EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2014)2334519

DG(SANCO) 2013-6674 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

IRELAND

FROM 21 TO 30 OCTOBER 2013

IN ORDER TO EVALUATE THE FOOD SAFETY CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF BIVALVE MOLLUSCS (FOLLOW-UP)

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 audit was carried out as part of the Food and Veterinary Office audit programme for 2013.

The main purposes of the audit were to verify that the official controls of bivalve molluscs, echinoderms, tunicates and marine gastropods are implemented in accordance with the relevant provisions of EU rules, to evaluate whether the control system in place for the production and placing on the market of these products is in compliance with EU requirements and to verify the extent to which the guarantees and the corrective action submitted to the Commission services in response to the recommendations of the previous 2011 FVO audit report for the sector have been implemented and enforced by the competent authorities.

The report concludes that the official controls of live bivalve molluscs echinoderms, tunicates and marine gastropods are organised and carried out at all stages of the production chain and are supported by an accredited laboratory network.

Improvements have been noted since the 2011 audit, the competent authorities took action to correct some deficiencies (related to laboratory analyses) and to improve certain aspects of the official controls (introduction of official control of scallops, improved controls in establishments and a reduction in tolerance levels in A Class production areas). However, a significant number of recommendations of the 2011 audit report still need to be fully addressed.

The control system in place for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods presents several deficiencies as regards the classification and monitoring of live bivalve mollusc production areas and the official control of scallops and gastropods harvested outside production areas

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

Table of Contents

1 Introduction 1
2 Objectives and Scope 1
3 Legal Basis 1
4 Background 2
4.1 Previous FVO reports 2
4.2 Production and trade information 2
4.3 Rapid Alert System for Food and Feed Notifications 2
5 Findings And Conclusions 2
5.1 Competent Authorities 2
5.2 Official controls on live bivalve molluscs from classified production and relaying areas 3
5.2.1 Classification of production areas 3
5.2.2 Monitoring of classified production areas 6
5.2.3 Decisions after monitoring 10
5.2.4 Additional monitoring requirements 11
5.2.5 Recording and exchange of information 12
5.3 Official controls on pectinidae and live marine gastropods not filter feeders harvested outside classified production areas 12
5.4 Official controls to verify food business operators' compliance with the requirements for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods 14
5.4.1 Requirements for placing on the market 14
5.4.2 Official control of FBOs 14
5.4.3 Facilities handling bivalve molluscs 15
5.5 Laboratories 17
6 Overall Conclusions 19
7 Closing Meeting 19
8 Recommendations 19
Annex 1 - Legal References 22

Abbreviations and definitions used in this report

Abbreviation	Explanation
ASP	Amnesic Shellfish Poison
CA	Competent authority
CoP	Code of Practice of the SFDA
EU Guide	Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regards to Regulation (EC) No 854/2004
EURL	European Union Reference Laboratory
EURL Guide	Guide to Good Practice: Technical Application regarding the Microbiological Monitoring of Bivalve Molluscs Harvesting Areas
FBO	Food Business Operator
FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Points
ISO	International Organization for Standardization
MI	Marine Institute
MPN	Most Probable Number
NRL	National Reference Laboratory
PSP	Paralytic Shellfish Poison
SANCO	General Directorate for Health and Consumers
SFPA	Sea Fisheries Protection Authority
SFPO	Sea Fisheries Protection Officer

1 Introduction

This audit took place in Ireland from 21 to 30 October 2013 and was undertaken as part of the FVO (Food and Veterinary Office) planned audit programme. The audit team comprised two auditors from the FVO and two national experts from EU Member States. An opening meeting was held in Clonakilty on 21 October with the Food Safety Authority of Ireland (FSAI), the central Competent Authority (CA), the Sea Fisheries Protection Authority (SFPA) which is a official agency acting as CA in the implementation of controls and enforcement of food legislation within the scope of this audit and the Marine Institute (MI). 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 FSAI and SFPA accompanied the FVO 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.
- Verify the extent to which the guarantees and the corrective action submitted to the Commission services in response to the recommendations of the previous FVO audit report DG(SANCO/2011-6007 have been implemented and enforced by the CA.

In terms of scope the audit focused mainly on the organisation and performance of the CAs, the official control system in place covering the classification and monitoring of live bivalve mollusc production areas and the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods. Accordingly, certain aspect of the legislation referred 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
Central Competent Authorities	1	FSAI
Competent Authorities	2	SFPA and MI
Regional offices of CAs	3	
Laboratories	3	
Production areas	1	
Harvesting vessels	1	
Dispatch/ purification centres	2	
Processing establishments	4	One also performing purification

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.

A 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 Ireland was carried out in 2011 (ref. DG(SANCO)/2011-6007). The report of this audit is available on the Health and Consumers Directorate General website at: http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2832.

The report concluded that due to serious deficiencies all along the production chain, the official control system at that time could not offer all the necessary guarantees that live bivalve molluscs and fishery products derived from them placed on the market for human consumption complied with EU public health standards.

Recommendations were made concerning the implementation of EU legislation, monitoring and classification of production areas, microbiology and biotoxins laboratory analysis and official control over establishments (especially those where purification and heat treatment processing took place).

A General Review Audit was carried out by the FVO in Ireland in December 2012 to monitor progress in relation to open FVO recommendations across all sectors including bivalve molluscs. The report of this audit is available on the Health and Consumers Directorate General website at: http://ec.europa.eu/food/fvo/follow_up_en.cfm?co_id=IE.

The FVO assessment, following the General Review Audit was that actions were still required to address a number of recommendations of the 2011 audit report.

4.2 Production and trade information

The SFPA informed the audit team that Ireland produced approximately 31,000 tonnes of bivalve molluscs and non filter gastropods in 2012. The main species produced are mussels (15,000 tons), oysters (7,300 tons) and marine gastropods (5,200 tons).

4.3 Rapid Alert System for Food and Feed Notifications

Since 2011, seven notifications related with bivalve molluscs were issued. These notifications refer to the presence of lipophilic toxins in mussels (one), microbiological contamination above 230 *E.coli*/100g in mussels (one), the presence of norovirus in oysters (three) and unauthorised placing on the market (two).

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 FSAI is the authority with responsibility for the enforcement of food legislation (see country profile at: http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=IE). As regards the implementation of official controls on bivalve molluscs the FSAI has service contracts with the SFPA and the MI.

The audit team was informed that the structures of the FSAI and SFPA and the organisation of the official controls had not changed since the previous audit, thus, it remains as described in the 2011 FVO audit report.

The audit team noted:-

- The FSAI carried out an audit to the SFPA in July 2013 to evaluate the action taken by the SFPA to address all the recommendations of the previous FVO report. A copy of the FSAI draft report was provided before the audit to the FVO team. The report concluded that a significant number of recommendations had been properly addressed. However, the SFPA still needed to take further action to properly address the remaining recommendations.
- Several training sessions have been organised by the CAs in response to recommendations of the previous FVO report. Amongst others, training was provided to FSAI and SFPA officials on sampling procedures, classification and monitoring of production areas, evaluation of purification processes, evaluation of heat treatment processes, etc. The CAs provided records of these training sessions to the audit team during the audit.
- The CA provided no documentary evidence that training had been provided to food business operators (FBOs) responsible for samples taken for official monitoring of production areas[1].
- The SFPA has developed or updated documented procedures to enhance official controls. During the audit updates of the Codes of Practice for biotoxins and for microbiology were provided. The SFPA produced new guidelines for the inspection of establishments, for purification, for microbiological criteria and updated existing checklists to address recommendations of the previous FVO report.

