EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2013)2191089

DG(SANCO) 2012-6516 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

DENMARK

FROM 12 TO 19 NOVEMBER 2012

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF BIVALVE MOLLUSCS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

The report provides the results of an audit performed by the Food and Veterinary Office in Denmark from 12 to 19 November 2012.

The main purpose of the audit was to verify that the official controls of live bivalve molluscs including echinoderms, tunicates and live marine gastropods are implemented according to the requirements of EU rules.

The report concludes that the competent authority has an official control system in place to control the production and placing on the market of live bivalve molluscs and fishery products derived from them. However, the system is undermined to some extent by a number of non-compliances identified in relation to classification and monitoring of microbiological quality and toxins.

The non-compliances and weaknesses detected during the audit must be corrected for the official controls to be fully compliant with EU legislation.

The report makes recommendations to the Competent Authorities aimed at addressing areas in which further improvements are required.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
ASP	Amnesic Shellfish Poisoning
CA	Competent authority
DAFA	Danish Agrifish Agency
DTU	Danish Technical University
DVFA	Danish Veterinary and Food Administration
EC	European Commission
EU	European Union
EURL	European Union Reference Laboratory
FBO	Food Business Operator
FCO	Food Control Office
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
HPLC	High Performance Liquid Chromatography
LC-MS	Liquid Chromatography – Mass Spectrometry
NRL	National Reference Laboratory
PAH	Polycyclic Aromatic Hydrocarbons
PSP	Paralytic Shellfish Poisoning
SANCO	General Directorate for Health and Consumers

1 Introduction

This audit took place in Denmark from 12 to 19 November 2012 and was undertaken as part of the Food and Veterinary Office (FVO) planned audit programme. The audit team comprised one auditor from the FVO and one national expert from an EU Member State. An opening meeting was held in Glostrup on 12 November 2012 with the Danish Veterinary and Food Administration (DVFA) which is the Competent Authority (CA) within the scope of this audit. At this meeting the team confirmed the objectives of, and the itinerary for the audit, and requested additional information regarding the specific elements of the control system in place. Representatives from the CA accompanied the audit team during the whole audit.

2 Objectives and Scope

The objectives of the audit were to:

- Verify that official controls of bivalve molluscs, echinoderms, tunicates and marine gastropods 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 feed and food law, animal health and animal welfare rules.
- Evaluate whether the control system in place for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods is in compliance with EU requirements.

In terms of scope, the audit focused on the organisation and performance of the CA, the official control system in place covering the classification and monitoring of live bivalve mollusc production and relaying areas, and the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods. Accordingly, certain aspects of the legislation referred to in Annex 1 were used as technical basis for the audit.

In pursuit of these objectives, the following sites were visited:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	1	DVFA
	Regional	2	Food Control Office, Viborg Danish Agrifish Agency, Nykøbing Mors
Laboratories		4	National Reference Laboratory (NRL) Microbiology NRL for Biotoxins Orbicon (phytoplankton) Eurofins laboratory, Holstebro
Production areas		1	
Dispatch centres		3	
Processing establishments		1	

3 Legal Basis

The audit was carried out under the general provisions of EU legislation and, in particular, Article 45 of Regulation (EC) No 882/2004.

Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

4 Background

4.1 Previous FVO reports

The previous FVO audit on this subject in Denmark was carried out in March 2005 (ref. DG(SANCO)/2005/7559). The report of this audit is available on the Health and Consumers Directorate General website at:

http://ec.europa.eu/food/fvo/ir_search_en.cfm

Recommendations relevant to the live bivalve mollusc sector concerned the verification of the sampling by fishermen, registration documents, testing for biotoxins and purification techniques. The FVO has received written guarantees in relation to the recommendations of the 2005 audit which were found satisfactory.

4.2 Production and trade information

According to information provided by the CA, in 2011 approximately 34,000 tonnes of mussels (*Mytilus edulis*), 800 tonnes of cockles (*Cerastoderma edule*) and 800 tonnes of oysters (*Ostrea edulis*) were placed on the market. Within the EU, the largest purchasers are Germany, United Kingdom, Sweden, the Netherlands and Italy.

4.3 Rapid Alert System for Food and Feed Notifications

Since 2005 there have been four notifications: one in 2009, one in 2011 and one in 2012 due to results of *E.coli* above the class A limit in live mussels. In addition, one notification was made in 2011 due to a foreign body found in cooked mussels.

5 Findings And Conclusions

5.1 Competent Authorities

Legal Requirements

Articles 3 to 10, 54 and 55 of Regulation (EC) No 882/2004.

Findings

The CA for monitoring and control of live bivalve molluscs is the DVFA, with headquarters in Glostrup. There are ten Food Control Offices (FCO). The FCO in Viborg has the responsibility for

classification, monitoring, evaluation and enforcement of live bivalve mollusc regulatory requirements in all production areas.

The Danish Agrifish Agency (DAFA) is responsible for the registration of aquaculture farms and harvesting vessels used for wild caught bivalve molluscs. The DAFA checks landings and also that harvesting of live bivalve molluscs is performed only when areas are open. The FCO Viborg registers and verifies the location and boundaries of temporary opened zones within production areas.

There is adequate laboratory capacity for official controls testing by using the official laboratories designated by the CA. A list of the official laboratories involved in analyses of bivalve molluscs was provided and the audit team visited one microbiology laboratory, one phytoplankton laboratory and two NRLs (See chapter 5.6).

Official staff met during the audit have access to appropriate facilities and equipment to perform official controls on live bivalve molluscs. Control of food business operators (FBO) is carried out by the FCO inspectors. There are written instructions and guidelines (Kontrolvejledningen) for the performance of official control, decisions and enforcement and also rules to ensure that official inspectors are impartial and free from conflicts of interest.

The CA has a risk assessment system for official controls of FBO covering both microbiological and chemical risk factors. This risk assessment system results in a number of standard inspections per year for each type of establishment across all food sectors. For the different categories of establishments handling live bivalve molluscs there are normally either three or five standard inspections per year depending on the risk group of the category. For "elite" establishments the frequency may be reduced to as low as one inspection per year for those in the lowest risk group. If there are no sanctions for a number of inspections within a year, an FBO can obtain “elite” or “elite2” status and the frequency can be reduced. The “elite” status is changed back to standard frequency if any finding during an inspection results in a sanction.

A standardised inspection report template including an assessment of the outcome of the inspection is used. Guidance on matters relating to enforcement issues and non-compliances is given in the written instructions for controls.

