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EFTA SURVEILLANCE
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Final report

EFTA Surveillance Authority mission to

NORWAY

21 to 25 February 2005

regarding the application of EEA legislation
related to health conditions for the production and the placing on the market of
fishery products

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

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List of abbreviations and terms used in the report

Authority	EFTA Surveillance Authority
CA	Competent Authority
CCP	Critical Control Point
DO	District Office of the NFSA
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EU	European Union
EU25	The European Union consisting of 25 Member States
FIDIR	Directorate of Fisheries/ <i>Fiskeridirektoratet</i>
HACCP	Hazard Analysis and Critical Control Points
HO	Head Office of the NFSA
KNT	Municipal Food Control Authority/ <i>Kommunalt næringsmiddeltilsyn</i>
NC	National Centre
NFSA	Norwegian Food Safety Authority/ <i>Mattilsynet</i>
NFSC	National Fish and Seafood Centre of the NFSA/ <i>Nasjonalt senter for fisk og sjømat</i>
NIFES	National Institute of Nutrition and Seafood Research/ <i>Nasjonalt Institutt for Ernærings- og sjømatforskning</i>
NIVA	Norwegian Institute for Water Research/ <i>Norsk Institutt for Vannforskning</i>
NOK	Norwegian Kroner/ <i>Norske kroner</i>
RASFF	Rapid Alert System for Food and Feed
RO	Regional Office of the NFSA
RSW	Vessels where seawater is refrigerated by mechanical means for chilling of fishery products
SDT	Norwegian Animal Health Authority/ <i>Statens dyrehelsetilsyn</i>
SLT	Norwegian Agricultural Inspection Service/ <i>Statens landbruksstilsyn</i>
SNT	Norwegian Food Authority/ <i>Statens Næringsmiddeltilsyn</i>

1 Introduction

The mission took place in Norway from 21 to 25 February 2005. The mission team comprised 2 inspectors from the EFTA Surveillance Authority (the Authority).

The opening meeting was held on Monday 21 February 2005 at the Norwegian Food Safety Authority's (NFSA)/*Mattilsynet's* Regional Office (RO) in Bergen. At this meeting the representatives of the Ministry of Fisheries and Coastal Affairs and of the Competent Authority (CA) added information to the Norwegian reply to the Authority's pre-mission questionnaire.

Throughout the mission two representatives of the NFSA (one from the Head Office (HO) and one from the National Fish and Seafood Centre (NFSC)/*Nasjonalt senter for fisk og sjømat* accompanied the mission team. In addition, representatives from the relevant District Offices (DO) participated in the establishments, vessels and the laboratory visited.

A final meeting was held at the HO of the NFSA in Oslo on 25 February 2005, at which the mission team orally presented the main findings and some preliminary conclusions from the mission.

2 Objectives of the mission

The main objective of the mission was to assess the Norwegian CA's application of the requirements of Council Directive 91/493/EC and related legislation (see Chapter 3 and 4). A particular focus was put on the CAs' follow-up of the conclusions and recommendations in the Authority's report from the last mission in this field, on the functionality of the NFSA, and on official inspections of fishery products establishments.

The meetings with the CA and the visits to establishments and vessels during the mission are listed in Figure 1.

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

	Number	Comments
Competent Authority	5	2 with the HO (opening and closing meeting), one meeting with the RO and two meetings with the DO
Laboratory	1	A laboratory analysing samples from aquaculture farms, fishery products establishments, etc.
Establishments	4	Processing of fishery products, one processing farmed fish, one processing white fish and two freezing and filleting pelagic fish.
Vessels	2	Vessels where seawater is refrigerated by mechanical means for chilling of fishery products (RSW). Both vessels were visited at the quayside during unloading.

3 Legal basis for the mission

The legal basis for the mission was:

- a) Point 4 of the Introductory Part of Chapter I of Annex I to the Agreement on the European Economic Area (EEA Agreement).
- b) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (Surveillance and Court Agreement).
- c) The Act referred to at Point 6.1.8 of Chapter I of Annex I to the EEA Agreement, *Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products*, as amended.
- d) The Act referred to at Point 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

Other main European Union (EU) Acts in the field of production and the placing on the market of fishery products incorporated into the EEA Agreement and applicable to Norway are:

- a) The Act referred to at Point 1.1.1 of Chapter I of Annex I to the EEA Agreement, *Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market*, as amended.
- b) The Act referred to at Point 6.1.9 of Chapter I of Annex I to the EEA Agreement, *Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC*.
- c) The Act referred to at Point 18 of Chapter XII of Annex II to the EEA Agreement, *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs*.
- 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 6.2.47 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2003/774/EC of 30 October 2003 approving certain treatments to inhibit the development of pathogenic micro-organisms in*

bivalve molluscs and marine gastropods.

