

AUDIT
REPORT

Audit of Sea-Fisheries
Protection Authority
Official Controls in
relation to Biotoxin and
Microbiological Monitoring
of Live Bivalve Molluscs

JULY 2014



AUDIT REPORT

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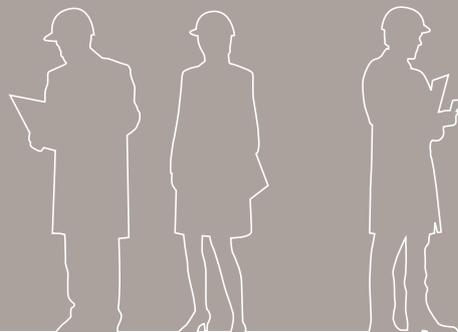


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Audit of SFPA Official Controls in relation to Biotxin and Microbiological Monitoring of Live Bivalve Molluscs

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1. GLOSSARY

FSAI	Food Safety Authority of Ireland
FSC	Food Safety Coordinator
FVO	Food and Veterinary Office
SFPA	Sea-Fisheries Protection Authority
SFPO	Sea-Fisheries Protection Officer
SPO	Senior Port Officer

2. AUDIT OVERVIEW

In accordance with Schedule 5 of the Food Safety Authority of Ireland (FSAI) Service Contract with the Sea-Fisheries Protection Authority (SFPA), two audit projects were carried out in relation to the SFPA official controls of live bivalve molluscs, as part of the FSAI audit programme for 2013.

Project 1: An audit was performed in order to determine the current effectiveness and appropriateness of SFPA official controls relating to live bivalve molluscs. The findings for this audit are outlined in this report.

Project 2: An audit was also carried out, in relation to the follow-up and close-out of the Food and Veterinary Office (FVO) Mission Dingle (SANCO)/ 2011-6007¹, where 29 recommendations requiring corrective action had been highlighted. The audit team assessed the implementation of the corrective actions and whether the measures taken addressed the FVO report findings.

[FSAI Audit Report on Close-out to Mission DG \(SANCO\)/2011-6007](#)

Both projects were carried out in tandem, and the audit team visited the SFPA at central, regional and local levels of the organisation. A number of food business operators were also audited, including harvesters, industry samplers and various types of live bivalve mollusc establishments, as part of the onsite verification of the effective implementation of official controls and the assessment of the food business operator's level of compliance with food law.

SFPA official controls are carried out in accordance with the requirements of the Food Safety Control Plan, documented procedures, codes of practice and guidance notes. In many cases, these were sufficiently detailed in order to provide clear instructions for staff for the performance of official controls, and in order to comply with the requirements of Article 8.1 of Regulation 882/2004. During the course of the audit, certain SFPA documents were also amended in response to audit findings, where certain deficiencies were identified and/or to strengthen official control requirements.

In certain instances, official controls were not carried out in accordance with the SFPA's planned arrangements, e.g. the minimum target frequencies for risk-based inspection and/or sampling activities had not always been met. In some cases, a full, detailed audit/inspection of some food business operator live bivalve mollusc establishments had not been carried out.

In relation to biotoxin verification sampling at live bivalve molluscs establishments, in general, in all three port offices (Dingle, Killybegs and Dunmore East) port offices, this did not happen on a quarterly basis and could not be considered as effective and/or in compliance with the requirements of the SFPA Food Safety Control Plan, the Code of Practice on Biotxin and Phytoplankton Monitoring, and SFPA headquarters instructions.

Deficiencies were also observed in relation to official controls of scallops. In the case of one harvester supplying live bivalve molluscs, i.e. whole scallops, visited during the course of the FSAI audit (in the Killybegs Port Office region), serious non-compliances were observed. Product was placed on the market, despite the fact the food business operator had been informed by the SFPA that the bay was closed due to toxicity levels above the legal limit in live bivalve molluscs. No biotoxin verification activities, i.e. as part of SFPA official controls, had been carried out on this food business operator, and registration documents were not on file within the Killybegs Port Office, which was also not fully in accordance with the SFPA's documented procedures.

¹ FVO Mission Dingle (SANCO)/ 2011-6007: *Governing the Production and Placing on the Market of Bivalve Molluscs*

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Appropriate enforcement action was however, taken on the day of the audit by the Killybegs Port Office in response to the audit findings. This involved the issuing of a Prohibition Order for the recall and destruction of whole scallops, and a compliance notice directing the food business operator to cease from harvesting and placing on the market scallops until such time as they could demonstrate compliance with the requirements of Regulation (EC) No 853/2004. As part of this incident, a compliance notice under S.I. No. 432/2009, was also issued to another food business operator dispatching live bivalve molluscs for the receipt of whole scallops which were being supplied for sale without a completed gatherer's registration document. The withdrawal of this product was verified by Sea-Fisheries Protection Officers (SFPOs) as part of the follow-up carried out by the Killybegs Port Office.

Following audit findings in the Dunmore East Port Office region, i.e. in relation to the supply of whole scallops by a food business operator to another Member State without prior testing for biotoxins, a strengthening of the requirements and information to be filled out in registration documents was put in place nationally. The SFPA confirmed also that the dispatched scallops were subsequently tested by the receiving establishment and were found to be within legal limits.

At the time of the FSAI audit, SFPA headquarters informed the audit team that it was currently in the process of evaluating how best to meet the 'effectiveness' and 'internal audit' requirements of Regulation (EC) No 882/2004. Following a tendering process, external consultancy had been commissioned by the SFPA to assist with its review of effectiveness, which had not been fully completed at the time of the FSAI audit. A report however, was submitted to FSAI post audit, where actions points for improvement were identified as a result of this review, and where the next steps were being considered by the SFPA's management.

A formalised approach to review the effectiveness of official controls, although initiated, was not in place at the time of the audit and SFPA procedures could not be considered as meeting with the requirements of Article 8.3 of Regulation (EC) No 882/2004. A system of internal audits for the assessment of the performance of official controls within SFPA was not in place in order to comply with the requirements of Article 4.6 of Regulation (EC) No 882/2004.

Corrective actions in order to address audit findings in this report and their updates, can be found in the hyperlink below.

[FSAI Corrective Action Plan](#)

In relation to follow-up to the FVO live bivalve molluscs audit in 2011, i.e. DG (SANCO) 2011-6007, the audit team confirmed that progress had been made with closing-out certain recommendations, whilst in other cases, they were either still in progress and/or remained open/in-progress, at the time of the FSAI audit. A summary of FVO recommendations and the status from the FSAI close-out audit report can be found in Table 1, Appendix 1 of this report. For the basis of the audit judgements, reference should be made to the FSAI close-out report.

[FSAI Audit Report on Close-out to Mission DG \(SANCO\)/ 2011-6007](#)

3. INTRODUCTION

The FSAI is responsible for the enforcement of all food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI.

The SFPA has entered into a service contract with the FSAI and is responsible for the implementation and enforcement of national and EU legislation as it applies to establishments under their supervision. It is a requirement of the service contract that the SFPA shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency.

As part of its legal mandate, and in accordance with Schedule 5 of the service contract, the FSAI is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls by the SFPA in relation to live bivalve molluscs, this audit focused on compliance by the SFPA with regard to relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant SFPA documented procedures and their Food Safety Control Plan.

The audits in the SFPA were undertaken as part of the FSAI's audit programme for 2013. This report describes the audit objective, scope, methodology and the findings from the audit.

3.1 Audit Objective

The objective of the FSAI audits was to verify the effectiveness and appropriateness of SFPA official controls in relation to biotoxin and microbiological monitoring of live bivalve molluscs. The audit projects outlined below were carried in out in tandem as part of the FSAI audit programme for 2013:

Project 1: An audit was performed in order to determine the current effectiveness and appropriateness of SFPA official controls relating to live bivalve molluscs. The findings for this audit are outlined in this report.

Project 2: An audit was also carried out, in relation to the follow-up and close-out of the FVO Mission DG (SANCO)/ 2011-6007², where 29 recommendations requiring corrective action had been highlighted. The audit team assessed the implementation of the corrective actions and whether the measures taken addressed the FVO report findings.

[FSAI Audit Report on Close-out to Mission DG \(SANCO\)/ 2011-6007](#)

3.2 Audit Scope

FSAI audits of official controls involve verifying compliance by the SFPA with regard to relevant legislation, adherence to the FSAI Service Contract and the official agencies own documented procedures.

The scope of the audit covered official controls of live bivalve molluscs, i.e. filter feeding Lamellibranch molluscs, which includes oysters, mussels, clams, cockles, scallops and products which contain these.

