

AUDIT
REPORT

Summary FSAI Close-out
Audit Report in relation to
FVO Mission DG (SANCO)
2011-6007 governing the
Production and Placing
on the Market of Bivalve
Molluscs

JULY 2014



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1. GLOSSARY

FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
SFPA	Sea-Fisheries Protection Authority

2. EXECUTIVE SUMMARY

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

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.

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. The FSAI carried out an audit of the Sea-Fisheries Protection Authority (SFPA) in order to verify the effectiveness and appropriateness of their official controls in relation to biotoxin and microbiological monitoring of live bivalve molluscs and selected a number of corrective actions from the FVO Live Bivalve Molluscs Mission 2011 (DG (SANCO) 2011-6007) in order to address the report recommendations, and to verify whether these had been adequately implemented and were effective.

The audit was carried out at central, regional and local levels of the organisation. A number of food business operations were also selected for on-site verification that effective control systems are in place.

The FVO close-out audit was carried out in tandem with a general audit of SFPA official controls in relation to biotoxin and microbiological monitoring of live bivalve molluscs ([FSAI Audit reference 03-2013-SFPA](#)).

Both audit projects were completed as part of the FSAI audit programme for 2013. Audit findings requiring corrective action, i.e. from both projects, have been combined into one [FSAI corrective action plan](#) in order to facilitate the management of their close-out.

In relation to follow-up to the FVO live bivalve mollusc 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 considered to be still in progress, i.e. remained open. Recommendations are given a disposition of 'in progress' by FSAI audit team, where additional audit findings requiring corrective action were identified in the course of the FSAI audit, and/or where insufficient evidence was present in order to confirm that they had been fully addressed at the time of the FSAI audit. A summary of the status of the FVO recommendations as a result of FSAI audit findings, is provided in Table 1 of this report.

Ultimately, the close-out of the recommendations in relation to the FVO live bivalve molluscs audit in 2011, i.e. DG (SANCO) 2011-6007 will need to be considered in the context of any additional/revised recommendations and their corrective action(s) arising from FVO Mission Report DG (SANCO) 2013 – 6674, when it is published, which had not yet been fully completed at the time of writing this report.

3. INTRODUCTION

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

The FSAI audit team commenced with an audit at SFPA central level in the SFPA headquarters, Clonakilty, in order to assess the status of the close-out of FVO mission findings including corrective actions and recommendations. This was followed by audits in three port office regions in order to confirm that follow-up had been implemented and was effective. As part of the assessment of official controls, a number of food business operators and industry samplers were selected as confirmation of the effective implementation of official controls. Food business operations to be covered included live bivalve molluscs producers/harvesters, samplers, purification and dispatch centres and processors.

This FVO close-out audit took place in tandem with the FSAI audit of SFPA official controls in relation to biotoxin and microbiological monitoring of live bivalve molluscs, as part of the FSAI audit programme for 2013, which included a wider remit than just the follow-up in relation to the 2011 [FVO Live Bivalve Molluscs Mission \(DG \(SANCO\) 2011-6007\)](#)

3.1 Audit Objective

The objective of the audit was to select certain recommendations and corrective actions from the 2011 FVO Live Bivalve Molluscs Mission (DG (SANCO) 2011-6007) and to verify whether these have been adequately implemented and were effective.

3.2 Audit Scope

The FSAI audit included an assessment of SFPA official controls in relation to Biotoxin and Microbiological Monitoring of Live Bivalve Molluscs and selected a number of corrective actions from the 2011 FVO Live Bivalve Molluscs Mission (DG (SANCO) 2011-6007) in order to address the report recommendations, and to verify whether these had been adequately implemented and were effective.

The scope of SFPA activities covered official controls of live bivalve molluscs, i.e. filter feeding Lamellibranch molluscs which including oysters, mussels, clams, cockles, scallops and products which contained these.

During the audit, the audit team verified that the official agency was complying with the audit criteria against which the audit was carried out (see Section 4.3).

3.3 Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit included:

- FVO Live Bivalve Molluscs Mission (DG (SANCO) 2011-6007)
- FVO General Follow-up Audit/Country Profile Mission (DG(SANCO) 2012-6418)
- Corrective action updates, letters and other communications from the FVO mission teams and their assessment in relation to the 2011 FVO Live Bivalve Molluscs Mission (DG (SANCO) 2011-6007) and the General Follow-up Mission (CP/GFA) DG(SANCO) 2012-6418
- [Food Safety Authority of Ireland Act, 1998](#) (No 29 of 1998), as amended
- [FSAI Service Contract with SFPA](#)
- National Control Plan for Ireland 2012-2016 (MANCP)
- SFPA Documented Procedures
- SFPA Food Safety Control Plan (2010, 2011 & 2012)
- [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

4. SUMMARY OF THE IMPLEMENTATION OF FVO RECOMMENDATIONS AND THEIR CLOSE-OUT STATUS

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*

Summary FSAI Close-out Audit Report in relation to FVO Mission DG (SANCO) 2011-6007 governing the Production and Placing on the Market of Bivalve Molluscs

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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
9	Un-satisfactory	Un-satisfactory	✓	Action Still Required	Action Still Required	Action Still Required	In Progress FSAI Corrective 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 Plans No.

Summary FSAI Close-out Audit Report in relation to FVO Mission DG (SANCO) 2011-6007 governing the Production and Placing on the Market of Bivalve Molluscs

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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
							<u>12 & 13*</u>
22	Satisfactory	Satisfactory	-	-	-	-	In Progress <u>FSAI Corrective Action Plans No. 9 – 16*</u>
23	Satisfactory	Satisfactory	✓	Action Taken	Action Taken	Action Taken	In Progress <u>FSAI Corrective Action Plan No. 7*</u>
24	Satisfactory	Satisfactory					Satisfactory
25	Satisfactory	Satisfactory	✓	Action Taken	Action Taken	In Progress	Satisfactory
26	Un- satisfactory	Satisfactory	-	-	-	-	Satisfactory
27	Satisfactory	Satisfactory	-	-	-	-	In Progress <u>FSAI Corrective Action Plan No 21*</u>
28	Satisfactory	Satisfactory	-	-	-	-	In Progress <u>FSAI Corrective Action Plan No 17*</u>
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](#)