- f) 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.*
- g) The Act referred to at Point 6.2.14 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 94/140/EC of 19 January 1993 laying down the detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products.*
- h) The Act referred to at Point 6.2.21 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 94/356/EC of 20 May 1994 laying down the detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products.*
- i) The Act referred to at Point 6.2.28 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 95/149/EC of 8 March 1995 fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used.*
- j) 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.*
- k) 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.*
- l) The Act referred to at Point 54zn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs, as amended.*
- m) 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.*
- n) The Act referred to at Point 54zxc of Chapter XII of Annex II to the EEA Agreement, *Commission Directive 2002/69/EC of 26 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs, as amended.*

5 National legislation

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

The regulation that provides the legal basis for the NFSA's application of Council Directive 91/493/EEC is 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* (adopted by the Ministry of Fisheries and Coastal Affairs). This regulation also implements, *inter alia*, Council Directive 92/48/EEC and Commission Decision 93/51/EEC, Commission Decision 94/140/EC, Commission Decision 94/356/EEC, Commission Decision 95/149/EC, Commission Decision 2002/225/EC and Commission Decision 2002/226/EC.

In addition to these legal texts, some other Acts regulate the handling, processing and distribution of marine products. The following list of Acts contains the main legal texts incorporating other EEA Acts related to the production and the placing on the market of fishery products in Norway.

- a) *Regulation of 21 December 1993 No 1385 on labelling etc of foodstuffs* implements Council Directive 2000/13/EC.
- b) *Regulation of 27 September 2002 No 1028 relating to certain contaminants in foodstuffs* (adopted by the Ministry of Health and Care Services) implements Commission Regulation (EC) No 466/2001, as amended, and Commission Directive 2001/22/EC.
- c) *Regulation of 23 May 2003 No 633 amending Regulation of 27 September 2002 No 1028 regarding certain contaminants in foodstuffs* implements Commission Directive 2002/69/EC.
- d) *Regulation of 4 December 2001 No 1372 on water supply and drinking water* implements Council Directive 98/83/EC.

According to the Norwegian reply to the Authority's pre-mission questionnaire, *Commission Decision 2003/774/EC of 30 October 2003 approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods* had not been implemented into Norwegian legislation. However, representatives of the NFSA informed the mission team that during the process of incorporating the Decision into the EEA Agreement, the NFSA had concluded that the content of the Decision was already covered by the Norwegian quality regulation on fish and fishery products. As this conclusion was supported by the relevant Ministries, it had been concluded that the Decision is implemented into Norwegian legislation.

6 Information on production and trade

The number of aquaculture farms registered by the CA is included in Figure 2, while the number of landing sites and fishing vessels, factory vessels, freezer vessels and fishery products establishments are included in Figure 3.

The total number of landing sites in Norway corresponds to the number of approved establishments. Fish can be landed at 524 establishments approved for packaging of fresh fish. However, shrimps and other shellfish can only be landed at establishments which are approved for landing of shrimps, and for processing of shellfish other than shrimps. Auction markets have not been approved in Norway.

Figure 2: Number of aquaculture farms registered by the CA

Type of farm	Species		
	Salmon and rainbow trout	Other	Total
Broodstock ¹	-	-	-
Hatcheries ²	291	-	291
Ongrowing	941 ³	747 ⁴	1 688
Total	1 232	747	1 979

¹ The number of brood stock farms is not specified in the statistical report for 2003.

² The number of hatcheries is not specified for other species than salmon and rainbow trout.

³ Including the number of brood stock farms.

⁴ Including brood stock farms and hatcheries.

Figure 3: Number of fishing vessels, factory vessels, freezer vessels and establishments

	2004
Fishing vessels	9 914
Factory vessels	63
Freezer vessels	110
Establishments	693

Figure 4 contains the production volume in tons of the main species produced in Norway in 2001, 2002 and 2003.

Figure 4: Production volume (in tons) of different species of aquaculture animals

Species	Total production (tonnes)		
	2001	2002	2003
Salmon	347 605	465 249	507 412
Rainbow trout	49 883	83 424	69 128
Char	317	319	269
Cod	864	1 253	2 181
Halibut	377	424	427
Other fish species	377	663	1 229

Figure 5 contains information on the total production in 2004 placed on the European Union (EU) market and exported to third countries. In Figures 6a and 6b the information in Figure 5 is split on the main countries of destination within European Economic Area (EEA).

Figure 5: Production 2004 exported to the EU and to third countries in Norwegian Kroner/Norske kroner (NOK) and tons

Species	1000 NOK			Tons		
	EU25	Others	Total	EU25	Others	Total
Salmon/trout	8 313 366	4 057 177	12 370 543	335 298	155 471	490 769
Whitefish	3 273 449	936 029	4 209 478	145 703	69 106	214 810
Conventional ¹	2 766 708	1 433 904	4 200 612	62 015	54 898	116 914
Pelagic	1 565 721	4 124 539	5 690 260	270 292	578 941	849 233
Shrimps/crustaceans	882 932	227 367	1 110 300	26 163	10 245	36 408
Other ²	314 227	288 649	602 876	220 153	65 086	285 238
Total	17 116 404	11 067 666	28 184 069	1 059 625	933 747	1 993 372

¹ Salted fish, dried and salted fish and klippfish from fillets and whole white fish

² Fish for aquariums, cod liver oil, marine gastropods, echinoderms, squid etc.