² FVO Mission DG (SANCO)/ 2011-6007: *Governing the Production and Placing on the Market of Bivalve Molluscs*

3.3 Audit Criteria and Reference Documents

The audit criteria referred to during the audit included the following non exhaustive list:

- [Food Safety Authority of Ireland Act, 1998](#) (No. 29 of 1998), as amended.
- [FSAI Service Contract with the SFPA](#)
- [National Control Plan for Ireland 2012-2016](#) (MANCP)
- SFPA Documented Procedures
- SFPA Food Safety Control Plans
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EC\) No 854/2004](#) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended
- [Regulation \(EC\) No 882/2004](#) on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- [Regulation \(EC\) No. 2073/2005](#) on microbiological criteria for foodstuffs, as amended
- S.I. No.432/2009: European Communities (Food and Feed Hygiene) Regulations, 2009, as amended.
- FVO 2011 live bivalve molluscs Mission DG(SANCO)2011-6007
- SFPA data supplied to FSAI
- Guidance Notes/Codes of Practice
- Other relevant legislation detailed in the FSAI Service Contract

4. OFFICIAL CONTROLS PERFORMED IN ACCORDANCE WITH REGULATION (EC) No 882/2004 AND 854/2004

4.1 Organisation and Structure of Official Controls

Article 4.1 of Regulation (EC) No.882/2004 states that “Member States are required to designate the competent authorities (CAs) responsible for the performance of the official controls as set out in the Regulation”

Article 4.2 (c) & (d) of Regulation (EC) No. 882/2004 and Schedule 3 of the FSAI Service Contract require the CA to fulfil a number of operational criteria (see below).

As part of the FSAI Service Contract with the SFPA, the official agency carries out official controls of seafood at all stages of production, processing and distribution, i.e. with the exclusion of retail establishments. The SFPA is also designated as a competent authority in the context of the Multi-annual National Control Plan for Ireland ([MANCP 2012-2016](#)).

At a central level, the SFPA Food Safety Unit operates from SFPA Headquarters in Clonakilty, Co. Cork. The Food Safety Unit coordinates SFPA activities nationally and interfaces directly with each of seven port offices which make up the regional levels of the organisation. Port offices are geographically distributed around the coast and food safety activities are managed under the supervision of a Senior Port Officer (Sport office). At regional level official controls in food business operators are performed by SFPOs who report directly to the port office.

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As part of the organisation and delivery of official controls and in order to meet both its legislative and service contract requirements, the SFPA is required to meet the following operational criteria:

- A sufficient number of suitably qualified and experienced staff (see Section 4.8 of this report for more details on experience and training)
- Adequate facilities and equipment in order to carry out duties properly

In relation to the quality and consistency of official controls and their effectiveness, see also Section 4.5 of this report.

The audit team was informed at central level, that staff reductions and restrictions on filling posts at all levels within the SFPA, i.e. without the possibility of filling posts, posed challenges for the organisation. Reduced resources were evident at both central and regional levels of the organisation, where due to the moratorium on recruitment within the public service, a number of positions remain unfilled. Resources issues have also been highlighted in previous FSAI audits.

At central level, a national manager and a port office position remained vacant. For one port office region visited, the port office was responsible for the supervision of two port offices, i.e. for both Dingle and Castletownbere.

In the case of the Killybegs Port Office in particular, the audit team was informed that port office staff numbers had decreased from 13 to 10 since 2012. This, coupled with the seasonal nature of food safety work by port offices due to pelagic landings, posed challenges within the port office (for both the Dingle and Dunmore East Port Offices however, staff losses were not observed).

Consequently, the audit team observed that reduced resources within the SFPA directly impacts on the whole time equivalent available for food control activities at both central and regional levels of the organisation.

The audit team verified that adequate facilities and equipment had been provided by the SFPA which was confirmed in each of the port offices visited.

4.2 Coordination and Planning of Official Controls

In accordance with Article 4.5 of Regulation (EC) No 882/2004, when within a competent authority, more than one unit carries out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

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

The audit team confirmed that in general, there was a structured and well organised approach to the coordination and planning of SFPA official controls nationally. From a delivery viewpoint, the annual Food Safety Control Plan issued by SFPA headquarters, specifies the prioritisation requirements for official control tasks to be performed by port offices nationally for all port office regions. Copies of the Food Safety Control Plan for 2012 and 2013 were provided to the audit team. The Food Safety Unit coordinates SFPA activities nationally.

At regional level, a Senior Port Officer is responsible for managing a team of SFPOs within the port office, and their responsibilities cover both food safety and fisheries control activities. The audit team was provided with local

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business plans for each region visited, drawn up by the port office in order to deliver the Food Safety Control Plan requirements and to manage and prioritise duties and resources within the port office region. The audit team confirmed that SFPOs are either assigned individually or as a group to carry out official controls at food business operator establishments and production areas, within port office regions.

Port offices are required to schedule their activities, e.g. inspections, follow-up to official control outcomes, etc. in order to meet the requirements of the SFPA Food Safety Control Plan, relevant SFPA codes of practice and standard operating procedures.

Microbiological sampling and biotoxin/phytoplankton monitoring requirements to be carried out were detailed in the SFPA code of practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012) and also the Code of Practice on biotoxin monitoring (Ver. 2: Jan 2013), and the Food Safety Control Plan for 2012 and 2013.

In relation to the planning of SFPA inspections and sampling activities at establishments, these were also required to be carried out in accordance with the SFPA Food Safety Control Plan and scheduled in order to meet the risk-based frequencies to be achieved as set out in the SFPA Code of Practice for approving land-based establishments. The audit team confirmed that live bivalve molluscs establishments visited had been classified as high, medium or low-risk in accordance with the SFPA Code of Practice for the Risk Assessment of Approved Establishments.

As part of the coordination and planning activities within the SFPA, meetings were organised at central level on a regular basis between SFPA headquarters and Senior Port Officers from each of the regional port offices and covered operational issues for both fisheries control and food safety activities. The Food Safety Unit also frequently held its own meetings at SFPA headquarters in relation to food safety matters. In the three port offices visited, regular meetings, i.e. by video conference, take place with SFPA headquarters, which cover both food safety and fishery control activities.

At regional level, as part of the coordination and planning of activities, the audit team were informed that discussions and meetings take place on an ongoing basis, i.e. as part of the general management of both food safety and fisheries control activities within port offices. Certain differences in approach were observed between the port offices visited, including:

- In the case of the Dingle Port Office, in general, minutes of meetings were available as evidence that formal discussions on official control priorities take place on an ad-hoc basis
- Minutes of meetings in general however, were not available for both the Killybegs and Dunmore East Port Offices as evidence that official control priorities are formally discussed and reviewed with staff

The audit team's view is that evidence should be captured of port office meetings, i.e. irrespective of whether they are formal/informal discussions, in order to demonstrate that official control priorities and activities are discussed, monitored and reviewed, as part of the management of regional official control activities (see also Section 4.4 on the performance, monitoring and review of the SFPA official controls in relation to planned activities).

4.3 Description of Official Control System and Documented Procedures

Article 8.1 of Regulation (EC) No.882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff and that they must keep these procedures up-to-date.

Article 8.3 (a) and (b), of Regulation 882/2004 requires competent authorities to have procedures in place to verify the effectiveness of official controls that they carry out, and to ensure that corrective action is taken when needed.

Documented procedures used by the SFPA include Standard Operating Procedures, Codes of Practice, Guidance Notes/Aide Memoirs and Inspection Forms. The audit team confirmed that all staff within each of the regions had access to these documents which were available via the SFPA intranet.

The main procedures used by the SFPA within the scope of the FSAI audit included:

- SFPA Food Safety Control Plan
- Code of Practice for Approving Land-Based Establishments
- Guidance for SFPA Official Controls - Microbiological Criteria for Sea Fishery Products and Other Seafood
- Code of Practice for the Risk Assessment of Approved Establishments
- Inspection Checklist for Fishery Products and live bivalve molluscs Establishments
- Guidance Document for Inspection of Fishery Products and live bivalve molluscs Establishments
- Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins)

IN general, the SFPA procedures were sufficiently detailed and provided clear instructions to port offices for the performance of official controls, i.e. in accordance with the requirements of Article 8.1 of Regulation (EC) No 882/2004, subject to a number of exceptions identified, below.

