttet (VI) in Oslo. The NRL is the only laboratory in Norway involved in diagnostics of Bonamia and Marteilia.

The Norwegian Ministry of Agriculture designated in 1995 the laboratory (originally the Veterinary Institute in Oslo) as the NRL for diseases affecting bivalve molluscs. Out of a total budget of 110 mills. NOK, the laboratory receives 60 mills. NOK from the Ministry of Agriculture and 30 mills. NOK from the Ministry of Fisheries.

The co-operation between the NRL and the NFSA was not formalised at the time of the visit. However, a review of the role of the NRLs has been initiated and a formalisation of the co-operation with the NFSA is foreseen before the end of June 2004.

Representatives of the NRL informed the inspection team that the co-operation with the CRL – the French Research Institute for Exploitation of the Sea (IFREMER), was established in 1995 and is well functioning. Additionally, the laboratory works closely with several other laboratories in the EC Member States.

A quality system based on the ISO 17025 standard of the International Organisation for Standardisation (ISO) was developed at the VI in 1997-98 and implemented at the NRL in 2002. The VI was accredited in 1998 and the NRL was accredited in November 2003. The inspection team was informed that an application for accreditation of the diagnostic methods related to Bonamia and Marteilia would be sent to the Norwegian Accreditation during May 2004. The methods developed are based on *Commission Decision94/306/EC*[2] *as amended by Commission Decision 2002/878/EC*[3].

Based on the monitoring program for the two diseases Bonamiosis and Marteiliosis a total of 500 samples are received at the laboratory annually. Samples are collected twice a year and the minimum *processing* time in the laboratory is 10 days. However, representatives of the NRL informed the inspection team that the average turnover time for these analyses is three months. The NFSA has continuous access to the results registered in the laboratory's database. Results of the samples collected have not documented any presence of the two diseases in Norwegian waters.

Two scientists *and one technican* (one man-labour year) are involved in preparation of samples and diagnostics. Job descriptions are prepared for all positions and procedures for supervision and training of staff are established. In addition to internal tests the NRL participates in the annual ringtests organised by the CRL.

The NRL has prepared a sampling manual and the NFSA is organising all sampling related to the program. Local inspectors or other qualified staff assigned by the NFSA are

[2] Commission Decision 94/306/EC of 16 May 1994 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain mollusc diseases.

[3] Commission Decision 2002/878/EC of 6 November 2002 establishing the sampling plans and diagnostic methods for the detection and confirmation of the presence of the mollusc diseases Bonamiosis (Bonamia ostreae) and Marteiliosis (Marteilia refringens)

responsible for collection of samples. *Samples are sent directly to the NRL for preparation*.

Results are notified both to the local CA and to the central office of the NFSA. The inspection team was informed that the established notification procedures are still to be updated according to the new organisation of the CA.

8.8.3 Laboratories involved in monitoring of the plankton situation in seawater

In Norway four laboratories are involved in the monitoring of plankton in seawater related to production of live bivalve molluscs. Samples from different regions are sent to the different laboratories.

The NFSA and the four laboratories have weekly meetings for exchange of results. At the end of each year a summarising meeting is arranged where, *inter alia*, the results of the algae monitoring are compared with positive results of toxins in molluscs, and action limits are evaluated and up-dated. However, the co-operation between the laboratory visited and the NFSA is not formalised.

The laboratory visited is a branch of several laboratories. Commercial analyses, surveys and studies cover 80 % of these laboratories' budget.

In relation to production of bivalve molluscs the laboratory receives approximately 100 samples per year. Procedures for collection of samples are established. The laboratory is using the sedimentation method before the samples are analysed. As a routine the laboratory checks the samples for the algae listed in Chapter 8.5.3.

Three scientists are involved in analysing the samples. The analyses are initiated immediately after the samples arrive at the laboratory and the results are, where relevant notified to both the producer and the CA. The presence of algae in the samples are both identified and quantified. However, written procedures were not prepared.

In addition to the co-operation with the NFSA, the laboratory also works directly with the producers. Ringtests arranged nationally are rare. However, the laboratory co-operates with other laboratories in both Sweden and Denmark.

The laboratory is currently participating in a project on preparation of a standard for analysis of algae including procedures for sampling. The standard will be based on the sedimentation method, but the filtration method will also be described.

8.8.4 Laboratories involved in monitoring of marine biotoxins in bivalve molluscs

The NRL for monitoring of marine biotoxins in bivalve molluscs is the Division of Food Hygiene at the Institute for Food Safety and Infection Biology at the NVH. The NVH is placed under the Ministry of Education and Research.

The formalised co-operation with the CA has not been up-dated following the establishment of the NFSA. However, the inspection team was informed that the contract with the CA would be updated during May 2004.