Figure 6a: Production placed on the EEA market with a breakdown by main products and main EEA countries

	Conventional		Whitefish		Pelagic	
	tons	1000 NOK	tons	1000 NOK	tons	1000 NOK
Denmark			41 668	754 788	92 395	345 906
Italy	10 279	710 476				
Netherlands					28 663	216 420
Poland					33 570	228 694
Portugal	34 605	1 468 399				
UK			27 815	725 811		
Total	62 015	2 766 708	145 703	3 273 449	270 292	1 565 721

Figure 6b: Production placed on the EEA market with a breakdown by main products and main EEA countries

	Salmon/trout		Shrimps/crustaceans		Other	
	tons	1000 NOK	tons	1000 NOK	tons	1000 NOK
Denmark	69 167	1 506 556	5 030	168 887	175 406	175 366
Finland					21 421	36 780
France	64 019	1 673 416				
Sweden			8 164	298 381		
UK			5 425	203 250		
Total	335 298	8 313 366	26 163	882 932	220 153	314 227

The statistical information included in Figures 5, 6a and 6b is based on information from the Norwegian Seafood Export Council.

7 Main findings

7.1 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 website: <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. However, as application of Directive 91/492/EEC is not covered by the objectives of this mission, only the conclusions related to Directive 91/493/EEC from that mission were followed up during this mission and included in this report.

In the report from the mission in 2002 it was concluded that, *inter alia*, evidence of application of Article 5 of Council Directive 89/662/EEC regarding non-discriminatory veterinary checks at the place of destination could not be provided.

The mission team received before the final meeting statistical information related to the official control carried out in accordance with Directive 89/662/EEC in 2004. According to this information a total of 17 inspections related to fish and fishery products were carried out in 2004. However, more detailed information on the extent of these checks was not made available to the mission team.

In the 2002 report it was also concluded that the CAs had not approved the laboratories used for analysing samples as required in Article 6 of Council Directive 91/493/EEC. In addition routines for approval of detergents and similar substances were still not established. Consequently, the requirement in Point II, A.5 of Chapter III of the Annex to Council Directive 91/493/EEC could therefore not be complied with.

As part of the re-organisation of the Norwegian CAs, the laboratory services were separated from the official services. After the establishment of the NFSA on 1 January 2004, official samples can only be analysed at laboratories having a contract with the CA. Representatives of the NFSA informed the mission team that a project has been initiated in order to establish procedures for approval of those laboratories not having contracts for analysing official samples. It is foreseen that these procedures should be in place and applied as of 1 January 2006.

According to information provided by the NFSA during the mission, *revised* procedures for approval of disinfectants are in place and applications must be sent to the NFSC in Bergen. These procedures are in the process of being formalised in a new set of regulations. It is the National Institute of Nutrition and Seafood Research/*Nasjonalt Institutt for Ernærings- og sjømatforskning* (NIFES) that is assessing the information enclosed to the applications. A list of all approved disinfectants is available on the NFSA's homepage.

In the report from the mission in 2002 it was also concluded that the necessary measures to be taken by the CAs, as required in Article 7 of Council Directive 91/493/EEC, were not sufficient, since lack of corrective actions to deficiencies reported were not always followed up by the establishments. Moreover, it was concluded that the follow-up by the

CAs of conclusions of visits by the Authority needed further improvement since some deficiencies reported after a visit in 2000 were still not remedied in 2002.

Furthermore, the size, design or layout and the maintenance of parts of the premises of some of the establishments visited were not fully in compliance with the requirements of Council Directive 91/493/EEC. Moreover, collection of waste and wastewater and storage of wrapping and packaging materials were not fully complying with the requirements of Council Directive 91/493/EEC.

During the visit to the DO, the mission team received a copy of a letter from the Directorate of Fisheries/*Fiskeridirektoratet* (FIDIR) dated June 2002 related to follow-up of the conclusions from the Authority's mission in March 2002. The mission team also received a copy of a letter from an audit of a regional office of the FIDIR carried out by the main office of the FIDIR late 2002. Both letters contained information and instructions related to follow-up in cases where the establishments had not taken proper action following inspections by the Authority or by the CA.

Information on the findings from the latest mission and related to the CA's follow-up of the establishments' corrective actions to deficiencies registered by the CA is included in Chapter 7.10.1 of this report.

According to the conclusions from the mission in 2002, the own-checks systems in the establishments visited were not fully in compliance with the requirements of Article 6 of Council Directive 91/493/EEC and with Commission Decision 94/356/EEC, since verification procedures were missing in most of the establishments. Moreover, relevant information such as a description of the products, identification of the intended use of the products, identification of hazards and critical limits, analysis of risks and procedures for corrective action were not always complete or available.

Information on the findings from the latest mission, and relevant for the conclusions listed above, is included in Chapter 7.10.2 of this report.

Finally, in the 2002 report it was also concluded that the training of inspection staff of the CAs authorised to assess the own-checks system of the establishments, needed to be continued in order to assure compliance with the requirement of Article 7 of Commission Decision 94/356/EC.

During the latest mission evidence of both centrally, regionally and locally organised training of inspection staff was observed. Several of these courses had a main focus on Hazard Analyses and Critical Control Points (HACCP).

7.2 Competent Authorities – general information

It follows from a Royal Decree of 19 December 2003 that the Norwegian Government considers the authority to instruct the NFSA to be split between the Ministry of Agriculture and Food, the Ministry of Fisheries and Coastal Affairs and the Ministry of Health and Care Services.