The CA has an internal system to assess staff performance.

Some official inspectors working in the live bivalve molluscs sector have participated in the Better Training for Safer Food courses. Almost all have participated in training organised by the central level.

The audit team saw examples of enforcement letters relating to live bivalve mollusc matters both from the FCO Viborg (biotoxin findings; change of classification) and the DAFA (withdrawal of licence due to not respecting quotas licenced).

Conclusions

There is a designated CA responsible for the official control of bivalve molluscs.

There are procedures in place for adequate reporting and enforcement actions, which in case of non-compliances, are implemented.

There is an internal system to ensure that the objectives of control programmes are correctly implemented at local levels.

5.2 Registration/approval of food business operators

Legal Requirements

Articles 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004, Article 3 of Regulation (EC) No 854/2004 and Article 31 of Regulation (EC) No 882/2004

Findings

Harvesting vessels used for wild caught bivalve molluscs are registered by the DAFA. Fishermen who dredge wild molluscs have to be licenced by the DAFA before they can start to harvest/fish.

Aquaculture farms are registered by the DAFA who control the locations of the farms and ensure that these farms are identifiable. Farm harvesting boats are not registered. The farms are also approved from a zoosanitary perspective by the Aquaculture Section within the CA.

Dispatch and purification centres and processing establishments are approved by the FCOs. The FBO has to apply for approval and send in blueprints, process descriptions, flow-charts and a HACCP-plan to the FCO. An initial inspection on-site is necessary to allow the start of production. Approval numbers for establishments are provided by the central CA. An establishment will have a conditional approval for a maximum three months period until a routine control inspection is conducted and the suitability of the premises in operation can be evaluated.

The CA maintains and updates lists of all approved establishments on its website.

The audit team verified that the procedures in place are followed.

Conclusions

The procedures in place for registration and approval of food business operators are compliant with EU regulations.

5.3 Official controls on live bivalve molluscs from classified production and relaying areas

Legal Requirements

Article 6 of Regulation (EC) No 854/2004 and Chapter II of Annex II to Regulation (EC) No 854/2004.

5.3.1 Classification of production and relaying areas

Findings

A total of 141 production areas have been defined by the CA. 32 of these have a permanent microbiological classification and the rest are temporarily classified when there is a demand for harvesting live bivalve molluscs. Lists and maps of all production areas, including their number, name and co-ordinates are included in the national legislation. The boundaries of each production area are clearly defined. These production areas cover all Denmark's live bivalve mollusc harvesting areas. The majority of the Danish production is dredged mussels – the rest is line mussels, dredged native oysters (*Ostrea edulis*), cockles and Pacific oysters (*Crassostrea gigas* - under trial).

There are also a number of identified sites (within production areas) designated to deposit mussels

harvested from other areas until harvested again later on when needed by the FBOs. The CA stated that this is not relaying as foreseen in Annex III, Section VII, Chapter II, point C of Regulation (EC) No 853/2004. Both the harvesting area and the receiving sites within them have the same classification. Harvesting in these sites is subject to the same opening procedure as production areas in general.

A total of 68 aquaculture shellfish farms are currently classified. Aquaculture farms are classified separately from the production area in which they are located. The CA explained that this was due to large differences in *E. coli* and biotoxin levels between bottom and line mussels in these areas and the audit team was presented with data to demonstrate this for *E. coli* and Paralytic Shellfish Poisoning (PSP) biotoxins.

Three classes of production area (class A, B and C) are used and the thresholds defining these comply with those set by the EU.

It was noted that the delineation of classified production areas does not exclude areas of industrial activities or with known waste water discharges. The national legislation specifies that harvesting should not take place near dumping areas, waste water discharges, harbours, marinas or in areas affected by pollutants that can cause a deterioration of the sanitary quality of shellfish.

The Danish classification system is based on sampling of water and live bivalve molluscs by the gatherers and the results are used for decisions concerning classification, opening and closure of production areas and aquaculture farms.

Fishermen take samples of water for phytoplankton counts and samples of live bivalve molluscs for biotoxin and microbiological analyses. There are detailed written instructions for the sampling procedure in national legislation and the CA expects all samplers to follow the instructions. However, sampling procedures are not supervised by the CA.

There are no areas classified as relaying areas in Denmark.

Sanitary surveys:

All existing production areas were defined prior to 2006, but the CA confirmed that the classification status of production areas may have changed since their original classification. This was verified by the audit team. None of the 141 existing production areas have been subject to a sanitary survey.

The CA also explained that a couple of applications for new aquaculture farms were received in 2011. A very preliminary review of sources of pollution was completed for one of the production areas where a farm was intended to be placed. The audit team noted that the assessment did not include all elements of a sanitary survey and did not provide sufficient information to enable the drawing up of a sampling programme.

The CA is investigating the possibility of contracting out the sanitary survey work and is aiming to complete the survey of all production areas and aquaculture farms by 2015.

Temporary and permanent classifications:

All defined production areas (wild fisheries or aquaculture farms) except the 32 permanently classified, have been given a notional B classification status. This has not been based on the results of a sanitary survey or microbiological testing. On submission of satisfactory own-check monitoring results, these temporarily classified areas are opened for harvesting for a minimum of a week at a time. Depending on the results of microbiology monitoring, the areas are opened as class B or can be opened as a zone (part of an area; see point 5.3.2) with class A within a class B area.

A temporarily classified area is permanently classified when a sufficient number of *E. coli* sample

results have been obtained for the production area (regardless of location of sampling or species sampled) within a given period. The national legislation specifies that a minimum of 20 results must be available within a four year period to permanently classify an area or maintain permanent classification status. This must include samples collected in the last 12 months (16 results had been required for the 2011 review, in accordance with a previous Danish Order).

The exact criteria are as follows:

- Where ≥95% results comply with A class status and the remaining results do not exceed class B status, the area is classified as permanent A.
- Where ≥90% results comply with B class status and the remaining results do not exceed class C status, the area is classified as permanent B.
- Where ≥90% results comply with C class status, the area is classified as permanent C.
- If less than 20 results are available, the area remains temporarily classified or the permanent classification reverts back to temporary classification.

The 95% compliance criterion used for class A classification and 90% compliance criterion used for class C classification do not comply with EU regulations.

The criteria used for permanent classification of areas do not follow the specifications of the EU Reference Laboratory (EURL) "Guide to Good Practice: Microbiological Monitoring of Bivalve Mollusc harvesting Areas" on sampling frequency and the data used is not for fixed sampling points or specific species.