5. DETAILED REVIEW OF THE IMPLEMENTATION OF FVO RECOMMENDATIONS AND THEIR CLOSE-OUT STATUS

Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref No. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-1 To comply with the requirements of Point A.6. of Chapter II of Annex II to Regulation (EC) No 854/2004 regarding sanitary surveys in newly classified areas.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) Irish authorities will carry out sanitary surveys in newly classified areas</p> <p>FVO Response: = <u>Unsatisfactory</u> (24th Feb. 2012) Please indicate if a sanitary survey is going to be carried out in the production areas that were classified between 1 January 2006 and the date when the Action Plan was submitted to the FVO.</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = <u>Satisfactory</u> (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>In-Progress</u> (August 2013)</p> <p>Response by Irish competent authorities (Sept. 2013) Updated action plan for FVO Mission 2013 – 6674 <u>Sanitary Surveys:</u> Since the FVO Mission, sanitary surveys have been completed in the two areas identified during the DG (SANCO) 2011-6007 Mission (copies available on request).</p> <p>A review of all shellfish production area maps in Ireland has been completed during Quarter 1 of 2013, and a meeting with the Microbiological Department in the National Reference Laboratory (the Marine Institute) to review Ireland’s sanitary survey requirements took place in November 2012.</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>The CP/GFA FVO Mission Report DG(SANCO) 2012- 6418 recognised follow up corrective action measures taken by Irish competent authorities (August 2013) .</p> <p>A programme of sanitary surveys is scheduled to be completed by January 2015 with priority being given to newly classified areas.</p> <p>The FSAI audit team confirmed that a template for conducting sanitary surveys had been developed and had been trialled</p> <p>The audit team were provided with the latest updated Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas in August/September 2013.</p>

	<p>Ireland has developed a template for conducting sanitary surveys; this template has been trialled. In accordance with EURL recommendation Ireland will strive to complete (within available resources) sanitary surveys in all existing production areas by January 2015. Clearly, priority will be given to newly classified areas.</p>	<p>According to FVO Draft Report (DG-SANCO 2013-6674) – this recommendation has been addressed.</p> <p>The audit team’s view is that this recommendation will be addressed on completion of sanitary surveys in 2015, and consequently, it was considered as in progress at the time of the audit.</p>
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-2 To comply with the requirements of Point A.3. of Chapter II of Annex II to Regulation (EC) No 854/2004 regarding compliance with the health standards described in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 when classifying and maintaining the classification of Class A production areas.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) Letter to FVO from FSAI (3rd Nov. 2011) Letter to FVO from SFPA (3rd Nov. 2011)</p> <p>FVO Response: = <u>Unsatisfactory</u> (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = <u>Satisfactory</u> (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>Action Still Required</u> (August 2013)</p> <p>The criteria used for the classification and maintaining of “A production areas” in the Code of Practice for live bivalve molluscs were improved (from 4,600 MPN/100g before to 1,000 MPN <i>E. coli</i>/100g) but are still non-compliant with the limits of health standards (230 MPN <i>E. coli</i>/100g) under this recommendation. (See also the limits under recommendation number 1 above). Therefore, certain progress was noted but the requirements under this recommendation have not yet been complied with.</p> <p>Response by Irish competent authorities (Sept. 2013) Updated action plan for FVO Mission 2013 – 6674 Since the Live Bivalve Mollusc Mission in May 2011, DG SANCO (2011-6007), Ireland has made changes to its classification system. For the 2012 Review of Classified Bivalve Mollusc Production Areas in Ireland a tolerance limit of 1000MPN <i>E. coli</i>/100grams was introduced in the 10% allowance for A classified areas.</p>	<p>FSAI Audit Conclusion: Progress Made</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>The CP/GFA FVO Mission Report DG(SANCO) 2012- 6418 recognised follow up corrective action measures taken by Irish competent authorities (August 2013) – see below .</p> <p>FVO Mission Report DG(SANCO) 2012- 6418 : Ireland has brought its system of classification more in line with the current EU requirements.</p> <p>The FSAI audit team’s view is that progress has been made in addressing this recommendation.</p> <p>The final disposition as to whether this recommendation has been satisfactorily addressed, is expected in the final published FVO Report to Mission DG(SANCO)2013-6674</p>

	<p>The EU legal requirements in the area of shellfish microbiological classification are under review and there has been active discussion between the Commission and Member State (MS) on this issue.</p> <p>At the February 2013 meeting of the European Commission DG-Sanco Working Group on Live Bivalve Molluscs, discussions continued between the Commission and Member States on basis for awarding A classification. The Commission proposed along with a modification to Regulation (EC) No 2073/2005 for <i>E. coli</i> in live bivalve molluscs, a change to Regulation (EC) No 854/2004 stipulating the 'codex over time' approach to awarding A classification to production areas whereby a 20% allowance would be allowed for monthly samples to exceed 230 and still award A micro classification, but zero tolerance for any sample >700 when awarding A classification.</p> <p>Ireland, along with other Member States, has given strong support to urgently addressing in legislation the need for a 'tolerance' in A classification.</p> <p>At this meeting, proposed changes were agreed and are currently proceeding through normal comitology procedures. Ireland will await the outcome of this before making further changes to the classification system.</p>	
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment /Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-3 To ensure that the procedures implemented for preliminary and seasonal classification of production areas are in line with the recommendations given by the relevant EU reference laboratory.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish Competent Authorities (25th April 2012)</p> <p>FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= In Progress (August 2013)</p> <p>The Code of Practice for live bivalve molluscs was amended in right direction concerning the preliminary and seasonal classification of production areas. <u>Now the Code of practice concerning the preliminary and seasonal classification of production areas is in line with the recommendations given by the relevant EU reference laboratory.</u></p> <p>However concerning the seasonal classification, the competent authority in its reply before the GFA mentioned that:</p> <p>Ireland uses a minimum of three years data with 100% compliance with Point A.3 of Chapter II of Annex II to Regulation (EC) No 854/2004 regarding compliance with the health standards described in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 to show a clear seasonal trend when assigning a seasonal classification to a production area. The period of seasonal classification will have a minimum 1 x month 'shoulder period' of the higher classification prior to and after the seasonal classification to ensure that the seasonal classification accurately reflects the microbiological health</p>	<p>FSAI Audit Conclusion: Progress Made</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>The CP/GFA FVO Mission Report DG(SANCO) 2012- 6418 recognised follow up corrective action measures taken by Irish Competent Authorities (August 2013) – see below .</p> <p>FVO Mission Report DG(SANCO) 2012- 6418: The Code of Practice for live bivalve molluscs was amended and the practice concerning the preliminary and seasonal classification of production areas is in line with the recommendations given by the relevant EU reference laboratory.</p> <p>The audit team was provided with the latest updated Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas in August/September 2013.</p> <p>The FSAI audit team's view is that progress has been made in addressing this</p>