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

The Ministry of Fisheries and Coastal Affairs is responsible for legislation related to aquatic production, *inter alia*, the national legislation implementing Council Directive 91/493/EEC related to fishery products, and for Directive 93/53/EEC related to fish diseases.

The Ministry of Health and Care Services is, *inter alia*, responsible for national legislation implementing Council Directive 98/83/EC related to quality of water, Commission Regulation (EC) No 466/2001 related to contaminants in foodstuffs, and Directive 2000/13/EC related to labelling, presentation and advertising of foodstuffs.

7.2.1 Competent Authorities - organisation

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

The NFSA is organised in three administrative levels, the central level with the HO, a regional level with eight ROs, and a local level with 64 DOs.

The HO, being located in Oslo, is responsible for co-ordinating the organisation's activities including, *inter alia*, inspections, surveillance and eradication of animal diseases, and preparation of new legislation.

Five different National Centres (NCs) having been assigned special tasks, are located at different ROs. The NCs have no legal power, take instructions only from the HO, but are administratively organised under the respective ROs. Being located at the RO in Bergen, the NFSC is the NC related to seafood production.

According to information provided by representatives of the NFSA, it is the principal rule that administrative decisions shall be adopted at the local level. Any appeal following these decisions shall be considered at the regional level. At the time of the mission, lawyers were employed at four of the eight ROs. These lawyers are also providing legal support to the case handlers at other ROs and at the local level. Seminars in administrative law are organised for case handlers at all three levels within the NFSA.

During the mission one region and two districts within that region were visited. One meeting was held at the RO and two meetings were held at the DO of one of the districts visited.

7.2.2 Regional Office visited

The RO visited is organised in three different groups, one working with food, one with fish health and one with animal welfare, feedingstuffs and plant health. Although the 10 case handlers were assigned to specific fields of work, the office aimed at having an extensive overlap between the different fields.

Four of the case handlers used to work in the former FIDIR and four in the former SDT, while one worked in the former KNT and one in the former SLT. The NFSC is an administrative part of the RO visited.

The region consists of eight districts, each with one district office. The number of staff at the DOs varies between 8 and 25. Seven of the eight offices are involved in application of national legislation implementing Directive 91/493/EEC and related EEA legislation.

The Head of the RO informed the mission team that meetings with all the DOs are held on a monthly basis. During 2004 these meetings were mainly of an administrative character. However, as of 2005 these meetings will focus more on harmonisation of activities, such as inspections.

Furthermore, the Heads of the eight ROs also have monthly meetings, six of which are phone meetings. These meetings focus on, *inter alia*, harmonisation of the activities between the different regions. A case handling system is in place which enables the case handlers to calibrate their case handling with similar cases in other regions.

Based on a letter on allocation of funds, the DOs prepare annual plans for the activity within their respective districts. It is foreseen that a new planning and reporting system will be in place before the end of 2005.

7.2.3 District Office visited

The DO visited had a total of 17 staff members out of which 14 were inspectors. Between 2,5 and 3 man-labour years were set aside for inspecting the 22 approved fishery products establishments, 2 fish oil factories, 3 factory vessels and 17 freezer vessels located or registered in the district. According to a workload assessment carried out in the district, the total workload equals approximately 22 man-labour years.

The Head of the DO informed the mission team that legal support was normally received from the RO or the NFSC.

At the time of the visit, the budgetary allocation for 2005 was still to be distributed from the HO. However, the Head of the DO indicated that the budget for 2005 would be between 9 and 10 million NOK.

Representatives of the DO informed the mission team that the FIDIR had issued guidelines for sampling in relation to verification of own checks. These guidelines had been used in 2003, but due to the re-organisation of the CA, only two samples had been collected from one establishment during 2004. For 2005, the DO had planned a local project for sampling and analysing products for presence of *Listeria*. However, since the budgetary allocation for 2005 had not been finalised, the DO had not managed to finalise this year's sampling plan.

In addition to the courses and seminars arranged for all staff of the NFSA, the DO had, during 2004, arranged a one day course in HACCP for the staff at the DO and a one day course in administrative tools related to, *inter alia*, case handling.

7.3 Fees paid by the establishments

Following the establishment of the NFSA, a new system for financing of official controls had been established. The legal basis for charging fees is to be found in the *Regulation of 28 January 2004 No 221 on taxes and fees in the food administration*. As part of this system, fees have been introduced for a number of the NFSA's services towards the establishments.

Services that are comprised by the Regulation referred to are, *inter alia*, assessment of applications for approvals and changes in approvals of establishments and issuing of certificates and declarations. However, inspections carried out in establishments are not comprised by the Regulation.

According to information provided by representatives of the NFSA during the mission, all invoices and payments are administered by the NFSA's National Centre of Accounts and Salaries. All fees are collected in arrears by the NC based on information provided by the case handlers.

7.4 Monitoring of contaminants in foodstuffs

During the mission information related to monitoring of contaminants in foodstuffs was not available. However, the mission team received information on results of the analyses carried out in 2004. All analyses referred to below are carried out at the NIFES in Bergen.

According to this information 121 composite samples each consisting of five farmed Atlantic salmon were analysed for cadmium, lead, mercury and dioxins. All results were below the maximum levels set out in the relevant EEA legislation.