Conclusions

Ireland has official control systems for bivalve molluscs and their production and placing on the market which respect, in general, the requirements established in Regulation (EC) No 882/2004. In particular, the CAs for the official control of activities within the scope of the FVO audit are designated as required in Article 4 of Regulation (EC) No 882/2004.

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

Legal Requirements

Article 6 and Chapter II of Annex II to Regulation (EC) No 854/2004; Council Decision 2002/226/EC.

1 In their comments to the draft report the CA stated that the FSAI, SFPA and MI organised five regional information sessions in October 2013 to which official agency officers and staff and the shellfish industry were invited to attend. During the events full description of the Irish Shellfish Monitoring Programme was provided, including an explanation of how it assists industry to ensure that live bivalve molluscs placed on the market meet the highest standards of food safety. The events also covered topics such as biotoxin and phytoplankton monitoring, phytoplankton sampling, shellfish traceability, microbiological classification and viruses. Demonstrations on sampling techniques were given during the sessions. 34 food business operators received training during the series. Record of the training is attached to the CA comment.

5.2.1 Classification of production areas

Findings

The SFPA Code of Practice (CoP) entitled *Microbiological Monitoring of Bivalve Mollusc Production Areas* (updated September 2013) sets out the procedures used for the classification and microbiological monitoring of live bivalve mollusc production areas in Ireland. This CoP includes procedures for the performance of sanitary surveys.

The SFPA fixed the delineation and boundaries of classified areas and the representative microbiological monitoring points. The SFPA website has maps showing the delineation and boundaries of classified areas and the representative microbiological monitoring points are also set out there. The SFPA website also contains a list of these areas and their classification. This list is renewed on an annual basis.

According to the CoP, classification of live bivalve mollusc production areas is based on three classes (A, B or C) and the *E.coli* criteria for those classes foreseen under legislation. The microbiological criteria in the CoP for class B and C is in line with EU requirements. For classification of A areas the CoP allows a tolerance of up to 1000 *E.coli* MPN (most probable number)/100g in 10% of the samples which is not in line with EU requirements.

The necessary classification time-frame and minimum dataset is set out in the CoP. The specification can be considered as fit for purpose.

Seasonal and preliminary classification of production areas is foreseen by the SFPA (there are no specific EU requirements covering these issues). The *Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regards to Regulation (EC) No 854/2004* (hereafter EU guide) and the European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination in bivalve molluscs *"Guide to Good Practice: Technical Application regarding the Microbiological Monitoring of Bivalve Molluscs Harvesting Areas"* (hereafter EURL guide) give certain guidance on this issue and provide the corresponding scientific explanations.

All newly classified production areas are required to have a sanitary survey in accordance with the CoP.

Since the 2011 FVO audit, two sanitary surveys have been conducted in two new areas. The sanitary surveys were provided to the audit team.

The CA informed the audit team that all production area maps with the indication of boundaries and sampling points for microbiology testing have been reviewed during 2012/2013. This revision was a full review of the boundaries. During the review all production areas were checked to ensure that production areas were covered by boundaries, that the appropriate sampling points were assigned to each area and that the reduction of boundaries was carried out in many areas to make them more accurate and relevant, and establishment of a microbiological sample point codes were developed.

The CA also initiated a process to identify and prioritise within the existing classified production areas those for which a sanitary survey needs to be conducted. The CA plans to have completed sanitary surveys of all classified production areas by 2015.

The audit team noted:-

- The SFPA CoP is, in general, a comprehensive document which provides important guidance on the procedures to be used by SFPA officers. With the exceptions noted below it is in conformity with Regulation (EC) No 854/2004 and also with the agreed EU Guide.
- The action taken by the SFPA to reduce the tolerance level of *E.coli* for classification of A

areas from up to 4,600 *E.coli* MPN/100g to up to 1,000 *E.coli* MPN/100g of molluscs in 10% of results for class A is an improvement from the situation described in the previous FVO audit report. It is still not, however in compliance with the EU legislation (230 *E.coli* MPN/100g). At the initial meeting the CAs (SFPA and FSAI) informed the audit team that Ireland holds the view that its tolerance threshold does not compromise the safety of the products.

- Sanitary surveys, as required by Point A.6 of Chapter II of Annex II to Regulation (EC) No 854/2004, have been performed for the four new classified production areas in Ireland since 2006.
- The audit team noted that some production areas had, since 2006, been reviewed resulting in a revised classification and/or new boundaries (i.e. resulting from the division of an area). However, sanitary surveys had not been performed in all these cases. The SFPA expressed their interpretation of EU rules in that sanitary surveys were only required for classification of entirely new production areas and that revisions of classification status, or classification boundaries, in existing areas did not constitute a requirement for a sanitary survey under Regulation (EC) No 854/2004.
- However, in relation to the above, the SFPA noted their support for the principle of sanitary surveys and stated that it is their intention to initiate a programme for completion of sanitary surveys in all existing areas by 2015 in line with recommendations in the EU Guide. The SFPA has, however, not yet established a programme (prioritised list with commencement and completion dates) or earmarked the resources necessary to implement this initiative.[2]
- The boundaries of production areas are clearly defined by maps. For some areas reviewed by the CA the boundaries incorporate potentially polluted areas (adjacent to centres of population, or include a significant sewerage discharge) that have not been properly represented by the sampling point. In some cases this was because aquaculture licences were not active and therefore there was no stock available to sample. In one case reviewed by the audit team (wild oyster fishery) the historical sampling point did not represent the most contaminated part of the classified area.
- In the absence of sanitary surveys for the large majority of production areas, sampling point locations are historically defined. Sampling points are fixed locations described by grid co-ordinates with sampling tolerances set out in the CoP. However, in some areas reviewed the sampling point did not adequately represent the microbiological status of the entire area classified. However, the SFPA did present evidence for the review of production area boundaries and sampling points location in some areas where increased risk (outbreaks or elevated monitoring results) had occurred.
- Seasonal and preliminary classification of production areas are carried out in line with the EU or EURL guides.
- Review of classification of all production areas was carried out at the beginning of 2013 taking into consideration the monitoring data from the last three years. The audit team reviewed the last three years monitoring data of some production areas and it was noted that most had been regularly monitored and that the SFPA carried out the correct classification or re-classification in line with CoP specifications and EU legislation other that for class A production areas where as mentioned above, a level of tolerance for *E coli* above regulatory limit is permitted.

2 In their comment to the draft report the CA stated that with respect to sanitary surveys, it is not a legal requirement to give a prioritised list of areas with commencement and completion dates but as per response to Recommendation two this area of work is a priority for the SFPA and work is ongoing.

Conclusions

Live bivalve molluscs are harvested from production areas classified in one of three categories according to the level of faecal contamination (class A, B ,C) and with fixed boundaries as required in Points A.1 and A.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.