These deficiencies included:

- Official control targets for inspection and sampling activities were not always achieved in accordance with risk- based priorities and SFPA procedures
- Full audits were not taking place for certain establishments on an annual basis
- For a number of establishments, detailed, i.e. full, audits of the establishment had not been conducted on an annual basis
- Checklists/contemporaneous notes were not always available for certain establishments audited, which was in accordance with the requirements of the SFPA Food Safety Control Plan, 2013
- A number of deficiencies were observed in certain port offices visited relating to records to be kept and maintained as part of the supervision of samplers/harvesters, which did comply with the SFPA Food Safety Control Plan and documented procedure requirements (see Section 4.4.2 of this report for more details)
- SFPA intranet worksheets were not fully maintained and were not reflective of official controls carried out. Certain audits were recorded incorrectly, i.e. some were referred to as full audits, where in fact they were routine audits/inspections on the intranet system (Dunmore East Port Office) (see Section 4.3 of this report for more details)
- The files for several registered food business operator establishments were not available, on the day of the audit (Dunmore East Port Office)
- Shellfish registration documents, i.e. formerly gatherer's documents, were not on file in the Killybegs Port Office for one food business operator, i.e. who was the subject of enforcement action during the audit. The list of shellfish registration documents in the Dunmore East Port Office were not being fully maintained and/or reflective of books supplied to food business operators, which was not in conformance with the SFPA records and checks to be kept on file within the port office, i.e. in accordance with section 3, Table 3 of the SFPA Food Safety Control Plan 2012/13

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The audit team acknowledges that a number of deficiencies identified during the course of the audit were promptly amended by the SFPA in order to strengthen existing official controls in place and to address audit findings.

For example:

- The issuing of a Trader Notice by the SFPA to industry as a result of FSAI audit findings, for the harvesting and dispatch of whole scallops (see Section 4.4.2 for further details)
- Several amendments made to the SFPA Code of Practice on Microbiological Monitoring of Live Bivalve Molluscs Production Areas (see Section 4.4.1 for further details)

Certain deficiencies/opportunities for improvement were also identified with current SFPA procedures, which in the audit team's view, require amendments to be made in order to more fully reflect delivery of official control requirements, to be met.

Although in many cases, official controls were being carried out in accordance with SFPA requirements and planned arrangements, this did not happen in other instances identified by the audit team, which were highlighted in detail in the individual audit reports for each port office.

A procedure to review effectiveness in accordance with the requirements of article 8.3 of Regulation (EC) No 882/2004 had not been fully developed at the time of the FSAI audit. A review of effectiveness had however been undertaken by the SFPA with the assistance of an external consultancy. Evidence of the review was provided to the audit team where action points for the SFPA were being considered by the SFPA management at the time of writing this report and consequently, were considered to be a work in progress (see Section 4.5 of this report for more details).

4.4 Performance of Official Controls

In accordance with Article 10 of Regulation (EC) No 882/2004, official controls should be carried out using appropriate control methods and techniques such as monitoring, surveillance, audit, inspection, sampling and analysis.

The audit team confirmed that official tasks performed by the SFPA, used a combination of the above methods and techniques.

4.4.1 Microbiological Sampling, Classification and Monitoring of live bivalve molluscs Production Areas

Annex II of Regulation (EC) 854/2004 requires that shellfish production areas are classified as being Class A, B or C depending on their level of Escherichia coli contamination.

Annex II of Regulation (EC) 854/2004 also requires classified live bivalve molluscs production areas to be periodically monitored to check the microbiological quality of live bivalve molluscs.

The SFPA and the Marine Institute have mapped out the location of shellfish production areas and designated sampling points. A list of production areas and their classification status were provided by the SFPA to the audit team.

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The National Shellfish Sampling Coordinator at SFPA headquarters develops the sampling plan for microbiological monitoring used for classification of live bivalve molluscs production areas. The National Shellfish Sampling Coordinator is also responsible for maintaining the national database of shellfish microbiological classification sampling results, i.e. Shellsan Database.

The audit team confirmed that an annual list of classified live bivalve molluscs production areas and their status is posted on the SFPA website in July of each year [Classified Shellfish Production Areas](#)

At the time of the FSAI audit, three sanitary surveys had been completed for new production areas, and evidence of these were provided to the audit team. The FSAI audit team confirmed that a template for conducting sanitary surveys had been developed and had been trialled by the SFPA for one new production area in the south. All classified production areas were reviewed by the SFPA in 2012 and 2013, and ten sites were identified as a priority, i.e. following a risk assessment, for conducting sanitary surveys in the next phase of this process. The audit team was informed that a programme to complete sanitary surveys for all production sites was planned to be completed by 2015. This however, was dependent on agreement at SFPA board level and the sanctioning of resources for completing this task.

The audit team confirmed that in general, official control microbiological samples for monitoring of classified live bivalve molluscs production areas were being taken on a monthly basis by SFPOs. In practice, sample results taken for monitoring purposes are used as part of the ongoing classification process for the production area(s).

In the three port office regions visited, the microbiological monitoring and classification samples were however, often being taken from a number of different sampling locations within a production area. This did not relate to the specific sample point, i.e. grid reference, as required by the SFPA Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012). Consequently, this did not comply with the requirements of Point A. 6 and B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004. In response to this finding and during the FSAI audit, the SFPA amended the code of practice to capture more accurately where microbiological samples should be taken by SFPOs.

An assessment as to whether these amendments to the Code of Practice were being fully applied in practice in port office regions and were effective, i.e. in order to address the FSAI audit findings, could not be made by the audit team as these changes to procedures were made following completion of the onsite audit activities.

In relation to out of specification, i.e. elevated, microbiological results obtained as a result of SFPA monitoring, follow-up investigations are required to be carried out by the SFPO when requested by the National Shellfish Sampling Coordinator at central level. The follow-up is also required to be documented using the 'Shellsan' *Elevated Micro Result Report* form. The audit team verified that in the three port office regions visited, evidence of appropriate follow-up, i.e. including discussions with local producers relating to potential reasons for contamination and also confirmation that they were not harvesting, was provided to the audit team.

In one case however, i.e. Dunmore East Port Office, for an elevated microbiological result, i.e. 5,400 most probable number *E. coli* per 100g, a follow-up investigation was not performed, although requested by the National Shellfish Sampling Coordinator, which did not comply with the requirements of the SFPA on microbiological monitoring of bivalve mollusc production areas.

The audit team confirmed that despite the absence of information returned from the Dunmore East Port Office, this did not prompt any further action by the SFPA at central level, in order to confirm that a follow-up investigation had been carried out, i.e. as part of the verification of the effectiveness of official controls in accordance with article 8.3 (b) of Regulation (EC) No 882/2004.

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In one port office region, i.e. Killybegs Port Office, SFPOs were routinely taking a follow-up microbiological sample, as part of the SFPA follow-up conducted. This approach however, was not routinely taking place, in either the Dingle or Dunmore East Port Offices, and was not captured as a requirement in the SFPA Code of Practice. This audit finding was raised at the closing meeting with the SFPA at central level, where the Code of Practice was subsequently amended to reflect this practice as a requirement. This was considered an important strengthening of SFPA procedures for consistency and protection of public health and food safety.

In accordance with procedural and legislative requirements, the audit team was also provided with evidence where elevated microbiological results for *E. coli*, i.e. as a result of monitoring of production areas, directly led to the decision to reclassify the production area, e.g. changing it from an A to a B classification, following a review of out of specification results detected.

4.4.2 Biotoxin Sampling, Monitoring and Verification of Live Bivalve Molluscs Production Areas

Annex II of Regulation (EC) 854/2004, requires classified live bivalve molluscs production areas to be periodically monitored to check for the presence of biotoxins from toxin-producing plankton.

The system for monitoring of production areas to check for the presence biotoxins, is defined in Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins). Each shellfish production area comes under the supervision of a Shellfish Manager, i.e. a designated SFPO. In the majority of cases, sampling is conducted by industry samplers.

The frequency of monitoring of production areas is based on an assessment of the latest toxicity information available and seasonal trends. Sampling frequencies were normally being set at weekly or monthly levels for each shellfish species in a production area.

Biotoxin sampling frequency may change for different species as toxicity levels increase or decrease. Such changes are communicated by the National Shellfish Sampling Coordinator and emails with these sampling instructions, i.e. received from SFPA headquarters, were seen in the three port offices visited.

During the audit however, a number of deficiencies were observed in relation to sampling where samples taken could not be considered as representative and/or consistent with SFPA procedural requirements.

- In the Dingle, Dunmore East and Killybegs Port Offices audited, biotoxin samples were being taken from a location/area within the production zone where harvesting was active. This did not relate to the specific designated sample point grid reference for monitoring of bivalve mollusc production areas, i.e. from the SFPA website and the *Manual on Molluscan Shellfish Production Areas, Sample Points and Co-ordinates for Biotoxin and Phytoplankton Samples (March, 2012)*.