According to the same information, a total of 74 individual samples, taken from herring (11), mackerel (13), redfish (12), saithe (10) and farmed salmon (28), were analysed for dioxins. All results were below the maximum levels set out in the relevant EEA legislation.

Furthermore, in accordance with a national monitoring programme, 35 samples were taken from different products of processed seafood (canned products). These samples were collected in 2003 but analysed in 2004. All samples were analysed for heavy metals and all but two samples were analysed for dioxins. All samples were below the maximum levels for lead, mercury and dioxins. In one of the samples of cod liver the amount of cadmium was 0,101 mg/kg fresh weight. The amount of dioxins in the same sample was 2,25 pg/g fresh weight. However, maximum levels of these parameters in cod liver are not fixed in the EEA legislation.

Based on a monitoring programme financed by the Norwegian Ministry of Fisheries and Coastal Affairs, the NIFES is also responsible for analysing 25 samples from each of the species herring, mackerel and farmed Atlantic salmon *every year*. These samples are analysed for other undesirable substances. *In addition*, three different wild caught species are sampled every year, and each of these species and sampling points are repeated every eight years.

7.5 Approval and suspension/withdrawal of approval of vessels and fishery products establishments

7.5.1 Approval of vessels and fishery products establishments

Criteria for approval of establishments and vessels are laid down in the Norwegian *Quality Regulation relating to fish and fishery products*. Following the re-organisation of the CAs, it is the responsibility of the DOs to approve/register vessels and to approve fishery products establishments. However, exemptions can only be granted by the ROs. Since the NFSA has not up-dated the guidelines for approval of establishments, the guidelines prepared by the FIDIR are creating the basis for the approval process.

The approval process is initiated by an application signed by the representative of the establishment or vessel. Annexed to the application should be, *inter alia*, the checklist from the establishment's own inspection of the facilities, drawings of the facilities where the equipment is included, documentation of the quality of the potable water, and a draft of the own-checks system (including HACCP).

It is required that the CA shall inspect the establishment before any approval is issued. Approvals can only be issued if the establishment complies with the requirements of the Norwegian quality Regulation. A checklist is available for use by the inspectors of the DO during inspections of the establishments before the approval is issued.

When the DO considers that the establishment is complying with the requirements of the Norwegian quality Regulation the approval document is issued. This document contains the relevant information about the establishment and the production codes related to the production for which the establishment is approved. A total of 21 different production codes are available.

The lists of approved or registered vessels and of approved fishery products establishments are available on the homepage of the NFSA. The lists are administered by the NFSC but updated by the DOs.

7.5.2 Suspension/withdrawal of approval of vessels and fishery products establishments

The Norwegian *Quality Regulation relating to fish and fishery products* also contains the legal basis for withdrawal of approvals. However, as the NFSA has not up-dated the relevant guidelines, the guidelines prepared by the FIDIR are still applied.

According to information provided by representatives of the NFSA during the mission, only the DO which approved the establishment has the legal power to withdraw the approval. Consequently, in cases of disagreement between the RO and the DO, the RO has to instruct the DO to withdraw the approval.

An approval can only be withdrawn when the DO has, by a formal decision, ordered certain deficiencies to be rectified within a given time limit, and the time limit has not been met by the representatives of the establishment.

It follows from the guidelines that deficiencies related to facilities, hygiene and production, the own-checks system and the quality of the water can result withdrawal of the approval.

Examples related to facilities, hygiene and production that might lead to withdrawal of the approval are risk of cross-contamination, deficiencies related to changing rooms, poor cleaning and extensive shortcomings related to maintenance.

Deficiencies related to the own-checks system that might lead to withdrawal of approval are, *inter alia*, incomplete HACCP plan, incomplete checks of critical control points (CCPs) and procedures for cleaning, for checking the quality of the water and for corrective action. Withdrawal of approval should also be considered if sufficient water quality cannot be documented.

Finally, depending on the extent of the deficiencies, withdrawal of approval can be limited to certain parts of the establishment or for some of the processes taking place.

7.6 Rapid alert notifications (RASFF notifications)

During October and November 2004 a number of notifications of the presence of *Anisakis* larvae in fresh mackerel originating in Norway was notified via the Rapid Alert System for Food and Feed (RASFF). The parasite was discovered during official checks carried out in Italy.

The NFSA provided relevant information via the RASFF system on expected presence of *Anisakis* larvae in fresh mackerel. The fact that the mackerel was fresh and not gutted, resulted in the NFSA concluding that the establishments handling the mackerel were not breaching the national legislation implementing, *inter alia*, Directive 91/493/EEC and Decision 93/140/EEC. However, information related to any contact with establishments in question could not be provided during the mission.

Based on the observations of the mackerel during official inspections in Italy, the mackerel containing *Anisakis* larvae were not placed on the EU market. Conclusions on the interpretation of Directive 91/493/EEC and Commission Decision 93/140/EEC is still to be drawn.

7.7 Laboratory visited

Two accredited laboratories were located within one of the districts visited. One of these laboratories had signed a contract with the RO for analysing official samples. The other laboratory was not involved in analysing official samples. In addition, one of the establishments approved in accordance with the requirements in Directive 91/493/EEC had its own laboratory.