The procedures set out in the SFPA CoP on microbiological monitoring regarding classification are, in general, satisfactory and are followed in practice. The criteria used for classification of class B and class C areas are in conformity with Points A.4 and A.5 of Chapter II of Annex II to Regulation (EC) No 854/2004. However, it should be noted that the criteria for classification of class A areas as set out in the SFPA CoP and as used in practice, are not in conformity with requirements under Point A.3 of Chapter II of Annex II to Regulation (EC) No 854/2004.

Requirements of Point A.6 of Chapter II of Annex II to Regulation (EC) No 854/2004 regarding sanitary surveys and sampling programmes for newly classified areas are met. However, sanitary surveys are not conducted where classification status or boundaries of existing areas is subject to change. Therefore, for some areas, evidence was not available showing that designated sampling points are representative of the microbiological contamination status of the entire classified area.

The procedures implemented by the SFPA for preliminary and seasonal classification of production areas are in line with the EURL and EU guides' recommendations.

Recommendations Nos 1 and 3 of the previous FVO report have been addressed. Recommendation No 2 has not been addressed. Although changes have been made in order to reduce the tolerance level for *E. coli* for classification of A areas, the standard applied is not yet in line with EU legislation.

5.2.2 Monitoring of classified production areas

Findings

The SFPA has a sampling plan for the monitoring of the microbiological quality of live bivalve molluscs, for the possible presence of toxin-producing phytoplankton in production water, for the presence of biotoxins in live bivalve molluscs, and for the levels of chemical contaminants in live bivalve molluscs.

The sampling plans have been drafted in accordance with the CoP on microbiology and biotoxins.

Sampling for the microbiological monitoring of live bivalve molluscs production areas is undertaken by the Sea Fisheries Protection Officers (SFPOs). For phytoplankton and biotoxins monitoring FBOs take samples. In this case SFPOs carry out random samples for verification.

Sampling should be carried out in the designated sampling points in the production areas. In addition, for biotoxins and phytoplankton monitoring samples are also taken from designated sentinel sites around the Irish coast.

The MI continuously monitors the data produced as a result of the routine monitoring of microbiology, phytoplankton in water and biotoxins in live bivalve molluscs. In the light of the trends and results obtained, the strategy and the frequency of monitoring may change. The MI advises the Irish Molluscan Shellfish Safety Committee through the SFPA and a management cell is convened to consider the data and to recommend to the SFPA when a change in sampling frequency is needed.

<u>Microbiological quality of live bivalve molluscs</u>

Procedures for monitoring the microbiological quality of live bivalve molluscs are set out in the CoP on microbiological monitoring of production areas.

Microbiological samples are, in general, taken by the SFPOs on a monthly basis and submitted to designated laboratories for *E.coli* analysis. Procedures for sampling and for transport to the laboratory are set out in the CoP.

The audit team verified data from monitoring of production areas in the regions visited and noted that:-

- Sampling plans are set out in the CoP for microbiological monitoring and, in general, required monthly monitoring at each defined sampling point. This is satisfactory and is in line with EU Guide. Production areas are regularly monitored and the frequency set in the CoP is respected.
- SFPOs do not necessarily take samples at the designated sampling points. Normally samples are taken where harvesting occurs. However, in one regional office visited samples of a razor clams production area were taken at the time of landing and not at the designated sampling point.
- The geographical distribution of the sampling points for monitoring of production areas is defined by geographical coordinates. The CoP requires SFPOs to have a GPS as part of sampling equipment. However, GPS is not used and GPS coordinates of the actual sampling location are not recorded, therefore it is not possible to verify the actual point of sampling. The SFPA informed the audit team that SFPA sampling officers are familiar with their areas and knowledgeable on the location of sampling points.
- A review of sampling records at one laboratory shows that the sample transport criteria had been respected.

Water from the classified production areas for phytoplankton monitoring[3]

The SFPA had a system in place to monitor the presence of toxin-producing phytoplankton in water. The sample should be representative of the water column. According to the CoP on biotoxins monitoring, sampling frequency for the monitoring of the presence of phytoplankton in production areas should be at a frequency agreed by the Molluscan Shellfish Safety Committee. This is typically the same as the frequency for biotoxins testing. However, currently based on a risk assessment carried out by the MI on biotoxin testing, the MI and the CA advise harvesters to take weekly samples for quantification of toxin-producing phytoplankton species.

Moreover, 25 sentinel sites should also be tested weekly for identification and quantification of all species of phytoplankton. The MI stated that these sentinel sites have been chosen to cover all the production bays and act as a early warning in case of change in the phytoplankton composition.

The MI established thresholds to trigger the sampling of live bivalve molluscs based on historical data for paralytic shellfish poison (PSP) and for amnesic shellfish poison (ASP) toxin-producing phytoplankton species (200 cells/litre for *Alexandrium* spp. and 1,000,000 cells/litre *Pseudinitzchia* spp. or 10,000 cells/litre for *P. delicatissima and P. seriata*).

The audit team noted:-

- Sentinel sites are not always monitored weekly as was indicated by the MI (i.e. in 2012 14 out of the 25 sentinel sites were monitored weekly, while five were monitored fortnightly

3 In their comments to the draft report the CA stated that commencing in April 2014, and with effect from 01 September 2014, shellfish producers will be required to maintain a minimum of 75% of the required weekly phytoplankton samples in the preceding three months, (in addition to the biotoxin analysis of shellfish samples), in order to maintain an open biotoxin status in a production area. Production areas that conduct seasonal harvesting will not go to an Open Biotoxin status on shellfish testing alone unless a minimum of 75% of the required weekly phytoplankton samples have been submitted in the preceding three months.

Once an area is closed for non submission of phytoplankton samples, the area will only be re-opened once sampling has been demonstrated to be back on track at the appropriate weekly frequency.

and the rest infrequently monitored).

- All production areas are monitored for toxin-producing phytoplankton. However, some are not regularly tested as advised by the MI and the SFPA. For example in the minutes of the last Molluscan Shellfish Safety Committee meeting in June 2013, the MI indicated that 48 out of 86 sites had submitted no phytoplankton samples.
- The SFPOs in the regions visited informed the audit team that monitoring of phytoplankton is not a requirement for harvesters, but the SFPA encourages harvesters to sample phytoplankton weekly to refine the monitoring strategy for biotoxins.
- In one production area visited, water was not taken from the designated sampling point and the sampling did not follow good practice. The FBO informed the audit team that samples are taken where and when harvesting occurs.

Presence of biotoxins in live bivalve molluscs[4]

The national biotoxin monitoring programme includes all the toxins (ASP, PSP, and lipophilic toxins). The monitoring strategy is described in the CoP, draft version 3, October 2013.

In most cases, samples are taken by FBOs' samplers. SFPOs occasionally take samples instead of the harvesters; such samples are considered to be verification samples.

As a general rule biotoxins are monitored in all production areas when in production.

The sampling frequency for biotoxins is not weekly throughout the year in all production areas and for all species. Biotoxins are monitored in accordance with a risk assessment study carried out by the MI for mussels, oysters, clams and cockles. The MI continuously monitors the data produced as a result of the routine monitoring of phytoplankton in water and biotoxins in live bivalve molluscs. In the light of the trends and results obtained the strategy and the frequency of biotoxin monitoring may change.