	<p>standards of the production area.</p> <p>The above statement is not in line with the Code of Practice which, e.g. has 2 years data (page 22)</p> <p>Therefore, <u>the competent authority will clarify how the Code of Practice will be in line with its comments</u> for seasonal classification and which the legal base of its comments is.</p> <p>Response by Irish competent authorities (Sept. 2013) Ireland is satisfied that the procedures implemented for preliminary and seasonal classification of production areas are in line with the recommendations given by the EU reference laboratory.</p> <p>Preliminary Classification For preliminary (provisional) classification of an area, at least 12 samples are taken from each identified sampling point not closer together than fortnightly. See following extract from current Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas.</p> <p>(Section 6.1.1): “The results of 12 samples taken not closer together than fortnightly should be assessed against the criteria given in the legislation (see Table1), and allowing for any anomalous results. After two years, a full classification should be determined on the basis of the criteria given in the legislation (see Table1) taking into account a minimum of 1 sample per month over a period of at least two years, and allowing for any anomalous results”.</p> <p>Seasonal Classification Seasonal classification is the classification of a production/harvesting area which allows for variation in the classification status of that area over a twelve month period. See following extract from current Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas.</p>	<p>recommendation The final disposition as to whether this recommendation has been satisfactorily addressed, is expected in the final published FVO Report to Mission DG(SANCO)2013-6674</p>
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	<p>(Section 6.1.4): At least 3 years' worth of data showing a clear seasonal trend of <i>E. coli</i> results is necessary to establish a seasonal classification. The minimum number of samples required will be 24 samples.</p> <p>The intended transition must be preceded by 2 months satisfactory sample results when changing from class C to B and 1 month satisfactory results when changing from class B to A, i.e. the historical results during this period must also conform to the better classification category. The minimum period to be considered for a seasonal classification will be three months. In addition to the transition period from one classification to another, the microbiological results obtained from the microbiological monitoring programme for the period under consideration for seasonal classification must be 100% compliant with the higher classification. Additionally, the overall % compliance from the three year dataset for the production area must be > 80% compliance with the higher classification. Reduced frequency (stable area) cannot be applied to production areas with a seasonal classification.</p>	
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
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<p>2011-6007-4 To guarantee that geographical distribution of the sampling points for microbiological monitoring of classified production areas ensure that the results of the analyses are as representative as possible for the area considered as required in Point B.2. of Chapter II of Annex II to Regulation (EC) No 854/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= In Progress (August 2013)</p> <p>The "Code of Practice on microbiological classification" was amended to reflect the requirements of Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.</p> <p>However, <u>there is no set up of a system for the worst case scenario for the different sampling points</u> and the competent authority will clarify how the regular intervals of sampling will be carried out as under 6.6. of the Code of Practice the required sampling is optional with the word "as necessary".</p> <p>Additionally, <u>this "Code of Practice on microbiological classification" does not specify how the competent authority guarantees that the geographical distribution of the sampling points for microbiological monitoring of classified production areas ensures that the results of the analyses are as representative as possible for the area considered. Therefore, the competent authority will provide the plans in order to explain for the sampling points to be reviewed and what is the procedure in order to be representative.</u></p>	<p>FSAI Audit Conclusion: In Progress Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418 and following the FSAI audit in 2013 in relation to this recommendation.</p> <p>The CP/GFA FVO Mission Report DG(SANCO) 2012- 6418 recognised follow up corrective action measures taken by Irish Competent Authorities (August 2013) – see below .</p> <p>FVO Mission Report DG(SANCO) 2012- 6418 : The "Code of Practice on microbiological classification" was amended to reflect the requirements of Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.</p> <p>During the audit, the FSAI audit team observed however, that in practice classification/Shellsan samples were often being taken from a number of different sampling locations within the production area, and did not correspond to the specific sample point grid reference, as detailed within the SFPA Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012)</p>

	<p>Response by Irish competent authorities (Sept. 2013) Code of Practice on microbiological classification: The Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas) was amended during Quarter 3 2012 and again most recently in September 2013.</p> <p>In this updated Code of Practice “Representative sampling point” is defined as follows: <i>A specified geographical location from which samples are taken to represent either a single, or several, wild bivalve mollusc beds or aquaculture sites. The representative sampling point should reflect the location at highest risk of faecal pollution within a classified production area</i></p> <p>See Section 2 of current Code of Practice: A Microbiological Sampling Plan will be maintained for all classified shellfish production areas and amended as necessary to record bivalve species, sample location code, position of sampling points and frequency of sampling. The sampling plan is the basis of the Microbiological Monitoring Programme of Classified Shellfish Production Areas, and the results from such programme are used in the annual review of classifications. The sampling plan must ensure that the results of the analysis carried out will be as representative as possible for the area considered.</p> <p>As part of the annual classification review, maps of production areas and their associated sampling locations will be reviewed and amended as necessary to ensure that the sampling locations are as representative as possible of the likely pollution sources entering the area.</p>	<p>Consequently this did not comply with the requirements of Point A. 6 (d) and B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004, Refer to FSAI Corrective Action Plan No.3</p> <p>The Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012) was amended during the course of the FSAI audit in response to this finding in order to more accurately reflect where microbiological samples are actually taken from within production areas. (Updated copy of the Code of Practice was provided to the audit team - 15th August 2013).</p> <p>Based on findings, the FSAI audit team’s view is that this recommendation was in progress at the time of the audit.</p>
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-5 To ensure that samples for microbiological monitoring of classified production areas are taken in the designated sampling 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.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012)</p> <p>Response by Irish competent authorities (Sept. 2013) The Irish authorities are confident that samples are sampled from the designated sampling points and will continue to do so. However, to further ensure this a communication was sent to all staff in March 2012 on the importance of taking samples from designated areas.</p> <p>See Section 2.1.4 of current Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas) which describes the selection of sampling points; the Code of Practice was amended during Quarter 3 2012 and again most recently in September 2013.</p> <p>The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	<p>FSAI Audit Conclusion: In Progress Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418 and following the FSAI audit in 2013 in relation to this recommendation.</p> <p>The CP/GFA FVO Mission Report DG(SANCO) 2012- 6418 recognised follow up corrective action measures taken by Irish Competent Authorities (August 2013) – see below .</p> <p>FVO Mission Report DG(SANCO) 2012- 6418 : The "Code of Practice on microbiological classification" was amended to reflect the requirements of Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004.</p> <p>During the audit, the FSAI audit team observed that in practice, e classification/ShellSan samples were often being taken from a number of different sampling locations within the production area, and did not correspond to the specific sample point grid reference, as detailed within the SFP Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012)</p> <p>Consequently this did not comply with the</p>