The CA explained that despite a permanent class B status, a zone within a class B can be temporarily opened as class A if the results of the three own-check samples collected for the opening of the area all indicate a class A result. This classification can stand as long as weekly samples verifying the A-status are taken. If no samples are taken the zone is closed and if the results of the weekly monitoring programme show a drop in the microbiological quality, the zone is downgraded. These temporary upgrades to A class, of zones within B class areas, do not comply with EU regulations or follow the specifications of the EURL Guide to Good Practice.

Classification is maintained regardless of the level of activity in an area. As a result, temporarily classified production areas which have been closed for long periods and therefore not monitored keep their classification status and can be opened and harvested on the submission of a set of three opening sample results. Permanently classified areas can also maintain their classification with a very low level of monitoring. For example, the FVO team verified that one area allowed to maintain a permanent Class A status had not been monitored in 2011 and had only been sampled twice in 2012. This level of monitoring does not follow the specifications of the EURL Guide to Good Practice.

Temporary downgrades or upgrades of areas given a permanent classification status are also implemented as a result of microbiological monitoring results and the audit team saw a few examples of this.

All Danish production areas must be given a classification status, either permanent or temporary and the national legislation specifies that shellfish can only be harvested from classified areas which are open to harvesting.
Danish legislation specifies that results of microbiological monitoring and the classification status of production areas are reviewed at regular intervals. Reviews are conducted by the NRL and recommendations for changes are submitted to the CA for approval and implementation.

The last update to the permanent classification list was approved in July 2011[1] and the audit team was shown the draft results of the classification review, currently being carried out by the NRL

Conclusions

Production areas are classified/reclassified without sanitary surveys. Decisions are made based on inadequate monitoring data from sampling points that are not fixed and the compliance criteria used for classes A and C do not comply with EU requirements or follow the specifications of the EURL Guide to Good Practice.

5.3.2 Monitoring of classified production and relaying areas

Findings

The Danish monitoring programme is largely based on FBO own-check results obtained using laboratories designated by the CA. The sampling protocols that must be used by the FBOs are decided by the CA and they are stated in the Danish Order on bivalve molluscs. Analytical methodology to be used by the laboratories is stated in agreements between the CA and the laboratories. It is noted that the competence of FBO samplers and compliance of the samples with the sampling and sample preparation specifications of the national legislation have never been audited.

Microbiological monitoring of bivalve molluscs

The monitoring requirements are specified in the national legislation and can be summarised as follows:

- In the week prior to intended harvesting a set of three opening samples must be collected from within a 3x3 nautical mile area for harvesting of wild bivalve molluscs or from within the aquaculture farm for analyses for *E. coli* and *Salmonella.* Satisfactory results open the whole production area if it has a permanent classification and for a temporarily classified area, a class A zone can be opened around the area from which the opening samples originated.
- To maintain the area/aquaculture site with permanent classification open:
  - Class A area: one sample to be collected and tested for *E. coli* every fourth week
  - Class B area: one sample to be collected and tested for *E. coli* every 13 weeks
  - Class C area: one sample to be collected and tested for *E. coli e*very six months (there are no Class C areas in Denmark at present)
- In temporarily classified areas, one sample to be collected and tested for *E. coli.* weekly

In addition, *Salmonella* testing must be conducted every three months in production areas which are permanently or temporarily A-classified.
Sampling points are not fixed as sampling takes place where harvesting is intended or occurs.
The CA officials take 100 samples per year for microbiological analyses for E. Coli and Salmonella for monitoring and verification purposes.

Phytoplankton monitoring (Presence of toxin-producing plankton in waters)

Until 2011, monitoring for toxin-producing plankton was carried out in each production area. This was changed in 2011 following the completion of a risk assessment by the Danish Technical University (DTU). This assessment enabled the creation of 25 “algae monitoring areas” each

1 In their response to the draft report the CA noted that a new permanent classification was posted on January 4, 2013 on the DVFA homepage.

covering a number of production areas. Samples are now collected from these larger monitoring areas and fewer samples are therefore required weekly. The CA has written guidelines with limits set for different phytoplankton species that, if exceeded, will trigger sampling in all production areas included in the "algae monitoring area". The triggers set for each phytoplankton species have been established in collaboration with the algal monitoring laboratory and are based on international consensus. Some triggers have been refined to suit the Danish waters.

The monitoring requirements are specified in the national legislation and can be summarised as follows:

- In the week prior to intended harvesting two samples (one for qualitative and one for quantitative analysis) must be collected from the same location within the monitoring area.
- To maintain an area/aquaculture farm open, two samples (one for qualitative and one for quantitative analysis) must be collected from the monitoring area on the first day of each fishing/harvesting week. The national legislation authorises the collection of fortnightly samples during the period November to March but this has not yet been implemented.

The water sampling methods (net and integrated sampling) used for FBO own-checks and official controls provide information on the presence of potentially toxic species in the water column and are therefore representative of the area sampled. The use of "algae monitoring areas" representative of several production areas has been validated by a risk assessment but data compiled by the official control laboratory undertaking water testing showed that within a monitoring area, phytoplankton occurrence is not consistent. Results obtained from one sample collected at one point within the monitoring area are therefore not representative of the whole monitoring area.

Sampling points are not fixed as sampling takes place where harvesting is intended or occurs.

Besides the FBOs weekly samples, the CA officials take 50 water samples yearly for phytoplankton analyses.

Processing establishments using sea water must also analyse weekly incoming water for toxic phytoplankton for monitoring purposes.

Biotoxin monitoring of bivalve molluscs

Data presented to the audit team show that PSP and amnesic shellfish poisoning (ASP) biotoxins have rarely been detected in Danish water above the maximum permitted limits, with the exception of two toxic events in 1987 and 2008 for PSP and one in 2005 for ASP. Lipophilic toxins are a more common occurrence with the maximum permitted limit being breached most years in 1 to 6% of the samples tested. Two human illness incidents have been recorded due to lipophilic toxins (1990 and 2002).

The monitoring requirements for biotoxins are specified in the national legislation and can be summarised as follows:

- In the week prior to intended harvesting one sample of each species must be harvested to be tested for marine biotoxins.
- To maintain an area/aquaculture farm open one sample of each species must be collected on the first day of each fishing/harvesting week.
- Toxin tests to be conducted:
  - ASP and lipophilic toxins: weekly throughout the year to maintain areas open.
  - PSP toxins: weekly from April to September to maintain areas open. Between October and March, PSP tests are only required to open an area. Once opened, no subsequent PSP testing is required.