The mission team visited the laboratory not involved in analysing official samples. The laboratory had maintained an accreditation by the Norwegian Accreditation/*Norsk Akkreditering* for more than five years. The laboratory was involved in analysing samples from both aquaculture farms and food processing establishments in addition to samples from a number of municipalities.

The head of the laboratory informed the mission team that, due to the accreditation requirements, copies of results from analyses carried out, were only sent to the NFSA if the laboratory had been instructed to do so by the owner of the samples. Only a few clients had instructed the laboratory to inform the CA of the results of the analyses.

Both accredited and non-accredited methods were used in the laboratory. Where internationally recognised methods had been adjusted, validation of the methods had been carried out.

The laboratory participated regularly in ring tests organised by the Norwegian Institute for Water Research/*Norsk Institutt for Vannforskning* (NIVA), and the Swedish National Food Administration/*Livsmedelsverket*. However, due to the increased competition between Norwegian laboratories, professional contact and co-operation between Norwegian laboratories were not extensive.

Procedures for taking and handling of samples had been established by the laboratory. Although some of the processing establishments took their own samples, the majority of the samples analysed at the laboratory were collected by the staff of the laboratory. During the analysing process, the owners of the samples were not known to the analysing staff.

For analysing histamine in samples from fish processing establishments, representatives of the laboratory informed the mission team that that the owners of the samples required the samples to be analysed within 14 days from the collection.

The staff seemed well qualified and the laboratory well organised and equipped for the activity taking place.

7.8 Official inspections of vessels and fishery products establishments

According to information provided by the NFSA as a reply to the Authority's pre-mission questionnaire, frequencies for inspections of fishery products establishments had not been established before 2003. During the mission representatives of the NFSA informed the mission team that such frequencies are still to be established.

However, during the mission the inspection team was informed that the Head Office of the FIDIR had recommended its Regional Offices to establish plans for supervision based on a risk assessment of the establishments. For 2003 each Regional Office sent a plan for inspections, audits and sampling to the Head Office.

Furthermore, the SNT had also established some criteria enabling the inspectors of the KNTs to divide the establishments in different groups in order to decide the inspection frequency. To a certain extent this system, in addition to the procedures established by the FIDIR, still constitute the basis for the determination of the inspection frequency.

Before the establishment of the NFSA, the FIDIR had established procedures to be followed when establishments were inspected. According to these procedures, and as part of the inspection, an inspection report had to be issued by the inspector and left at the establishment visited. Based on the findings included in these reports, the inspector or the Regional Office of the FIDIR adopted, where necessary, formal decisions where the representatives of the establishments/vessels were given a time limit for rectification of the deficiencies revealed during the inspection.

According to the Norwegian reply to the pre-mission questionnaire the same procedures are applied within the NFSA. However, it is the respective DO which adopts the formal decisions and is responsible for the enforcement of legal requirements.

Before 1 January 2004 the reports issued in the establishments constituted the basis for monthly reports from the Regional Offices of the FIDIR to the Head Office. Following the establishment of the NFSA all information regarding official inspections carried out is included in the same case handling system. However, at the time of the mission, the integrated reporting tool was not fully developed.

During the mission, representatives of the NFSA informed the mission team that official sampling as foreseen in Chapter V of the Annex to Directive 91/493/EEC is not carried out by the NFSA. It follows from the *Quality Regulation of 14 June 1996 No 667 relating to Fish and Fishery Products* that such sampling (both upon landing, during processing and before the products are released for human consumption) is to be carried out by the establishments.

7.9 Vessels visited

7.9.1 Official inspections

Two vessels were visited at the quayside in two different districts of the NFSA. None of the visits were included in the itinerary.

The first vessel visited had not recently been inspected by the CA. The head of the DO informed the mission team that such vessels had not been inspected in that district during 2004. However, according to the annual plan, 10 out of 140 fishing vessels were foreseen to be inspected during 2005.

Both the CA and the captain confirmed that the second vessel visited had not been inspected by the CA (neither FIDIR nor NFSA) for several years.

None of the vessels visited were included in the “List of vessels equipped for chilling in RSW (refrigerated seawater) or in CSW (chilled seawater)” available at the NFSA’s website.

7.9.2 Conditions related to the vessels including handling of fish

The vessels visited were both RSW vessels. Representatives of both vessels informed the mission team that the paint used in the tanks for storage of chilled fish was approved for use on materials in contact with foodstuffs.

The first vessel visited was about to empty some 450 tons of herring. The vessel was almost 40 years old but was in an acceptable state of repair.

Detailed information was provided on the procedures established on board for storage of fish in water from the fishing grounds to the processing establishments. However, temperature registrations were not easily accessible.

The second vessel visited was built some five years ago and was in a good state of repair. The approval number issued by the FIDIR was not known to the captain. The digital registrations of the temperature in the tanks where the fish were kept were not functioning.

In addition, although the temperature was frequently checked visually, no written documentation of these checks was made.

The disinfectant used on board this vessel was included in the list of approved disinfectants available at the NFSA's website.

7.10 Fishery products establishments visited

7.10.1 Official inspections

During the visits to the establishments, the mission team had a particular focus on the inspections carried out by the CA and also evidence of any action taken following the conclusions of the inspection carried out in 2002.