		<p>requirements of Point A. 6 (d) and B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004. Refer to FSAI Corrective Action Plan No.3</p> <p>The Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012) was amended during the course of the FSAI audit in response to this finding in order to more accurately reflect where microbiological samples are actually taken from within production areas (an updated copy of the Code of Practice was provided to the audit team - 15th August 2013).</p> <p>An assessment of whether these amendments were fully applied in practice in order to address the FSAI audit findings was not made by the audit team as they occurred, post on-site audit activities.</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>
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Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-6</p> <p>To ensure that the sampling frequency for toxins analysed in all species of mollusc are in line with Point B.5. of Chapter II of Annex II to Regulation (EC) No 854/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = <u>Unsatisfactory</u> (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = <u>Unsatisfactory</u> (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>Action Still Required</u> (August 2013)</p>	<p>FSAI Audit Conclusion: Not Reviewed</p> <p>This recommendation was not reviewed in detail by the FSAI audit team in 2013</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO) 2013-6674</p>

Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-7 To ensure that decisions according to EU legislation are taken where health standards for microbiological contamination are exceeded, as required in Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/2004, and that live bivalve molluscs exceeding EU microbiological limits are not placed on the market as required by Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>Action Still Required</u> (August 2013))</p> <p>Response by Irish competent authorities (Sept. 2013) Procedures for Out of Range Classification Results: The Irish authorities are satisfied that there is a robust system in place to respond to elevated <i>E. coli</i> results. All out of range classification results, i.e. those results above the upper limit for the classification of the area (Cat. A >230 MPN 100g⁻¹ Cat. B >4600 MPN 100g⁻¹ Cat. C > 46000 MPN 100g⁻¹) are investigated. The relevant producer/harvester is informed without delay of the out of range result.</p> <p>Investigations are carried out by the SFPA to establish potential risk to public health, manage any risks identified, and endeavour to establish the cause of out of range result. If any identified potential risk to public health is identified, the SFPA would verify that appropriate action has been taken by the producer to protect consumer health.</p>	<p>FSAI Audit Conclusion: In progress</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>During the FSAI audit in 2013, the audit team found that follow-up by the SFPA in relation to elevated <i>E. coli</i> results was inconsistent in the different port office regions visited, where in some cases follow-up samples took place, while in others, they did not.</p> <p>The FSAI confirmed that investigations were in general being carried out for all elevated levels including those above Cat. A >230 MPN 100g⁻¹ (in one case, this was found not to be the case where an investigation was not carried out which was not in accordance with SFPA procedures). Refer to FSAI Corrective Action Plan No.4</p> <p>In order to improve the consistency of follow up in relation to elevated micro results the current version of the Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012) was updated during the course of the FSAI audit, to</p>

	<p>To provide further clarification on how out of range classification results are investigated, the Shellsan Elevated Micro Result Report which is completed by the relevant local Sea-Fisheries Protection Authority for all out of range classification results, has been amended.</p> <p>The Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas was reviewed and revised during Quarter 3 2012 and again most recently in September 2013 to provide further clarification on investigation and follow up of out of range classification results and on measures taken if necessary to protect public health. (Reference: Section 6.4.1- Responding to out of range or elevated <i>E. coli</i> results from the monitoring programme).</p>	<p>provide clearer instruction to Sea Fisheries Protection Officers in dealing with out of specification results, particularly in class A areas. Harvesting operations should now cease until a follow up sample taken by SFPA indicates that <i>E. coli</i> levels are within range.</p> <p>This was deemed an important improvement to the Code of Practice by the FSAI audit team and confirms that progress has been taken by the SFPA in dealing with this recommendation.</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>
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Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-8</p> <p>To establish a control system comprising laboratory tests to verify food business operators' compliance with EU requirements for biotoxins and contaminants at all stages of production, processing and distribution as required by Point D.2. of Chapter II of Annex II to Regulation (EC) No 854/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = <u>Unsatisfactory</u> (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = <u>Satisfactory</u> (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>In Progress</u> (August 2013)</p> <p>Extract: The "Code of Practice on Biotoxin Monitoring" was amended and comprises an updated section on Official Control Sampling which includes the official sampling requirements:</p> <ul style="list-style-type: none"> • Shellfish from classified production areas are sampled on a periodic basis; • Scallops from approved food business operators are sampled on a quarterly basis; • Marine gastropods from approved food business operators are sampled a quarterly basis when in production; • Shellfish from purification and dispatch centres are sampled on a quarterly basis. <p>Therefore, certain progress was noted but not at all stages, not all environmental contaminants are covered and there is a different approach for scallops.</p> <p>The competent authority has not provided yet:</p> <ul style="list-style-type: none"> • The analytical plan for official laboratory tests to be taken in 2013 to verify food business operators' compliance with EU requirements for biotoxins and contaminants for the end product at all stages of production, processing and distribution as required by Point D.2. of Chapter II of Annex II to Regulation (EC) No 854/2004 and, • The results of this new analytical plan to date for biotoxins and contaminants. 	<p>FSAI Audit Conclusion: In progress</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>The audit team found that random sampling of certain production areas for biotoxins was taking place.</p> <p>The audit team confirmed that that there was a sampling plan to cover sampling for the presence of biotoxins at purification, dispatch and processing establishments.</p> <p>The audit team observed however, that in several cases, the quarterly sample frequency requirements were not being met for several establishments visited during the course of the FSAI audit. Refer to FSAI Corrective Action Plan No.11</p> <p>The FSAI audit team did not review requirements in relation to testing for environmental contaminants and compliance with the Shellfish water Directive and the Water Framework Directive (WFD).</p>