Monitoring frequency is different between toxin groups and may be modified in specific areas or for specific species of molluscs as a result of ongoing risk assessment by the SFPA using data supplied by the MI.

The strategy followed by the MI for the monitoring of marine biotoxins was explained to the audit team during the visit to their premises. However, the CA did not present to the audit team a formal documented risk assessment wherein the strategy designed by the MI is set out.

For areas where several species (cockles, clams, oysters) are harvested, mussels are used as indicator species based on their propensity to accumulate toxins at the highest rates. In this case, the MI informed the team that as soon as toxins are quantified in mussels, the other commercial shellfish species within the area are analysed weekly.

Lipophilic toxins are, in general, monitored weekly in mussels as required under EU rules. This frequency can revert to fortnightly or monthly based on the information provided by the MI. Other

4 In their comment to the draft report the CA stated that "Toxins in shellfish using risk assessment relying on phytoplankton are supplemented with additional information from sub-threshold trends of low levels of toxins detected by chemical analysis. In addition an ASP screen is included in the lipophilic toxin method to detect Domoic acid in all samples. Sentinel stations are tested on a monthly basis year round for all toxins, and phytoplankton not only from production areas but also from neighbouring areas which will provide alerts to changing trends that may lead to toxin accumulation in the shellfish. The legislation (Annex II Chapter II Part B of 854/2004) states that "production areas must be periodically monitored", the frequency of phytoplankton sampling is not specified.

Notwithstanding this the above risk assessment to be carried out in 2014 / 2015 will examine the frequency, positioning of samples and methodology used in taking samples of phytoplankton. In addition the sampling review group has recommended that areas failing to submit at least 75% of requested (weekly) samples of phytoplankton will be closed from September 2014 onwards".

species considered a low risk (oysters, clams and cockles) are as a general rule monthly monitored for lipophilic toxins (the frequency may revert to weekly based on information provided by the MI, i.e. when other indicators reveal a high risk, or when toxins are present in an adjacent area, or when toxic phytoplankton is detected in the water samples, etc.).

ASP and PSP (normally not present in Irish waters other than in Cork Harbour, according to the MI) are monitored in production areas only when the corresponding toxin-phytoplankton is detected above the established threshold in the water. The MI showed evidence of correlation between the presence of PSP and ASP toxin-phytoplankton in water and toxicity in live bivalve molluscs. The MI view is that if phytoplankton is systematically monitored weekly it is safe not to monitor for the presence of ASP and PSP in live bivalve molluscs unless phytoplankton is detected above the defined thresholds.

The monitoring strategy is complemented by a monthly monitoring of 13 sentinel sites for all biotoxins carried out all year around.

In parallel with the above monitoring, lipophilic toxins and ASP monitoring of scallops has recently (October 2013) been implemented in production areas with a fortnightly frequency. Analysis of scallops for ASP involves three separate parts of the mollusc's flesh: remainder (hepatopancreas and soft tissues), adductor muscle and gonad. If the result of the remainder is above the regulatory limit and muscle and gonad separately analysed are below the regulatory limit the area concerned is placed under restricted status. It means that only gonad and muscle are allowed to be placed on the market where both are below the regulatory limit. If muscle is above the regulatory limit and the gonad below it, only the gonad may be marketed. The total ASP content in the whole body is calculated from the results obtained in the three separate analyses (remainder, gonad, and muscle).

Lipophilic toxins are only tested for in the remainder. If the result is above the regulatory limit the area is placed under restricted status. Following this result the gonad and adductor muscle are tested and placed on the market if the results are found to be below the regulatory limit.

PSP is not tested for in scallops. The CA informed the audit team that in case of detection of *Alexandrium* above the threshold PSP will be tested for in the same way as for lipophilic toxins.

The audit team noted that:-

- The sampling frequency is in general respected.
- Sampling for ASP and PSP as a general rule is only carried out when toxin-producing phytoplankton is detected above threshold levels as set out by the MI (see above). However, based on the results of a risk assessment carried out to justify the reduced frequency of ASP and PSP testing, samples for testing for toxin-producing phytoplankton are not taken weekly in all areas as recommended by the MI.
- The presence of domoic acid (ASP) may also be detected using the lipophilic multi-toxins method of analysis as a qualitative screen throughout the year on a weekly basis.
- ASP is also monitored for in high risk areas during high risk periods.
- In one production area visited samples of water and molluscs were taken for biotoxin and phytoplankton testing. In this case the samples were not taken from the designated sampling points. Also in one region visited the SFPO informed the audit team that samples are taken at the port where product is landed.
- FBO samplers do not have clear instructions how to effectively collect samples to be representative (i.e. a composite sample from bottom, middle and upper level).
- The monitoring plan of production areas for scallops could not be evaluated in detail by the audit team as it had only recently been implemented (14/10/2013). However, based on a

summary review of the document it cannot be considered in compliance with EU requirements. For example, in one instance the ASP level in the remainder was 558.6mg/Kg and 18.4 mg/Kg in gonad and adductor muscle (regulatory limit is 20 mg/Kg) leading to a calculated concentration in the whole body of 247.1 mg/Kg. In this case the area should have been closed for scallops as the CA has not availed of derogations contained in Decision 2002/226/EC which allows, under special conditions, Member States to harvest scallops where the biotoxins level (ASP) of the whole body exceeds regulatory limits.

- In one case in Mulroy Bay lipophilic toxin was detected in the remainder of scallops (the only part tested) above the regulatory limit which resulted in the closure of the area. After two weeks a second analysis was carried out in the three individual parts (remainder, gonad and muscle) and lipophilic toxin was detected above the regulatory limit in the remainder but in this case the area was kept open (because the results of analysis of muscle and gonad were below the regulatory limit). Despite this finding it was indicated on the MI website that the product could be marketed as whole body (remainder, muscle and gonad).

Presence of chemical contaminants in live bivalve molluscs

There is a monitoring plan for contaminants in live bivalve molluscs. The monitoring plan includes heavy metals (e.g. mercury, lead and cadmium), PCBs, Dioxins and Polycyclic Aromatic Hydrocarbons.

The audit team noted that the results for the 2011 monitoring programme were satisfactory.

Samples were also taken in 2012 but the results were not available at the time of the visit.

Conclusions

The monitoring of the microbiological quality of live bivalve molluscs was in general carried out according to the CoP and EU legislation (Part B of Chapter II of Annex II to Regulation (EC) No 854/2004).

The monitoring for the presence of toxin-producing phytoplankton was in general carried out according to the CoP and EU legislation (Part B of Chapter II of Annex II to Regulation (EC) No 854/2004).

The monitoring for the presence of biotoxins in live bivalve molluscs is not carried out according to EU legislation as the risk assessment upon which this monitoring of biotoxins is based requires systematic weekly monitoring of toxin-producing phytoplankton in all production areas which is not being implemented by the CA.

