Brussels, 3 July 2009
Case No: 65620
Event No: 523231

Final report

EFTA Surveillance Authority mission to

NORWAY

9-18 March 2009

regarding the application of EEA legislation related to

live bivalve molluscs

The information on the corrective actions already taken and planned by the Norwegian competent authority are included in Annex 4 (except for the enclosures referred to in the document).

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1 Introduction

The mission took place in Norway from 9 to 18 March 2009. The mission team comprised 3 inspectors from the EFTA Surveillance Authority (the Authority) and a national expert.

The opening meeting was held with representatives of the Ministry of Fisheries and Coastal Affairs, the Ministry of Health and Care Services and the Norwegian Food Safety Authority (NFSA) on 9 March at Gardemoen airport in Oslo. At the meeting representatives of the NFSA added information to the reply to the Authority's pre-mission questionnaire.

For parts of the mission, the mission team split into two sub-teams in order to visit more production areas, establishments and district offices. Throughout the mission, representatives of the head office of the NFSA accompanied the mission team. In addition, representatives of the relevant regional offices and district offices of the NFSA participated during meetings at the district offices and the visits to the different production areas and establishments.

A final meeting was held at the NFSA head office in Oslo on 18 March 2009, at which the mission team presented its main findings and some preliminary conclusions from the mission.

The abbreviations used in the report are listed in Annex 1.

2 Scope and objectives of the mission

The scope of the mission was Council Directive 91/492/EEC on health conditions for placing on the market of live bivalve molluscs.

The main objective of the mission was to assess the Norwegian Competent Authorities'(CAs) application of Council Directive 91/492/EEC and other related legislation referred to in Chapter 3 and Annex 2 to this report. A particular focus was put on the following issues:

a) procedures for the classification of production areas;
b) procedures for the evaluation of methods for handling live bivalve molluscs;
c) planning, carrying out and follow-up of official controls, including official sampling;
d) performance of laboratories; and
e) co-operation between the NFSA and laboratories.

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

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

		Comments
Competent Authority	8	Including opening and final meetings, six meetings with regional offices and with local offices of the NFSA
National reference laboratories (NRLs)	2	The NRL for marine biotoxins, bacterial and viral contamination of bivalve molluscs The NRL for chemicals elements in food of animal origin such as dioxins and polychlorinated biphenyls (PCBs), heavy metals in food and feed, and polycyclic aromatic hydrocarbons (PAHs)
Other laboratories	5	Two laboratories analysing water samples for phytoplankton, one laboratory preparing samples for analyses for marine biotoxins , one laboratory for chemical analyses of biotoxins and one laboratory for biological analyses of biotoxins
Production areas	4	
Vessel/establishments	7	One boat harvesting and transporting live bivalve molluscs, one approved dispatch centre/purification centre, three approved dispatch centres, one establishment approved for processing live bivalve molluscs and one approved canning factory

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 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 6.1.10 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

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.

Other legislation relevant for the mission is listed in Annex 2.

4 National legislation

The main Norwegian Act creating the general framework for the functioning of the NFSA is Act No 124 of 19 December 2003 relating to food safety and plant and animal health (the Food Act). The Food Act also provides the legal basis for regulations in the relevant fields adopted by the Ministry of Agriculture and Food, the Ministry of Fisheries and Coastal affairs and the Ministry of Health and Care Services.

The Food 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 5 January 2007 No 15 *(Kvalitetsforskrift 14. juni 1996 nr 667 for fisk og fiskevarer, sist endret ved forskrift av 5. januar 2007 nr 15,* adopted by the Ministry of Fisheries and Coastal Affairs).

Proposals for changes to the Food Act would be drafted by the three Ministries. Any changes are to be decided by the Parliament. The legal power to issue regulations within closer defined areas within the scope of the Act is given to the same ministries. By way of ministerial delegation of 5 May 2004, legal power to issue regulations within the scope of some of the Articles of the Food Act is given to the NFSA.

5 Previous missions

The Authority carried out a mission in this field to Norway in March 2002 and one mission in April 2004. During the mission in 2002 the Authority assessed the CAs application of both Council Directive 91/493/EEC on fishery products and Council Directive 91/492/EEC on bivalve molluscs. During the mission in April 2004 Council Directive 95/70/EC for the control of certain diseases affecting bivalve molluscs was also assessed. The final reports from both missions are available on the Authority's website: http://www.eftasurv.int/information/reportsdocuments/vetcontrolmatters/fishery/.

In the report from the mission carried out in 2002 it was concluded that, *inter alia*, Directive 91/492/EEC was not applied on production of marine gastropods. It was also 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.

In the report from the mission carried out in 2004 the following was, *inter alia*, concluded:

- compliance with point 1 and 2 of Chapter VI of the Annex to Directive 91/492/EEC could not always be ensured as the monitoring program did not cover the period for which live bivalve molluscs are harvested;
- compliance with Article 3(1)(a) of Directive 91/492/EEC could not always be ensured since live bivalve molluscs sometimes could originate from production areas not classified according to Chapter I of the Annex to the Directive;
- 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 ensured.

A general review mission to Norway took place from 15 to 19 January 2007. Concerning the two missions in 2002 and 2004, some issues were still outstanding at that time, in particular:

- information verifying that the official sampling programme covers the period for which live bivalve molluscs are harvested;
- information on procedures for approval of dispatch centres and for wrapping of products.

6 Main findings

6.1 Competent Authorities

A detailed description on the NFSA's organisation, its structure and responsibilities was already provided in the final report of the Authority mission to Norway from 14 to 18 April 2008 regarding the control and eradication of bluetongue. The report is available on the Authority's website:
http://www.eftasurv.int/information/reportsdocuments/vetcontrolmatters/contagiousanimal diseases/.

6.1.1 National Surveillance Programme

Every year, the NFSA establishes a national surveillance programme (NSP) to monitor the production sites for shellfish located all over the country. The NSP is based on the times of year and locations harvesting is expected to be carried out during the coming 12 months. This information is supplied by the producers/owners of classified production areas. Sampling points, apart from four permanent stations, are established each year on the basis of the expected locations for harvesting. Several production areas are therefore included in the programme. In 2009, 38 fixed stations to be monitored throughout the year have been established. In addition, during the summer months sampling will also take place at an additional 11 stations. Samples are also taken from production areas outside the fixed stations at the time of harvesting.