	<p>Response by Irish competent authorities (Sept. 2013) A programme of specific sampling is in place to ensure compliance with Point D.2. of Chapter II of Annex II to Regulation (EC) No 854/2004.</p> <p>Biotoxins: Harvesting Stage: SFPA officers randomly take live bivalve mollusc samples for biotoxin analysis at the harvesting stage instead of the assigned sampler/harvester. These samples are official control samples that go towards the national monitoring and are considered to be biotoxin verification samples to verify food business operator compliance.</p> <p>Establishments: During Quarter 4 of 2012, a programme of official sampling was implemented where samples of live bivalve mollusc were taken from establishments handling live bivalve molluscs. Results from this sampling programme were made available at the General Follow up Audit in December. This programme of official control testing has also been implemented during 2013. Results of analysis will be available if required, at upcoming Mission.</p> <p>Contaminants: The Marine Institute is the official agency carrying out monitoring of contaminants in bivalve molluscs.</p> <p>Harvesting Stage: Live bivalve molluscs (primarily mussel and oyster) are collected from shellfish growing waters around the Irish coast and samples are analysed for environmental contaminants, specifically trace metals, polychlorinated biphenyls (PCBs) and organochlorine pesticides (OCPs). This contributes to the requirements of the Shellfish Waters Directive (SWD - Directive 2006/113/EEC) and national food safety monitoring obligations. Concentrations of these contaminants are assessed against appropriate regulatory limits (Regulation (EC) No 1881/2006 as amended and SI 268 of 2006 implementing Directive 2006/113/EC). Shellfish samples from designated shellfish growing areas are collected by officers of the SFPA and also staff of the Marine Institute. Physico-chemical parameters and trace metals are also determined in water for designated sites as part the SWD/WFD programme. All samples are tested for nine trace metals including mercury, cadmium and lead. Selected samples are analysed for PCBs and OCPs, focussing on areas where these pollutants would be most likely</p>	<p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>
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	<p>found. More recently analysis of polyaromatic hydrocarbons (PAH) including benzo(a)pyrene has been included in testing. There are currently 64 designated shellfish growing waters.</p> <p>Dioxin and dioxin-like PCB surveillance is carried out by the Marine Institute in conjunction with the FSAI as part of occasional surveys for these parameters in seafood.</p> <p>More information on contaminant testing in shellfish is available in McGovern et al. (2012) (http://oar.marine.ie/handle/10793/706). More recent information on dioxins and other persistent organic pollutants is available in FSAI (2013) <i>Investigation into Levels of Dioxins, Furans, Polychlorinated Biphenyls and Brominated Flame Retardants in Fishery Products in Ireland</i> Monitoring & Surveillance Series. Food Safety Authority of Ireland, Dublin www.fsai.ie (FSAI/ Marine Institute).</p> <p>Establishments: The SFPA has scheduled monitoring programmes with three Public Analysts Labs. As part of this monitoring programme, samples of live bivalve molluscs are submitted for heavy metal analysis. During 2013, some samples of live bivalve molluscs have been submitted for heavy metal analysis.</p>	
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Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-9 To ensure that official controls on pectinidae verify compliance with: Point 2 of Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004 (regarding the classification of fishing grounds where data from official monitoring programmes enable the competent authority to do so), as required by Chapter III of Annex II to Regulation (EC) No 854/2004); and, the health standards laid down in Annex II, Section VII, Chapter V to Regulation (EC) No 853/2004, as required by Chapter III of Annex II to Regulation (EC) No 854/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish Competent Authorities (25th April 2012) FVO Response: = Unsatisfactory (27th July 2012)</p> <p>Response by Irish competent authorities – FSAI Letter (12th Sept. 2012) FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= Action Still Required (August 2013)</p> <p>Extract: The competent authority stated that :</p> <ul style="list-style-type: none"> • For pectinidae being harvested from a classification area, the product would take on the classification category of the species with the lowest classification status in the particular production area • The classification of pectinidae had been completed in 2012 and published on the SFPA website • A programme of official controls for pectinidae harvested outside production areas has been developed and incorporates official control/sampling at 2 processing establishments for domoic acid •The 'Code of Practice on Biotoxin Monitoring' was amended (ver. 2 January 2013) and comprises an updated section on Official Control - Sampling of Scallops which provides that" the whole scallops from approved food business operators should be sampled on a quarterly basis"; 	<p>FSAI Audit Conclusion: In Progress</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>The Irish competent authorities have communicated to the FVO Mission teams regarding pectinidae harvested from unclassified production areas</p> <p>At the time of the FSAI audit, SFPA controls on pectinidae were focussed principally at the processing establishment level.</p> <p>The Code of Practice for the Microbiological Monitoring of Bivalve Production Areas (Sept. 2013) has been amended to include the harvesting of pectinidae from classified production areas.</p> <p>http://www.sfpa.ie/SeafoodSafety/Shellfish/GuidanceDocuments.aspx</p> <p>During the FSAI audit in 2013, enforcement action was taken in relation to a harvester of pectinidae who placed whole scallops on the market without them being tested for biotoxins, i.e. in the Killybegs</p>