The monitoring system in place for the presence of biotoxins on pectinidae cannot ensure that pectinidae placed on the market comply with the health standards laid down in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004; in particular pectinidae can be placed on the market when test results for ASP and lipophilic toxins in the remainder exceed the regulatory limits. As a result since the SFPA has decided not to apply Decision 2002/226/EC, scallops with a concentration of ASP in the whole body exceeding 20 mg/kg may be harvested and processed without following the conditions laid down in Decision 2002/226/EC.

The fact that samples are not always taken at the defined sampling points cannot ensure that results of the analyses are representative of the areas concerned, which is not in line with Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.

The monitoring for contaminants is carried out as required in Point B.8 of Chapter II of Annex II to Regulation (EC) No 854/2004.

Recommendations Nos 4, 5 and 6 of the previous FVO report covering designation and representativeness of sampling points and biotoxin monitoring have not been fully addressed.

5.2.3 Decisions after monitoring

Findings

SFPA has procedures to take action when the results of sampling show that the health standards for molluscs are not met.

Procedures for responding to high *E.coli* levels during ongoing monitoring of production areas are documented in the SFPA CoP on microbiological monitoring. Results above the assigned classification category (MPN per 100g of 230 for class A; 4,600 for class B and 46,000 for class C) trigger an investigation into the cause of the high result which is reported upon using a standard template. In addition an alert procedure is triggered for *E.coli* MPN per 100g values above 1,000 (class A areas), 18,000 (class B areas) or 46,000 (class C areas). In these instances, in addition to the above procedures, investigations focus on 'additional risk to public health'.

When the presence of *E.coli* in live bivalve molluscs shows a result above the EU limits in samples taken for monitoring of A classified production areas, live bivalve mollusc production areas are not closed for harvesting as a general rule until further microbiological contamination is confirmed. This means that areas with an A classification may remain open despite initial sample results being above the regulatory limit. In this scenario the SFPA should take measures to ensure that FBOs only place on the market live bivalve molluscs that respect the health standards defined in EU legislation. In case of A class areas, live bivalve molluscs can be sent to a purification centre.

The audit team noted:-

- When one or more of the three regulated families of biotoxins are detected in live bivalve molluscs other than scallops above the regulatory limit, the SFPA closes the areas. The SFPA takes the decision to re-open an area in accordance with EU legislation; based on two negative results (i.e. biotoxins levels below regulatory limits from two consecutive samples taken not less than 48 hours apart).
- For scallops, when lipophilic toxin or ASP are found over the regulatory limit in the remainder (i.e. tissue other than the gonad or adductor muscle) the production area is not closed but placed under restricted status (scallops can be harvested but only gonad and muscle can be marketed if they are found below the regulatory limit). Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/2004 requires that where results of sampling show that the health standards for molluscs are exceeded the CA must close the production area concerned, preventing harvesting of live bivalve molluscs.
- In one case in Mulroy Bay lipophilic toxin was detected in scallops above the regulatory limit in the remainder and below the regulatory limit in gonad and muscle, the area was not closed and the product was allowed to be marketed as a whole.
- The SFPA provided the audit team with investigation reports for all above threshold results for microbiology in 2013 (31 reports). From this it was evident that the procedures set out in the CoP were followed.
- In most cases the investigation performed identified that no harvesting had occurred at the time of sampling and therefore there was not a public health risk. In a few cases the investigation documented that the FBO was sending product for purification on a voluntary basis. In a few cases the SFPA provided evidence that the FBO had been instructed to cease harvesting. In a number of cases additional sampling was performed to assess the microbiological status.
- As a general rule live bivalve mollusc production areas are not closed for harvesting following results exceeding the threshold for the class A area involved.

- Risk management actions are not always consistent. In the Rossaveal office of the SFPA whenever regulatory limits are exceeded for microbiology in live bivalve molluscs, SFPO are responsible for issuing an improvement notice (enforcement of temporary measures) for the production areas concerned. Examples of action taken were reviewed and were found to have been correctly implemented. In these instances, harvesting was not forbidden but an improvement notice was issued giving two options to the harvester: either to stop harvesting or send product for purification. However, in Castletownbere the SFPO informed the audit team that no measures are taken for mussels if *E.coli* is found above the regulatory limit as this is a product that will be cooked by the consumer before consumption.
- There was a lack of clarity in the SFPA CoP on microbiology monitoring regarding the above risk management actions and the circumstances where harvest area closure was to be regarded as mandatory.

Conclusions

Decisions after monitoring are taken by the SFPA when certain non-compliances are detected.

When non-compliances are related to the presence of biotoxins in live bivalve molluscs other than scallops, production areas are closed in line with the requirements of Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/2004. However, when scallops are found above the regulatory limit for ASP or lipophilic toxin in the whole body, production areas are not closed.

When non-compliances are related to the presence of *E.coli* exceeding class A threshold, production areas are not closed which is not in line with the requirements of Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/2004.

Recommendation No 7 of the previous FVO report has not been fully addressed.

5.2.4 Additional monitoring requirements

Findings

Classified production areas from which the harvesting of bivalve molluscs had been forbidden are routinely monitored as part of the official controls by SFPOs to ensure that products harmful to human consumption are not placed on the market.

The audit team verified that a control system comprising laboratory tests to verify FBOs' compliance with the requirements (biotoxins, contaminants and microbiological quality) for the end product at all stages of production, processing and distribution is in place at national level.

The control system sampling includes microbiology, contaminants and biotoxins. However, the audit team noted that not all the regulated biotoxins are tested for.

The audit team saw evidence that official samples were taken by the SFPA in the establishments visited. All the results reviewed were within regulatory limits.

Conclusions

Laboratory tests to verify FBOs' compliance with EU requirements as required by Point D.2. of Chapter II of Annex II to Regulation (EC) No 854/2004 are carried out. However, such laboratory tests do not include all the regulated biotoxins.

Recommendation No 8 of the previous FVO report has been addressed.

5.2.5 Recording and exchange of information

Findings

A list of approved production areas, with details of their location and boundaries, as well as the classification status of the areas has been established and is kept up-to-date by the SFPA. These lists are regularly communicated to interested parties, whenever changes in the location, boundaries, class or closures of production areas occur.

The audit team saw evidence that the regional CAs act promptly when a decision is taken that a production area must be closed.

Conclusions

Recording and exchange of information is largely performed as required under Point E of Chapter II of Annex II to Regulation (EC) No 854/2004.

5.3 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 FBOs' compliance with Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004; Council Decision 2002/226/EC.

Findings

Gastropod harvesting takes place outside production areas in the regions visited.

Official control of marine gastropods should be carried out by the SFPA in approved establishments. The SFPA's 2013 Food Safety Control Plan established that SFPOs should take biotoxin samples from approved FBOs handling marine gastropods on a quarterly basis when in production.

The majority of the scallops produced in Ireland are harvested outside production areas.

The SFPA stated that the majority of scallops when landed at harbours are transported to processing establishments.

According to the CoP on monitoring of biotoxins only adductor muscle and gonad are analysed separately from scallops harvested outside production areas. If ASP is found below the regulatory limit in both compartments then both the gonad and adductor muscle from that batch may be placed on the market. The batch from which these scallops come from is said to have a “harvest restricted status”, it means that scallops can only be placed on the market after being shucked and the separate parts analysed for ASP. If ASP is found above the regulatory limit in any of these parts the CA requires the destruction of the batch.