In relation to the supervision of samplers in the port offices visited, and the fulfilment of responsibilities of Shellfish Managers/SFPOs, as outlined in the Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins), and the SFPA Food Safety Control Plan 2012 & 2013, the audit team observed the following:

- Samplers visited had been provided with the necessary consumables, labels, and equipment for sampling in accordance with the monitoring programme requirements
- Inspections of sampling activities, i.e. by Shellfish Managers/SFPOs, for conformity by industry with *the Code of Practice on Biotoxin and Phytoplankton Monitoring of Shellfish Production Areas*, was not observed in the three port offices audited. These activities were not included on SFPA checklists

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- Surveillance of production areas during closed periods is required to ensure no illegal harvesting of shellfish occurs. The frequency of these checks however, is not defined in the SFPA Food Safety Control Plan
- The audit team observed that biotoxin verification checks were more regularly/routinely being performed in certain port offices, than in others (in case of the Dingle Port Office, they were very regular, whilst in the case of the Dunmore East and Killybegs Port Offices, they were less frequent). From a review of toxicity results for 2012/13, the audit team observed that all three port office regions had experienced closed harvesting periods throughout this time period which did not explain the reduced verification checks performed.

Maintaining records of shellfish samplers and all other relevant documentation is required to be kept by SFPOs within port offices. Certain records were being kept and maintained appropriately for certain port offices visited whilst for others this was not fully the case.

For example:

- The Dunmore East Port Office did not maintain a register/list of industry samplers and harvesters on file
- Both the Killybegs and Dingle Port Offices had in place, a register/list of industry samplers and harvesters on file
- One harvester/biotoxin sampler, i.e. for scallops, however, was not present on the Killybegs Port Office list. This food business operator was also the subject of enforcement action during the FSAI audit (see Section 4.6 of this report) and copies of registration documents for this harvester were not available which was not in compliance with the SFPA records and checks to be kept on file within the port office, i.e. in accordance with section 3, Table 3 of the SFPA Food Safety Control Plan 2012/13
- Records of the training of samplers were not on file within the three port offices audited. Samplers interviewed during the course of the audit were however, generally knowledgeable of sampling requirements. Specific instruction for sampling had been developed and issued to samplers by the Dingle Port Office. A series of training workshops were being organised for industry samplers during 2013. Evidence of these workshops was provided to the audit team following the audit
- The list of shellfish registration documents, i.e. formerly gatherer's documents, in the Dunmore East Port Office, i.e. which include a unique serial number, were not being maintained and/or reflective of books supplied to food business operators, which was not in conformance with the SFPA records and checks to be kept on file within the port office, i.e. in accordance with section 3, Table 3 of the SFPA Food Safety Control Plan 2012/13. This information should be maintained in port offices as it is also used as part of subsequent checks performed in order to confirm the authenticity of food business operator's paperwork relating to harvesting and supply of live bivalve molluscs products

In two port offices, detailed instructions and/or information had been developed as part of a local initiative to assist with sampling as part of the monitoring of production areas which were considered good practices by the audit team. Notably:

- A detailed folder was in place in the Killybegs Port Office which included maps of sampling points and directions for SFPOs to get to these locations
- Instructions had been specifically developed by the Dingle Port Office to assist industry samplers with the taking of Biotoxin/Phytoplankton samples

The audit team observed variation in the frequency of verification checks performed, i.e. as part of the oversight of production areas by Shellfish Managers/SFPOs, which were more regularly being applied in the case of the Dingle Port Office, and where surveillance was considered to be more active by comparison to other port offices visited.

The audit team observed variation in the consistent surveillance of live bivalve molluscs production areas by

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SFPA, where in certain port offices, e.g. Dingle Port Office, these checks were more routinely performed and documented.

Biotxin verification samples and surveillance inspections were not always recorded on the SFPA WS4 worksheet in the Killybegs Port Office and Dunmore East Port Office regions, which was not in compliance with the SFPA Food Safety Control Plan requirements for 2013.

The audit team confirmed that for one food business operator in the Dunmore East Port Office region, harvesting whole scallops was taking place, i.e. where the company stamp of the Irish live bivalve molluscs establishment was being inserted on registration documents and these were being dispatched to an approved establishment in another Member State. These were however, not being tested prior to dispatch and consequently, the biotoxin status had not been completed on the registration document.

Following this FSAI audit finding, a strengthening of the requirements for completing registration documents was put in place, i.e. after subsequent discussions between the FSAI and the SFPA on this matter, where the gatherer's registration document must now include "Testing Required", i.e. where whole scallops are sent for dispatch to an approved processing establishment and this section could not be left blank.

The audit team confirmed that on two occasions, samples of Pectinidae (scallops) were taken by the Dingle Port Office in order to check the toxicity levels of scallops for harvesting purposes from two different harvesting sites. These had not been recorded as official control samples, and were being used to test the toxicity of the production area. The FSAI audit team's view was that these samples were not in compliance with the requirements of the Code of Practice on biotoxin and phytoplankton monitoring and the SFPA Food Safety Control Plan for 2013.

4.4.3 Official Controls at Approved Live Bivalve Molluscs Establishments

In relation to the performance of SFPA official controls, i.e. audits/inspections and sampling activities, relating to live bivalve molluscs, these are required to be carried out in accordance with the SFPA Food Safety Control Plan 2012/13, and scheduled in order to meet the risk-based frequencies to be achieved as set out in the SFPA Code of Practice for approving land-based establishments, and the Code of Practice on biotoxin monitoring for sampling activities.

Although in many cases, regular official controls, i.e. inspections and audits, were being carried out at live bivalve molluscs establishments in the three port office regions visited, in certain cases, the minimum inspection frequencies were not fully met. Although in many cases, full audits of food business operator establishments had been conducted on an annual basis, for others, this was not the case, which was not in accordance with the requirements of the SFPA Food Safety Control Plan 2012/13 and could not be considered as a fully effective evaluation of food business operator controls.

As part of the FSAI verification, in relation to important deficiencies identified during a previous FSAI fish and fishery product audit from 2012, i.e. for the Dingle Port Office, regular and systematic follow-up audits and inspections were scheduled, and evidence was provided that the previous deficiencies, had been adequately closed out (see Section 4.6 of this report).

The following findings were observed for the Dingle Port Office

- For the purification and dispatch live bivalve molluscs establishment visited in the Dingle Port Office, regular SFPA audits and inspections of this food business operation had been conducted during 2012 and 2013. These included both full and routine inspections/audits of the food business operation

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- The audit observed however, that for a number of other establishments in the Dingle Port Office, a full audit had not been conducted on annual basis

The audit team verified that for another establishment which had been the subject of a Closure Order in April 2012 as a result of enforcement action taken by the SFPA and remained closed at the time of the FSAI audit, the food business operator had received one routine inspection during 2012 and 2011. Whilst appropriate enforcement action had been taken in 2012, no full audit had taken place during this preceding time period (the establishment had been classified as high-risk, requiring four annual inspections per year, i.e. with a minimum of one of these being a full audit of the premises).

The audit team was informed that several attempts had been made to inspect these premises in 2011, but difficulties surrounding the availability of the food business operator had prevented the inspections. Recording of these visits/attempted inspections was however, not kept/on file within the Dingle Port Office at the time of the FSAI audit.

The following findings were observed for the Dunmore East Port Office:

- Regular audit and inspection reports were available for certain establishments which also included full audits of the food business operations
- For certain other food business operator files reviewed, full audits and inspections of these establishments had not taken place in 2012, which was not in accordance with SFPA Food Safety Control Plan requirements
- For the official control reports for one establishment reviewed, this was being recorded on the SFPA intranet worksheets as a 'full audit', when clearly they were not

Additionally, in other cases, certain audits were recorded incorrectly as routine audits, where in fact they were full audits. Consequently, SFPA intranet worksheet entries did not reflect completed official controls carried out and which are reported as returns to the SFPA's headquarters. The audit team's view is that without a system of file review and verification of effectiveness, these findings would in general not be picked up.