The NRL was accredited according to Norwegian Standard NS-EN 45001 and ISO/IEC Guide 25 (1990) in 2001. The chemical analyses for Diarrhetic Shellfish Poison (DSP), Paralytic Shellfish Poison (PSP) and Yessotoxins (YTX) were accredited in 2002. DSP and YTX toxins are analysed by LC-MS, PSP toxins are analysed by HPLC-FLD and ASP toxins by HPLC-UV. The mouse bioassay method used for detection of DSP is Yasumoto (1984), while the mouse bioassay method for detection of PSP is NMKL-81 and AOAC 1995, Chapter 35.

In addition to the mouse bioassay carried out at the NRL, the regional hospital in Trondheim is also carrying out such analyses. The representative of the NRL informed the inspection team that the capacity at the regional hospital is 10 to 25 samples per week for the mouse bioassay while the NRL has a capacity of 12 to 15 samples per week. The NRL has capacity to analyse by chemical methods 25 to 30 samples per week of the fat soluble toxins and 20 to 30 samples per week of the ASP/PSP toxins.

The NRL receives between 500 and 1000 samples every year. Local laboratories are preparing some of these samples before they are forwarded to the NRL. However, a list of such laboratories was not prepared.

All samples sent to the NVH are received at a special unit where the samples are registered and split before they are distributed to the respective analysing laboratories. Samples related to bivalve molluscs are normally received on Tuesdays and the results are distributed before the end of the same week.

The inspection team was informed that samples collected by the CA were only analysed by chemical methods, while samples collected by the producers for the issuing of harvesting authorisations are analysed by both chemical methods and mouse bioassay.

The co-operation with the CRL is well functioning and the NRL has also established contact with laboratories in, *inter alia*, Ireland, Canada and New Zealand.

At the laboratory a total of five man-labour years are involved in analyses related to monitoring of marine biotoxins in bivalve molluscs. Job descriptions are prepared for all positions and procedures for supervision and training of staff are established.

The inspection team was also informed that procedures for collection and handling of samples are in the process of being up-dated. The new procedures will be distributed to the relevant parties during May 2004.

Although a considerable effort is put into the implementation of chemical methods as a replacement for the mouse bioassay, the NRL has recommended the mouse bioassay as analytical method for screening of samples for new toxins. These samples should be collected from a few predefined sampling points along the Norwegian coast.

The representative of the NRL also informed the inspection team that samples collected during December, January and February, when the official monitoring program is not running, sometimes are positive for DSP.

8.8.5 Laboratories involved in monitoring of bacteriological and viral contamination of bivalve molluscs

The NRL for the monitoring of bacteriological and viral contamination in bivalve molluscs is the Division of Microbiology, Immunology and Parasitology of the Institute for Food Safety and Infection Biology at the NVH. The laboratory was appointed as NRL by the SNT late 2002.

The laboratory was accredited in 1999 and the accreditation was renewed in 2003. At the time of the visit 27 methods were accredited, out of which 13 were microbiological methods and 14 were chemical methods. However, none of the methods related to analyses of samples of bivalve molluscs are accredited.

Standard Operation Procedures (SOPs) are established for all analyses carried out at the laboratory. A SOP had been prepared for the new method for analysing samples for *E. coli* (Donovan 1998). At the time of the visit the method was in the process of being implemented.

A total of eight persons are involved in analyses related to monitoring of bacteriological and viral contamination of bivalve molluscs. Job descriptions are prepared for all positions and procedures for supervision and training of staff are established.

Representatives of the NRL informed the inspection team that the co-operation with the NFSA is in general well-functioning. However, the role as NRL, including co-operation with the NFSA is still to be formalised.

The laboratory has established contact with the CRL – the Centre for Environment, Fisheries & Aquaculture (CEFAS), UK. Contact has also been established with some national laboratories. However, at the time of visit the NRL did not have a complete overview of the national laboratories involved in monitoring bacteriological contamination of bivalve molluscs and procedures for communication between the NRL and the national laboratory are still to be established.

Twice a year the laboratory participates in ringtests related to *Vibrio* spp. It has also participated in ringtests related to *E. coli*. These ringtests are organised by Statens Livsmedelsverk in Sweden and by the Food Examination Performance Assessment Scheme (FEPAS) of the Central Science Laboratory, UK. So far the laboratory has not participated in any ringtests organised by CEFAS. Ringtests related to bivalve molluscs organised by the NRL at a national level are still to be established.

During 2000 a project related to a possible presence of virus in bivalve molluscs was initiated by the laboratory. The project is foreseen to terminate in September 2004. At the time of the visit a prolongation of the project had not been decided. However, a memo on monitoring of virus contamination in bivalve molluscs was foreseen in May 2004.

Normally, samples collected in the beginning of one week are analysed the same week and the results distributed the same day. However, procedures for turn-over time in the laboratory, priority of official samples and notification of results to the CA were not established.