In the programme for 2009 the NFSA states that the aim of the NSP is to prevent consumers in Norway and the countries to which live bivalve molluscs are exported to being exposed to algae toxins, pathogenic microorganisms and/or chemical contaminants. The NSP is also used to verify the producers/harvesters internal control, and for strengthening the basis for opening and closing of production areas. Finally the NSP also creates the basis for the classification of production areas. The results from samples taken as part of the NSP can also result in the banning of live bivalve molluscs (LBM) from a particular production area being placed on the market, if the shellfish contain marine biotoxins, microorganisms and/or chemical contaminants in concentrations that are considered to pose a risk to public health.

During the mission the NFSA representatives stated that the NSP is mainly in place for the monitoring of the conditions along the Norwegian coast in order to advise the Norwegian consumers on the quality of shellfish collected for their own consumption.

The 2009 NSP comprises analyses of the following parameters: phytoplankton, marine biotoxins, microbiological quality and chemicals contaminants. Results for chemical contaminants (heavy metals, PCBs PAHs etc) are also used to monitor the situation of production areas while harvesting is taking place. Regarding lipophilic toxins, results are mainly based on chemical methods as only one in five samples are analysed using the mouse bioassay method.

The mission team noted that the number of samples analysed in 2008 did not correspond to the 2008 NSP. The mission team observed that:

- concerning heavy metals (samples should be collected twice a year; in April and August) 62 samples had been analysed compared to the 94 samples included in the NSP;
- chemical contaminants, PCBs, Dioxins and PAHs were monitored at ten sampling stations instead of the 47 indicated in the NSP. For some areas with significant production of bivalve molluscs no results were available;
- results for Salmonella analyses were not available for some of the production areas in the districts visited;
- results from three laboratory analyses for *E.coli* and enterococci out of twelve planned were observed in one sampling station. For the same station, in August 2007 a result of *E.coli* equivalent to 1 750 MPN/100g was obtained without any changes in the classification by the NFSA;
- despite several laboratory results above the legal limits concerning Yessotoxins (YTX) and one for Azaspiracid (AZA), the NFSA advised the consumers that own consumption of LBM was allowed. This was based on a scientific opinion concluding that such consumption is not hazardous to the consumers;
- in some occasions, and for the detection of liphophillic toxins, the results of the chemical method was taken into account by the NFSA for the final decision to allow own consumption of LBM despite positive mouse bioassay;
- after a period with several results for liphophillic toxins above the legal limit, one result below the limit is normally considered enough to re-establish advice of consumption for consumers and to allow for resumption of harvesting;
- results from the NSP are sometimes used for the issuing of harvesting permissions. However, the sampling frequency set out in the NSP is not respected.

6.1.2 Documents, certification and labelling

The mission team observed some irregularities in the documents. Registration documents for tracing LBM are prepared by the District Offices (DO) and sent to the gatherers by fax or e-mail. The documents bears the NFSA logo but it is filled in and signed by the gatherer. It should accompany each batch of LBM. The following was noted by the mission team:

- the numbering of registration documents was not harmonized between district offices;
- up to four registration documents with the same document number accompanying different batches of products from production areas to dispatch centres were found in a DO;
- in several cases the section in the registration document indicating the status of the production area was not filled in.

Inconsistency in the use of Norwegian production codes was identified by the mission team. For example, in the application form used by the establishments in order to be approved for different activities, code 23 indicates approval for crustaceans except shrimps in the Norwegian version, while in the English one the same code is used for shellfish except prawns. In the same form, code 22 is used for production of tunicates, echinoderms etc., while on the NFSA website code 22 indicates establishments approved for processing molluscs.

In one establishment visited, the label used for wrapped LBM did not contain a complete health mark as the approval number of the dispatch centre was not included.

6.1.3 Classification of production areas for live bivalve molluscs

When the NFSA was established in 2004, classification of production areas became a duty of the DOs. According to figures from 2008, approximately 400 production areas are classified in Norway. The mission team was informed by the Central CA that it is the respective DO that is responsible for the classification of production areas, by issuing classification documents. The following was observed by the mission team:

- at the NFSA's head office no information was kept about the situation concerning class A and B areas;
- there was no central list of the LBM production areas. However, the NFSA's new case handling system (*Mattilsynets Tilsynssystem* = MATS) will, when developed, be a tool that gives directions, guidance and support to the inspectors who perform official control on-the-spot. MATS is defined as the operational quality management system with regard to official control. The module for control of fishery products was in place March 2008 but the module for classifying and opening and closing of shellfish production areas is still not finished;
- a system for distribution of relevant information between DOs and Regional Offices (ROs) will be included in MATS. Currently, the NFSA has no internal system for distribution of relevant information;
- the NFSA does not have an overview of the amount of molluscs originating from production areas classified as "B";
- in one DO visited, procedures for reclassification of production areas have not been established;
- in the same DO no procedure for the maintenance of classification was in place;
- prior to 2008 the production areas did not have boundaries, as the Directorate of Fisheries only gave one coordinate to indicate the production area. From 2008 the Directorate of Fisheries has set the boundaries for the production areas by at least 3 or more coordinates indicating the boundaries for the areas. However, it was not evident that all classified production areas had their boundaries indicated;
- relaying as defined in Council Directive 91/492/EEC is not taking place in Norway. However, small shells can be re-immersed in the same production area or moved to a different production area, as was observed in one of the districts visited;
- one production area in one of the districts visited was classified on 16 January 2008 as an "A" area despite samples not having been taken from this production area since 2005. Instead, results for 2008 from another production area, 1.4 km away, were used when classifying the area. In the same district, another production area was classified as "A" based on results from another small production area, located 800 metres away.
- in another district visited, 35 production areas were registered. However, despite only one area having been classified as an "A" area, an additional four areas had also been authorized by the DO for harvesting in 2008. The DO based its decision to allow harvesting to take place in these five areas on a single result for microbiology before harvesting instead of periodic monitoring.

6.1.4 Harvesting licence

The DO issues a licence to the gatherer to harvest molluscs. The gatherer must take samples two weeks in advance before the harvesting period starts. Samples are dealt with as follows: two weeks before harvesting starts, on the Monday, samples of water for phytoplankton analyses are taken; and on the following Monday samples are taken of water and molluscs' flesh (for phytoplankton, microbiology and toxins analyses). The DOs receive the results from the microbiology and toxin analyses on the Friday of the week the samples are taken.