<ul style="list-style-type: none"> • The competent authority provided confirmation that the updated requirement was submitted to the SFPA staff (dated 04 December 2012); • The results of the sampling were not available at the time of the GFA in December 2012 but the competent authority committed to forward the results as soon as they became available but not yet received. <p>However,</p> <ul style="list-style-type: none"> • The 'Code of Practice on Microbiological Monitoring does not mention that "for pectinidae being harvested from a classification area, the product would take on the classification category of the species with the lowest classification status in the particular production area" • No programme of official controls for pectinidae was provided by the competent authority; • There is no monitoring for biotoxins concerning official controls and sampling at harvesting for pectinidae from wild areas • There is no monitoring of pectinidae for domoic acid at harvesting stage to ensure that the levels of acid domoic are below 20mg/kg • Sampling in processors is carried out in edible parts (adductor and gonads) after sucking (see also rec 2011-6007-8, 10 and 11) <p>Note: the competent authority provided the information that there is no fisheries auction hall in Ireland.</p> <p>In their response to the draft CP the Irish authorities provided the information that the relevant Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas will be updated to include the criteria for pectinidae harvested from classified production areas. This information is currently on the SFPA website.</p> <p>Concerning the official controls of Pectinidae, the competent authority stated that this recommendation, along with recommendation 10, refers to official controls of wild pectinidae at the harvesting stage. There is not a requirement in the legislation to carry out official controls at the harvesting stage. A programme of official controls has been</p>	<p>Port Office region. Appropriate enforcement action was taken against this harvester where both a Compliance Notice and Prohibition Order were served.</p> <p>In another instance, the FSAI audit team observed whole scallops were being dispatched to an approved processor in the UK and not via one of the five processing establishment in the Republic of Ireland (ROI).</p> <p>Following the identification of this finding during the FSAI audit, i.e. in the Dunmore East Port Office region, a strengthening of the requirements/information to be filled out in registration documents is now in place, where in particular, the gatherer's registration document now requires that the previously blank section on biotoxin status must be included "Testing Required" i.e. where scallops are sent for dispatch to an approved processing establishment.</p> <p>http://www.sfpa.ie/Portals/0/Food%20Safety/Notice%20to%20Trade%20on%20the%20Harvesting%20of%20Scallops.pdf</p> <p>Certain improvements have been made/proposed to deal with this recommendation and consequently the view of the FSAI audit team is that it is currently in progress,</p> <p>The audit team confirmed that a sampling plan</p>
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	<p>put in place for pectinidae harvested outside classified production areas. This programme is in accordance with Chapter III, Annex II of Regulation 854/2004 where official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. The proposed system of official controls was described at the time of the GFA in December along with some official control results of pectinidae taken from processing establishments. See extract from Control Plan 2013 provided. A broad classification criteria has been put in place for pectinidae harvested from production area i.e. All Scallops harvested within classified production areas are classified as B unless harvested within classified production areas where all other mollusc shellfish are classified of being class A where such scallops may be classified as A. The monitoring of marine biotoxins in pectinidae harvested from classified production areas will be brought in line with the current National Biotoxin Monitoring Programme for classified areas.</p> <p>Therefore, the competent authority has not provided yet the plan of official controls for 2013 on pectinidae from classified production areas and from wild areas and how it is intended to verify compliance for health standards (microbiological criteria, organoleptic characteristics and all marine biotoxins) in all stages from harvesting to dispatch centres and all processing establishments. The competent authority has not ensured that official controls on pectinidae verified compliance with the legal requirements under this recommendation.</p> <p>Response by Irish competent authorities (Sept. 2013) Classification of Pectinidae: In general, pectinidae are harvested outside production areas in Ireland. A broad classification criteria has been put in place for pectinidae harvested from production areas. It was decided by the competent authority that in the event of pectinidae being harvested from within a classification area, they would be classified as B unless harvested within classified production areas where all other mollusc shellfish are classified of being class A where such scallops may be classified as A (pending species specific classification).</p>	<p>was in place to cover sampling for the presence of biotoxins at purification, dispatch and processing establishments.</p> <p>The audit team observed however that in several cases the quarterly sample frequency requirement was not being fully met for several establishments visited during the FSAI audit</p> <p>Refer to FSAI Corrective Action Plan No.11</p> <p>Based on findings, the FSAI audit team’s view is that this recommendation was in progress at the time of the audit.</p>
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	<p>This classification system was implemented during Quarter 4 2012.</p> <p>Official controls by the competent authorities re: sampling at processors A programme of official controls has been put in place for pectinidae harvested outside classified production areas. This programme is in accordance with Chapter III, Annex II of Regulation 854/2004 where official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. The proposed system of official controls was described at the time of the General Follow up Audit in December along with some official control results of pectinidae taken from processing establishments. See extract from Control Plan 2013.</p> <p>The monitoring of marine biotoxins in pectinidae harvested from classified production areas will be brought in line with the current National Biotoxin Monitoring Programme for classified areas.</p>	
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<p>2011-6007-10 To ensure in particular that official controls on pectinidae are implemented and use appropriate methods and techniques, as foreseen in Article 10 of Regulation (EC) No 882/2004, in order to determine the level of domoic acid in the whole body of pectinidae harvested outside classified production areas.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>Action Still Required</u> (August 2013)</p> <p>The "Code of Practice on Biotxin Monitoring" was amended January 2013 ver 2 and comprises updated sections on Official Controls on pectinidae, (instructions, decision trees, methods and techniques used). In addition, the competent authority provided confirmation that the updated requirements were submitted to the SFPA staff (dated 04 December 2012) and also provided a copy of sampling results (for heavy metals, microbiological criteria – pre and post purification, biotoxin test results for pectinidae, sampled from different production areas).</p> <p>There is no official sampling for domoic acid at harvesting in the whole body of pectinidae from wild areas but only in parts after shucking at destination and Code of Practice allows this. The competent authority stated that there is no fisheries auction hall in Ireland.</p> <p>However, no programme of official controls for pectinidae was provided and it is not always clear from the evidence provided whether sampling is carried out by the</p>	<p>FSAI Audit Conclusion: Not Reviewed</p> <p>This recommendation was not reviewed in detail by the FSAI audit team in 2013</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674</p>