The following findings were observed for the Killybegs Port Office:

- Detailed audit and inspection reports were available for certain establishments which also included full audits of the food business operations
- For certain establishments, audits and inspection frequencies complied with the SFPA Food Safety Control Plan requirements, whilst in other instances this was not the case. The audit team was informed that this was due to diminished resources within the port office at the time of the audit
- In certain other cases, full audits had not taken place at approved establishments on an annual basis which was not in accordance with the requirements of the SFPA Food Safety Control Plan 2012/13
- In relation to one food business operator, i.e. a grower and harvester of scallops, there were no SFPA inspection reports on file for this food business operator. Gatherer's/Registration documents were not available in the port office. No official control verification checks for biotoxins had been conducted for this food business operator. A subsequent onsite visit to this food business operator by the FSAI audit team resulted in enforcement action being taken by the SFPA as a result of FSAI audit findings (see Section 4.6 of this report)

Joint audits and inspections, i.e. involving a team of two SFPOs, were routinely carried out in both the Killybegs and Dingle Port Office, e.g. for full/re-approval audits. However, this was generally not the case for the Dunmore East Port Office.

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Consequently, variation in the consistency and effectiveness of certain inspections and official controls performed were observed when comparing the three port offices visited. Due to the lack of detailed information being recorded on certain inspection checklists/records used, and the fact that no contemporaneous notes had been kept and/or were available for certain inspections, it was not possible to verify the thoroughness of certain official controls conducted as they were not auditable/verifiable.

The SFPA's verification of food business operator own checks frequently did not specify the evidence being relied upon as confirmation of the food business operator's satisfactory compliance with requirements.

The audit team observed that SFPO inspections had in certain cases, i.e. for the Dunmore East and Killybegs Port Office, not identified that certain food business operators were not using the appropriate number of test samples, e.g. n = 5, in order to comply with the requirements of Regulation (EC) No 2073/2005.

In relation to biotoxin verification sampling at live bivalve molluscs establishments, the audit team observed that although in some cases these were taking place, in general however, for all three port offices, i.e. Dingle, Killybegs and Dunmore East Port Offices, this did not happen on a quarterly basis and could not be considered as effective and/or in compliance with the requirements of the SFPA Food Safety Control Plan, the *Code of Practice for Irish Shellfish Monitoring Programme* and SFPA headquarters instructions.

Additional official controls, i.e. other than inspections and audits, as part of the SFPA Food Safety Control Plan 2013 and Regulation (EC) No 854/2004 include testing/analysis of water, ice, labelling, temperature checks, and microbiological checks, i.e. under Regulation (EC) 2073/2005. For all three port offices visited, i.e. Dingle, Killybegs and Dunmore East Port Offices, the audit team observed that for certain establishments, these official controls were being carried out regularly, whilst in other instances, this was not fully the case.

In general, at the purification/dispatch centres visited, confirmatory microbiological samples had been taken by the SFPA, pre- and post-depuration, as confirmation of the effectiveness of the food business operator's activities and operations, in accordance with SFPA procedures.

4.5 Monitoring, Review and Evaluation of the Effectiveness of Official Controls Performed

In accordance with Article 4.2 of Regulation (EC) No. 882/2004, requires competent authorities to ensure the effectiveness and appropriateness of official controls conducted.

Article 4.6 of Regulation (EC) No. 882/2004 requires that competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation.

Article 8.3 of Regulation (EC) No. 882/2004 requires competent authorities to have procedures in place to verify the effectiveness of official controls that they carry out, and to ensure that corrective action is taken when needed.

Monitoring of the delivery of SFPA official control activities at central level was being carried out principally by Food Safety Unit staff. Evidence of this monitoring was provided in the form of communications issued to port offices in order to prompt completion of quarterly returns (official controls) in line with the requirements of the Food Safety Control Plan. Additionally, reminders were also seen for some port offices for SFPOs to complete quarterly return information and associated official control documentation.

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In the case of both the Killybegs and Dunmore East Port Offices, the audit team was informed that a white board prominently located in the main office, is used for tracking and prompting of official controls.

In the case of the Killybegs port office, the Sea Food Coordinator is responsible for updating the white board with new inspection reports as completed by SFPOs and reflected official control activities within the port office. The audit team was informed that the port office uses the white board for monitoring of SFPOs official control activities. The audit team observed that one live bivalve mollusc establishment had not received a full audit in 2012/13. This had not been detected during monitoring.

In the case of the Dunmore East Port Office, the audit team verified however, that the white board was not being maintained and consequently, did not reflect official controls activities completed and/or outstanding.

The audit team was informed by the SPO for the Dunmore East Port Office, that SFOs were individually responsible for monitoring and reviewing their own performance and official control targets and delivery.

The audit team was provided with a review document. This was issued by the SFPA at central level to all SPOs supervising port offices, requesting them for updates in relation to outstanding official control activities performed, versus their risk-based targets to be delivered in accordance with the SFPA Food Safety Control Plan. The document was circulated by SFPA headquarters on the 8th of August 2012 to port offices, and required feedback from the SPO to the Food Safety Unit at central level. The audit team was informed however, that none of these questionnaires were completed and returned to SFPA headquarters. Consequently, although this new review initiative had been commenced by the SFPA at central level, and was seen as a progressive improvement step by the audit team, it had however, not been successfully completed and/or delivered at the time of the audit.

At regional level, as part of the coordination and planning of activities, the audit team was informed that discussions and meetings take place on an ongoing basis, i.e. as part of the general management of both food safety and fisheries control activities, within port offices. Differences in approaches were observed however, when comparing port offices visited, for example:

- In general, in the case of the Dingle Port Office, minutes of meetings were available as evidence that formal discussions take place on an ad-hoc basis, in relation to official control activities and priorities
- Formal meetings, i.e. where minutes were kept, were in general, not available for both the Killybegs and Dunmore East Port Offices, as evidence that official control activities and priorities are discussed and reviewed, i.e. between the SPO and SFPOs

In the three regional port offices visited, there was a lack of evidence of formal reviews of performance, i.e. either on a group or on an individual basis. As part of the verification of effectiveness of official controls, SPOs in general, did not accompany SFPOs on audits, inspections and/or sampling activities in relation to live bivalve molluscs, and evidence of file reviews were in general, not available/taking place.

SFPA headquarters informed the audit team that it was in the process of evaluating how best to meet the 'effectiveness' and "Internal Audit" requirements of Reg. (EC) No 882/2004 through external consultancy. This process had commenced, but had not been fully completed at the time of the FSAI audit. A report was submitted to the FSAI, post audit, where actions points for improvement were being considered by the SFPA.

Consequently, a formalised approach to review the effectiveness of official controls, although initiated, was not in place at the time of the audit, and SFPA procedures could not be considered as meeting with the requirements of Article 8.3 of Regulation (EC) No 882/2004. A system of internal audits for the assessment of the performance of official controls within SFPA was not in place in order to comply with the requirements of Article 4.6 of Regulation (EC) No 882/2004.

4.6 Non-compliances, Follow-up, Enforcement Action, Complaints, Incidents and Alerts

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

In accordance with Article 55 of Regulation (EC) No. 882/2004, Member States shall lay down the rules on sanctions applicable to infringements of food law and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

The audit team confirmed that a system for tracking non-compliant samples resulting from official controls checks was in place which provided the SFPA at central level, with details on their status and related follow-up activities by SFPOs at food business operator establishments. A number of non-compliant samples were also selected by the audit team for verification that they had been satisfactorily closed out.

The SFPA non-complaint tracking system however, does not include follow-up in relation to elevated results from official control microbiological monitoring of live bivalve molluscs production areas. In one case, an elevated result, i.e. 5,400 most probable number *E. coli* per 100g, was not investigated by the Dunmore East Port Office. This was not followed up and/or picked up by the SFPA at central level. Consequently, current SFPA procedures to review the effectiveness of follow-up action did not verify that adequate follow up had taken place for this particular example.

Following a review of documentation in relation to enforcement activities, the audit team observed that for another port office, i.e. not visited, but where results were available at the SFPA central level, improvement notices were routinely issued for elevated *E. coli* results, i.e. for the Rossaveal Port Office. This approach however, was not observed in other SFPA regions.

In relation to follow-up to audits and inspections, the audit team observed that where deficiencies had been identified, in general, these were followed and closed-out at subsequent visits to these establishments.

Evidence that findings at food business operator level requiring corrective action, i.e. from previous FSAI audits, was provided to the audit team for the Dingle Port Office, where effective follow-up had taken place.

In relation to follow up to the FVO live bivalve molluscs audit in 2011, i.e. DG (SANCO) 2011-6007, the audit team confirmed that progress had been made with closing out certain recommendations, while in other cases, they were either still in progress and/or remained open, at the time of the FSAI audit.

In general, active and appropriate enforcement action by the SFPA was confirmed as taking place by the audit team in each of the three port office regions visited in response to infringements, food safety incidents, and food business operator's history of compliance.