Sampling points are not fixed as sampling takes place where harvesting is intended or occurs. Besides the samples taken by the FBOs, the CA officials take 50 samples yearly of live bivalve molluscs for biotoxin analyses.

The CA explained that Denmark does not have a policy for monitoring of new and unknown toxins in classified production areas and confirmed that no monitoring is currently undertaken for these.

Monitoring of contaminants in bivalve molluscs

Monitoring of classified production areas for chemical contaminants has been undertaken by the CA since 2005 under the scope of central coordinated projects and it is included in the 2010-2014 sampling plan. Samples have been collected from wild bivalve molluscs as well as aquaculture farms. Given the absence of organotin and dioxins, monitoring now focuses on heavy metals and Polycyclic Aromatic Hydrocarbons (PAH). A total of 12 samples from open production areas are scheduled to be collected each year and in 2011 12 samples were collected and all results were below the EU limits.

Furthermore, the CA requests that FBOs provide evidence that levels of regulated chemical contaminants in bivalve molluscs are below EU limits prior to any new production area or aquaculture farm being permitted to open for harvesting. This is a requirement under Danish law.

Conclusions

There is a monitoring programme in place for open classified production areas, covering *E. coli*, *Salmonella*, biotoxins, toxin-producing plankton and chemical contaminants. However, no monitoring (i.e. testing) is undertaken in areas which are not open for harvesting and the CA does not supervise control methods and techniques applied by the gatherers when sampling.

The microbiological monitoring cannot be considered as meeting EU requirements in that the sampling plan is not based on the outcome of a sanitary survey for areas where the classification has changed or where a class A zone is opened within an class B area. Monitoring is not conducted at fixed sampling points and the frequency of monitoring is also not in compliance with EU requirements.

Maximum permitted limits for marine biotoxins used in the national monitoring programme are those set in EU legislation.

For ASP, lipophilic toxins and water monitoring, the frequency of testing is acceptable and in compliance with EU requirements when taking into account results from both official control and FBO own-checks. For PSP, the absence of weekly monitoring during the period October to March is not in compliance with EU requirements and no risk assessment has been completed to justify this lower testing frequency.

5.3.3 Decision after monitoring

Findings

All closure and opening decisions are delegated to the FCO in Viborg and at this office, it is done by one member of staff supported by a colleague in case of absence. Both members of staff are knowledgeable and efficient.

The national legislation specifies that the maximum permitted limits for *E. coli, Salmonella*, biotoxins and chemical contaminants in bivalve mollusc flesh used in the Danish monitoring programmes are those specified by EU legislation. Both results of CA sampling and FBO own-

checks inform decisions on the opening and closing of production areas and both results have the same weight in decision making.

The CA updates lists of open production areas and areas from where water may be used on its website weekly. If there are results that change the classifications or cause closure of areas, the CA when notified by the laboratory, calls the FBO involved, informs other CA offices and the DAFA and updates the lists on the website.

The laboratories inform the CA when the results are available.

Decisions after monitoring of microbiological quality of live bivalve molluscs

The audit team was informed that the results of opening samples collected from an area are used to decide whether an area should be opened or maintained closed. All three results below 230 *E. coli*/100g will open an area as class A (whole area or limited zone, depending on whether the zone has been temporary or permanently classified), one result between 230 and 4600 *E. coli*/100g will open an area as B and one result above 4600 will open an area as C (same limitations on area size). In a temporarily classified area, class A results will open a 1.5 nautical mile radius zone around the centre of the three opening sampling points.

Subsequent results exceeding the classification status of an area when opened will immediately downgrade the area. To reopen a permanently classified area which has been temporarily downgraded, an intensive monitoring must take place for three successive weeks with three opening samples followed by samples for two consecutive weeks.

The audit team reviewed the implementation of the rules on a few examples and was able to confirm that areas were opened and downgraded according to the set criteria.

Decisions after monitoring for presence of toxin-producing plankton in waters

The audit team was informed that the detection of toxin-producing phytoplankton species above set limits defined in CA guidelines will trigger monitoring of all production areas within the monitoring area. This was verified in two cases.

When toxic phytoplankton are detected above the set limits in a production area, this can lead to the precautionary closure of the area concerned. These decisions are taken on a case by case basis following discussions between the CA, the Marine Biotoxins NRL and the phytoplankton monitoring laboratory.

Where an area has been closed on a precautionary basis because of the presence of toxic phytoplankton, the satisfactory results of two samples taken at minimum 48h intervals are required before it can reopen again.

Decisions after monitoring for presence of biotoxins in live bivalve molluscs

The audit team was informed that the detection of biotoxins above the EU maximum permitted limits prevents the opening of production areas and when these are already open, it automatically closes them. Two consecutive results below the maximum permitted limit from samples collected at least one week apart are required before the area may reopen again. An example for a production area affected by a lipophilic toxin event in August 2010 was reviewed and the audit team was able to verify that the reporting of the results prompted the immediate closure of the area. Results were quickly communicated by the laboratory to the CA, decisions taken rapidly and dissemination of information to the FBO was swift, allowing a rapid confirmation that no harvesting had taken place in the area and no recall was necessary. The example also showed the release of a public notice for information of casual gatherers.

The audit team was also informed that open areas can be closed when biotoxin levels are below the maximum permitted limit. This possibility is included in the national legislation and is used on a case by case basis following discussions between the CA, the Marine Biotoxins NRL and the water monitoring laboratory.

Finally the audit team was informed that in the event of biotoxins being detected below the maximum permitted limits in opening samples, the results are assessed on a case by case basis and may lead to the precautionary decision not to open the area.

Conclusions

Decisions are taken to prevent the harvesting of samples when monitoring results show that maximum limits have been exceeded.

Decisions after monitoring were found to be taken quickly and were well documented and in line with national and EU legislation.