In processing establishments scallops are shucked, and only the adductor muscle (roe-on/roe-off) are kept and subsequently frozen. According to the SFPA, it is obligatory for FBOs to ensure that samples of parts are tested for ASP for each batch prior to placing the products on the market. This must be built into FBOs' Hazard Analysis and Critical Control Points (HACCP) system. These own-check samples are sent to the MI which publishes the results on its website indicating the fishing ground from which the product has been harvested. The fulfilment of the requirement for ASP testing by FBOs is verified by the SFPO during official controls.

The SFPA signals that whole body scallops should not be placed on the market through indicating on the registration document “not analysed for biotoxins”.

The 2013 Food Safety Control Plan required that official control samples of pectinidae should be taken for verification purposes for ASP analysis from those establishments handling pectinidae.

Scallops should be tested in the form that they are to be placed on the market, which is normally shucked. However, random samples of the whole body should also be taken during 2013.

The audit team noted that:-

- Official control to verify compliance with health standards for marine gastropods and scallops are carried out by the CA. When these controls were done not all the regulated biotoxins were tested for. For scallops only ASP was tested for as is specified in the 2013 Food Safety Control Plan.
- Official control procedures did not ensure that FBOs carried out the necessary own-checks to ensure that gastropods met the health standards laid down in EU legislation as is required in Point 1 of Chapter IX of Annex III to Regulation (EC) No 853/2004.
- Official control procedures did not ensure that FBOs carried out the necessary own-checks to ensure that scallops met health standard laid down in EU legislation as is required in Point 1 of Chapter IX of Annex III to Regulation (EC) No 853/2004. Furthermore the audit team noted that own-checks on scallops did not include testing for PSP and lipophilic toxins.
- adductor muscle and gonads from scallops harvested outside production areas were the only parts analysed by the MI for ASP as part of both FBOs' own-checks and official controls.
- In one establishment visited the audit team noted that the FBO had sent samples from each batch of scallops to the MI for analysis for ASP. In this case the final product was frozen roe-on scallops but the MI analysed gonad and adductor muscle separately. In this case the MI did not analyse the scallops in the form that they were to be placed on the market to deliver an accurate estimation of the toxin content.[5]
- When results of ASP content in the end product show results above the EU limit the SFPA requires the destruction of the batch. No other actions (i.e. harvesting restrictions or prohibition) concerning the fishing grounds from which theses scallops were harvested are taken.

Conclusion

The official controls on pectinidae required by Chapter III of Annex II to Regulation (EC) No 854/2004 are not able to verify compliance with:-

a) The health standards laid down in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004; in particular the test for ASP in the whole body is not carried out and lipophilic toxins and PSP are not tested for.

b) The requirements of Point 1, Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 related to FBO own-checks.

As a result of the above (i.e. no checks on the whole body of the scallops to determinate the ASP concentration, no harvesting restrictions in production areas when ASP levels exceed the limit) and since the SFPA has decided not to apply Decision 2002/226/EC, scallops with a concentration of ASP in the whole body exceeding 20 mg/kg may be harvested and processed without following the

5 In their comments to the draft report the CA stated that "Scallop adductor muscle seldom contains domoic acid above the regulatory limit (0.1% occurrence of domoic acid > regulatory limit in adductor muscle in 10 years) whereas the gonad may, on infrequent occasions, contain domoic acid greater than the regulatory limit. If the adductor muscle and gonad were homogenised together prior to testing, this would have the effect of diluting the domoic acid that may be present in the gonad and inadvertently allowing gonad tissue above the regulatory limit to be placed on the market. Also the opportunity to establish the concentration of domoic acid in the gonad would be lost if both tissues were homogenised together. The MI records the weights of adductor muscle and gonad samples separately when presented for testing. It would be possible to report a calculated domoic acid concentration for the combined tissues, in the same way as is acceptable for total tissue calculations, if it were required. The CA is of the opinion that it is better to test the tissue separately to prevent a gonad tissue with domoic acid above the regulatory limit entering the market and that this provides consumers with a greater level of protection".

conditions laid down in Decision 2002/226/EC.

The official controls on marine gastropods required by Chapter III of Annex II to Regulation (EC) No 854/2004 are not able to verify compliance with requirements of Point 1, Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 related with FBOs own-checks.

Recommendations Nos 9 to 12, 14 and 15 of the previous FVO report have not been fully addressed. Recommendation No 13 has been addressed.

5.4 Official controls to verify food business operators' compliance with the requirements for 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.

5.4.1 Requirements for placing on the market

Findings

Live bivalve molluscs are placed on the market via dispatch centres and contain the prescribed identification mark.

When moved from production areas to dispatch/ purification centres or processing establishments live bivalve molluscs must be accompanied by a registration document.

The audit team noted, during the visit to establishments that registration documents were available. However, in some cases it was noted that these documents were not always correctly filled in (status of the area and week of harvesting not recorded). At the dispatch/purification centres visited, lists of suppliers of live bivalve molluscs were kept for each batch together with the accompanying document.

Conclusions

Live bivalve molluscs are placed on the market in line with requirements of Chapter I of Annex III to Regulation (EC) No 853/2004.

Recommendations Nos 23 and 29 of the previous report have been addressed.

5.4.2 Official control of FBOs

Findings

The SFPA implements an annual programme of official controls. The audit team received a copy of the 2013 Food Safety Control Plan where the official controls of live bivalve molluscs and marine gastropods are included. Establishments are subject to inspection at a frequency determined in accordance with a documented risk assessment. Official controls are carried out in accordance with SFPA documented procedures and guidance documents.

The visits/inspections are carried out by the SFPOs who use checklists and inspection reports to document their visits. All relevant parts of EU regulations applicable to approved FBOs are looked at.

The audit team noted that:-

- Inspections are in general carried out at the frequency established in the risk analysis, in

accordance with the categorisation of the FBO.
- Inspection reports are available that identify deficiencies and specify deadlines for correction. Follow-up of the actions taken by the FBOs are carried out.
- The 2013 Food Safety Control Plan includes sampling in establishments handling bivalve molluscs and marine gastropods for microbiology, biotoxins and contaminants.
- Checklists and guidance documents used to inspect bivalve mollusc premises have been updated to address recommendations of the previous FVO report.
- Official control is carried out in all establishments visited. Inspection visits also cover audit of HACCP plans.
- In all establishments visited a HACCP based procedure was established. In general, HACCP plans were well implemented. However, the audit team identified some deficiencies. In most cases the FBO had not identified all biotoxins for all species as a risk.
- Official samples are also taken when visiting the establishments for end product testing.

Conclusions

The official controls of FBOs are carried out based on risk and the frequency is in general respected by the relevant SFPO. Official controls include official testing of end product. Procedures have been revised or updated to address certain recommendations of the previous FVO reports.

Recommendations Nos 21 and 22 of the previous FVO report have been addressed.

5.4.3 Facilities handling bivalve molluscs

Findings

Two establishments were visited which were applying purification as the control measure for class B live bivalve molluscs.