According to information provided by representatives of the NFSA, inspections are not pre-notified. However, due to the scope of the annual audits, these are normally notified approximately 14 days in advance. In one of the establishments visited representatives of the DO informed the mission team that the establishment is inspected 10-15 times per year. Only the audit visit had been notified in advance. Inspections where only documents and registrations are checked or samples taken can last for up to two hours, while audits normally take a full working day.

In three of the establishments visited, mission reports were normally not left after the inspections, but sent by mail or facsimile from the DO the same day or the day after. However, documents checked on-the-spot by the inspectors were stamped and signed.

In at least two of the establishments visited the mission team also observed that the inspectors of the DOs had taken some samples of the products. In one of these establishments the samples taken were related to the different monitoring programmes running. Samples for verification were normally taken once or twice per year.

Representatives of the DO informed the mission team that the type of samples and parameters had not been decided and risk factors had not been considered. However, they told the mission team that samples were more often taken during processing rather than of raw materials or final products, and more often in large rather than small establishments.

The sampling frequency for verification was in accordance with the content of a letter issued by the FIDIR in September 2003. This letter also contained information on products to be sampled and parameters to be analysed.

In one of the establishments visited the mission team observed that, during an inspection in 2002, a local inspector had registered a shortcoming related to separation between clean and contaminated parts of the facilities. The subsequent case handling had involved both the Head Office of the FIDIR and the Ministry of Fisheries and Coastal Affairs. However, the final decision confirming the observation made by the local inspector was made by the Ministry of Fisheries and Coastal Affairs in December 2004. Moreover, at the time of the mission, the DO had not been informed about the decision adopted by the Ministry.

The mission team also observed that this establishment had not been inspected by the DO during 2004. However, it had been inspected three times during 2003, but two of these visits were only for taking samples.

In another establishment visited the mission team observed that comments related to the findings during previous inspections by the DO were included in the reports kept at the premises. However, in at least two establishments visited, it was observed that deadlines in decisions adopted by the DO or proposed by the establishments for rectifying deficiencies, were not followed up by the DO. Finally, it was also observed that follow-up inspections by the DO were carried out several months after the deadlines had expired.

7.10.2 Conditions related to own-checks systems including HACCP plan

All the establishments visited had in place an own-checks system including HACCP plan. In one of the establishments visited an own-checks system had been in place and applied since 1997. The system, including the HACCP plan, had been approved by the CA (FIDIR) in 2000.

This establishment had in place procedures for annual revision of the HACCP plan. Following these revisions the number of CCPs had been reduced. Consequently, at the time of the visit, the establishment did not have any CCPs.

In another of the establishments visited, more training of the staff involved in the HACCP system seemed necessary in order for the establishment to fully apply the HACCP plan. In this establishment procedures for revision were insufficient and procedures for verification of the plan and keeping of records were missing.

7.10.3 Conditions related to premises and equipment

In all the establishments visited the premises were of sufficient size taking into account the production taking place.

In at least three of the establishments visited there was not a clear separation between clean and contaminated parts of the premises. In two of the establishments visited the majority of the outer doors were not closing properly.

At least two of the establishments visited had maintenance plans in place. However, in one of these establishments the maintenance of the premises was not sufficient.

Most of the equipment observed was in an acceptable state of repair. However, in one of the establishments visited both the cutting tables and some of the conveyer belts were not sufficiently maintained.

7.10.4 Conditions related to hygiene and production

In two of the establishments visited the mission team observed that only a few samples were collected annually and analysed for presence of histamine. Moreover, in one of these establishments the samples collected throughout the year (in total nine) were stored and analysed at the end of the year. The frequency of sampling could not be justified in any of these establishments.

In one of the establishments visited samples taken from the equipment in 2004 had been positive for *Listeria*. Action was taken to rectify the problem. However, verification of the effectiveness of the action taken, including follow-up sampling could not be documented.

The positive results of the samples taken by the establishment were not known to the NFSA.

In at least two of the establishments visited working clothes and private clothes were observed in the same lockers in the changing rooms. A representative of one of the establishments visited informed the mission team that the staff were themselves responsible for cleaning of working clothes.

In the establishments visited during operation, waste was accumulating around the machinery and wastewater was not sufficiently drained away from the production area.

In one of the establishments visited frozen fish was partly thawed in a mixture of ice and water without sufficient drainage of the melt water. In this establishment the mission team also observed that fish fillets were kept on the working tables during a break. Wrapped products intended for block freezing were also kept at ambient temperature during the break. The machine for mechanical recovery of fish flesh was not cleaned at regular intervals. Mechanically recovered fish flesh was kept at ambient temperature during the break.

Wooden pallets were observed in the clean parts of the premises of one of the establishments visited. In the same establishment the mission team observed that at least two of the staff members had to carry out a number of operations involving both handling of products during processing, and handling of wooden pallets and other equipment.

In one of the establishments visited ice was stored close to the area where tubs used for raw materials were hosed. The ice was stored in tubs not properly cleaned and the ice was contaminated. In this establishment the mission team also observed that a contaminated tub containing ice was stored under open air on the quayside without any lid. Furthermore, raw material for transport for processing in another establishment was transported out of the processing area and stored unprotected on the quayside. A door from the production area to the outside was kept permanently open during processing.