5.3.4 Additional monitoring requirements

Findings

Monitoring of closed production areas:

Prior to leaving port, all harvesting vessels that want to fish in Natura 2000 areas or want to fish for oysters are required to notify the DAFA of their intention to fish and to specify their intended fishing location. This is one of the means by which the DAFA undertakes controls to check that closed areas are not being harvested. All harvesting vessels are required to notify the DAFA of their expected landing time allowing controls of quotas and sizes of live bivalve molluscs to be done at landing sites. In addition the DAFA has developed a new vessel monitoring system enabling GPS tracking of all licenced harvesting vessels and their dredging activities. The tracking system is intended to be launched in December 2012 and its use was demonstrated to the audit team. One example showed that a vessel had harvested in two production areas, but in the documents the fisherman had only notified his fishing activity in one area. Therefore the new integrated software showed that the registration documents which accompanied the catch did not show the true origin of all the live bivalve molluscs.

Verification of FBO compliance with requirements for end products:

The CA confirmed that there had been a lapse in verification checks conducted by FCOs. This was addressed prior to the FVO visit and provisions were made for such official control checks to be undertaken under the scope of a central sampling project for microbiological criteria for fish and fishery products including live bivalve molluscs.

Some official controls had taken place in the past with official samples taken by the inspectors as and when appropriate. Official inspectors have the power to take decisions after sampling of final products. However, the audit team saw one example of an official control for microbiological quality conducted on an end product that showed a class B result for mussels sold live as class A. The result was promptly reported by the laboratory but no actions were taken for 11 days post receipt of the results. This led to contaminated products remaining on the market without any actions being taken by the CA or by the FBO. This was acknowledged by the local CA during the audit.

There is a central sampling plan for testing for chemical contaminants such as cadmium, mercury,

lead and arsenic and PAH but no control system for verification of biotoxin levels in bivalve mollusc flesh.

Conclusions

Additional monitoring requirements are implemented by the DAFA and the CA. However, these are not fully in line with EU requirements as levels of biotoxins in end products are not verified.

5.3.5 Recording and exchange of information

Findings

The CA keeps up to date a list of all open production areas and another of all aquaculture farms where harvesting is allowed and provides details on the classification of each area and farm (species, location, class). The CA also maintains a list of establishments using sea water which are approved to operate. All lists are available on the CA's website and are updated at least weekly. The audit team noted that all FBOs visited used the website to identify which areas are open and which are closed. The website also provides reminders to the FBO on sampling requirements (for example intensified water sampling if toxic phytoplankton have been detected above set thresholds) and highlight results which indicate a possible health risk (for example, detection of biotoxins below the maximum permitted limits). Suitable sample turnaround times have been set for the laboratories by the CA and when results suggesting a risk to public health are released, the audit team verified that these were generally promptly acted upon. The CA is immediately notified when limits of toxins are exceeded and when level of phytoplankton exceeds the action limits set.

Conclusions

There is an efficient system for recording and exchange of information in place and it is in line with EU legislation.

5.3.6 Food Business Operators' own checks

Findings

The Danish official control system takes into account results of FBOs' water samples for analyses of microbiology and toxin-producing plankton species and live bivalve mollusc samples for classification, opening and closure of production areas and checks for marine biotoxins as described under points 5.3.1, 5.3.2 and 5.3.3 in this report.

Samples taken by FBOs or their organisation's representative are analysed in laboratories designated by the CA and sampling procedures are included in the national legislation.

Conclusions

FBOs' own-check results are used by the CA for classification, opening and closure in line with EU legislation.

5.4 Official controls on pectinidae and live marine gastropods not filter feeders harvested outside classified production areas

Legal Requirements

Article 6 of Regulation (EC) No 854/2004 and Chapter III of Annex II to Regulation (EC) No 854/2004, having particular regard to the CA's official controls to verify FBO's compliance with Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004; Council Decision 2002/226/EC.

5.4.1 Requirements for placing on the market

Findings

There is no production of pectinidae or marine gastropods in Denmark. In 2011, in total, 19 kilos of whelks and three kilos of scallops were registered as by-catch, but were not placed on the market.

There are no authorised establishments under the provisions of Commission Decision 2002/226/EC.

5.5 Official controls of the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods

Legal Requirements

Article 4 of Regulation (EC) No 854/2004, having particular regard to the CA's official controls to verify FBO's compliance with Regulation (EC) No 852/2004, Regulation (EC) No 853/2004 (section VII and VIII of Annex III) and the microbiological criteria laid down in Regulation (EC) No 2073/2005.

5.5.1 Harvesting and handling following harvest

Findings

The audit team observed one harvesting vessels unloading at a landing site. Conditions on board and at the landing site were adequate. Mussels are in general transported in containers from the landing sites to the dispatch centres. During visits to four establishments the audit team also verified the handling of live bivalve molluscs following harvesting.

Conclusions

The activities carried out by the FBOs during handling and following harvesting are in line with EU requirements.

5.5.2 Registration document accompanying the batch

Findings

Registration documents accompany every batch of live bivalve molluscs. Information about species, size of the batch and the status of the area (A, B or C) from where they are harvested are filled in and signed by the gatherer and the document accompanies the batch.

At dispatch centres, list of customers receiving live bivalve molluscs were kept for each batch

together with the accompanying document. The audit team reviewed those documents in all visited establishments and they were found to be correctly filled in..

Conclusions

The documentary requirements laid down in EU legislation are complied with.

5.5.3 Official control of establishments

Findings

A grading/scoring system is foreseen for approved premises in relation to food hygiene and risk factors. A risk assessment for the type of production combined with FBO production standards applied, determine the number of inspections per year for inspection and control. The grading system identifies all FBOs handling shellfish as either "very high risk" requiring five standard inspections per year (e.g. Canning establishments, dispatch and purification centres) or "high risk" requiring three standard inspections per year e.g. de-sanding establishments). The frequency of inspections is reduced if the last four inspection reports or all inspection reports during the last 12 months are without sanctions – then the establishment receives "elite" status. The frequency for "elite" establishments in the group "very high risk" is three and for the group "high risk"is one. "Elite" establishments in the group "very high risk" become "elite2" after another year without sanctions and will have a frequency of two standard inspections. The audit team verified in the visited establishments that official controls follow the frequency set. Official controls are carried out on a risk basis, with appropriate frequency and in accordance with documented procedures. All FBOs could show an updated approval document which included all their activities.

The audit team visited three approved dispatch centres of which one only did de-sanding.

There is a requirement that incoming sea water used for rinsing and de-sanding/conditioning must come from areas where monitoring has taken place and authorisation to use the water has been granted. Such authorisation is granted by FCO Viborg following the submission of water samples for phytoplankton testing and testing is to be conducted weekly to maintain a production area open for the use of water. Conditions of approval do not include any microbiological requirement, as the CA considers it to be the FBOs responsibility to ensure that the water used meets legal requirements. Samples are collected by the FBOs from the water inlet tap.