In 2012 the SFPA established a guidance document[6] for its inspectors regarding the control of live bivalve molluscs purification centres. Considering the different designs and operating parameters of purification plants a requirement of this guidance is that a full written specification should be available covering the purification system in use. This can also be considered a requirement of the HACCP plans. The guidance also gives recommendations for high risk species (e.g. oysters) during periods of high risk for norovirus contamination.

Purification was only in operation at one of the plants visited, and at this plant the audit team were informed that it was operating for the purposes of the visit. Consequently this inspection visit had some limitations since practices observed or described were not necessarily those in use during normal commercial operations.

The audit team noted:-

- Both establishments visited had structural and hygiene conditions that can be considered as compliant with Regulations (EC) Nos 853/2004 and 852/2004.
- The 2012 SFPA purification guidance document and relevant checklist can be considered an important and necessary tool to assist SFPOs in conducting checks on the technical aspects of purification centres.
- Validation checks as required by the SFPA guidance, demonstrating a satisfactory reduction in *E.coli* in molluscs during purification, had been performed at both plants visited. The results were found to be satisfactory.
- In one of the plants visited the SFPO had undertaken a comprehensive audit of the plant using the purification centre checklist and a number of deficiencies had been identified

6 *SFPA Guidance Document for Inspecting LBM Purification Centres*

which were subject to corrective actions. The operation of the plant in this case, as described to the audit team, and subject to the outstanding actions being corrected, was found to be satisfactory.

- At the other plant visited several operational parameters (to ensure purification) were observed to be non-compliant with the SFPA guidance (plant specification not properly described and specific to the plant, cascades disturbing shellfish, excessive depth of molluscs in the bins, non-recording of operational water temperatures). Although the audit team were shown an inspection report, based on the SFPA checklist, the report lacked any detail and the deficiencies identified by the FVO team had not been recorded.
- The SFPA informed the audit team that specific training on audit of purification centres, according to the guidelines, has not been provided to the SFPO conducting this audit.
- Only molluscs of the same specie are purified in the same tank and are sent to dispatch centres with a label certifying that they have been purified.

Three establishments which heat treat bivalve molluscs were visited. In one establishment only class A bivalve molluscs were processed. In the other establishments processing included class B bivalve molluscs where heat treatment was used as a control measure. In both of these, thermal criteria for cooking were identified as Critical Control Points in their HACCP evaluations and both establishments monitored cooking temperature and its duration as part of their HACCP procedures.

Studies had been conducted at both establishments to measure the internal temperature profiles of bivalve mollusc flesh during the cooking processes used. In addition at one of them internal meat temperature profile verification studies had been conducted by an external contractor. The requirement for compliance with Point A.5 of Chapter II, Section VII of Annex III to Regulation (EC) No 853/2004 had been clearly identified by SFPA inspections at establishments and was the subject of follow-up actions.

As regards the two establishments processing class B molluscs, the audit team noted that:-

- In one establishment internal meat temperature profiles of several cooking processes inspected appeared to meet the 90°C for 90 seconds criteria as laid down in EU legislation.
- In the second establishment is was clear that for one cooking process used for mussels (vacuum packed) the heat treatment criteria required in Regulation (EC) No 853/2004 were not achieved since the internal temperature failed to reach 90°C during the cooking process. This was evident from both own-check results and an external study. However, the external consultant verification report for this process had concluded that the heat treatment profile obtained (at least 74°C for 2 minutes) was adequate since it provided equivalent health guarantees. The report states that "viruses are not as heat resistant as vegetative pathogens' and "it can be taken as fact that the mussel cooking process of 74°C for 2 minutes, or its equivalent, is the same as a cooking process of 90°C for 90 second as outlined in the European legislation". No evidence was presented to support these assertions. The CA had found the report satisfactory and had closed the enforcement action on this issue at this establishment[7].

In all establishments visited a HACCP based procedure was in place. In general, HACCP plans were well implemented. However, the audit team identified some deficiencies. In most of the cases the FBO had not identified all biotoxins for all species as a risk.

7 In their comments to the draft report the CA stated that the Irish CAs are of the view is of the view that the legislation (Point A.5 of Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004) governing this specific area as currently laid down as it does not allow an alternative treatment approved by the CA to manage risk arising from pathogens. A change in the legislation which would introduce some flexibility into the prescribed treatment to manage risk would be welcomed by Ireland.

FBOs own-checks include analyses of bivalve molluscs to check compliance with microbiological criteria. The method used is the EU analytical reference method.

Conclusions

The establishments visited are broadly compliant with Regulations (EC) Nos 852/2004 and 853/2004. However, compliance of FBOs with the requirements of Parts A.2, A.3 and A.5 of Chapter IV and Part A.5 of Chapter II of Section VII of Annex III of Regulation (EC) No 853/2004 was not assured by the CAs in all the cases.

Improvements have been noted in the official control to verify HACCP system implementation. However, identification of hazards related to the presence of certain biotoxins were not properly carried out by the FBOs.

Recommendations Nos 24 and 28 of the previous audit report have been addressed. Recommendations Nos 25, 26 and 27 have not been fully addressed.

5.5 LABORATORIES

Legal Requirements

Articles 11, 12 and 33 of Regulation (EC) No 882/2004, and Article 3 of Regulation (EC) No 2074/2005.

Findings

Laboratories testing for phytoplankton

The MI carries out phytoplankton analyses in Ireland in the context of the monitoring plan for live bivalve molluscs production areas. These analyses are carried out at two sites: Bantry and Galway. The audit team visited the two laboratories.

The MI is the official laboratory responsible of coordinating sampling under the monitoring plan. It also has a role as advisor to the CAs.

The phytoplankton test results are usually available the day after the reception of the sample by the laboratory so that the MI can immediately inform the SFPA if an unexpected toxic episode is occurring. The results of phytoplankton analyses are published on the MI website.

The laboratory (both sites) is accredited by the Irish National Accreditation Board against ISO standard 17025 for the Utermohl method for phytoplankton analysis. The last audit by the accreditation body was carried out in 2012.

As regards sampling coordination, the MI has established protocols for sampling of water in production areas. Samplers are provided with the sampling protocol in the code of practice on biotoxins monitoring, which adequately describes the procedures to be followed.

During the visit to the laboratory the audit team noted that the internationally recognised Utermohl method is used and a detailed standard operational procedure was available to the audit team. Internal and external quality controls are performed. The laboratory participated in proficiency testing in 2011 and 2012 with satisfactory results. Internal proficiency tests are organised once a year between all the analysts involved and a double check of the results is carried out by the MI phytoplankton coordinator once a month.