For example:

Enforcement action taken within the Dingle Port Office:

- The audit team verified that two Compliance Notices had been issued during 2013. A number of Compliance Notices had also been issued in 2012

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- Good follow-up and close-out to a Compliance Notices issued by the Dingle Port Office, i.e. following a previous FSAI audit in 2012 was confirmed by the audit team. The Compliance Notice had also been amended to include additional corrective action measures to be undertaken by the food business operator after a follow-up inspection by the SFPOs from the Dingle Port Office in 2012, which identified additional deficiencies
- One Closure Order had been issued in 2012 following the food business operator's breach of a signed voluntary closure and the view of the Dingle Port Office that the food business operator's operation and activities posed a risk to public health. The food business operator had been the subject of a food incident in 2012. The Closure Order was still in place at the time of the FSAI audit

Enforcement action taken within the Dunmore East Port Office:

- The audit team verified that three Compliance Notices had been issued during 2012 and one in 2013. The 2013 Compliance Notice was also the subject of a food safety incident and enforcement was still active at the time of the audit. Consequently, it was not reviewed in detail by the audit team. A Prohibition Order had also been issued in 2012, for harvesting of oysters from an unclassified area

Enforcement action taken within the Killybegs Port Office:

- The audit team verified that two Compliance Notices had been issued during 2012 and one in 2013, at the time of the FSAI audit. One Improvement Notice had also been issued in 2012

As a result of FSAI audit findings:

In the case of one harvester supplying live bivalve molluscs, i.e. whole scallops, who was visited during the course of the FSAI audit, numerous non-compliances were observed on the day of the audit, including the illegal placing of whole scallops on the market. Appropriate enforcement action was taken on the day of the audit by the Killybegs Port Office. The food business operator had not been formally inspected previously by the SFPA.

- A Prohibition Order was issued to the food business operator under the FSAI Act by the SFPA ordering the recall and destruction of whole scallops.
- A Compliance Notice was issued to the food business operator under S.I. No. 432/2009 directing them to cease from harvesting and placing on the market of scallops until such time that the food business operator can demonstrate compliance with the documentary requirements of Annex III, Section VII, Chapter I of Regulation (EC) No 853/2004
- A Compliance Notice was issued to another food business operator under S.I. No. 432/2009, directing that all scallops dispatched from a certain production area are traced and withdrawn/recalled from the market without delay for the receipt of these products without a completed gatherer's registration document and supplied for sale. The food business operator was further instructed to cease distribution of live bivalve molluscs until such time that compliance with the documentary requirements as set out in Regulation (EC) No 853/2004 Annex III, Section VII could be demonstrated.

A number of Rapid Alerts and Food Incidents in 2011 and 2012 falling within the scope of the audit were reviewed. In general, the audit team was satisfied that detailed investigations and follow-up had been carried out.

In relation to food complaints, these were provided to the FSAI audit team by SFPA headquarters, i.e. for 2012-13. The audit team was satisfied that in general, these had been adequately followed up and closed out.

4.7 Approval of Establishments

Article 31 of Regulation (EC) No 882/2004: Article 4 of Regulation (EC) No. 853/2204

Live bivalve molluscs establishments are required to be approved in order to meet the requirements of Regulations (EC) 853/2004 and 882/2004 and in accordance with SFPA approval processes.

The audit team observed as part of the audit of the establishment files within the Dingle Port Office, that while approvals at the time of the audit were in many cases, reflective of live bivalve molluscs activities and operations, others were identified where this was not the situation. For example:

Findings in relation to the approval of establishments within the Dunmore East Port Office:

- In the case of one food business operator, the SFPA approval was not reflective of the activities performed, i.e. food business operator does not carry out frozen storage
- In the case of another food business operator, the SFPA approval was not reflective of the activities performed. The food business operator was approved to carry out purification of razor clams, whereas in fact purging, i.e. conditioning, was being performed. This discrepancy was communicated by the Dunmore East Port Office to SFPA headquarters, but was not amended by the SFPA at central level. An amended approval certificate was provided to the audit prior to the closing meeting, which addressed this discrepancy

Findings in relation to the approval of establishments within the Dingle Port Office:

- In the case of two other food business operators, they had been approved for dispatch of live bivalve molluscs, which had also been taken into account as part of their risk categorisation. However, the audit team was informed that these activities are not carried out in reality and consequently, did not reflect the food business operator's current scope of business operations at the time of the audit

In the case of the approvals reviewed within the Killybegs Port Office, in general, they reflected the actual activities and operations performed, and also related to the relevant species covered.

The audit team view is that a review of approvals should be carried out by the SFPA at central level.

4.8 Staff Performing Official Controls

Article 6 of Regulation (EC) No 882/2204 requires that the competent authority shall ensure that all of its staff performing official controls receives for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. Details of training of SFPA staff which took place in 2010, 2011 and 2012 and relevant to the performance of official controls falling within the scope of the FSAI audit was provided by the Food Safety Unit at SFPA headquarters. A detailed review of training was not carried out by the FSAI audit team.

5. FOOD BUSINESS OPERATOR CONTROLS PERFORMED IN ACCORDANCE WITH REGULATIONS (EC) Nos 178/2002, 852/2004 & 853/2004 and S.I. No.432/2009

As part of the FSAI audit, a number of food business operations were also selected for onsite verification that an effective control system is in place and for their compliance with food law.

Food business operations included live bivalve molluscs production areas, harvesters, samplers, purification, dispatch centres and processors.

5.1 Food Business Operator findings relating to Non-compliance(s) with Food Law, observed for the Dingle Port Office

Food Business Operator No. 1:

The food business operator is an approved establishment under Regulation (EC) No 853/2004, for the purification, dispatch and processing, i.e. cooking, of live bivalve molluscs. Products also included cooked and breaded products. Clams were also a component of the food business operator's approval but were not currently processed.

Non-compliances relating to Food Law:

The audit team verified that for at least five of the food business operators, registration documents examined, i.e. gatherer's documents, details of biotoxin status from the areas where the live bivalve molluscs had been harvested were missing, which was not in compliance with the requirements of Annex III; Section VII; Chapter 1; Point 4 of Regulation (EC) 853/2004³ (this information is important as it ensures that the production areas were open at time of harvesting and that biotoxin levels were within safe/legal limits and forms part of the food business operator's food safety management system controls).

The audit team verified that the packing of some products in a modified atmosphere was not indicated on the product label, i.e. Packaged in a protective atmosphere, which was not in compliance with the requirements of Annex I, of Directive 2008/5/EC.⁴

Certain additional findings in relation to the food business operator's operations and activities were not in full conformity with the SFPA guidance document for inspecting live bivalve molluscs purification centres. These were outlined in the individual report to the Dingle Port Office.

Food Business Operator No. 2:

The food business operator is a harvester/gatherer of oysters and is also an industry sampler as part of the biotoxin monitoring programme.

³ SFPA Response: The food business operator now ensures all incoming live bivalve molluscs are accompanied by a fully completed Shellfish Registration Document. Any incoming live bivalve molluscs accompanied by incomplete documentation are rejected.

⁴ SFPA Response: The label has been amended to indicate that the product is packed in a modified atmosphere.

Non-compliances relating to Food Law:

No non-compliances relating to food law were observed on the day of the audit.

5.2 Food business operator findings relating to Non-compliance(s) with Food Law, observed for the Dunmore East Port Office

Food Business Operator No. 3:

The food business operator is a harvester/gatherer of oysters.

Non-compliances relating to Food Law:

- Shellfish registration (gatherers) documents were not always being fully completed, e.g. Harvest Location Code or biotoxin status were missing, which was not in compliance with the requirements of Regulation (EC) 853/2004; Annex III; Section VII; Chapter I; Point 4 (this information is important as it ensures that the production areas were open at time of harvesting and that biotoxin levels were within safe/legal limits and forms part of the food business operator's controls)
- The food business operator informed the audit team that they only check the production areas status once, i.e. at the start of harvesting. The audit team was informed that the food business operator no longer checks the status of the production area itself and assumes that the bay remains open until told otherwise. The audit team's view is that food business operators are required to take responsibility for the harvesting of live bivalve molluscs and to remain vigilant to changing toxicity levels, in order to ensure that product placed on the market is safe and within specification. Consequently, the audit team's view is that the food business operator was not in full compliance with the requirements of Regulation (EC) 853/2004; Annex III; Section VII; Chapter II A; Point 6, of Regulation (EC) 853/2004, Annex III; Section VII; Chapter V; Point 2, and Chapter II, Article 3, of Regulation (EC) 852/2004
- The audit team observed 20kg bags of oysters on pallets which were not clearly labelled/identified, in order to facilitate their traceability, which did not fully comply with the requirements of Annex III; Section VII; Chapter VII; Points 1 and 2 of Regulation (EC) 853/2004

Food Business Operator No. 4:

The food business operator is a Regulation (EC) No 853/2004 approved establishment for the following activities: grading, shucking, chilled and frozen storage and distribution, relating to the following species: whitefish and scallops.