All three FBOs visited had an HACCP plan available at the time of the visit. The plans had been reviewed by the CA. All plans had as a critical control point that raw material must come from an open classified production area. The CA website had to be checked to control the status of the area and the registration documents accompanying all the received batches were also checked. Biotoxins are not tested for by the FBOs. The presence of biotoxins in live bivalve molluscs was identified as a risk and included in the HACCP plans but no biotoxin testing is undertaken by FBOs, who fully rely on the fact that they only harvest from production areas which have been opened by the FCO Viborg and are therefore considered by the FBOs to be free of biotoxin risk.

One of the dispatch centres was in need of maintenance due to rust on equipment and peeling paint on the walls, but not in contact with products. Actions were planned by the FBO to correct these.

All three dispatch centres operated a conditioning process for dredged mussels. This allows the removal of sand from the live bivalve molluscs prior to packing and dispatch. The process was conducted in large metal containers with a capacity of between 10 and 15 tonnes of live bivalve molluscs each. The audit team observed that the quality of the process varied between establishments:

- Whilst all dispatch centres may receive Class A live bivalve molluscs and some sold

shellfish as live, the audit team observed that they can use water from production areas classified B as well as A.

- One dispatch centre kept its conditioning containers outdoors and without cover. Sea water was pumped onto the mussels in the same end of the container as the outlet for water. The volume of live bivalve molluscs in the container and the design of inlet/outlet raised questions concerning the suitability of the system to maintain the microbiological standard of the mussels. The FBO stated that mussels could be kept for up to 10 days in the container before being packed. The microbiology quality of the inlet water was tested monthly with satisfactory results by the FBO at an official laboratory but that of the live bivalve molluscs was never tested. The audit team noted that the establishment was operating despite no phytoplankton testing having been done in the production area from where seawater was taken in. The FCO Viborg emphasized to the FBO that this was not in compliance with the Danish Order on bivalve molluscs as phytoplankton testing also has to be done in the establishment itself. The DVFA informed the audit team that a follow-up was done after the visit.
- A second dispatch centre kept its conditioning containers outdoors with covers. The same design issue as above was observed with the set up, but it was noted that the containers were not more than 2/3rd full to allow circulation of water. The FBO stated that mussels are kept in these conditions for ten hours up to two days. FBO own-checks of live end product were performed every second week for microbiology. Incoming water is tested weekly for phytoplankton and monthly for *E. coli* and *Salmonella* with in general satisfactory results.
- The third dispatch centre had containers indoors and kept mussels for 12 to 72 hours prior to sending them to a processing establishment. The containers were fully loaded and the audit team observed a lot of dirty foam floating on top of the water indicating that the circulation of water was not adequate. Weekly water testing for *E.coli* and *Salmonella* was performed in the FBO's own laboratory and monthly in an official laboratory with satisfactory results. Phytoplankton samples were taken weekly.

The audit team was informed by the CA that the two listed purification centres are not active because there is no need for purification. 90% of mussels produced in Denmark are cooked and can come from class B areas. Shellfish sold live for direct consumption must come from class A areas.

Traceability checks were performed in all dispatch centres visited and the FBO could show both the origin of the raw material (date, vessel, area) and the customers of the products.

In one centre the label of one product did not show the shelf life and did not mention that the product should be sold live. This was noted by the CA and corrected by the FBO during the visit.
The audit team saw examples of heavy metals and PAH testing with satisfactory results included in the own-check programme in one centre.

Conclusions

Official control inspections of dispatch centres are carried out based on risks, are well documented and the set frequency is respected.

The dispatch centres visited during the audit are, in general, compliant with EU requirements. However, the suitability of the conditioning systems in use has not been evaluated and there are risks that current practice could lead to additional contamination of live bivalve molluscs.

The lack of testing of the end products for *E.coli* and *Salmonella* is not in line with EU

requirements.

Traceability of products placed on the market are in line with EU requirements.

5.5.4 Facilities handling bivalve molluscs

Findings

The audit team visited one processing establishment that was in operation at the time of the visit. There was a HACCP plan available describing the processing and the heat-treatment steps included. There were three critical control points covering raw material coming from open areas, cooking and, pasteurisation of the mussels. The cooking required a temperature of 127 – 137ºC for 65 seconds under a pressure of 1.5 bar. The temperatures are checked for compliance by logs placed in three different parts of the cooker and are registered continuously in a computer system. The pasteurisation required a water temperature of 72ºC for 100 seconds and 65ºC in the mussels. The process was checked by manual measurements and equipment readings of the water temperature, time in heat-treatment and the final temperature in the mussels. The audit team saw a demonstration of the manual checks and records of the cooking processes with satisfactory results.

The cold store temperature was also continuously recorded and a printout was shown to the audit team to show that the temperature was kept below -18 ºC.

Microbiology testing of total plate count, coliforms*, E. coli, Salmonella, Staphylococcus aureus* and *Listeria monocytogenes* is performed for every batch in the FBO's laboratory. All results shown to the audit team had satisfactory results.

One product was labelled with an oval identification mark clearly showing the country of origin and establishment's approval number. However the approval number was followed by an unexplained additional three digit code which confused the identification mark. This was noted by the local CA.

A traceability exercise from the labelling of one finished product was performed during the visit and the FBO could show from what area the incoming raw material came and which fishing vessel had harvested it.

Five results of official control samples showed results of microbiological analyses for *E. coli, Salmonella* and *Listeria monocytogenes* and one PAH analysis, all with satisfactory results.

Conclusions

Official control inspections are carried out in accordance with the risk-based matrix designed by the CA. Set frequencies are respected and hygiene requirements are complied with.

5.6 Laboratories

Legal Requirements

Articles 11, 12 and 33 of Regulation (EC) 882/2004, and Article 3 of Regulation (EC) 2074/2005.

Findings

A number of laboratories are involved in the testing of live bivalve molluscs for the purpose of the Danish monitoring programme.