	<p>competent authority or by the food business operator. (see also rec. 2011-6007-8,9 and 11)</p> <p>In their response to the draft CP, the Irish authorities indicated that under recommendation 9 above, they give update information on official controls on pectinidae.</p> <p><u>Therefore, the competent authority has not provided yet the plan of official controls for 2013 on pectinidae harvested outside classified production areas and documentary evidence of the verification of compliance with health standards for the level of domoic acid in the whole body of these pectinidae and this recommendation has not yet been addressed.</u></p> <p>Response by Irish competent authorities (Sept. 2013) Official controls on pectinidae:</p> <p>Food business operators approved by the SFPA for the processing of scallops are responsible for the sampling of all scallop landings from wild fisheries. A programme of official controls on pectinidae has been implemented by the SFPA whereby samples are taken by official staff of the SFPA at the establishments for biotoxin verification purposes.</p> <p>Establishments handling pectinidae are subject to ongoing official controls in accordance with Article 10 of Regulation 882/2004.</p> <p>See Recommendation 9 for update information on official controls on pectinidae.</p>	
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<p>2011-6007-11 To 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 would be allowed only where the requirements of Decision 2002/226/EC are implemented.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = <u>Unsatisfactory</u> (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = <u>Satisfactory</u> (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= <u>Action Still Required</u> (August 2013)</p> <p>The competent authority stated that they do not apply the requirements/derogation of the Commission Decision 2002/226/EC, e.g. sealed under supervision of competent authority, container, registration document, sampling frequency for analysis etc. However, the revised Code of Practice for marine biotoxins confirms that harvesting and processing of scallops in Ireland is allowed when a concentration of domoic acid (DA) in the whole body of the scallops exceeds 20mg/kg.</p> <p>There is no mechanism to ensure that live scallops exceeding 20 mg/kg DA in the whole body are not harvested as there is no testing carried out at harvesting to detect if concentration is above the limits of Decision 2002/226/EC (see also rec 2011-6007 -8, 9 and 10)</p> <p>In their response to the draft CP, the Irish authorities provided the information that IE disagrees that action is still required for this recommendation. IE implements the requirements of Regulation 853/2004 and Regulation 854/2004. IE does not implement Commission Decision 2002/226/EC. Commission Decision 2002/226/EC was</p>	<p>FSAI Audit Conclusion: Not Reviewed</p> <p>This recommendation was not reviewed in detail by the FSAI audit team in 2013</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674</p>

	<p>introduced as an optional derogation from Council Directive 91/492 EC to allow Member States more flexibility. The Decision specifies- <i>“By way of derogation from point 7a of Chapter V of the Annex to Directive 91/492/EEC, Member States may authorise the harvesting of”</i> The Decision was optional for MS to implement, if it was not implemented the provisions of Council Directive 91/492 EC had to be fully complied with. Council Directive 91/492 was revoked with the introduction of the Hygiene Package. Regulation (EC) No 853/2004 lays down health standards for live bivalve molluscs. Annex III Section VII Chapter V of Regulation 853/2004 specifies that “live bivalve molluscs must not contain ASP in total quantities (measured in the whole body or any part edible separately) that exceeds 20mg of domoic acid/100g). Regulation 854/2004 sets out official controls concerning pectinidae harvested outside classified production areas. IE implements the requirements of Regulation 853/2004 and Regulation 854/2004. It remains the view of the Irish Authorities that it is not compulsory to implement Commission Decision 2002/226/EC.</p> <p><u>Therefore, the competent authority has not yet provided assurances that the requirements of Decision 2002/226/EC are implemented and the harvesting of scallops with over 20 mg/kg DA in the whole body continues to be allowed in Ireland and this recommendation has not yet been addressed.</u></p> <p>Response by Irish competent authorities (Sept. 2013)</p> <p>Ireland implements the requirements of Regulation 853/2004 and Regulation 854/2004.</p> <p>Commission Decision 2002/226/EC was introduced as an optional derogation from Council Directive 91/492 EC to allow Member States more flexibility. The Decision specifies- <i>“By way of derogation from point 7a of Chapter V of the Annex to Directive 91/492/EEC, Member States may authorise the harvesting of”</i> The Decision was optional for MS to implement, if it was not implemented the provisions of Council Directive 91/492 EC had to be fully complied with. Council Directive 91/492 was revoked with the introduction of the Hygiene Package.</p>	
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	<p>Regulation (EC) No 853/2004 lays down health standards for live bivalve molluscs. Annex III Section VII Chapter V of Regulation 853/2004 specifies that “live bivalve molluscs must not contain ASP in total quantities (measured in the whole body or any part edible separately) that exceeds 20mg of domoic acid/100g). Regulation 854/2004 sets out official controls concerning pectinidae harvested outside classified production areas.</p> <p>Ireland operates an intensive sampling programme for monitoring ASP levels in pectinidae.</p> <p>Ireland implements the requirements of Regulation 853/2004 and Regulation 854/2004. Ireland recognises that a derogation is available (Commission Decision 2002/226/EC). From results to date Ireland has not found it necessary to consider this derogation for implementation.</p>	
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-12 To ensure that when non-compliances in pectinidae are identified, in particular concerning the EU biotoxin content, appropriate measures as foreseen in Article 54 of Regulation (EC) No 882/2004 are taken in the production areas from which non-compliant scallops were harvested</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= Action Still Required (August 2013)</p> <p>The SFPA uses a variety of legal actions in different circumstances - from informal actions (verbal to written warnings) to formal actions (served under Statutory Instruments), i.e. Compliance Notices, Fixed Penalty Notices, Closure or Prohibition Order, Prosecution) in order to ensure compliance with seafood safety legislation.</p> <p>According to the information provided by the competent authority :</p> <ul style="list-style-type: none"> • There are several guides which set out instructions and criteria that local and port health authorities (food authorities) should comply with when enforcing food law. Food authorities must follow and implement the provisions of these guides • The Code of Practice for marine Biotoxins (COB), was amended in January 2013 in order to include instructions related to non-compliances concerning pectinidae (in particular the biotoxin content) and appropriate measures as foreseen in Article 54 of Regulation (EC) No 882/2004 <p>However, the competent authority does not apply the requirements of Commission Decision 2002/226/EC and consequently, no conditions/measures are imposed</p>	<p>FSAI Audit Conclusion: Satisfactory</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418</p> <p>During the FSAI audit in 2013, enforcement action was taken in relation to a harvester of pectinidae, who placed whole scallops on the market without them being tested for biotoxins, i.e. in the Killybegs Port Office region.</p> <p>Appropriate enforcement action was taken against this harvester where both a Compliance Notice and Prohibition Order were served. These scallops should not have been placed on the market and should have been sent to an approved processor as the production area had not yet received a full A classification status. Although a number of samples had been taken as part of the classification process at the time of the FSAI audit classification was incomplete.</p> <p>The FSAI audit team was satisfied that effective, proportionate and dissuasive enforcement action was taken when required and a wide range of enforcement measures are available to deal with</p>