Non-compliances relating to Food Law:

- The audit team observed a lack of traceability relating to a number of pallets of scallops landed from different boats which were not identified by the food business operator in its chilled storage area which did not comply with the requirements of Regulation (EC) 178/2002; Article 18; Point 2
- Some structural issues were observed, including:
 - A potential pest entry point around the door, i.e. where shucking was taking place, which was not in compliance with Regulation (EC) 852/2004; Annex II; Chapter I; Point 2(c)
 - In the older part of the premises, adjacent to the shucking area was in a poor condition with flaking paint on the walls and ceiling, evident, i.e. - which was not in compliance with Regulation (EC) 852/2004; Annex II; Chapter I; Point 1 (b)

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- Certain weaknesses were identified in the food business operator's food safety management system which did not comply with the requirements of Article 5 of Regulation (EC) 852/2004, for example:
 - The scallop shucking process was not identified by the food business operator as a (CCP). The supply of whole, live scallops is not captured in the food business operator's HACCP system
 - Analysis of scallops for ASP, i.e. the monitoring of relevant biotoxins by the food business operator as part of their own checks, was not being carried out for each batch as part of the food business operator's HACCP plan
- Whole, live scallops were being dispatched to another Member State without biotoxin analysis or an indication of biotoxin status on the shellfish registration (gatherers) documents. The audit team's view is that this was not in accordance with the requirements of Annex III; Section VII; Chapter I; Point 4a (iv); Chapter 5; Point 2; Chapter IX; Point 1 of Regulation (EC) 853/2004

SFPA guidance was issued as a result of this audit finding following a meeting with the FSAI and the SFPA.

The food business operator also owned a number of vessels for harvesting scallops and also supplied the live bivalve mollusc establishment.

- For one vessel, a discrepancy was observed for harvesting location/coordinates declared on the live bivalve molluscs registration, i.e. gatherer's document, and the electronic reporting systems (ERS) logbook which is required to accurately record their compliance with fishery quota legislation. This was not in accordance with the requirements Annex III; Section VII; Chapter I; Point 4a of Regulation (EC) 853/2004.
- For another vessel, incorrect weights for scallops were observed, i.e. discrepancy between ERS logbook and the shellfish registration, i.e. gatherer's, document. This was not in accordance with the requirements Annex III; Section VII; Chapter I; Point 4a of Regulation (EC) 853/2004.
- The food business operator had no results on file in relation to compliance with the Articles 3 and 4 of Regulation (EC) 2073/2005. The food business operator informed the audit team that testing for compliance with this Regulation had only begun in June 2013 and the food business operator was awaiting test results.

Food Business Operator No. 5:

The food business operator is a Regulation (EC) No 853/2004 approved establishment for the following activities: glazing, chilling and frozen storage, wrapping and packaging, live bivalve molluscs purification of razor clams, shucking and shelling for the following species: demersal, pelagic, nephrops and live bivalve molluscs (including scallops).

Non-compliances relating to Food Law:

- The food business operator's approval includes live bivalve molluscs purification of razor clams. However, the food business operator informed the audit team that it had informed the SFPA that purification doesn't take place at the premises but rather purging and the approval certificate should be amended. This was not in accordance with the requirements of Regulation (EC) 853/2004; Article 4. The audit team was provided with an amended approval certificate at the closing meeting, which addressed this finding (see Section 4.7 of this report for more details)
- Microbiological analysis performed by the food business operator included testing of certain live bivalve molluscs, i.e. razor clams, for *Salmonella* and *E. coli*, which was not in accordance with the requirements of Articles 3 and 4 of Regulation (EC) No 2073/2005⁵

⁵ SFPA Response: The SFPA has stated in response to this finding that the lab has been informed that five separate tests are to be carried out on the same sample in line with the requirements of Regulation (EC) No 2073/2005

5.3 Food Business Operator findings relating to Non-compliance(s) with Food Law, observed for the Killybegs Port Office

Food Business Operator No. 6:

The food business operator is a harvester/gatherer of oysters. The food business operator is a Regulation (EC) No 853/2004 approved establishment for the following activities: purification, dispatch and processing of live bivalve molluscs, i.e. mussels and oysters. The food business operator is also an industry sampler and takes samples as part of the biotoxin monitoring programme.

Non-compliances relating to Food Law:

- In relation to food business operator validation of their live bivalve molluscs purification system, the following was observed:
 - Mussels were not being tested for *Salmonella*
 - Oysters were not being tested for *E. coli* and *Salmonella*
 - Purification tanks were not identified in the results provided by the food business operator for *E. coli* testing of musselsThis was not in accordance with the requirements of Article 4; Point 3(a) of Regulation (EC) No 852/2004 and Article 3; Point 1 and Article 4; Point 1 of Regulation (EC) No 2073/2005.
- There were a number of structural issues with the premises including:
 - Major pest entry point, i.e. under the modified truck container, which housed the food business operator's purification tanks
 - No fly guard was present on the door from the processing area to the yard
 - A minor pest entry points was observed where the roof meets the walls, in the food business operator's purification plantwhich was not in accordance with the requirements of Annex II; Chapter I; Point 2(c) of Regulation (EC) No. 852/2004
- Seawater used in purification is abstracted by the food business operator in close proximity to a commercial pier and transported to the food business operator premises in 1,000 litre containers. No microbiological testing of this sea water is performed either pre- or post-UV treatment by the food business operator, which was not in accordance with the requirements of Annex II; Chapter VII; Point 1(b) of Regulation (EC) No. 852/2004
- No records of temperature checks of refrigerated transport used for delivery of products by the food business operator were kept or made available to the audit team, which was not in accordance with the requirements of Annex II; Chapter IV; Point 7 Regulation (EC) No 852/2004.
- No evidence of staff training was held on file by the food business operator, which was not in accordance with the requirements of Annex II; Chapter XII; Points 1 & 2 of Regulation (EC) No 852/2004.
- No testing of the potable water supply is performed by the food business operator which was not in accordance with the requirements of the European Communities (Drinking Water) (No. 2) Regulations 2007 - S.I. No. 278/2007

Certain additional findings in relation to the food business operator operations and activities were not in full conformity with the SFPA guidance document for inspecting live bivalve mollusc purification centres. These were outlined in the individual report to the Dingle Port Office.

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Food Business Operator No. 7:

The food business operator is a grower, harvester and supplier of scallops.

A significant level of non-compliance was observed for this food business operator on the day of the audit.

- A Prohibition Order was issued to the food business operator under the FSAI Act by the SFPA, ordering the recall and destruction of whole scallops.
- A Compliance Notice was issued to the food business operator under S.I. No. 432/2009 directing them to cease from harvesting and placing on the market scallops until such time that the food business operator can demonstrate compliance with the documentary requirements of Annex III, Section VII, Chapter. I of Regulation (EC) No. 853/2004.⁶
- A Compliance Notice was issued to another food business operator dispatching live bivalve molluscs under S.I. No.432/2009, directing that all scallops harvested from a production area are traced and withdrawn/recalled from the market⁷ without delay for the receipt of these products without a completed gatherer's registration document, and supplied for sale. The food business operator was further instructed to cease distribution of live bivalve molluscs until such time that compliance with the documentary requirements as set out in Regulation (EC) No 853/2004 Annex III, Section VII could be demonstrated.

Appropriate enforcement action was taken on the day of the audit by the Killybegs Port Office. The food business operator had not been formally inspected previously by the SFPA (see also Section 4.6 of this report).

6. POSITIVE PRACTICES OBSERVED DURING THE AUDIT

- Detailed information/instructions had been developed by the Killybegs Port Office, i.e. which included maps of sampling points and directions for SFPOs to get to sampling point locations.
- Detailed local instructions within the Dingle Port Office have been developed to assist industry samplers with the taking of Biotoxin/Phytoplankton samples in order to supplement existing guidance as part of the National Biotoxin Monitoring Programme
- In relation to elevated microbiological results, the audit team verified that there was good follow-up and investigation by the Killybegs Port Office for possible reasons of contamination and retesting of samples. Follow-up sampling in relation to elevated results was in general, carried out by the Killybegs Port Office.
- [SFPA Guidance](#) was introduced during the course of the FSAI audit in order to strengthen controls around harvesting and dispatch of scallops and completion of gatherer's registration documents.