- Microbiology: DVFA, Esbjerg laboratory (FBO and CA samples), Højmark laboratory

(NRL) (FBO and EURL samples), Eurofins, Holstebro (FBO samples)

- Toxins: Danish Technical University (DTU), Søborg (NRL)(CA and EURL samples), Eurofins, Lidköping, Sweden (under subcontract from Eurofins, Holstebro) (FBO samples)
- Toxic phytoplankton: Orbicon, Viby (FBO and CA samples)
- Chemical contaminants: DVFA, Aarhus laboratory (FBO and CA samples)

Laboratories undertaking testing of own-check samples collected by FBOs have been designated and approved by the CA. The laboratories are not audited by the CA. Agreements between a laboratory and the CA define the methods to be used, specify the requirement for accreditation and for taking part in proficiency tests and stipulate result turnaround times. All results for samples submitted in the week are to be reported within three working days of receipt of samples and no later than Friday 13:00. All results are copied to the CA.

The audit team saw evidence that the competence of designated microbiology laboratories is checked by the NRL through a review of proficiency test results and follow-up action taken when results fall short of satisfactory. The CA and laboratories could not provide evidence that similar checks had been carried out for the biotoxin and phytoplankton laboratories.

The CA and the laboratories explained that organisations and key staff involved in the delivery of the Danish monitoring programme used to meet regularly in expert group meetings. These regular meetings are no longer held. There are also no meetings between the NRLs and the official control laboratories. There is however evidence of informal communication between CA offices, between these and the NRLs and between laboratories and NRLs but these appear to be ad hoc and rely on individual initiative rather than being regular coordinated meetings involving all relevant stakeholders.[2]

Laboratories delivering official control testing within the scope of central sample projects have specific agreements with the CA which define the aim of the project, the number of samples to be collected, the tests to be conducted and the protocols to be used. Results turnaround times are as above. All results are sent to the CA. Sample turnaround times are satisfactory and results are reported promptly. Results suggesting a possible risk to human health are immediately reported, allowing a quick response by the CA.

The CA explained that whilst the national legislation quotes the PSP reference method as the biological assay, in line with EU legislation, there are currently no provisions for such testing in Denmark and no official control laboratory designated for such testing.

Eurofins, Holstebro - Microbiology testing:

The Eurofins laboratory based in Holstebro was designated by the CA in August 2009. The laboratory receives and tests own-check samples collected by the FBO for *E. coli* and *Salmonella*.

The methods used by the laboratory are those specified by the national legislation. Methods are accredited to ISO 17025:2005 standard and the laboratory has taken part in regular live bivalve mollusc proficiency testing exercises. All but one *E.coli* proficiency test results have been satisfactory. One *Salmonella* result has been unsatisfactory. In both cases, the laboratory was able to demonstrate that investigative actions had taken place to prevent a re-occurrence. No issues have been noted since 2010.

Results of all internal and external quality audits were satisfactory.

2 In their response to the draft report the CA noted that in the future all results of proficiency tests will be sent to the NRL for biotoxins and appropriate follow-up action will be taken. Furthermore, the CA will together with the NRLs address how communication between all relevant stakeholders involved in the monitoring programme can be improved.

The audit team verified that the processes used for *E. coli* testing conformed to the specifications of the EURL procedure with the exception of sample rejection criteria (three days old samples tested – no temperature check) and use of quality controls. All stages of the process are logged in a database providing full traceability of samples and equipment. Temperatures are electronically controlled and logged.

The laboratory is well equipped and adequately staffed. Training records are maintained and the competence of staff was observed.

The result reporting process was reviewed. All results are checked prior to release to an agreed distribution list, including the CA. The audit team verified that results are reported in accordance with the requirements of the agreement signed with the CA. Whilst alerts are immediately released when results suggest the presence of toxins above set limits, the audit team found that no mechanism was in place for the immediate release of positive *Salmonella* or above 230/100g *E. coli* results. This was acknowledged by the CA and instructions have since been sent to all microbiology laboratories to remedy this situation.

DTU Food, Søborg – NRL biotoxin testing laboratory:

The Division of Food Chemistry at the National Food Institute of the DTU has held the role of NRL for marine biotoxins for over 15 years. The laboratory is well equipped and well resourced.

The methods used for toxin testing are those specified by the CA. All methods are within the scope of ISO 17025:2005 accreditation of the laboratory. For all methods and regardless of the live bivalve mollusc species tested (mussels, oysters or cockles), the matrix used is cooked, drained and shelled bivalve molluscs which is subsequently frozen prior to shipment to the laboratory and testing. Such sample preparation will lead to results which are not representative of live bivalve molluscs. For lipophilic toxins, this process can be considered as acceptable as the higher concentrations measured in cooked material as opposed to live bivalve molluscs will provide additional food safety guarantees, when results exceeding the maximum permitted limits are obtained and actions taken. However, the sample preparation is not suitable for ASP and PSP toxins.

The audit team was presented with validation reports for all three methods currently used. The PSP HPLC method was validated for use in mussels, oysters and scallops and for all toxins of relevance. The LC-MS/MS method was validated for use in the same species and for ASP and for all regulated lipophilic toxins. The laboratory confirmed that all validation work was conducted on cooked matrices. Performance characteristics were established with the exception of measurement uncertainty. None of the methods have been validated for use in cockles or in Pacific oysters, the other two shellfish species harvested from Danish waters and subject to testing.

The audit team verified that analytical runs included a suitable number of calibration standards and suitable controls including blanks and reference standards but quality criteria for acceptance or rejection of the controls or the performance of the run were not specified.[3]

Results of PSP proficiency tests have mostly been satisfactory but as these schemes are being run using frozen homogenised uncooked bivalve molluscs, these results are not representative of the performance of the methods in cooked bivalve molluscs. Due to recent changes to lipophilic toxin and ASP methodologies the laboratory does not yet have data to demonstrate satisfactory proficiency test results for these methods. The laboratory has taken part in recent exercises and results are awaited.

The audit team noted that results are reported in a format that does not allow a direct comparison of the okadaic acid, dinophysis toxins and pectenotoxin levels measured to the EU maximum

3 In their response to the draft report the CA noted that the DTU has informed the DVFA that in the future the criteria for acceptance will include at least those specified in the EU SOP.

permitted limits. Details of uncertainty values for each toxin and each bivalve mollusc species are not provided.

The audit team was provided with a document summarising the key duties to be delivered by the chemistry NRL of the DTU. The audit team could verify that the duties specified in the document encompassed all of those listed in Regulation (EC) No 882/2004. However there was insufficient evidence of the NRL for marine toxins delivering these tasks.