The harvesting licence issued is valid for 14 days from the date of flesh sampling. The harvesting licence can be renewed weekly for a total of six weeks (42 days), following weekly sampling of water (for phytoplankton examination) and fortnightly sampling of molluscs' flesh (for microbiology and toxins). The described procedure is set up for production areas only at the time of harvesting of LBM and their placing on the market. However, the mission team observed the absence of a periodic monitoring in order to check the microbiological quality of the LBM in relation to the production areas.

No sampling plans are established by the CA for checking the possible presence of chemical contaminants on a case-by-case basis in the event of irregular periods of harvesting. However, a periodic monitoring of LBM production areas in order to check the possible presence of toxin producing plankton in production waters and biotoxins in live bivalve molluscs is established and running.

In one of the districts visited the mission team observed that 31 production areas for LBM were listed. However, only six had been classified as "A" areas and monitored for harvesting. , In 2008, two out of six results for *E. coli* for a production area in this district were at levels to classify it as a "B" area (2 400 MPN/100 g in April 2008, and 500 MPN/100 g in August 2008). Furthermore, the mission team observed that of PSP toxins and lipophilic toxins had been registered at this production area during a period starting 28 April 2008. A harvesting licence had been issued for this production area on the basis of just one sample, from 30 June 2008, with a result just below the legal limit for both PSP and YTX using chemical methods, but with a positive result using a mouse bioassay . Also in the same district, the mission team observed that a harvesting licence, dated 4 July 2008, had been granted despite the production area not having been classified. This harvesting licence was issued based on results of analysis from the production area mentioned above, situated 5 km away.

In another DO visited, written procedures for withdrawing of harvesting licences and for recalling from the market molluscs already distributed from the production area/dispatch centre were not available. However, detailed information on how to handle such situations was provided. In his absence, the person responsible for molluscs gives advice on the phone in order for those replacing him to take decisions.

In a third DO visited, 35 production areas were licensed. However, harvesting licences had been issued by the DO for only four of the production areas. For one of these production areas, a harvesting licence was issued on 20 January 2009 without results of lipophilic toxins using the mouse bioassay, while for some other licences mouse bioassay results were available.

For the same DO, results for phytoplankton counting were often found incomplete as no figures in the column of net haul samples were reported in case of no detection (normally the figure 0 should be indicated in the result sheet).

6.1.5 Approval of establishments

The list of approved establishments is updated on a weekly basis through MATS. Establishments can be approved for activities they do not perform at all or perform very rarely (e.g. establishments visited by the mission team and approved for purification and canning of LBM without such activity taking place or had taken place for a long period). Representatives of the NFSA informed the mission team that approval can be withdrawn but not because of no production.

6.1.6 Official control

The following was noted by the mission team in relation to the checks and inspections carried out by the NFSA:

- the methods for harvesting, handling and transporting mussels from the harvesting areas to dispatch centres had not been assessed/evaluated by the NFSA;
- in one establishment visited the mission team observed that the NFSA had not followed-up all non-compliances revealed during previous visits;
- in a dispatch centre for scallops analyses of the chemical quality of the sea water used were not carried out;
- in one of the DOs visited the mission team observed that the NFSA was not always on-the-spot when official samples were taken. In this DO the NFSA had not inspected the harvesting boats. However, in one of the NFSA's inspection reports a comment on the harvesting technique was included.

6.2 Laboratories

6.2.1 Laboratories dealing with water samples and net haul materials, counting phytoplankton

The mission team visited two laboratories analysing water samples and net haul materials for algae. In the reply to the PMQ, the Authority was informed that three laboratories are involved in phytoplankton analysis; however representatives of one of the laboratories visited told the mission team that a fourth private laboratory is also carrying out such analysis. The mission team observed that inter-laboratory tests between the different laboratories involved in the above mentioned analysis were not established. However, laboratory representatives informed the mission team that pictures of algae were distributed by e-mail to a network of laboratories as part of verification of findings.

In the first laboratory visited scientific experience and expertise as well as equipment were found to be satisfactory. The mission team was informed by the personnel responsible for sample registration that 80% of samples for phytoplankton samples arrive at the laboratory without the forms being filled in. The laboratory assumes who the sampler is (instead of registering the sampler as unknown). Results of analyses are not reported using a standardized form but by sending an excel table by e-mail which does not contain the following information:

- time/date of sampling;
- date of analysis;
- person responsible for the analysis;

The other laboratory visited analyses both private and official water samples for algae. However, the system for identification of samples observed was not so distinct that tracing back samples through the laboratory could be guaranteed. The laboratory was not accredited and a system of good laboratory practice (GLP) or equivalent was not in place. However, a GLP was in the process of being drafted and a decision on whether to apply for accreditation would probably be taken later this year. The mission team observed that it could take up to a week to detect that samples had been sent for analyses but not arrived at the laboratory (procedures for notifying the laboratory of samples being sent were not established). Prioritisation was given to official samples and the laboratory notified the NFSA when a sample taken in respect of the NSP had not arrived at the laboratory.

The mission team had also the possibility to check several test reports from the third laboratory involved in counting phytoplankton and observed the absence of data/figures related to results on phytoplankton analysis.

Finally, and specifically for the NSP, it has to be mentioned here the frequent absence of figures in the section dedicated to phytoplankton "*Algetokins Overvakning*". The measurement of the mentioned parameter is therefore missed.

6.2.2 Laboratory dealing with biological and chemical analyses of biotoxins

This laboratory has been accredited since November 1994. The mission team was informed by the personnel responsible for sample registration that some of the samples arriving at the laboratory were not registered (samples not possible to analyse or damaged samples).

Regarding LBM, the scope of the accreditation includes:

- Domoic acid by HPLC in shellfish flesh;
- extraction procedure for lipophilic toxins (method based on ether extraction);
- extraction procedure for PSP toxins (method based on acid extraction);
- Salmonella (foodstuffs and environmental samples); and
- *E.coli* by ISO TS 16649-3 method.