Guidelines for collecting samples had been prepared, but the inspection team was informed that they would be updated later this year. Samples are collected by both the producers and the local CA. The laboratory is involved in how samples should be packed and transported to the laboratory but not in where and how to collect samples. However, samples are normally collected together with the samples to be analysed for presence of algae toxins.

The laboratory receives normally approximately 5 samples per week related to bivalve molluscs. At the time of the visit the laboratory had a capacity of analysing up to 40 such samples per week.

8.9 The establishments own-checks related to live bivalve molluscs

According to information contained in the NFSA's reply to the Authority's pre-mission questionnaire the harvesters of live bivalve molluscs are, during periods of harvesting, obliged to collect samples of water on a weekly basis to be analysed for presence (quantification) of algae. Furthermore, samples of live bivalve molluscs shall be collected every fourteen days and analysed for possible presence of marine biotoxins and faecal coliform bacteria.

Based on the results of these analyses, the NFSA issues certificates for the placing on the market of bivalve molluscs. The producers themselves have to bear the costs of these analyses.

8.10 Vessel for harvesting of mussels, means of transport of live bivalve molluscs and establishment visited

8.10.1 General comments

During the mission the inspection team visited one vessel used for harvesting and transport of bivalve molluscs, and a truck for transport of bivalve molluscs. During the visit landing of mussels and loading onto the truck took place. The inspection team also visited one dispatch centre for live bivalve molluscs. At the time of the visit the dispatch centre was not in full production.

8.10.2 Vessel for harvesting and transport of mussels

One vessel used for harvesting and transport of live mussels was visited at the quayside. The owners of the vessel had developed the production- and harvesting system. The harvesting machine had a capacity of between five and six tonnes of mussels per hour. The vessel and the harvesting machine were used for harvesting both from their own production area and from other producers having the same production system.

The mussels were harvested directly into polypropylene sacks, each taking up to one ton of bivalve molluscs. The owner informed the inspection team that two – three percent of the mussels were damaged during harvesting of young shells and less for the older ones.

The sacks were sealed and marked off shore with name of the country of production, gatherers name and registration number, location of production area, temperature requirements during transport, shellfish species and quantity and date of harvesting. During landing the sacks were placed on new wooden pallets and loaded directly onto the truck.

The method for harvesting live bivalve molluscs demonstrated to the inspection team had been in use since 2002. However, the method had neither been assessed by any of the former Competent Authorities nor by the NFSA. Representatives of the CA informed the inspection team that procedures for evaluating methods for harvesting, transport and handling of bivalve molluscs were not finalised.

8.10.3 Means of transport of live bivalve molluscs

The inspection team observed loading of mussels onto a truck at the quayside. The truck was approved for transport of foodstuffs by a competent authority in one of the EEA States. Representatives of the local CA informed the inspection team that the truck had not been checked by the local CA and that checks on trucks at this stage of the transport of mussels where not done routinely by the local CA. However, the inspection team was informed that checking means of transport of foodstuffs used to be the responsibility of the KNTs.

8.10.4 Establishment visited

The inspection team visited one dispatch centre approved for handling of live bivalve molluscs. The dispatch centre was built in 1999, but a new company had started production in July 2003. The new company had a temporary approval issued in October 2003, with the same registration number as the previous company. During July and parts of August 2003 the centre had placed live bivalve molluscs on the market under the name of the previous company before using its own labelling.

The establishment buys live bivalve molluscs from producers located as far away as 1.500 km. Transport of molluscs from the different production areas to the dispatch centre can take up to two days. The molluscs are transported by truck or boat in two sizes of polypropylene sacks, either 3-400 kg or 8-900 kg.

The mission team was informed that the shells can be kept in tanks at the dispatch centre for up to two months. However, when in full production the molluscs will normally be kept in the tanks for up to one week. Out of a production of approximately 100 tons during the last 9 months, 80 tons were placed on the EU market, approximately 15 tons on the domestic market and a few tons exported to third countries.

The mission team was informed that bivalve molluscs from different production areas are never mixed in the storage tanks and that the dispatch centre does only accept bivalve molluscs that have been approved for export by the NFSA.

Since July 2003 the establishment had been inspected twice by the local CA. Reports from both inspections were available at the establishment. The Norwegian legislation requires that bivalve molluscs establishments have an own-checks system, including HACCP principles, approved by the CA. The establishment’s own-checks system had partly been assessed during the approval process. However, after the issuing of the approval in October 2003, the CA had not verified the system.

Although having its own laboratory facilities, samples collected at the establishment are sent to an external laboratory recognised by the NFSA.

The seawater intake was on the depth of 100 m in the fjord outside the establishment. Samples of the seawater are collected four times per year and in the start-up face samples were collected once a month. The establishment had applied for approval of the system for seawater supply. However, at the time of the visit the approval process had not been finalised.

The seawater was mixed with a special blend of gasses before used in the molluscs tanks. The inspection team was informed that the different gasses used had not been made known to the CA. The system had not been assessed by the CA.

Potable water used in the establishment was non-treated groundwater provided by a municipal waterworks. The waterworks had been approved by the CA. Water samples are collected every month.

The premises and equipment were well maintained although some deficiencies related to facilities, equipment and procedures were observed. There was not a clear separation between clean and unclean parts of the premises. The inspection team was informed that cleaning of storage tanks could also be carried out during production and close to where the conditioning took place.

Ice produced from potable water was stored in open containers in one of the cold stores used for final products. Finally, wooden pallets stored in the cold store for final products were reused.

9 Final meeting

A final meeting was held on Friday 30 April 2004 at the NFSA in Oslo with representatives of the Norwegian Ministry of Fisheries and of the NFSA. At this meeting the inspection team orally presented the main findings and preliminary conclusions of the mission. The CA agreed to the findings and the conclusions.

At the meeting the inspection team also informed that, based on a more detailed assessment of the supplementary information received during the mission, additional conclusions could be included in the report. The CA accepted that additional conclusions could be included in the report and that the findings creating the basis for these conclusions could be commented on when receiving the draft report.

10 Conclusions

10.1 Competent Authority

10.1.1 Compliance with the requirements laid down in Directive 91/492/EEC and in particular Article 5(1)(a) thereof could not always be assured since the CA had not taken into account all the findings and conclusions from the last mission carried out by the Authority.

10.1.2 The procedures to be followed by the CA when inspections and monitoring reveal that the requirements of Directive 91/492/EEC are not being met, including when

results of analyses for algae toxins in bivalve molluscs exceed the action limits, need to be improved in order to fully comply with the requirements of the Directive and in particular Article 5(1)(b) thereof.

10.1.3 The turn-over time at the NRL involved in the monitoring of diseases affecting bivalve molluscs does not always ensure a sufficiently swift initation by the CA of the measures foreseen in Directive 95/70/EC and in particular Article 5 thereof.

10.2 Official checks according to Directive 91/492/EEC

10.2.1 Compliance with the requirements laid down in Directive 91/492/EEC and in particular Article 3 and 5(1)(a), Chapter II and point 4 and 5 of Chapter VI of the Annex thereof could not always be assured as it could not be documented that inspections carried out by the CA covers a check of all the relevant requirements of the Directive, in particular those in points II and IV of Chapter IV of the Annex thereof.

10.2.2 Compliance with point 1 and 2 of Chapter VI of the Annex to Directive 91/492/EEC could not always be assured as the monitoring program did not cover the period for which live bivalve molluscs are harvested.

10.2.3 Checks on end products, as required in point 3 of Chapter VI of the Annex to Directive 91/492/EEC, could not be documented at the local office visited.

10.2.4 Checks on transport, as required in point 5 of Chapter VI of the Annex to Directive 91/492/EEC, could not be documented.

10.3 Laboratories

10.3.1 Compliance with the requirements laid down in Council Decision 93/383/EEC as amended by Council Decision 1999/312/EC related to laboratories involved in analysing samples for marine biotoxins could not always be assured since, *inter alia*, the division of tasks between the CA and the NRL was not clarified.

10.3.2 Compliance with the requirements laid down in Council Decision 1999/313/EC related to monitoring of bacteriological and viral contamination of bivalve molluscs, and in particular Article 2(1) thereof, could not be assured since the NRL was not in possession of information about all national laboratories involved in such monitoring.

10.3.3 Compliance with Council Directive 93/99/EEC and in particular Article 3 thereof could not always be assured since it was not required that the relevant laboratories should be accredited.

10.4 Production areas

10.4.1 Compliance with Article 5(2) and Point 2 of Chapter I of the Annex to Directive 91/492/EEC could not always be assured as the list of approved production areas was not up-dated.

10.4.2 Compliance with Article 3(1)(a) of Directive 91/492/EEC could not always be assured since live bivalve molluscs sometimes could originate from production areas not classified according to Chapter I of the Annex to the Directive.

10.5 Establishments, production, transport and handling of bivalve molluscs

10.5.1 Compliance with Directive 91/492/EEC and in particular points 1, 2 and 3 of Chapter II of the Annex could not be assured as methods for harvesting, transport and handling of live bivalve molluscs had not been evaluated in order to check if they cause excessive damage to the shells or tissues or result in additional contamination of the product.

10.5.2 Compliance with Directive 91/492/EEC and in particular Chapter IV and Chapter VII of the Annex thereof related to approval of dispatch centres and wrapping of products could not always be assured.

11 Recommendations to the Competent Authorities of Norway

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

Norway should send 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 and 93/99/EEC.

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 are complied with.