⁶ SFPA Response: This Compliance Note has since been lifted by the SFPA

⁷ SFPA Response: Follow up inspections as part of the supervised recall/withdrawal of product confirmed that no product remained on the market for human consumption

7. CONCLUSIONS

The audit team confirmed that there was a structured and well organised approach for the prioritisation, planning, and coordination of SFPA official controls and in general, good level of communication was noted between the SFPA central and regional levels.

Monitoring of the delivery of SFPA official control activities was being carried out principally by Food Safety Unit staff at central level. Evidence of this monitoring was provided in the form of communications issued to port offices in order to prompt completion of quarterly returns (official controls) in line with the requirements of the Food Safety Control Plan. A certain level of monitoring also takes place at regional level but could not be considered as fully effective.

Internal audits for the assessment of the performance of official controls within the SFPA in order to comply with the requirements of Article 4.6 of Regulation (EC) No 882/2004, were not being conducted.

At the time of the FSAI audit, SFPA headquarters informed the audit team that it was in the process of evaluating how best to meet the 'effectiveness' and 'internal audit' requirements of Regulation (EC) No 882/2004. Following a tendering process, external consultancy had been commissioned by the SFPA to assist with their review of effectiveness, which had not been fully completed at the time of the FSAI audit. A report however, was submitted to the FSAI post audit, where actions points for improvement were identified as a result of this review, and where the next steps were being considered by the SFPA management.

Consequently, a formalised approach to review the effectiveness of official controls, although initiated, was not in place at the time of the audit, and SFPA procedures could not be considered as meeting with the requirements of Article 8.3 of Regulation (EC) No 882/2004. A system of internal audits for the assessment of the performance of official controls within the SFPA was not in place in order to comply with the requirements of Article 4.6 of Regulation (EC) No 882/2004.

The findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across all regions.

8. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings requiring corrective action are listed in the corrective action plan.

These should also be addressed by referencing the results of the FSAI close-out audit to FVO Mission DG (SANCO)/2011-6007, and ultimately will likely need to take account of the recommendations from the FVO Mission Report DG (SANCO) 2013 – 6674, when published.

APPENDIX 1: FSAI CLOSE-OUT AUDIT REPORT IN RELATION TO FVO MISSION DG (SANCO) 2011-6007

A close-out audit was also performed by the FSAI as a follow up to *FVO Mission DG (SANCO)/ 2011-6007, (Governing the Production and Placing on the Market of Bivalve Molluscs)*.

This close-out audit took place in tandem with the general audit of SFPA official controls, i.e. as covered in this report, as part of the FSAI audit programme for 2013.

In relation to follow-up to the FVO live bivalve molluscs audit in 2011, i.e. DG (SANCO) 2011-6007, the audit team confirmed that progress had been made with closing out certain recommendations, while in other cases, they were either still in progress and/or remained open at the time of the FSAI audit. A summary of FVO recommendations and their status, i.e. as a result of FSAI audit findings, is provided in Table 1 of this report.

For the basis of the audit viewpoints outlined in Table 1, refer to the FSAI close-out audit report for further information.

[FSAI Audit Report on Close-out to Mission DG \(SANCO\)/ 2011-6007](#)

Ultimately, the overall recommendation status determination for each of the recommendations, i.e. 1-29, and their follow-up status will be determined when the final FVO Mission Report DG (SANCO) 2013 – 6674, is published, which had not yet been completed at the time of writing this report.

The close-out of audit findings will likely need to take into account any new recommendations and/or corrective action requirements arising from FVO Mission Report DG (SANCO) 2013 – 6674.

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Table 1: Summary of FVO Recommendations and their Status

No.	FVO Mission DG (SANCO) 2011-6007	FVO re-assessment (July 2012)	Reviewed in CP/GFA DG (SANCO) 2012-6418	DG (SANCO) 2012-6418 Closing meeting	DG (SANCO) 2012-6418 Draft Report	DG (SANCO) 2012-6418 Final Report	FSAI FVO Close-out Audit Report 2013 Status of Recommendation
1	Un-satisfactory	Satisfactory	✓	In Progress	In Progress	In Progress	In Progress To be complete by 2015
2	Un-satisfactory	Satisfactory	✓	Action Still Required	Action Still Required	Action Still Required	Progress Made
3	Un-satisfactory	Satisfactory	✓	In Progress	In Progress	In Progress	Progress Made
4	Satisfactory	Satisfactory	✓	Action Taken	In Progress	In Progress	In Progress FSAI Corrective Action Plan No. 3*
5	Satisfactory	Satisfactory	-	-	-	-	In Progress FSAI Corrective Action Plan No. 3*
6	Un-satisfactory	Un-satisfactory	✓	Action Still Required	Action Still Required	Action Still Required	Not reviewed
7	Un-satisfactory	Satisfactory	✓	In Progress	Action Still Required	Action Still Required	In Progress FSAI Corrective Action Plan No. 4*
8	Un-satisfactory	Satisfactory	✓	Action Still Required	In Progress	In Progress	In Progress FSAI Corrective Action Plan No 11*
9	Un-satisfactory	Un-satisfactory	✓	Action Still Required	Action Still Required	Action Still Required	In Progress FSAI Corrective

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No.	FVO Mission DG (SANCO) 2011-6007	FVO re-assessment (July 2012)	Reviewed in CP/GFA DG (SANCO) 2012-6418	DG (SANCO) 2012-6418 Closing meeting	DG (SANCO) 2012-6418 Draft Report	DG (SANCO) 2012-6418 Final Report	FSAI FVO Close-out Audit Report 2013 Status of Recommendation
							Action Plan No 11*
10	Un-satisfactory	Satisfactory	✓	In Progress	Action Still Required	Action Still Required	Not reviewed
11	Un-satisfactory	Satisfactory	✓	Action Still Required	Action Still Required	Action Still Required	Not reviewed
12	Un-satisfactory	Satisfactory	✓	In Progress	Action Still Required	Action Still Required	Satisfactory
13	Un-satisfactory	Satisfactory	✓	In Progress	In Progress	Action Taken	In Progress FSAI Corrective Action Plan No 11*
14	Un-satisfactory	Satisfactory	✓	In Progress	Action Taken	Action Taken	Action Taken ¹
15	Satisfactory	Satisfactory	✓	Action Taken	Action Taken	Action Taken	Action Taken ¹
16	Satisfactory	Satisfactory	-	-	-	-	Satisfactory
17	Satisfactory	Satisfactory	-	-	-	-	Satisfactory
18	Satisfactory	Satisfactory	-	-	-	-	Not reviewed
19	Satisfactory	Satisfactory	-	-	-	-	Not reviewed
20	Satisfactory	Satisfactory	-	-	-	-	Not reviewed
21	Un-satisfactory	Satisfactory	-	-	-	-	In Progress FSAI Corrective Action Plan No. 12 & 13*

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No.	FVO Mission DG (SANCO) 2011-6007	FVO re-assessment (July 2012)	Reviewed in CP/GFA DG (SANCO) 2012-6418	DG (SANCO) 2012-6418 Closing meeting	DG (SANCO) 2012-6418 Draft Report	DG (SANCO) 2012-6418 Final Report	FSAI FVO Close-out Audit Report 2013 Status of Recommendation
22	Satisfactory	Satisfactory	-	-	-	-	In Progress FSAI Corrective Action Plan No. 9 – 16*
23	Satisfactory	Satisfactory	✓	Action Taken	Action Taken	Action Taken	In Progress FSAI Corrective Action Plan No. 7*
24	Satisfactory	Satisfactory					Satisfactory
25	Satisfactory	Satisfactory	✓	Action Taken	Action Taken	In Progress	Satisfactory
26	Un-satisfactory	Satisfactory	-	-	-	-	Satisfactory
27	Satisfactory	Satisfactory	-	-	-	-	In Progress FSAI Corrective Action Plan No 21*
28	Satisfactory	Satisfactory	-	-	-	-	In Progress FSAI Corrective Action Plan No 17*
29	Un-satisfactory	Satisfactory	-	-	-	-	Satisfactory

Note 1: The CP/GFA Mission had concluded that action had been taken for this recommendation

Note 2: Recommendations 19 & 20 were not reviewed as they related to the Marine Institute which was outside the scope of the audit

* [FSAI Corrective Action Plan](#)



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