Around 350-400 shellfish samples per year are analysed for marine biotoxins. According to the NFSA these are private samples usually collected on Mondays by the owners of production areas. Samples arrive normally within 24 hours (Tuesday mornings). The samples are fresh shellfish with shells, shellfish meat unshackled either by the producers or by other local laboratories, or only the hepatopancreas. The mission team also observed two forms in 2009 requesting analysis of pre-cooked shellfish.

Analyses start on the same day the samples arrive. For PSP and lipophilic toxins, extracts are sent to two other laboratories both acting as sub-contractors. Results are available by Thursday the same week and sent by e-mail to the owner, to the head office and the relevant DO of the NFSA. This procedure allows the DO to issue harvesting licences (normally done on Fridays).

At the laboratory the mission team observed that:

- the laboratory provides boxes used for transporting samples to the laboratory. A sampling form accompanies the samples to the laboratory. The first section of the form is completed by the producer providing information on the production area, specifying the type of samples and listing the analyses required. When samples are prepared at a local laboratory before being sent to the analysing laboratory, the local laboratory complete the second section;
- forms accompanying samples have several layouts (at least seven types observed). Several of them were noted with hand written comments. The responsible for the department analysing samples explained the mission team that was difficult for the laboratory to instruct the owner on the right updated form to use and that several inconsistencies on the right way to fill in the form occurred despite instructions were available on the web page of the laboratory. As a consequence of these inconsistencies, the laboratory had to prepare an internal form to interpret the request from the owners (this form is not covered by the quality control system as it has neither code nor version reported on it);
- the mission team observed that facilities, equipment and skills of staff were adequate as well as the presence and correct use of standards and positive control quality material related to the relevant analyses carried out;
- despite the methods being accredited, samples are not accompanied by working sheets during the analysing process, as laid down in the NS-EN ISO/IEC 17025 (traceability of samples). A single sheet of paper per sample is used, without neither

code nor version indicated. It only contains the date, the operator and the confirmation that the different analyses have been done for each sample;
- the weighing scales in use in the laboratory was not properly labelled as expiration date of the calibration period was missing. Furthermore, the weight used for the verification purposes was 200 g while the amounts weighed in the methods were only 5 g and 50 g;
- the mission team observed that extracts for lipophilic toxins used in the mouse bioassay in samples of scallops, are normally prepared only using muscles and gonads following the SOP available and provided by the NRL. However, during the visit to the NRL the mission team was informed by the quality manager that this SOP was not to be used but the mission team observed that it was still set out in the accreditation manual.

Ring tests were organized by this laboratory in 2008 for ASP, lipophilic toxins (chemical method) and PSP (chemical method) involving the two other laboratories, including the NRL, carrying out these tests in Norway. The representative of the laboratory informed the mission team that:
- for ASP, one ring test was carried out in 2008, two samples (one positive and one negative) had been tested;
- for lipophilic toxins, chemical method, two ring tests were carried out in 2008, two samples (one positive and one negative) per ring test had been tested;
- for PSP, chemical method, two ring tests were carried out in 2008, two samples (one positive and one negative) per ring test had been tested.

Checking the test reports issued by the laboratory the mission team observed that much of the detailed information required by ISO/IEC 17025:2005 concerning test reports were not included: identification of the method used (point 5.10.2.e), the date of receipt of the test item (point 5.10.2.g), the date of performance of the test (point 5.10.2.g), a statement on the estimated uncertainty of measurements (point 5.10.3.c), and the identification of the test performed by subcontractors (point 5.10.6) .

6.2.3 Laboratory performing mouse bioassay for lipophilic toxins

The laboratory visited by the mission team is the only one in Norway performing mouse bioassay for lipophilic toxins for samples collected by the farmers in order to get harvesting licences. The laboratory acts as sub-contractor of the laboratory described in point 6.2.2 where extracts from samples are previously processed and sent to the sub-contractor on Tuesdays. Injections on mice are normally performed on Wednesdays and results are available on Thursdays. The laboratory is not accredited. In 2008, 287 mouse bioassays (16 above the legal limit) were performed and 34 so far in 2009. The following was observed by the mission team:
- mice between 13 and 25 g can be used. This is a wider interval that the 17 to 22 g described in the harmonized EU SOP for detection of lipophilic toxins by mouse bioassay provided by the CRL (version 4, 2007);
- the weighing scales used was not calibrated and was moved from one place to another depending on the use, compromising its stability and balance. Results, reported as DSP instead of lipophilic toxins, were not issued using a standardized test report but copying and sending a row from excel program by e-mail;
- no results from participation in any ring tests were available (at the NRL the mission team was informed that a ring test was carried out on 6 March 2009 but results had not yet been processed).

6.2.4 Laboratory performing chemical analyses of biotoxins

This laboratory acts as sub-contractor of the laboratory described in point 6.2.2. The laboratory receives on Tuesdays, from the said laboratory, two extracts per shellfish sample, one for lipophilic toxins and one for PSP, both to be analysed with the chemical method. During the visit the mission team observed that the laboratory had a high standard on the equipment, staff were highly motivated and performance of the methods was observed to be good. The laboratory has been accredited since June 2006. Regarding LBM, the scope of the accreditation includes seven PSP toxins in shellfish using HPLC-FD and five lipophilic toxins in shellfish (OA, YTX, DTX1, PTX2 and AZA1) using LC-MS.

In the case of lipophilic toxins, the chemical method used did not include all the toxins described in the Annex of Commission Decision 2002/225/EC. The method used does not include PTX1, OH YTX, Homo YTX, 45 OH Homo YTX, AZA2 and AZA3, and consequently can not be considered as an alternative to the mouse bioassay for lipophilic toxins. Nevertheless, it should be noted that mouse bioassay for lipophilic toxins are carried out for the same samples in the other sub-contractor laboratory.

It should be mentioned the fact that even though the samples that this laboratory receives are extracts of samples prepared at the laboratory described in point 6.2.2, the scope of the accreditation is issued for shellfish in general.

For PSP (chemical method) the mission team noted that in the ring test from August 2008, results from the other laboratory involved did not match with those reported by the NRL. The mission team was told that, after scientific support provided by the NRL, the method in the laboratory concerned was improved. In the following ring test carried out in December 2008 the results from this laboratory were satisfactory.

6.2.5 National reference laboratory for dioxins and PCBs, heavy metals, polycyclic aromatic hydrocarbons and chemical elements in food of animal origin

In the context of the NSP, this laboratory is in charge of the analyses regarding microbiological quality, heavy metals and chemical contaminants.

The laboratory is accredited for *E. coli*, Salmonella, enterococci, PCB and pesticides. For heavy metals the accreditation was temporarily suspended because facilities used for this analysis had recently been moved from one building to another.

The mission team checked the forms accompanying the samples and found them correctly filled in. Files were properly organised and available. However, the frequency of sampling was not consistent with the NSP. Traceability of samples in the section for microbiology was adequately implemented.

6.2.6 National reference laboratory for marine biotoxins and for monitoring the viral and bacteriological contamination of bivalve molluscs

In relation to the objective of the mission, the NRL is only involved in the analyses of marine biotoxins (95% of the samples relate to the NSP and 5% to private operators). If some stations of the NSP correspond to production areas, these analyses are used by the DOs to issue harvesting licences. Around 1 000 samples per year are tested covering the complete range of toxins using chemical methods (ASP, PSP and lipophilic toxins). Around 100 mouse bioassays for lipophilic toxins were carried out in 2008.
All chemical analyses were accredited. However, the following was observed by the mission team in relation to the accreditation:

- the accreditation document issued by the accreditation body (Accreditation no. Test 137, page 2 of 6) mentions general ASP-toxins, fat soluble marine algae toxins and PSP toxins instead of listing the necessary details as found in the accreditation documents issued by the same accreditation body for the laboratory performing chemical analysis of biotoxins (see point 6.2.4, Accreditation no. Test 202, page 2 of 4). In the latter, the exhaustive description of the parameter object of the accreditation is given (e.g Neosaxitoxin Gonyautoxins 1 and 4, Saxitoxin, Gonyautoxins 2 and 3 Decarbamoylsaxitoxin, Okadaic, Yessotoxins Pectenotoxin 2 Azaspiracid 1, etc). Detailed parameter (Domoic acid) is also mentioned in the accreditation document (Accreditation no. Test 028, page 2 of 8) issued for the laboratory dealing with biological and chemical analysis of biotoxins (see point 6.2.2);
- checking the quality of registration forms used in the laboratory and test reports it was noted that much of the detailed information required by ISO/IEC 17025:2005 concerning test reports (points 5.10.2 and 5.10.3) were not included in the test report but in an attached sheet (date of sampling and unambiguous identification of the item tested).

The laboratory had a quality assurance system in place and participates in inter-laboratory ring tests for all methods regarding marine biotoxins. However, it was observed that tasks required under Commission Decision 93/383/EEC concerning the NRL are not fully fulfilled (e.g. ensuring that the information supplied by the CRL on the harmonised SOP for detection of lipophilic toxins are disseminated to the CA and to the national laboratories responsible for analyzing marine biotoxins).

6.3 Vessels, means of transport and establishments visited

The mission team visited one boat harvesting and transporting live bivalve molluscs (at the quayside), one dispatch centre approved also as purification centre, three approved dispatch centres, one establishment approved for processing live bivalve molluscs and one approved canning factory.

Every shipment of shellfish is accompanied by a registration document. These papers are issued by the DO, upon request by the gatherer, and have a unique document number. They are sent by fax to the gatherer and for each batch the gatherer must complete legibly and indelibly the relevant sections which contain several information related to the batch. When the establishment uses this paper a copy is sent back to the DO that issued the original document. Checking registration documents available on the spot, the mission team observed the following inconsistencies:

- in several production areas visited the registration document was not completed or was not used. It was therefore not possible to trace back the mussels to the production area of origin;
- in one dispatch centre receiving LBM from several (around 200) production areas in several districts the mission team noted that:
  a) the health status of the production area was not always filled in;
  b) the approval number of place of destination was not mentioned (one case);
  c) the quantity of products processed deviated from the quantity recorded on the forms: 8000 kg declared and 9200 kg processed; 10000 kg declared and 11300 kg processed. The explanation from the person responsible for the dispatch centre was that this is a procedure established by the producer in order to save money for transport fees;
- in another establishment visited, approved as a dispatch centre for scallops, the mission team observed that, in 2009, 13 registration documents were not filled in with the health status of the production areas of origin. Two registration documents

from a production area were issued in the absence of a harvesting licence: the owner explained that harvesting licences from a neighbouring area were considered applicable for harvesting due to the limited distance between the two areas.

In the processing part of one establishment the mission team observed wooden shelves in the ice boxes and final products in polystyrene crates not properly sealed.

In another establishment visited, approved as a dispatch centre, the mission team observed that:

- molluscs were sent in 900 kg bags to dispatch centres in Norway or in other EEA Countries without being labelled. At the same time the registration document was not accompanying the consignment but faxed to the dispatch centre;
- different batches of mussels were not labelled. Consequently, tracing back the mussels to the production area was not possible;
- according to the owner, harvesting could sometimes start a day before the results of analyses were available;
- a clear separation between clean and contaminated parts of the production facilities could not be ensured;
- packaging materials were stored directly on the floor and some materials were stored unpacked together with different production equipment and papers;
- doors to the outside were not closing properly and parts of floors, walls and ceilings were not well maintained;
- ice was not protected from contamination (a hole in the floor under the ice machine placed on a mezzanine not properly cleaned);
- waste (shells etc) was kept outside the production facilities not protected from pests and the area around the establishment was not tidy.

7 Final meeting

The final meeting was held on 18 March 2009 at the NFSA head office in Oslo with representatives of the Ministry of Fisheries and Coastal Affairs, the Ministry of Health and Care Services and of the NFSA. At this meeting, the mission team presented its main findings and some preliminary conclusions.

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

The representatives of the NFSA accepted the observations and preliminary conclusions presented.

8 Follow-up and corrective action taken

While drafting the report the NFSA supplied additional information in response to the observations made by the mission team during the mission. The NFSA also provided information about some corrective actions which have already been taken.

9 Conclusions

9.1 Overall conclusion

Compared with previous missions in this field, not much improvement was observed during this mission. Norway should take appropriate action in order to increase its focus on the application of Council Directive 91/492/EEC. The action taken should in particular focus on the following topics:

- classification of production areas;
- official control;
- enforcement of legislation;
- traceability of samples including all steps from sampling through to distribution of results;
- traceability of products at all times from harvesting to retail sale;
- quality management of laboratories.