Laboratories testing for microbiology

The CoP on microbiology includes the requirements for laboratory analysis and supervision of this analysis by the MI which act as National Reference Laboratory (NRL). In Ireland four laboratories and the NRL perform official analyses for microbiological monitoring of production areas. The SFPA informed the mission team that the same laboratories are used for official control verification

checks at establishments. The audit team visited two laboratories performing official control analysis for production area monitoring, the NRL which is part of the MI and one of the four private laboratories contracted by the MI.
The audit team noted that:-

- The delegation of responsibilities was found to be and well controlled with the NRL working to a contract agreement with the FSAI and each of the four laboratories working under a contract with the NRL. Contracts are clear and detailed and cover the necessary responsibilities, tasks, and requirements including the test methods to be used, the quality assurance requirements, and the performance targets for analysis.
- In both laboratories visited analysis for *E.coli* was performed according to the EU reference method. The method was accredited by the Irish National Accreditation Board, and the laboratory was able to demonstrate satisfactory performance in proficiency testing. In both laboratories visited the accreditation body had specifically audited the *E.coli* method during the last two years with satisfactory outcome.
- The NRL provided evidence of supervision of analysis for production area monitoring in all the four laboratories involved. The NRL conducted audits every second year in each laboratory under contract and also provided technical assistance to the CA through participation in training events and production area management activities.
- Regarding the laboratories used by SFPA for establishment verification checks, the SFPA were not able to demonstrate specific designation of these laboratories as required by Article 12.1 of Regulation (EC) No 882/2004. However, in practice the same laboratories were used for both production area monitoring and establishment verification checks. The SFPA provided evidence that SFPA officers were instructed to specify the EU reference methods on sample submission forms accompanying samples. In several laboratory reports reviewed, the audit team noted that the correct methods for *E.coli* and *Salmonella* had been used.
- The requirements for microbiological verification checks (methods of analysis, designated laboratories, frequency of checks, etc.) are not described in the 2013 Food Safety Control Plan.

<u>Laboratory for testing for biotoxin</u>

The audit team visited a MI laboratory which is also the NRL for marine biotoxins and the laboratory in Ireland which carries out official testing for biotoxins in the context of the monitoring of classified production areas.

The MI laboratory is accredited against ISO standard 17025 by the Irish National Accreditation Board. The scope of its accreditation includes all the EU reference methods used for all groups of marine biotoxins. The last audit was carried by the accreditation body was in 2012.

The methods used for the routine analysis of biotoxins are the EU reference ones for the three groups of regulated marine biotoxins.

The MI fulfils the majority of the tasks as set out in Article 33 of Regulation (EC) No 882/2004. As the NRL for marine biotoxins, it collaborates with the EURL and participates in working groups and provides scientific and technical assistance to the CAs.

The MI has access to an adequate laboratory capacity for testing. The laboratory participates in proficiency testing organised once a year by the EURL for lipophilic toxins, PSP and ASP and also to the proficiency testing organised by other parties once or twice a year with satisfactory results.

In 2013, up to the 25 October 2013, 335 analyses for PSP, 1,370 analyses for ASP and 2,221 analyses for lipophilic toxins had been carried out by the MI.

Conclusions

Laboratories designated to carry out official controls are accredited to ISO 17025 and use the EU reference methods. The NRLs visited carried out their duties as established in Article 33.2 (B), (C) of Regulation (EC) No 882/2004.

Recommendations Nos 16 to 20 of the previous FVO report have been addressed.

6 Overall Conclusions

The official controls of live bivalve molluscs echinoderms, tunicates and marine gastropods are organised and carried out at all stages of the production chain and are supported by an accredited laboratory network.

Improvements have been noted since the 2011 audit, the CA took action to correct some deficiencies (related to laboratory analyses) and to improve certain aspects of the official controls (introduction of official control of scallops, improved controls in establishments and a reduction in tolerance levels in A class production areas). However, a significant number of recommendations of the 2011 audit still need to be fully addressed.

The control system in place for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods presents several deficiencies as regards the classification and monitoring of live bivalve mollusc production areas and official controls of scallops and gastropods harvested outside production areas.

7 Closing Meeting

A closing meeting was held on 30 October 2013 with representatives of the CAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CAs present did not make any comments thereon.

8 Recommendations

The CAs should provide the Commission services with an action plan, including a time table for its completion, within 25 working days of receipt of the report, in order to address the recommendations mentioned in the following table.

N°.	Recommendation
1.	The CAs should ensure that the requirements of Point A.3 of Chapter II of Annex II to Regulation (EC) No 854/2004 regarding compliance with the health standards set out in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 are met when classifying and maintaining the classification of class A production areas.
2.	The CAs should ensure that the requirements regarding sanitary surveys of Point A.6. of Chapter II of Annex II to Regulation (EC) No 854/2004 are taken into account when necessary for reclassification of areas. In particular, they should ensure that the geographical distribution of the sampling points gives assurance that the results of the analysis are as representative as possible for the area considered.
3.	The CAs should ensure that samples for monitoring of classified production areas are taken at the designated samplings points in order to guarantee that the requirements of Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004 are met.

N°.	Recommendation
4.	The CAs should ensure that, the sampling frequency for biotoxins analyses in all species of bivalve molluscs is in line with Point B.5 of Chapter II of Annex II to Regulation (EC) No 854/2004.
5.	The CAs should ensure that, decisions in accordance with EU legislation are taken when live bivalve mollusc health standards for microbiological contamination and the presence of biotoxins in scallops are exceeded as required in Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/2004 and that live bivalve mollusc exceeding EU microbiological limits and scallops exceeding biotoxins limits are not placed on the market as required by Chapter V of Annex III to Regulation (EC) No 853/2004.
6.	The CAs should ensure that the established control system comprising laboratory tests to verify FBOs' compliance with EU requirements (as required by Point D.2 of Chapter II of Annex II to Regulation (EC) No 854/2004) covers all the regulated biotoxins.
7.	The CAs should ensure that official controls on pectinidae and marine gastropods harvested outside production areas verify compliance with Point 1 of Chapter IX, Section VII of Annex III to Regulation (EC) No 853/2004 (regarding FBOs' own-checks) and, the health standards laid down in Chapter V, Section VII of Annex III to Regulation (EC) No 853/2004, as required by Chapter III of Annex II to Regulation (EC) No 854/2004.
8.	The CAs should ensure that official controls on pectinidae implemented include analysis to determine the level of biotoxins in the whole body of pectinidae harvested both inside and outside classified production areas in order to ensure that standards in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 are met.
9.	The CAs should ensure that when a concentration of domoic acid in the whole body of the scallops exceeding 20 mg/kg is identified the harvesting and processing of scallops will only be allowed where the requirements of Decision 2002/226/EC are implemented.
10.	The CAs should ensure that when, following analysis, non-compliances concerning pectinidae are identified in particular concerning non-respect of EU thresholds for biotoxin content, appropriate measures as foreseen in Article 54 of Regulation (EC) No 882/2004 are taken for production areas from which non-compliant scallops have been harvested.
11.	The CAs should ensure that FBOs carrying out purification comply with the requirements of Parts A.2, A.3 and A.5 of Chapter IV of Section VII of Annex III of Regulation (EC) No 853/2004.
12.	The CAs should ensure that FBOs of establishments processing live bivalve molluscs from B and C classified production areas, can demonstrate that processed bivalve

N°.	Recommendation
	molluscs undergo appropriate treatment to eliminate pathogenic micro-organisms, as required in Point A.5 of Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004.
13.	The CAs should ensure that the requirements established in Article 5 of Regulation (EC) No 852/2004 for HACCP based procedures are fulfilled by FBOs, in particular identification of hazard related with biotoxins.

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=2013-6674

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
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. 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
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. 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
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
Reg. 2406/96	OJ L 334, 23.12.1996, p. 1-15	Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products

Legal Reference	Official Journal	Title
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	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
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
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
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products