Eurofins, Lidköping, Sweden – Biotoxin testing laboratory:

This laboratory was not visited during this audit. However the following information was presented to the audit team to confirm that:

- Samples submitted to the laboratory for toxin analyses are pre-cooked and most of them also frozen before dispatch to Sweden.
- The methods used by the laboratory are those specified within the CA agreement. All methods are included within the scope of accreditation to ISO 17025:2005 of the laboratory.
- Copies of the validation report for the PSP quantitative method by HPLC and lipophilic toxin and ASP method by LC-MS were provided. It was unclear whether the performance of the methods had been assessed for use in cooked matrices.

The audit team verified that the PSP HPLC method has been validated for use in live mussels only and for all relevant PSP toxins. Performance characteristics had been established but robustness in the laboratory has not been assessed. The method's performance for Pacific oysters, native oysters or cockles has not been assessed, despite the fact that they are subject to monitoring and are tested by the laboratory.

The audit team verified that the lipophilic toxins and ASP LC-MS methods have been validated for use in mussels, oysters and cockles.

Results of proficiency tests were satisfactory but with the same caveats as highlighted above for the DTU laboratory.

A similar issue to the DTU results reporting template was noted with the format of the PSP results provided by the laboratory that does not allow a direct comparison with the maximum permitted EU limits. Details of uncertainty values for each toxin and each shellfish species are not provided.

DTU Food , Søborg – NRL for bacteriological and viral contamination of bivalve molluscs:

The Division of Food Microbiology at the National Food Institute of the DTU has held the role of Danish NRL for bacteriological and viral contamination of bivalve molluscs since 2001. The laboratory does not receive any samples for testing and as a result is not accredited. The laboratory does not take part in EURL proficiency tests but has a written agreement with another designated laboratory which participates in these tests on its behalf.

The audit team was able to verify that the microbiology laboratory at the DTU undertakes the NRL duties specified in EU Regulation (EC) No 882/2004 other than proficiency testing.

Orbicon laboratory - Toxic phytoplankton testing:

The laboratory tests all water samples collected within the scope of the Danish monitoring programme (FBOs' own-checks, CA verification samples, samples taken from establishments using sea water). The laboratory uses a combination of qualitative and quantitative methods to detect and enumerate phytoplankton species of specific interest. These include all relevant toxic phytoplankton species known to be present in Danish waters as well as other species which are known to occur in neighbouring countries (for example *Azadinium*). The list also includes nuisance phytoplankton species. The methods used are those defined under national legislation. They are well established

and recognised internationally (Utermohl and calcofluor).

The laboratory is not accredited to ISO 17025:2005 and it has only participated in one proficiency test in 2009 (with satisfactory results) and one in 2012 (results not yet known). According to the agreement between the CA and Orbicon, the laboratory should take part in regular proficiency testing (at least every second year where available).

Three members of staff are involved in the delivery of tests and reporting activities. Their competence was well demonstrated. Staffing levels are sufficient for the requirements of the programme.

A database is maintained and covers all monitoring data since 1990. Reports are checked prior to release but qualitative/quantitative results are not routinely checked before they are reported. The laboratory has informal contacts with the toxin NRL and it liaises regularly with the CA on the interpretation of results and required action.

Conclusions

The NRL for bacteriological and viral contamination of live bivalve molluscs performs the duties of an NRL as specified in EU legislation, but this is not the case for the marine biotoxins NRL.

Official control laboratories show some deficiencies with regards to accreditation, quality controls and proficiency testing. Issues with the methods used in the biotoxin testing programme (sample preparation and lack of performance characterisation) raise concern about the ability of the methods to monitor marine biotoxins in live bivalve molluscs in accordance with EU requirements and the suitability of the Danish monitoring programme.

6 Overall Conclusions

The competent authority has an official control system in place to control the production and placing on the market of live bivalve molluscs and fishery products derived from them. However, the system is undermined to some extent by a number of non-compliances identified in relation to classification and monitoring of microbiological quality and toxins.

The non-compliances and weaknesses detected during the audit must be corrected for the official controls to be fully compliant with EU legislation.

7 Closing Meeting

During the closing meeting held in Glostrup 19 November 2012, the CA acknowledged the findings and the preliminary conclusions presented by the audit team. The CA also acknowledged the audit team's request for additional information that was provided to the team at the meeting or sent via e-mail after the meeting.

8 Recommendations

The CA should provide the Commission Services with an action plan, including a timetable for its completion, within 25 working days of receipt of the report, in order to address the following recommendations for the production of live bivalve molluscs.

N°.	Recommendation
1.	To ensure that sanitary surveys are conducted in classified areas as established in Point A.6 of Chapter II of Annex II to Regulation (EC) No 854/2004.
2.	To ensure that the sampling programme established for the classification of live bivalve mollusc production areas guarantees that the geographical distribution of the sampling points and that the frequency guarantees that the results of the analyses are as representative as possible for the area considered as established in Point A.6 of Chapter II of Annex II to Regulation (EC) No 854/2004.
3.	To ensure that monitoring of toxin-producing plankton complies with the requirements of Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.
4.	To ensure that the sampling frequency for monitoring for PSP toxins are in line with Point B.5 of Chapter II of Annex II to Regulation (EC) No 854/2004.
5.	To ensure that FBOs operating dispatch centres comply with the requirements mentioned in part B.1 of Chapter IV and of Chapter V of Section VII of Annex II of Regulation (EC) 853/2004.
6.	To ensure that when taking into account the results of sampling undertaken by a food business operator or its representative (with a view to classifying, opening or closing an area), the sampling and analysis have taken place in accordance with the protocol agreed between the CA and the food business operator as foreseen in part F of Chapter II of Annex II of Regulation (EC) 854/2004.
7.	To establish a control system comprising laboratory tests to verify food business operators' compliance with EU requirements at all stages of production, processing and distribution as required by Point D.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.
8.	To ensure that only laboratories that are accredited in accordance with specified European standards are designated to carry out the analyses of samples taken during official controls, as required in Article 12.2 of Regulation (EC) No 882/2004.
9.	To ensure that methods, including sample preparation, for toxin analyses are suitable and validated as required by Article 11 of Regulation (EC) No 882/2004.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6516

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dec. 1999/120/EC	OJ L 36, 10.2.1999, p. 21-47	1999/120/EC: Commission Decision of 27 January 1999 drawing up provisional lists of third country establishments from which the Member States authorise imports of animal casings
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	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
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	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
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	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
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	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
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Legal Reference	Official Journal	Title
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	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
Dec. 2002/226/EC	OJ L 75, 16.3.2002, p. 65-66	2002/226/EC: Commission Decision 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
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	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
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs