Brussels, 19 August 2015
Case No: 76409
Document No: 762088

Final report

EFTA Surveillance Authority's Mission to Norway

on live bivalve molluscs

from 20 to 24 April 2015

Please note that comments from Norway to the draft report are referred to in footnotes in *underlined italic* print in this final report. Comments and information on the corrective actions already taken and planned by Norway are included in Annex 3.

Executive Summary

This report describes the outcome of a mission carried out by the EFTA Surveillance Authority in Norway from 20 to 24 April 2015.

The objective of the mission was to verify that official controls related to live bivalve molluscs were carried out in compliance with the European Economic Area (EEA) legislation.

The mission team found that limited progress is seen since the last Authority mission on live bivalve molluscs in 2009 and that EEA legal requirements for harvesting and placing on the market of live bivalve molluscs produced in Norway are not fully complied with.

The relevant legislation regarding the application of EEA legislation related to the production and the placing on the market of live bivalve molluscs is implemented in Norway. Norway has designated the Norwegian Food Safety Authority (NFSA) as the competent authority responsible for official controls. Responsibility for coordination of controls regarding live bivalve molluscs has been delegated to one region of the NFSA.

The mission team noted that official controls done by the NFSA departments are not fully coordinated, that there is limited overview of department activities at central level and that the effectiveness and appropriateness of official controls and the consistency and quality of official controls on live bivalve molluscs at all levels are not ensured.

It was noted that harvesting areas in Norway have in general not been classified in accordance with EEA legal requirements and sanitary surveys are not done or not done according to requirements. A national monitoring programme is in place but the monitoring cannot be considered as fully in compliance with EEA legal requirements and appropriate decisions after monitoring are not always ensured.

The report includes a number of recommendations addressed to Norway aimed at rectifying the identified shortcomings and enhancing the control system in place.

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1 Introduction

The mission took place in Norway from 20 to 24 April 2015. The mission team comprised two inspectors from the EFTA Surveillance Authority (the Authority), one national expert and an observer from the Food and Veterinary Office of the European Commission.

The opening meeting was held on 20 April 2015 in Oslo with representatives of the Norwegian Food Safety Authority (NFSA), The Ministry of Health and Care Services and The Ministry of Trade, Industry and Fisheries. At the meeting, the mission team confirmed the objectives and the itinerary of the mission and the Norwegian representatives provided additional information to that set out in the reply to the Authority's pre-mission document.

Throughout the mission, the mission team was accompanied by representatives of the NFSA and met with NFSA regional and central representatives and district representatives in charge of official controls related to live bivalve molluscs (LBMs) in the visited NFSA districts.

The final meeting was held on 24 April 2015 in Oslo where the mission team presented its main findings and preliminary conclusions from the mission.

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

2 Scope and objective of the mission

The main scope of the mission was to verify that official controls in Norway of LBMs (and by analogy, live echinoderms, live tunicates, live marine gastropods and pectinidae) are organised and carried out in accordance with the relevant provisions of *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with legal requirements*.

In particular, the objective of the mission was to assess the application by the Norwegian competent authorities of the following EEA Acts and other related EEA legislation referred to in Annex 2 to this document:

a) Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
b) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;
c) Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;
d) Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

The mission covered all stages of LBM production and processing, with a particular focus on the following areas:

a) the national legislation, policy and operating procedures regarding the scope of this mission;
b) organisation of official controls in place for production and placing on the market of LBMs;
c) classification of production areas and the monitoring programme in place;
d) performance of national reference laboratories;
e) non-compliance actions and procedures, reporting and training of personnel.

The assessment included the gathering of relevant information, and appropriate verifications, by means of interviews/discussions, review of documents and records, and on-the-spot inspections, to demonstrate the normal control procedures adopted and measures in place to ensure that necessary corrective actions are taken when necessary.

Meetings with the competent authority and types of establishment visited during the mission are listed in table 1.

Table 1: Competent authorities and establishments/sites visited during the mission

Meetings	No	Comments
Competent Authorites	5	Opening and final meeting with NFSA representatives from the central level and the NFSA region responsible for coordination of official controls related to LBMs. Meetings with staff in charge of LBM official controls in three NFSA departments in two NFSA regions.[1]
Production areas	2	Two licensed production areas with harvesting of LBMs.
Dispatch and purification centres	3	One establishment approved for dispatch and two establishments approved for dispatch and purification of LBMs (the establishments were also approved for processing although with no processing of LBMs).
Laboratories	3	National Reference Laboratory for microbiological and chemical contaminants in LBMs. National Reference Laboratory for biotoxins in LBMs. One designated laboratory for phytoplankton in sea water.

For parts of the mission, the mission team split into two sub-teams in order to visit more busness operators and to have more time for meetings with NFSA department office officials. Throughout the mission representatives of the NFSA regional office responsible for official controls on LBMs and the head office of the NFSA, accompanied the mission team. In addition, representatives of relevant department offices of the NFSA participated during meetings at the department offices and the visits to the different production areas and establishments.

[1] *The Ministry of Health and Care Services and The Ministry of Trade, Industry and Fisheries were also represented at the opening and final meeting.*

3 Legal basis for the mission

a) Article 1(e) of Protocol 1 to the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice;

b) Point 4 of the Introductory Part of Chapter I of Annex I to the EEA Agreement;

c) *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;*

d) Article 45 of *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.*

Legislation relevant for the mission is listed in Annex 2.

4 Background

4.1 Previous missions

The previous mission concerning LBMs was carried out in Norway from 9 to 18 April 2009. The final report from that mission is accessible on the website of the Authority, www.eftasurv.int. The Authority concluded on a number of issues in the report from the mission in 2009 and subsequently the Norwegian competent authorities informed the Authority of corrective measures taken, or to be taken.

4.2 Information on production

Production volume in Norway for main LBM species, according to information provided by Norway in its reply to the Authority's pre-mission document, are given in table 2.

Table 2: Production volume for different species in Norway (in tonnes)

	From registered production areas			From other areas	
Species	**2011**	**2012**	**2013**	**2013**	**2014**
Blue mussels	1742.5	1966.9	2328.4		
Great Atlantic scallops	12.7	21.0	23.0	678.4	747.8
Oysters	1.8	2.0	5.0		
Other species	169.4	10.8	6.8	554.0	328.1
total	**1926.4**	**2000.8**	**2363.3**	**1232.4**	**1075.9**

5 Findings and conclusions

5.1 Legislation and implementing measures

Legal requirements

Article 7 of the EEA Agreement states that acts referred to or contained in the Annexes to the Agreement are binding upon the Contracting Parties and shall be, or be made, part of their internal legal order.

Findings

As stated in the information provided by Norway in its reply to the Authority's pre-mission document, the relevant legislation regarding the application of EEA legislation related to the production and the placing on the market of live bivalve molluscs is implemented in Norway.

Conclusions

The relevant EEA legislation has been made part of the Norwegian legal order.

5.2 Competent Authorities and official controls

5.2.1 Designation of competent authorities and organisation of official controls

Legal requirements

Article 3(1)(a) of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency taking account of identified risks.

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls at all levels.

Article 4(5) of Regulation (EC) No 882/2004 requires that when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Article 8(3) of Regulation (EC) No 882/2004 states that the competent authority must have procedures in place to verify the effectiveness of official controls.

Article 4(9) of Regulation (EC) No 854/2004 requires that the nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk.

Findings

Norway has designated the NFSA as the competent authority responsible for official controls of LBMs for the purposes of Article 4(1) of Regulation (EC) No 882/2004.

According to information provided by Norway in its reply to the pre-mission document of the Authority, the NFSA is from 2 February 2015 reorganised. The NFSA new structure consists of two administrative levels, the head office and the regional level. There are five NFSA regions in Norway with 32 departments. The regional level with its five regional directors coordinates the activity of the departments at local level. Individual decisions related to specific inspections/audits is delegated to the regional level. The head office is the appeal body if business operators disagree with decisions made by the regions.

The NFSA head office annually prepares a document outlining main targets, special assignments and prioritisations for official control to be done in the regions (the annual Budget Disposing Letter - BDL). On that basis each region shall further develop the BDL, addressing in more detail areas already identified by head office. According to information provided by Norway in its reply to the pre-mission document of the Authority, an internal NFSA document states that one of the five NFSA regions has been delegated the national responsibility for official controls on LBMs. The mission team noted that the document does not provide further details relating to this delegation. The region in question has under its jurisdiction the main areas for production and placing on the market of LBMs. In one department visited by the mission team and belonging to this region, the following areas had been identified for year 2015 as key issues to focus on concerning LBM official controls: the risk of LBM containing biotoxins above legal limits being placed on the market and routines for sampling, analysis and traceability in relation to harvesting. In other departments visited no information could be provided detailing specific focus areas. Officials met in the departments explained that very limited guideline was to be found from central level concerning issues to focus on related to official controls on LBMs.

According to information provided by Norway in its reply to the pre-mission document of the Authority, there are several general mechanisms in place to ensure effective coordination and cooperation between the different levels within the NFSA (for further information, see the Country Profile for Norway available at www.eftasurv.int). The mission team observed that the system heavily relies on personal commitment and oral communication rather than standardised procedures. The same applies for feedback from the departments up the hierarchy. Coordination of control activities are therefore mainly based on an annual update of the National monitoring program for LBMs, supported by a general guideline that was last updated in 2011 (see chapter 5.3.2).

It was explained to the mission team that the NFSA uses an electronic database to verify that NFSA departments carry out the planned number of inspections in a given sector of official controls. The mission team noted that the data produced in this system does not identify specific scope or results of official controls. It was explained to the mission team that the reports generated were quite general and not suitable to verify effectiveness of the controls, merely whether the number of controls carried out corresponded to the number of planned controls.

According to information provided by Norway in its reply to the pre-mission document of the Authority, a general risk based approach is described for the organisation of official controls on fishery products. The mission team noted that the in NFSA departments visited no details could be provided on how controls were risk based related to official controls on LBMs.

Conclusions

Norway has designated a competent authority responsible for official controls in line with the requirements laid down in the Article 4(1) of Regulation (EC) No 882/2004 although efficient and effective coordination and cooperation between different units within NFSA is not ensured, as required by Article 4(5) of Regulation (EC) No 882/2004, regarding official controls related to LBMs.

A general system for risk classification for organising official controls, in line with Article 3(1) of Regulation (EC) No 882/2004, is in place however the nature and intensity of auditing tasks in respect of individual establishments do not depend upon the assessed risk as required by Article 4(9) of Regulation (EC) No 854/2004.

There are no procedures in place to verify the effectiveness of official controls related to LBMs as required by Article 8(3) of Regulation (EC) No 882/2004.

5.2.2 Personnel and training of staff

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receives appropriate training and are kept updated in their area of competence.

Findings

The Multi-Annual National Control Plan for Norway (MANCP) 2011-2014 describes the general training programmes for NFSA employees (see MANCP - point 7.2, available on www.mattilsynet.no).

According to information provided by Norway in its reply to the pre-mission document of the Authority, NFSA has in place a general procedure on training of new employees, including an online module. A list of training courses related to official control on fishery products was provided to the mission team. It was noted that last training courses related specifically to official controls on LBMs was held in 2012. Centrally organised training regarding sampling procedures related to monitoring was last held in 2009.

The mission team met with a number of NFSA officials, responsible for official controls related to the scope of the mission. It was noted that although the officials met were in

general qualified and in most cases experienced, control staff in the visited NFSA departments were not in all cases aware of specific requirements and non-compliances detected by the mission team in the visited establishments had not always been detected by the NFSA control staff (see chapter 5.2.3).

The mission team noted that there is no centralised system in place and no overview of competencies or training carried out for personnel involved in official controls on LBMs.

Conclusions

The competent authority has, in general, access to qualified and experienced staff but it is not always ensured that relevant control staff has received appropriate training and are kept up to date in their area of competence as required by Article 6 of Regulation (EC) No 882/2004.

5.2.3 Documented control procedures and reporting on official controls

Legal requirements

Article 8(1) of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of Regulation (EC) No 882/2004 requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and operators past record with regard to non-compliance.

Findings

The mission team visited three NFSA departments in charge of official controls for approved establishments. The mission team noted that in general official controls are regularly carried out and inspection reports are generated in accordance with documented procedures although it was noted that reporting routines in establishments and between department offices varied both in detail and frequency and that checklists were not consistently used. Inspection reports seen were not always detailed and did not address all issues noted by the mission team such as concerning HACCP system, system for traceability, validation of purification process, etc.

According to information provided by Norway in its reply to the pre-mission document of the Authority, the NFSA’s routines and legal powers related to infringement procedures are

described in the document "Virkemiddelbruk ved tilsyn" (administrative provision concerning infringement procedures, 3. Edition, last amended 28.10.2014). In case of non-compliances the NFSA is given the legal authority to make the necessary administrative decisions to ensure compliance. This includes the prohibition of imports, export and marketing, and orders on withdrawal from the market, isolation, killing, destruction, rejection, restrictions, labelling or special treatment. Further, orders may be issued for special cleansing and disinfection procedures or closure of premises. The NFSA also has the authority to impose coercive fines until compliance is reached.

In the establishments visited, the mission team noted several examples where non-compliances had been identified and followed up by a written decision and where feedback had been provided by the business operator within the given deadlines and the case had subsequently been closed. The mission team although noted some examples where follow-up of the shortcomings identified was not fully documented. Also the mission team noted some non-compliances that had not been detected or where active enforcement in case of non-compliances was not in place.

Conclusions

Official controls and reporting of official controls are mostly carried out in accordance with Article 8 and Article 9 of Regulation (EC) No 882/2004.

Actions are in general taken by the competent authority when non-compliances are identified, as required by Article 54 of Regulation (EC) No 882/2004.

5.2.4 Approval of food business operators

Legal requirements

Article 31 of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 854/2004 require Member States to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of approval, for granting conditional approval and for the withdrawal of approvals.

Findings

According to information provided by Norway in its reply to the Authority's pre-mission document, NFSA has established general procedures for business operators to follow when applying for approval. The NFSA electronic database for official controls (MATS) includes web-based self-services where business operators may log on with a secure identifier and manage information concerning their business and have access to relevant forms regarding their business. This includes applying for approval or registration. A list of approved establishments with production codes can be found on the NFSA web page.

The mission team noted that the visited dispatch and purification centres were listed as a processing plants although at the time of approval (or since) there had been no processing activities in the establishments and they were not equipped for processing of LBMs.

According to information provided by Norway in its reply to the pre-mission document of the Authority, no processing establishments are authorised in Norway for the processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) above the legislative limit and no processing establishments are authorised in Norway where class B or C bivalve molluscs can be sent to undergo treatment to eliminate pathogenic micro-organisms.

Conclusions

The competent authority has established procedures for food business operators to follow when applying for the approval of their establishments and an up-to-date list of approved establishments is maintained in line with Article 31(2)(a) and (f) of Regulation (EC) No 882/2004. However, it is not ensured that establishments are approved only for activities for which the food business operator has demonstrated that it complies with the relevant requirements in line with Article 31(2)(c) of the same Regulation.

5.2.5 Official controls of food business operators

Legal requirements

Article 3 of Regulation (EC) 852/2004 establishes that food business operators, must ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

Article 4(2) of Regulation (EC) 852/2004 establishes that food business operators must comply with the general hygiene requirements laid down in Annex II to this Regulation and Article 4(3) requires food business operators to adopt (amongst others) the following specific hygiene measures: compliance with microbiological criteria for foodstuffs, sampling and analysis.

Article 5 of Regulation (EC) 852/2004 establishes that food business operators, other than those carrying out primary production and associated operations, must put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles as further outlined in the same Article.

Article 3 of Regulation (EC) 853/2004 establishes that food business operators shall comply with relevant provisions of Annexes II and III to the same Regulation.

Article 4(2) of Regulation (EC) No 854/2004 requires the competent authority to carry out official controls to verify food business operator's compliance with Regulation (EC) 852/2004 and 853/2004.

Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004 establishes general requirements for the placing on the market of live bivalve molluscs. Food business operators may only accept batches of live bivalve molluscs if documentary requirements, set out in points 3 to 7 of Chapter I, have been complied with.

Findings

The mission team visited one dispatch centre and two dispatch and purification centres. In these establishments the mission team noted deficiencies in HACCP systems, traceability was not always fully ensured and shortcomings were detected related to validation of purification processes. In particular, in neither of the two purification centres, did the competent authority confirm that the parameters applied in the purification process were adequate to ensure a reduction in the microbiological level of contamination to the prescribed limits. The mission team noted that the HACCP plan in one of the visited purification centers, regularly receiving LBMs from class B areas, did not include any procedures for purification of such LBMs. Furthermore, evidence was seen of LBMs from class B areas being dispatched from the center on the same day as they were harvested. In general official control reports seen during the mission were not detailed and did not address all deficiencies noted by the mission team.

According to information provided by Norway in its reply to the pre-mission document of the Authority, every shipment of LBMs needs to be accompanied by a registration document. These documents are issued by the respective NFSA department and contain a unique number. The harvester must send a copy of a completed and signed document to the respective NFSA department office and documents accompanying each batch must be date-stamped when arriving at a dispatch centre. Both the harvester and the dispatch centre are obliged to keep a copy of the registration document for two years. The registration documents seen by the mission team were correctly used and contained relevant information. The mission team noted that, under Norwegian law, use of registration documents is not obligatory when batches of LBMs are transported directly from harvesting areas to dispatch and purification centres belonging to the same company. In these cases the NFSA issues general transport licenses.

Conclusions

Although the competent authorities have a system in place to ensure that official controls are carried out, it cannot always be ensured that official controls are carried out in line with Article 4 of Regulation (EC) No 854/2004 to verify compliance of the food business operators with Regulations (EC) No 852/2004 and 853/2004.

NFSA document requirements for traceability of harvested LBM batches, transported and received at land based establishments, are in accordance with relevant requirements of Regulation (EC) 853/2004, Annex II, Section VII, Chapter I.

5.3 Official controls concerning live bivalve molluscs from classified production areas

Article 6 of Regulation (EC) No 854/2004 requires Member States to ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Chapter II of Annex II to this Regulation.

5.3.1 Classification of production areas

Legal requirements

Classification of production areas shall be carried out according to Point A of Chapter II of Annex II to Regulation (EC) No 854/2004. The competent authority must:

- fix the location and boundaries of production and relaying areas that it classifies (point A.1) and must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination (points A.2 to 5);
- make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area (point A.6.a);
- examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc (point A.6.b);
- determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area (point A.6.c);
- establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered (point A.6.d).

Findings

According to information provided by Norway in its reply to the Authority's pre-mission document, the Directorate of Fisheries is responsible for granting permits to farmers involved in aquaculture activities, including LBM production. Withdrawal of permits shall be done if there is a period of inactivity of three years. An identification code is to be given to each production area. An on-line overview of location and boundaries of licensed aquaculture activities can be found on the Directorate of Fisheries webpage. The Directorate of Fisheries also provides an on-line aquaculture registry which gives an overview over activities for the licensed production areas.

According to information provided by Norway in its reply to the Authority's pre-mission document, licences for harvesting of LBMs and classification of production areas is fully the responsibility of NFSA departments. Regularly data is transferred from the Directorate of Fisheries databases to the NFSA database for official controls (MATS). In the MATS system it is possible to make a search for all licensed LBM production areas. The mission team noted that the system does not differentiate between active harvesting sites and inactive sites and it was described in the departments visited that an overview of activity in the areas was based on personal knowledge of local activities and that there are challenges concerning having an overview of areas actively harvesting in relation to the two main supporting electronic tools (MATS and the Fishery Directorate database). It was noted by the mission

team that there is no central list available in Norway indicating which production areas are classified, based on sanitary surveys.

The mission team was informed by the NFSA that currently there are approximately 200 LBM production areas registered in the Directorate of Fisheries database and thereof around 30 active areas.

According to information provided by NFSA a production area can be granted a permanent classification following at least 12 shellfish samples, analysed for *E.coli*, in a period of one year. To maintain the classification at least six samples have to be taken each year. According to information provided to the mission team, producers can also receive temporary classification and in Norway LBMs (both in production areas for farmed bivalve molluscs and in areas for wild bivalve molluscs) can only be harvested if a harvesting licence is given by the NFSA at department level. In order to issue this permit, harvesters are requested to take samples and have a certain number of compliant results for microbiology, biotoxins and phytoplankton (see chapter 5.3.2).

The NFSA LBM Guideline describes NFSA's general procedure to perform an initial sanitary survey. It was noted that in the document there is a web-link to an outdated version of the EURL guide (*Microbiological Monitoring of Bivalve Molluscs Harvesting Areas. Guide to Good Practice: Technical Application).* The mission team noted that in the departments visited, it varied if classification of production areas had been done, and if areas were classified the sanitary surveys seen were not sufficiently detailed. In one department visited it was explained that it was the responsibility of the farmer to compile the sanitary survey, in another department visited the control staff compiled the sanitary surveys. In the third department visited it was explained that the compilation of the sanitary survey was a joint venture between NFSA and the applicant for classification.

According to information provided by Norway in its reply to the Authority's pre-mission document, information concerning sanitary surveys which have led to the initial classification of a production area should be located at the NFSA departments. In the departments visited it was noted that sanitary surveys were absent or rudimentary and linked to a very recent classification of harvesting areas. In the department where it was stated that areas had already been classified based on sanitary surveys when the hygiene package was implemented in Norway, these could not be provided.

In one department visited by the mission team there were 23 licensed production areas for blue mussels, all controlled by staff belonging to this department. In year 2014 there were 22 inspections registered in MATS for this department for the processing areas and on 56 occasions sampling in these areas had been registered in MATS. The mission team was informed that none of the active production areas were formally classified, that the process was on-going and that most of the areas will be classified as class A except one area that will be classified as a B area. It was noted by the mission team that for the area that is considered with the B status, the seen certificates for harvesting issued by the NFSA

department, included no indication of the necessity for the food business operator to purify the harvested LBMs.

In another department visited by the mission team it was noted that the three active production areas were classified as class A areas. Formal classification documents issued on the same week of the audit were provided to the mission team. It was noted that detailed sanitary surveys for these classified production areas were not available. In this department some results were seen above the class A limit (>230 *E. coli* /100g) without the area being reclassified. The reasoning given by the responsible official was that samples from other LBM species, monitored at the same time in the same area, provided results below limits and also that the positive samples were samples collected by the farmer and possibly the results were due to poor sampling and handling.

According to information provided by Norway in its reply to the Authority's pre-mission document, there are no relaying areas in Norway.

Conclusions

In Norway, production areas where harvesting of LBM is authorised, are in general not classified as required by Chapter II, Point A of Annex II to Regulation (EC) No 854/2004.

In Norway when it is decided to classify a production area, requirements of Chapter II, Point A (6) of Annex II to Regulation (EC) No 854/2004 are not fulfilled.

5.3.2 Monitoring of production areas

Legal requirements

Monitoring of production areas is to be carried out according to Point B of Chapter II to Annex II to Regulation (EC) No 854/2004. The competent authority must:

- periodically monitor the classified production areas to check that there is no malpractice with regard to the origin and destination of LBM, monitor the microbiological quality of LBM in relation to the production areas and monitor the presence of toxin-producing plankton in production areas and biotoxins in LBMs (point B.1);
- draw up sampling plans providing for that checks take place at regular intervals, or on case-by-cases basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered (point B.2);
- ensure that the sampling frequency for toxin analysis in the molluscs, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes (point B.5).

Findings

According to information provided by Norway in its reply to the Authority's pre-mission document, monitoring of production areas is described in the official LBM guideline and in the National Monitoring Programme (NMP) that is issued annually. The NMP includes the number of samples to be taken and lists the parameters to be analysed and frequencies of sampling. The respective laboratories analysing official samples report directly to the NFSA region responsible for LBM monitoring in Norway and to the departments where samples are taken. Sampling results generated via the NMP are assessed at the NFSA region responsible for coordination of LBM official controls and reports are published weekly. According to information provided by Norway the main rule is that all official sampling shall be performed by the competent authority, except for water samples for phytoplankton where samples can be taken by the producers. According to information provided by Norway in its reply to the Authority's pre-mission document, in 2014 there were 1341 official samples of phytoplankton analysed, 480 official samples of biotoxins and 236 official samples for *E. coli*. Official samples analysed for heavy metals were 28, 9 for polycyclic aromatic hydrocarbons (PAHs) and 10 for dioxins.

According to information provided to the mission team, LBM production areas can only be opened for harvesting (issuance of harvesting licence) after three microbiology samples, two marine biotoxin samples and two phytoplankton samples, for both quantitative and qualitative purposes, have been taken in advance. The mission team was informed that issued harvesting licenses shall in general be valid for two weeks from the date when the last sample was taken and that samples can be taken by the competent authority and/or by harvesters. The mission team noted that harvesters have in general neither received formal training on sampling nor are sampling points always clearly defined.

The mission team noted that the monitoring programme for 2015 comprises 44 locations. Of these, about 21 are in active production areas, 19 sampling locations are in areas where harvesting of LBMs takes place mainly for private harvesting and consumption and 4 sampling points are permanently fixed (routine stations) mainly used for monitoring of composition of phytoplankton trends and marine biotoxins. It was noted that not all active production areas are included in the NMP and that the sampling points of the NMP are changed each year (except for the 4 routine stations) based on input from the departments and results of the previous year's monitoring.

It was explained to the mission team that in connection with the monitoring programme, additional sampling is performed at all active production areas in association with harvesting, EEA bulk trading (products not destined for a dispatch or purification centre in Norway) and at end-product controls at approved establishments. Production areas that are included in the plan (the 21 areas) shall be sampled monthly for biotoxin and *E.coli* analysis and during harvesting weekly samples for phytoplankton and biotoxins are required as for all other active harvesting sites not included in the NMP.

It was noted by the mission team in the departments visited that certificates for harvesting were sometimes issued for 12, 14, 18, 21 or even 28 days. In a NFSA department visited, it

was noted that in two areas that were checked, licences for harvesting were issued for a period of one month taking into account toxin results of samples collected more than two weeks earlier. The licence to harvest was therefore valid in a period without any weekly result neither for biotoxins nor for phytoplankton. In another NFSA department visited for one area a certificate for harvesting was issued with only one result of marine biotoxins analysis. It was noted that for some areas included in the NMP the sampling frequency for phytoplankton analysis was not fulfilled. No formal risk assessment on toxin or phytoplankton occurrence was seen by mission team.

The mission team noted that geographical distribution of sampling points in the departments visited was not always clearly described and the sampling was explained to be done approximately in the same area. It was noted by the mission team that sampling is done either by the farmers or by NFSA department officials and for the harvesting areas NFSA neither verifies correct sampling methods/techniques nor regularly checkes the equipment used. The mission team noted that as the paper request for analysis is always prepared by the official, and thereafter sent to the producers, it is not possible to assess from the request for analysis available at the laboratories, who actually took the samples.

The mission team noted that Norway has established a marine biotoxin programme based on mouse bioassay to detect new or unknown marine biotoxins in four locations (routine stations).

Conclusions

Not all active production areas are periodically monitored in Norway.

Sampling frequency and geographical distribution of sampling points for monitoring the microbiological quality of LBMs in classified production areas is not always carried out in accordance with Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.

It is not ensured that sampling frequency for biotoxin analysis during periods of harvesting of LBMs is according to requirements in Chapter II, point B.5 of Annex II to Regulation (EC) No 854/2004.

5.3.3 Decisions after monitoring

Legal requirements

Point C to Annex II to Regulation (EC) No 854/2004 sets out provisions on decisions that should be taken in the event of unfavourable results of the monitoring, including provisions on closing and subsequent re-opening of production areas.

Findings

According to information provided by Norway in its reply to the Authority's pre-mission document, the MATS module for classifying and opening and closing of production areas

is still not finished. It was explained to the mission team that development of this module has previously not been given priority, but this year NFSA has established a working-group which aims to establish an internet-based system for opening and closing of the production areas. The system is intended as a temporary solution until it might be implemented in MATS.

According to the official LBM guideline, production areas shall be closed if the presence of toxin-producing planktons are above the set limits. The area can only be re-opened when the sampling results of marine biotoxins in LBMs are below the threshold values. The decision of classification status, closing and re-opening of harvesting areas is made at the respective NFSA department. Both the results from the NMP and from the producers' own-checks are reported to the NFSA at both local level and central level.

The mission team noted that regarding marine biotoxins monitoring, an example was seen that one single result below the legal limit was considered satisfactory to issue a certificate for harvesting after a long episode of presence of ASP toxins in the same harvesting area. The mission team noted an example where results above the class A limit (>230 *E. coli*/100g) did not result in a re-classification for the area in question.

Conclusions

It is not always ensured that production areas are closed for harvesting when results of sampling indicate that the health standards for LBMs are exceeded as required in Chapter II, C.1 of Annex II to Regulation (EC) No 854/2004.

It is not always ensured that closed production areas are only re-opened after at least two consecutive results below the regulatory limit for biotoxins as required in Chapter II, C.2 of Annex II to Regulation (EC) No 854/2004.

5.3.4 Recording and exchange of information

Legal requirements

Point E of Chapter II of Annex II to Regulation (EC) No 854/2004 contain requirements relating to recording and exchange of information. The competent authority is required to establish and keep up to date a list of approved production and relaying areas, and immediately inform interested parties about any change of the location, boundaries or class of a production area.

Findings

According to information provided by Norway in its reply to the Authority's pre-mission document, sampling results generated via the NMP and the harvesting controls are assessed in one NFSA region with weekly reports being published every Friday. Information of classification status and authorisation for harvesting of the licensed production areas is located at the NFSA department offices (see chapter 5.3.1).

According to information provided by Norway in its reply to the Authority's pre-mission document, all 44 sampling locations included in the NMP form the basis to advise the public on the risk associated with consumption of wild mussels and sampling results from the monitoring program are published on a weekly basis in an internet site (http://www.matportalen.no/verktoy/blaskjellvarsel/).

Conclusions

Norway has established and keeps up to date a list of licenced production areas, with details of their location and boundaries, and accessible to the general public, although classification of production areas in Norway is not done according to EEA requirements.

5.4 Laboratories

Legal requirements

Article 4(2)(c) of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 of Regulation (EC) No 882/2004 establishes requirements for sampling and analysis.

Article 12 of Regulation (EC) No 882/2004 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down criteria for laboratories so designated.

Article 33 of Regulation (EC) No 882/2004 requires that Member States shall arrange for the designation of national reference laboratories.

Findings

The mission team visited the National Reference Laboratory for bacteriological and chemical contaminants in bivalve molluscs and in charge of the analysis of *E. coli*, heavy metals, PAHs, polychlorinated biphenyls (PCBs) and dioxins in official samples. The laboratory also receives samples from food business operators' own checks. The mission team noted that laboratory facilities and equipment used was in order and staff was adequately trained and provided all the information requested. The laboratory is accredited for all the methods involved in the LBM analysis. Regarding microbiological analysis, in 2013 the laboratory received a total of 305 LBM samples in relation to the NMP and additionally 106 samples were directly sent to the laboratory by farmers. The mission team noted that 15% of the total samples received in 2013 provided results above the class A limit of 230/100 g of *E.coli*. Regarding chemical contaminants, in 2013 the laboratory analysed 40 LBM samples. None of the concentrations of heavy metals, PCBs and PAH exceeded the EEA maximum level. *E. coli* testing is done using the most probable number (MPN) test according to the EU reference method (Donovan´s method, ISO 16649-3) and heavy metals analysis are done by ICP-MS. Satisfactory results from proficiency test were available (the laboratory participates twice a year in proficiency tests for *E. coli* and once a year in proficiency tests for heavy metals). It was noted that the laboratory had not stated the

acceptable criteria for the results of *E. coli* in the proficiency tests. The sections of microbiology and heavy metals were visited and the mission team noted that there was no continuous registration in place of temperature during incubation of microbiological samples. The mission team noted that an internal standard operation procedures SOP for *E. coli* did not include the new update of the ISO 7218:2013 even though the new version of the SOP was issued in February 2015.

The mission team visited a laboratory involved in the analysis of phytoplankton in LBM production waters. The laboratory is one of the three laboratories involved in the analysis of phytoplankton samples in Norway. The laboratory carries out the analysis of phytoplankton in water samples belonging to the 44 stations included in the 2015 NMP. Apart from that, the laboratory receives also samples collected by the harvesters. Laboratory facilities were visited and considered as adequate, staff was well trained and provided all the information requested. Samples arrived at the laboratory accompanied by an analytical request form in a set of two plastic tubes properly labelled indicating the day and time of sampling, the code of the production area and the name of the sampler. The mission team noted that geographical coordinates of the sampling points were not indicated. The integrated sample is analysed using the Norwegian standard NS-EN 15972:2011 based on the Uthermöhl method to provide quantitative figures of the main toxic species while the plankton net sample is observed to provide a semi qualitative indication of the abundance of toxic species. The mission team noted that the laboratory is currently neither accredited nor participating in intercomparison exercises, the last one took place more than 10 years ago.

The mission team visited The National Reference Laboratory for marine biotoxins which is in charge of the analysis of marine biotoxins in the official samples. The laboratory also receives samples from food business operators' own checks. Laboratory facilities were visited and considered as adequate, staff was well trained and provided all the information requested. The laboratory is accredited for the analysis by chemical methods of ASP (HPLC-PDA method), paralytic shellfish poison (PSP) (AOAC 2011.02 method, post-column oxidation method) and lipophilic toxins (EURLMB LC-MS/MS method). Accreditation was renewed on the 13/04/2015. Validation of LC-MS/MS method for lipophillic toxins and HPLC-FD method for PSP were reviewed and considered as adequate. Results from proficiency tests were available for lipophilic toxins, PSP toxins and ASP toxins using chemical methods (participates twice a year). The mission team noted that results of proficiency test of LC-MS/MS method for lipophilic toxins and HPLC post column oxidation method for PSP toxins compromise the efficiency of the laboratory as an important number of unsatisfactory results were observed. The laboratory also receives samples collected at the four routine stations in Norway. In those samples, apart from the chemical analysis of lipophilic toxins, PSP and ASP, the laboratory carries out mouse bioassay (MBA) analysis for the detection of unknown toxins. The mission team noted that in year 2015, at least on 5 occasions samples from the routine stations provided a positive result in the MBA. Although laboratory reporting of results was in general considered adequate, in some occasions results reporting for MBA was delayed for two and even six weeks.

Conclusions

Norway has designated relevant national reference laboratories and the visited laboratories were adequately equipped and with trained staff. The analytical methods used are mostly in line with EEA requirements. Not all laboratories participate in proficiency tests and results from proficiency tests for biotoxins were not always seen satisfactory.

5.5 Rapid Alert System for Food and Feed (RASSF)

Legal requirements

Article 50(2) of Regulation (EC) No 178/2002 requires EEA States to immediately notify any information relating to the existence of a serious direct or indirect risk to human health deriving from food under the rapid alert system for food and feed (RASFF).

Regulation (EU) No 16/2011 lays down implementing measures for the RASSF network.

Findings

In its reply to the Authority's pre-mission document, the NFSA provided a list of RASFF notifications in 2012, 2013 and 2014 related to LBMs and products thereof where Norway was involved. Norway also provided a copy of the national guideline for handling RASFF. The mission team noted that the latest version of the guideline, version 3 (approved 29 October 2013 and last amended 31 October 2013) has not been updated taking into account the new structure of the newly reorganized NFSA.

According to the national RASFF guideline, after verification by the national contact point, an alert notification shall be forwarded by the national contact point no later than 48 hours after the risk was identified. The mission team noted that the time line for two notifications showed a delay in notification of identified hazards through RASFF:

- *Hazard identified; Paralytic Shellfish poisoning (PSP) toxins (1823 µg/kg):* Samples were collected on 18 August 2014, and the analytical report issued on 21 August 2014. National measures entered into force 21 August 2014, however, it was only notified through RASFF on 28 August 2014. The product concerned was distributed in Norway, Spain and the Netherlands.
- *Hazard identified: norovirus:* Samples collected 3 December 2014, analytical result was ready 5 December 2014. On 9 December 2014 the remaining consignment was destroyed and a warning published on the Norwegian website "www.matportalen.no". On 10 December 2014, the findings were notified through RASFF. The product concerned was oysters from Ireland distributed to Germany and Norway.

According to the NFSA's guideline, RASFF notifications where Norwegian operators are involved and received by the national contact point, are followed up by the national contact point who asks the local NFSA office(s) to ensure follow-up regarding operators and that other required measures are taken.

Conclusions

The NFSA has a system set up to follow up RASFF notifications, both when notifications originates in other EEA states as well as when hazards are identified in Norway. However, the NFSA should ensure that hazards are notified in RASFF in due time.

6 Final meeting

A final meeting was held on 24 April 2015 in Oslo with representatives from NFSA central and regional level, The Ministry of Health and Care Services and The Ministry of Trade, Industry and Fisheries. At this meeting, the mission team presented its main findings and preliminary conclusions of the mission.

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.

7 Recommendations

In order to facilitate the follow-up of the recommendations hereunder, Norway should notify the Authority no later than 1 October, of additional corrective actions planned or taken other than those already indicated in the reply to the draft report of the Authority. In case no additional corrective actions have been planned, the Authority should be kept continuously informed of all changes made to the already notified corrective actions and measures, including changes of the deadlines indicated for completion and also the completion of the measures included in the timetable.

No	Recommendation
1	The competent authorities should ensure efficient and effective coordination and cooperation between different units within NFSA as required by Article 4(5) of Regulation (EC) No 882/2004 regarding official controls related to live bivalve molluscs.
2	The competent authority should ensure that the procedures in place to verify the effectiveness of official controls, as required by Article 8(3) of Regulation (EC) No 882/2004, include verifying effectiveness of official controls related to live bivalve molluscs.
3	The competent authority should ensure that staff in charge of official controls related to live bivalve molluscs receive appropriate training, and are kept up-to-date in their areas of competence in line with the requirements of Article 6 of Regulation (EC) No 882/2004.
4	The competent authority should ensure that establishments handling live bivalve molluscs are approved only for activities to which the food business operator can demonstrate compliance with the relevant requirements in line with Article 31(2)(c) of Regulation (EC) No 882/2004.

5	The competent authorities should ensure that official controls verify that permanent procedures based on the HACCP principles, in accordance with Article 5 of Regulation (EC) No 852/2004, are in place in live bivalve molluscs dispatch and purification centres.
6	The competent authorities should ensure that official controls are carried out to verify that purification of live bivalve molluscs in purification centres is done in accordance with Point A.3 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004.
7	The competent authority should ensure that live bivalve molluscs production areas are classified in line with requirements of point A of Chapter II of Annex II to Regulation (EC) No 854/2004.
8	The competent authority should ensure that the sampling frequency and geographical distribution of sampling points for monitoring the microbiological quality of live bivalve molluscs in classified production areas comply with Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.
9	The competent authority should ensure that the sampling frequency for toxin analysis in live bivalve molluscs is in accordance with Point B.5 of Chapter II of Annex II to Regulation (EC) No 854/2004.
10	The competent authority should ensure that the decisions taken after monitoring, related to the monitoring of the microbiological quality of live bivalve molluscs and of biotoxins in live bivalve molluscs are in accordance with Point C of Chapter II of Annex II to Regulation (EC) No 854/2004.
11	Norway should ensure that any information relating to the existence of a serious direct or indirect risk to human health deriving from food is immediately notified under the rapid alert system for food and feed (RASFF), as required by Article 50(2) of Regulation (EC) No 178/2002.

Annex 1 - List of abbreviations and terms used in the report

ASP	Amnesic Shellfish Poison
Class A area	Areas from which live bivalve molluscs can be collected for direct human consumption.
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 or through a processing establishment, where they must undergo treatment to eliminate pathogenic microorganisms.
Community Guide	Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004
EC	European Community
EEA	European Economic Area
EEA Agreement	Agreement on the European Economic Area
EURL	European Union Reference Laboratory
EURL Guide	Microbiological Monitoring of Bivalve Molluscs Harvesting Areas. Guide to Good Practice: Technical Application"
HACCP	Hazard Analysis and Critical Control Points
HPLC-FD	High Performance Liquid Chromatography – Fluorescence Detection
ISO	International Organisation for Standardisation
LBM	Live Bivalve Molluscs
LC-MS/MS	Liquid Chromatography – Tandem Mass Spectrometry
MANCP	Multi Annual National Control Plan
MATS	NFSA Electronic database for official controls
MBA	Mouse Bioassay
MPN	Most Probable Number
NFSA	Norwegian Food Safety Authority/Mattilsynet
NMP	National Monitoring Program for LBMs
PAHs	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
PSP	Paralytic Shellfish Poison
RASSF	Rapid Alert System for Food and Feed
SOP	Standard Operation Procedure

Annex 2 - Relevant legislation

The following legislation has also to be taken into account in the context of this mission:

a) The Act referred to at Point 1.1.11 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules*, as amended;

b) The Act referred to at Point 1.1.12 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption*, as amended.

c) 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*;

d) The Act referred to at Point 6.1.16 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs*, as amended.

e) The Act referred to at Point 6.1.17 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin*, as amended.

f) 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.*

g) The Act referred to at Point 6.2.52 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*, as amended.

h) The Act referred to at Point 6.2.53 of Chapter I of Annex I to the EEA Agreement, *Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004*, as amended.

i) The Act referred to at Point 7.1.13 of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, as amended.

j) The Act referred to at Point 7.1.9b of Chapter I of Annex I to the EEA Agreement, *Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption*, as corrected and amended.

k) The Act referred to at Point 7.1.2 of Chapter I of Annex I to the EEA Agreement, *Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC,* as amended.

l) The Act referred to at Point 7.2.19 of Chapter I of Annex I to the EEA Agreement, *Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results,* as amended.

m) The Act referred to at Point 8.1.18 of Chapter I of Annex I to the EEA Agreement, *Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC,* as corrected.

n) The Act referred to at Point 54zzzz of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum level for certain contaminants in foodstuffs*, as amended.

o) The Act referred to at Point 54zzzp of Chapter XII of Annex II to the EEA Agreement, *Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs*, as amended.

p) The Act referred to at Point 54zzzzr of Chapter XII of Annex II to the EEA Agreement, *Regulation (EC) No 1333/2008 of 8 December 2008 on additives setting maximum level for certain contaminants in foodstuffs*, as amended.

q) The Act referred to at Point 86 of Chapter XII of Annex II to the EEA Agreement, *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004*, as amended.

r) 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 amended.

Annex 3 - Plan for corrective measures from Norway

No	Recommendation	Corrective measures	Time limit
1	The competent authorities should ensure efficient and effective coordination and cooperation between different units within NFSA as required by Article 4(5) of Regulation (EC) No 882/2004 regarding official controls related to live bivalve molluscs.	**Competent Authorities and official controls** NFSA will establish routines to ensure efficient and effective coordination and cooperation between different units within NFSA as required by Article 4(5) of Regulation (EC) No 882/2004. Especially for LBM NFSA will establish a sufficient internal function to ensure efficient and effective coordination and cooperation between different units within NFSA. The NFSA will revise the LBM guideline and new issues will be included.	2015 / 2016
2	The competent authorities should ensure that the procedures in place to verify the effectiveness of official controls, as required by Article 8(3) of Regulation (EC) No 882/2004, include verifying effectiveness of official controls related to live bivalve molluscs	**Competent Authorities and official controls** The NFSA will ensure that procedures are in place to verify the effectiveness of official controls, as required by Article 8(3) of Regulation (EC) No 882/2004 Especially for LBM NFSA will revise the LBM guideline as one of the appropriate measures. The revised LBM guideline will focus on the assessed risk to perform a sufficient number of audits in the establishments and supervisions of the production areas. An effective coordination function will verify the effectiveness of official controls of LBM.	2016
3	The competent authorities should ensure that the staff in charge of official controls related to live bivalve molluscs receive appropriate training, and kept up-to-date in their areas of competence in line with the requirements of Article 6 of Regulation (EC) No 882/2004	**Training of staff** The NFSA will establish routines that ensure regular training of staff in charge of official controls related to LBM. Intranet based training courses will be considered in this respect. The training will include practical training as sampling and equipment maintenance.	July 2016
4	The competent authorities should ensure that establishments handling live bivalve molluscs are approved only for activities	**Approval of establishments** The NFSA will establish routines that ensure that the approval of	2015

	to which the food business operator can demonstrate compliance with relevant requirements in line with Article 31 (2c) of Regulation (EC) No 882/2004	Food Business Operators in Norway is in line with Article 31 (2c) of Regulation (EC) No 882/2004. Interregional and regional meetings for seafood inspectors will cover this issue at a regular level.	
5	The competent authorities should ensure that official controls verify that permanent producers based on the HACCP principles, in accordance with Article 5 of Regulation (EC) No 852/2004, are in place in live bivalve molluscs dispatch and purification centres.	**Official controls based on the HACCP principles** The NFSA will review the routines for official control of LBM in order to assure that Food Business Operators of LMB at dispatch and purification centres put in place, implement and maintain a permanent procedure based on the HACCP principles. <u>Follow up by the regions</u> The regions of the NFSA will be informed about the recommendation from the Authority. The concrete follow up will be an agenda issue at the professional meetings for seafood inspectors at regional level and also included in the revised guideline to LBM.	July 2016
6	The competent authorities should ensure that official controls are carried out to verify the purification of live bivalve molluscs in purification centres is done in accordance with Point A3 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004	**Purification of LBM** NFSA will ensure that the duration of purification of LBM from B and C areas at the purification centres are adequate to ensure food safety and make sure that this is part of the HACCP plan in the establishments. <u>Follow up by the regions</u> The regions of the NFSA will be informed about the recommendation from the Authority. The concrete follow up will be an agenda issue at the professional meetings for seafood inspectors at regional level. NFSA will also consider online internal training and regular LBM seminars.	2015
7	The competent authorities should ensure that live bivalve molluscs production area are classified in line with requirements of Point A of Chapter II of Annex II to Regulation (EC) No 854/20014	**Classification of production areas** NFSA will establish routines to ensure that all LBM production areas are classified in line with requirements of Point A of Chapter II of Annex II to Regulation (EC) No	July 2016

		854/20014. The NFSA LBM guideline including boundaries and sanitary survey will be revised to cover this aspect more completely. Follow up by the regions The concrete follow up will be an issue on the professional meetings for seafood inspectors at regional level. NFSA will also consider online internal training and regular LBM seminars.	
8	The competent authorities should ensure that the sampling frequency and geographical distribution of sampling point for monitoring the microbiological quality of live bivalve molluscs in classified production areas comply with Point B.2 of chapter II of Annex II to Regulation (EC) No 854/2004.	**Sampling frequency** The NFSA will establish sufficient requirements on sampling frequencies in line with Point B.2 of chapter II of Annex II to Regulation (EC) No 854/2004. Follow up by the regions The concrete follow up will be an issue on the professional meetings for seafood inspectors at regional level. This will also be an issue at seminars and courses.	2015
9	The competent authorities should ensure that the sampling frequency for toxin analysis in live bivalve molluscs is in accordance with Point B.5 of Chapter II Annex II to Regulation (EC) No 854/2004.	**Sampling frequency for toxins** NFSA will establish internal control routines to ensure correct sampling frequency for toxins analysis in LBM in accordance with Point B.5 of Chapter II Annex II to Regulation (EC) No 854/2004. Based on a documented risk assessment, sampling frequency for toxin analysis could be reduced only when such documentation exists. Follow up by the regions The concrete follow up will be an issue on the professional meetings for seafood inspectors at regional level, as well as on training seminars and courses for the staff in charge.	2015
10	The competent authorities should ensure that the decisions taking after monitoring of the microbiological quality of live bivalve molluscs and of biotoxins in live bivalve molluscs are in accordance with Point C of Chapter II of Annex II to Regulation (EC) No 854/2004.	**Decision after monitoring** NFSA will ensure that decisions after monitoring are encompassed by sufficient documentation and adequate sampling to re-open an area after closure are in accordance with point C of Chapter II of Annex II to Regulation (EC) No 854/2004.	2015 – 2016