9.2 Competent Authority

9.2.1 Compliance with the requirements laid down in Council Directive 91/492/EEC in particular points 3, 4, 6 and 7 of Chapter V, and points 1, 2 and 3 of Chapter VI of the Annex could not always be ensured since results of analysis from the national surveillance programme, used to allow the placing on the market of live bivalve molluscs, were not all the time consistent with the above mentioned requirements.

9.2.2 Compliance with point 6 of Chapter II of the Annex to Directive 91/492/EEC, concerning the registration document for the identification of batches of live bivalve molluscs, could not always be ensured since the section on the health status of the production areas was not always completed.

9.2.3 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular Article 3(1)(i) and Chapter X of the Annex could not always be ensured since, as observed in one establishment, LBM placed on the market did not bear a complete health mark.

9.2.4 Compliance with Article 3(1)(a) of Council Directive 91/492/EEC could not always be ensured since live bivalve molluscs could sometimes originate from production areas which had not been classified in accordance with Chapter I of the Annex to the Directive.

9.2.5 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular Article 3(1)(f) and point 1(b) of Chapter VI of the Annex could not be assured since harvesting from production areas is allowed by the NFSA based on one single result for microbiology before harvesting commence instead of periodic monitoring.

9.2.6 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular, point 1(d) of Chapter VI of the Annex could not be assured since sampling plans are not established by the CA for checking the possible presence of chemical contaminants at regular intervals or on a case-by-case basis in the event of irregular periods of harvesting.

9.2.7 Compliance with the requirements laid down in point 7 of Chapter V of the Annex to Council Directive 91/492/EEC and the Annex to Commission Decision 2002/225/EC could not always be assured since the NFSA allowed harvesting without results of lipophilic toxins using the customary biological testing methods.

9.2.8 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular point 1(a) of part IV of Chapter IV to the Annex could not always be assured since no attention was paid by the competent authority to the chemical quality of the sea water used in a dispatch centre.

9.3 Laboratories

9.3.1 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular point 1(c) of Chapter VI to the Annex could not always be ensured because of:

- an inconsistent approach for completing test reports, including the absence of data/figures related to results on phytoplankton analysis, observed in the laboratories dealing with water samples and net haul materials, and
- the frequent absence of figures included in the NSP in the section dedicated ""*Algetokins Overvakning*" in relation to results for the possible presence of toxin-producing plankton in production and relaying waters.

9.3.2 Compliance with Council Directive 93/99/EEC in particular Article 3 thereof could not always be ensured since certain inconsistencies were observed in the laboratories visited in relation to traceability of samples and the use of harmonized EU SOPs (e.g. mouse bioassay).

9.3.3 Compliance with the requirements of Commission Decision 2002/225/EC in particular the Annex thereof could not be ensured since extracts for lipophilic toxins used in the mouse bioassay in samples of scallops were normally prepared using only muscle and gonads.

9.3.4 Compliance with the requirements of Commission Decision 2002/225/EC in particular the Annex thereof could not be ensured since, in the case of lipophilic toxins, the chemical method used did not include all the toxins described in the Annex.

9.3.5 Compliance with the requirements laid down in point 6 of Chapter V of the Annex to Council Directive 91/492/EEC and Article 5 of Commission Decision 2002/225/EC could not always be ensured since the mouse bioassay was not always used as the reference method in cases of discrepancies between the different methods of analysis.

9.3.6 Compliance with the requirements laid down in Commission Decision 93/383/EEC in particular with Article 2(1) could not always be ensured since the NRL was not ensuring that the information supplied by the CRL on harmonised SOP for detection of lipophilic toxins were disseminated to the NFSA and to the national laboratories responsible for analyzing marine biotoxins.

9.4 Vessels, means of transport, establishments visited

9.4.1 Compliance with point 6 of Chapter II of the Annex to Council Directive 91/492/EEC related to the registration document for the identification of batches of LBM could not always be assured since the information related to the health status of the production areas was sometime missing.

9.4.2 Compliance with the requirements laid down in Council Directive 91/492/EEC in particular Article 3(1)(i) and Chapter X of the Annex thereof could not be always ensured since dispatched LBM were not properly identified.

9.4.3 Compliance with Council Directive 91/492/EEC in particular Chapter IV of the Annex thereof related to conditions for the approval of dispatch or purification centres could not always be assured because of the shortcomings identified as general hygiene requirements.

10 Recommendations to the Norwegian Competent Authority

Norway should inform the Authority in its reply to the draft report, by way of written evidence, of the corrective actions taken and a plan for corrective measures and actions, including a timetable for completion of measures still outstanding, relevant to all the conclusions under Chapter 9 of this report. This information will be annexed to the final report. The Authority should also be kept informed of the completion of the measures included in the timetable.

Annex 1 List of abbreviations and terms used in the report

ASP	Amnesic Shellfish Poison
Authority	EFTA Surveillance Authority
AZA	Azaspiracid
CA	Competent Authority
Class A area	Areas from which live bivalve molluscs can be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the requirements set out in Chapter V of the Annex of Council Directive 91/492/EEC.
Class B area	Areas from which live bivalve molluscs can be collected but only placed on the market for human consumption after treatment in a purification centre, after relaying. Live bivalve molluscs from these areas must not exceed the limits of a five-tube three-dilution MPN-test of 6 000 faecal coliforms per 100 g of flesh or 4 600 *E. Coli* per 100 g of flesh in 90 % of samples. After purification or relaying, all the requirements et out in Chapter V of the Annex of Council Directive 91/492/EEC must be met.
CRL	Community Reference Laboratory
DO	District Office
DSP	Diarrhetic Shellfish Poison
EC	European Community
EEA Agreement	Agreement on the European Economic Area
GLP	Good Laboratory Practice
HPLC-FD	High Performance Liquid Chromatography – Fluorescence Detection
ISO	International Organisation for Standardisation
LBM	Live Bivalve Molluscs
LC-MS	Liquid Chromatography – Mass Spectrometry
MATS	*Mattilsynets tilsynssystem*
MPN	Most Probable Number
NFSA	Norwegian Food Safety Authority/*Mattilsynet*
NRL	National Reference Laboratory
NSP	National Surveillance Programme for shellfish production
PAHs	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
PSP	Paralytic Shellfish Poison
RO	Regional Office
SOP	Standard Operation Procedure
YTX	Yessotoxins

Annex 2 - Other relevant legislation

The main EEA Acts regarding live bivalve molluscs and relevant for this mission 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.

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 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* as adapted to the EEA Agreement by the sectoral adaptations referred to in Annex XX to that Agreement.

d) The Act referred to at Point 3.1.10a 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*.

e) 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 and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement.

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

g) The Act referred to at Point 54zzzn of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation 1883/2006/EC of 19 December 2006 laying down methods of sampling and analyses for the official control of levels of dioxins and dioxin like PCBs in certain foodstuffs.*

h) 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*.

i) 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.*

j) 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.

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

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

m) The Act referred to at point 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 labelling, presentation and advertising of foodstuffs,* as corrected by OJ L 124, 25.5.2000, p.66, as amended and adapted to the EEA Agreement by the sectoral adaptations referred to in Annex II to that Agreement.

Annex 3 Information on production and trade[1]

The production volume of the different species is included in Figure 2 while export quantity and the value thereof split into the main markets are listed in Figure 3. The figures for the production volume in 2007 and 2008 were not available at the time of the mission.

Figure 2: Production volume for different species (in tonnes)

	Year		
Species	**2006**	**2005**	**2004**
Blue mussels (*Mytilus edulis)*	3714	4885	3747
Great Atlantic scallops	4	3	46
Oysters	1	2	3
Other species	30	14	21
Total	**3749**	**4904**	**3817**

Figure 3: Export quantities (tonnes) and value (thousand NOK) split into species and main markets

	Year					
	2008		**2007**		**2006**	
Species and countries	**Quantity**	**Value**	**Quantity**	**Value**	**Quantity**	**Value**
Blue mussels, total	815	7820	1050	10566	2115	12185
EU, total	738	5833	966	8558	2065	11019
Belgium	-	2	15	112	3	76
Czech	1	21	-	1	-	2
Germany	36	142	42	81	212	379
Denmark	71	533	33	320	325	1791
Estonia	2	38	1	15	-	1
Finland	5	127	23	112	19	76
France	461	3049	608	4976	886	5272
Great Britain	4	84	3	55	4	99
Greece	-	13	-	-	-	-
Latvia	1	16	1	15	-	1
Lithuania	1	15	2	37	2	52
Luxembourg	-	-	-	-	1	3
Netherlands	54	313	95	445	505	445
Poland	37	790	24	434	11	215
Spain	-	-	37	419	3	141
Sweden	66	687	82	1188	93	841
Third countries, total	77	1987	85	2007	50	1165
Great scallop, total	783	33383	804	29947	671	29971
EU, total	770	32345	786	29193	655	29941
Belgium	33	1397	28	1108	46	1789
Czech	-	4	-	-	-	-
Denmark	256	10474	157	6259	116	4665
Estonia	-	1	-	-	-	-
Finland	-	-	-	23	-	-
France	6	290	73	544	2	68
Germany	51	2324	56	2338	49	1991
Great Britain	34	1447	62	2436	32	1244
Greece	1	77	-	1	-	-
Hungary	-	-	-	-	-	3
Italy	114	4732	129	5163	79	3118
Latvia	-	-	-	3	-	6
Lithuania	-	8	-	-	-	1
Luxembourg	-	-	-	-	3	109

[1] Source: Norwegian Food Safety Authority, 2009

Netherlands	168	7057	165	6586	146	5762
Poland	2	80	1	27	-	43
Portugal	-	11				
Spain			103	4090	156	6636
Sweden	30	1897	10	614	26	4002
Third countries, total	13	1038	23	975	19	669
Oysters, total	-	1	4	214	1	186
EU, total	-	1	4	214	1	159
Third countries, total	-	-	-	-	-	27

Annex 4 Information on the corrective actions already taken and planned by the Norwegian competent authority

	SUBJECT	ACTION	TIME ASPECT	ENCLOSURES
9.2	**Competent Authority**			
9.2.1	Compliance with the requirements laid down in Council Directive 91/492/EEC in particular points 3, 4, 6 and 7 of Chapter V, and points 1, 2 and 3 of Chapter VI of the Annex could not always be ensured since results of analysis from the national surveillance programme, used to allow the placing on the marked live bivalve molluscs, were not all the time consistent with the above mentioned requirements.	• Letter has to be sent to the Regional offices to explain the findings during the mission and to instruct them to take corrective actions regarding the findings. • The ROs have to return their replies including time table for corrective actions. • Meetings with two of the regions visited during the inspection for discussing the findings. TMR 25. March HSF 28. April • The findings during the mission and follow up of the findings will be discussed at a meeting between the Directors and the Chief regional officers of the NFSA at 11th of June. • Training of staff will take place during autumn 2009 or at the latest spring 2010	Done The timetables will be forwarded to ESA by the end of June Done Done Autumn 2009, Spring 2010.	letter to the regional offices Letter to the region HSF Letter to the region TMR
9.2.2	Compliance with point 6 of Chapter II of the Annex to Directive 91/492/EEC, concerning the registration document for the identification of batches of live bivalve molluscs, could not always be ensured since the section	Registration document Letter has to be sent to the Regional offices with instruction take corrective measure.	Done	

	on the health status of the production areas was not always completed.			
9.2.3	Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular Article 3(1) (i) and Chapter X of the Annex could not always be ensured since, as observed in one establishment, LBM placed on the market did not bear a complete health mark.	Letter to be sent to the Regional offices to instruct them to check the labelling of LBM placed on the marked. In addition a letter has to be sent to the regional office of Trøndelag, Møre og Romsdal instructs them to take corrective action against the establishment.	Done Done	
9.2.4	Compliance with Article 3(1)(a) of Council Directive 91/492/EEC could not always be ensured since live bivalve molluscs could sometimes originate from production areas which had not been classified in accordance with Chapter I of the Annex to the Directive.	Letter has to be sent to the Regional offices with instructions to make sure that LBM only comes from areas that are classified:	Done	
	9.2.5 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular Article 3(1)(f) and point 1(b) of Chapter VI of the Annex could not be assured since harvesting from production areas is allowed by the NFSA based on one single result for microbiology before harvesting commence instead of periodic monitoring.	Letter to be sent to the Regional offices with instructions stating that classification can only be maintained when at least four samples of shellfish have been analysed for E. coli each year.	Done	
	9.2.6 Compliance with the requirements laid down in Council Directive 91/492/EEC in particular, point 1(d) of Chapter VI of the Annex could not be assured since sampling plans are not established by the CA for checking the possible presence of chemical contaminants at regular intervals or on a case-by-case basis in the	This point will be corrected when the hygiene package is implemented in Norway. Each production area will be allowed one analysis of chemical contaminants per year paid by the CA. If the hygiene package is not implemented in	January 1st 2010	

	event of irregular periods of harvesting.	Norway by January 1st 2010, the placing of the sampling stations in the National Surveillance Program will be revised in order to include more production areas in the programme.		
	9.2.7 Compliance with the requirements laid down in point 7 of Chapter V of the Annex to Council Directive 91/492/EEC and the Annex to Commission Decision 2002/225/EC could not always be assured since the NFSA allowed harvesting without results of lipophilic toxins using the customary biological testing methods.	Letter has to be sent to the Regional offices with clarifications on the biological testing method. The regional offices are to be instructed that the reference method is the biological method. With any discrepancy between the biological testing and the chemical method the biological method is the valid one.	Done	
	9.2.8 Compliance with the requirements laid down in Council Directive 91/492/EEC, in particular point 1 (a) of part IV of Chapter IV to the Annex could not always be assured since no attention was paid by the competent authority to the chemical quality of the sea water used in a dispatch centre.	In order to avoid contamination from seawater on the LBMs in the dispatch centres, the chemical quality of the sea water must be satisfactory. An evaluation on the requirements for chemical quality will be accomplished when the hygiene regulations are implemented in Norway.	As soon as possible after the hygiene regulations are implemented in Norway.	
	9.3 Laboratories			
	9.3.1 Compliance with the requirements laid down in Council Directive 91/492/EEC in particular point 1(c) of Chapter VI to the Annex could not always be ensured because of- • an inconsistent approach for completing test reports, including the absence of	Letters have to be sent to the laboratories to give directions for them to change the report in a way that the necessary details are included in the report.	Done The corrective measures taken by the	 IMR  MPC

	data/figures related to results on phytoplankton analysis, observed in the laboratories dealing with water samples and net haul materials, and • the frequent absence of figures included in the NSP in the section dedicated "*Algetokins Overvakning"* in relation to results for the possible presence of toxin-producing plankton in production and relaying waters.		laboratories will be forwarded to ESA by the end of June.	NIVA SINTEF
	9.3.2 Compliance with Council Directive 93/99/EEC in particular Article 3 there of could not always be ensured since certain inconsistencies were observed in the laboratories visited in relation to traceability of samples and the use of harmonized EU SOPs (e.g. mouse bioassay).	Letter to the Norwegian school of veterinary science (see point 9.3.2) Reply from the Norwegian school of veterinary science	Done The reply from NVH will be forwarded to ESA by the end of June.	
	9.3.3 Compliance with the requirements of Commission Decision2002/225/EC in particular the Annex thereof could not be ensured since extracts for lipophilic toxins used in the mouse bioassay in samples of scallops were normally prepared using only muscle and gonads.	See point 9.3.2		
	9.3.4 Compliance with the requirements of Commission Decision 2002/225/EC in particular the Annex thereof could not be ensured since, in the case of lipophilic toxins, the chemical method used did not include all the toxins described in the Annex.	The mouse bioassay is the reference method on lipophilic toxins and is performed when the bivalve molluscs are harvested.	A statement from NVH will be sent by the end of June.	
	9.3.5 Compliance with the requirements laid down in point 6 of Chapter V of the Annex to Council Directive	The NFSA does not recognize any reference to where point 6 in chapter V in		

	91/492/EEC and Article 5 of Commission Decision 2002/225/EC could not always be ensured since the mouse bioassay was not always used as the reference method in cases of discrepancies between the different methods of analysis.	91/492 EEC is not fulfilled in the draft report. In Norway the chemical test (Lawrence method) is used as a routine test, not the mouse bioassay. However, if both the mouse bioassay and the chemical test are performed, the mouse bioassay is the reference method and the valid one.		
	9.3.6 Compliance with the requirements laid down in Commission Decision 93/383/EEC in particular with Article 2(1) could not always be ensured since the NRL was not ensuring that the information supplied by the CRL on harmonised SOP for detection of lipophilic toxins were disseminated to the NFSA and to the national laboratories responsible for analyzing marine biotoxins.	See point 9.3.2		
	9.4 Vessels, means of transport, establishments visited			
	9.4.1 Compliance with point 6 of Chapter II of the Annex to Council Directive 91/492/EEC related to the registration document for the identification of batches of LBM could not always be assured since the information related to the health status of the production areas was sometime missing.	See point 9.2.2		
	9.4.2 Compliance with the requirements laid down in Council Directive 91/492/EEC in particular Article 3(1)(i) and Chapter X of the Annex thereof could not be always ensured since dispatched	See point 9.2.3		

	LBM were not properly identified.			
	9.4.3 Compliance with Council Directive 91/492/EEC in particular Chapter IV of the Annex thereof related to conditions for the approval of dispatch or purification centres could not always be assured because of the shortcomings identified as general hygiene requirements.	Letter has to be sent to the Regional office in Trøndelag, Møre og Romsdal. The follow ups from the region are enclosed	Done	 Instructions to the DO  Plan for follow up of establishment

EFTA SURVEILLANCE AUTHORITY

EFTA Surveillance Authority
Rue Belliard 35
B-1040 Brussels
BELGIUM

v/ Luca Farina

Deres ref: Case No: 65620
Vår ref: 2009/58924
Dato: 26.06.2009
Org.nr: 985 399 077

Statens tilsyn for planter, fisk, dyr og næringsmidler

Mattilsynet

EFTA SURVEILLANCE AUTHORITY MISSION TO NORWAY 9-18 MARCH 2009, REGARDING APPLICATION OF EEA LEGISLATION RELATED TO LIVE BIVALVE MOLLUSCS

We refer to our letter 15. of June with written evidence of the corrective measures taken by the NFSA according to the draft report of the mission to Norway on live bivalve molluscs. In this letter we promised to send written evidence of the follow ups by NFSA regional offices and from the laboratories involved in testing of live bivalve molluscs. Pleas find this evidence enclosed.

Regional offices

Laboratories

Yours Sincerely

Kristina Landsverk
Director