These observations resulted in immediate action taken by the inspector from the DO. The mission team was informed that the representative of the establishment had been instructed to make sure that both storage of ice and icing of products only took place inside the premises. Further action by the DO based on the observations in this establishment is included in Chapter 9.

7.10.5 Conditions related to labelling, storage and transport

In one of the establishments visited the mission team observed packed unlabelled products in one room used for storage of, *inter alia*, final products. In the freezer store for final products in another of the other establishments visited, the mission team observed both exposed fish intended for further processing and packed final products.

In this establishment the mission team also observed that the wrapping of the packaging materials had been damaged during transport. Consequently, the packaging materials were contaminated upon arrival at the establishment.

In another establishment visited, the room for storage of packaging materials was not well organised, wrapping and packaging materials were not protected from dust and contamination and the room was dusty and not sufficiently cleaned. In the same room the mission team observed ingredients, some of which were outdated.

Finally, a third establishment stored some wrapping and packaging materials in the same room as spare parts, wooden pallets and sacks with cement.

8 Final meeting

A final meeting was held on Friday 25 February 2005 at the HO of the NFSA in Oslo with representatives from the Ministry of Fisheries and Coastal Affairs and from the NFSA. At this meeting the mission team orally presented the main findings and some preliminary conclusions of the mission.

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

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

9 Additional information provided by the Norwegian Competent Authority

Before the final meeting the mission team received a copy of a letter regarding formal action towards one establishment visited during the mission. The content of the letter confirmed the information provided to the mission team on-the-spot. The letter contained additional information related to observations made during the visit. In the letter the establishment was instructed to take immediate and proper action and provide relevant information to the DO within 12 working days.

10 Conclusions

10.1 Official inspections of vessels and fishery products establishments

10.1.1 Measures taken by the persons responsible for establishments

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

10.1.2 Action taken by the CA

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

10.1.3 Official sampling

Compliance with Directive 91/493/EEC, and in particular Article 7 and Points II(1), II(3)(a) and II(4) of Chapter V of the Annex thereof, could not be assured, since sampling and analyses were not included in the official inspections. Moreover, verification of such sampling by the establishments' representatives could not be documented.

10.1.4 Listing of fishing vessels

Compliance with the requirements of Council Directive 92/48/EEC, and in particular Point 9 of Annex II thereof, could not be assured since the vessels visited were not included in the NFSA's official list of such vessels.

10.2 Fishery products establishments visited

10.2.1 Conditions related to own-checks systems including HACCP

Deficiencies related to the own-checks systems were observed in at least one of the establishments visited. For example, procedures for revision were insufficient and procedures for verification of the plan and keeping of records were missing. Compliance with the requirements of Article 6 of Directive 91/493/EEC and with Decision 94/356/EEC could therefore not always be assured.

10.2.2 Conditions related to premises and equipment

There was not a clear separation between clean and contaminated parts of the facilities in three of the establishments visited. Some outer doors were not closing properly or not kept closed during processing. Maintenance was not sufficient in one of the establishments visited. Wooden pallets were observed in the production area in at least one of the establishments visited. Compliance with the requirements in Point I and II(A) of Chapter III of the Annex to Directive 91/493/EEC could therefore not always be assured.

10.2.3 Conditions related to hygiene and production

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

10.2.4 Conditions related to labelling

Unlabelled products (both products for further processing and final products) were observed in a store for final products. Compliance with the requirements of Chapter VII of the Annex to Directive 91/493/EEC and Directive 2000/13/EC could therefore not be assured.

10.2.5 Conditions related to storage and transport of products

Final products were temporarily kept outside at the quayside before further transport. This is not in compliance with the requirements of Chapter VIII of the Annex to Directive 91/493/EEC.

10.2.6 Conditions related to storage of packaging materials

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

11 Recommendations to the Norwegian Competent Authority

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

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

11.2 Official control of production of fishery products

The NFSA should take the necessary action to make sure that the requirements of Article 7 and Chapter V of the Annex to Directive 91/493/EEC are complied with, in particular related to sampling and verification of results of analyses carried out.

11.3 Fishery products establishments

The CA should take the necessary action to make sure that approved establishments comply with the requirements of Directive 91/493/EEC. Focus should also be put on the procedures for follow-up of deadlines set out in decisions adopted by the NFSA or proposed by the establishments and on the application of these procedures. In this process the Authority would like to reiterate the importance of equal treatment of establishments.

Enclosure:

Action taken by the NFSA:

7.9 Vessels visited

The two visited vessels were not included in the “list of vessels equipped for chilling in RSW or in CSW”:

The head of the DO responsible for supervision of the first vessel visited has provided information about the ongoing work regarding updating of the list of RSW vessels in this district.

The NFSA has informed the second vessel that they must contact their local DO (another DO than the one visited by the Authority) for registration. This vessel is also asked to repair the digital registrations of the temperature in two of the tanks where the fish is kept, and to ensure that documentation of the temperature registrations is available.

9. Additional information provided by the Norwegian Competent Authority

The mission team has received a copy of a letter regarding formal action towards one establishment visited during the mission. In a letter from the DO dated 29 March 2005, the corrective action and time limits suggested by this establishment was accepted.