	<p>regarding non-compliances above the threshold of 20mg/kg for DA at harvesting and storage. On the contrary, the relevant part of the COB (par. 4.4.2, 4.4.3) for non-compliance with the limits for scallops allows this. (see also recommendation 2011-6007-8,9, 10 and 11)</p> <p>In their response to the draft CP the Irish authorities provided the information that Sea Fisheries Protection Officers have the necessary enforcement powers (under Food Safety Authority of Ireland Act 1998, Sea Fisheries and Maritime Jurisdiction Act 2006 and SI 432/2009) to take appropriate action in the case of noncompliant scallops (non-compliant against the requirements of Regulation 853/2004). The Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins) includes a section (section 5.5) “Controls in the event of non-compliant scallops” see Code of Practice Biotoxin Monitoring. With reference to Commission Decision 2002/226/EC see response to Recommendation 10.</p> <p><u>Therefore, the competent authority has not provided yet assurances that appropriate actions are taken for the non-compliant scallops concerning the biotoxin content at harvesting and storage and this recommendation has not yet been addressed.</u></p> <p>Response by Irish competent authorities (Sept. 2013) Sea Fisheries Protection Officers have the necessary enforcement powers (under Food Safety Authority of Ireland Act 1998, Sea Fisheries and Maritime Jurisdiction Act 2006 and S.I. No 432/2009) to take appropriate action in the case of non-compliant scallops (non-compliant against the requirements of Regulation 853/2004). The Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins) includes a section (section 5.5) “Controls in the event of non-compliant scallops” See Code of Practice Biotoxin Monitoring</p>	<p>all potential situations should they arise.</p> <p>Based on the FSAI audit outcomes, although enforcement action was appropriate, verification of the effectiveness of SFPA official controls (i.e. particularly in relation to scallops) should be considered for the other areas from which scallops are harvested, and in the context of fulfilling the requirements of article 8.3 of Regulation 882/2004.</p> <p>Based on the enforcement action taken during the FSAI audit, the audit team at the time of the audit viewed that this recommendation was satisfactory.</p>
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-13 To ensure that official controls verify that fishery products derived from bivalve molluscs comply with the standards laid down in Chapter V, point 2, Section VII, Annex III of Regulation (EC) No 853/2004, as required by Point G.3 of Chapter II of Annex III to Regulation (EC) No 854/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= Action Taken (August 2013)</p> <p>Response by Irish competent authorities (Sept. 2013) As part of official control inspections, the SFPA verify that the food business operator has systems in place to ensure that fishery products derived from live bivalve molluscs containing marine biotoxins in excess of legal limits are declared unfit for human consumption. The SFPA would also verify that disposal of such product is carried out in accordance with the relevant legislation (Regulation 1069/2009). A final revised version of the Establishment Inspection Checklist was provided at the FVO General Follow-up Audit in December 12</p> <p>Following the General Follow up Audit, this recommendation was given status “Action taken” (appropriate measures to address the recommendation have been implemented by the competent authority) and therefore closed.</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012)</p> <p>CP/GFA Mission Report 2012- 6418= Action Taken (August 2013)</p> <p>During the FSAI audit, the audit team observed that a system of official control verification samples for biotoxin was in place for fishery products derived from live bivalve molluscs, e.g. shucked scallops/Pectinidae, at processing establishments. The audit team confirmed that for certain establishments, these checks were taking place on a regular basis while for others, they were not. The audit team confirmed that the official control frequencies for these enhanced checks did not always meet the quarterly requirements specified by SFPA HQ in their e-mails to the Port Offices (Reference: National Shellfish Sampling Coordinator (NSSC) biotoxin instructions to all Port Offices - 4th December 2012 & 15th May 2013).</p>

		<p>Refer to FSAI Corrective Action Plan No.11</p> <p>Sampling requirements were not fully delivered and consequently this recommendation could not be considered as fully closed.</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-14 To ensure that fishery products derived from bivalve molluscs containing marine biotoxins in total quantities exceeding the limit referred to in Regulation (EC) No 853/2004 are declared as unfit for human consumption (Chapter III, 3, (iii) of Annex III to Regulation (EC) No 854/2004).</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= Action Taken (August 2013)</p> <p>Extract: The SFPA indicated that:</p> <ul style="list-style-type: none"> • It had implemented a programme of official control checks for biotoxins where samples of fishery products derived from live bivalve molluscs are being analysed at all stages of production • Official controls verify food business operator HACCP plans during inspections to ensure that fishery products derived from bivalve molluscs containing marine biotoxins in excess of legal limits are declared unfit for human consumption. The SFPA verifies that disposal of such product is carried out in accordance with the relevant legislation (Regulation 1069/2009) • The Establishment Inspection Checklist was reviewed and the final version was made available to the inspectorate of the SFPA, via Intranet system, at the end of March 2012). A copy of the checklist was provided. 	<p>FSAI Audit Conclusion: Action Taken</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>CP/GFA Mission Report 2012- 6418 = Action Taken (August 2013)</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674. Consequently, based on the CP/GFA Mission report, the FSAI audit team’s view at the time of the audit, was that action had been taken regarding this recommendation.</p>

	<p>Response by Irish competent authorities (Sept. 2013)</p> <p>As part of official control inspections, the SFPA verifies that the food business operator has systems in place to ensure that fishery products derived from live bivalve molluscs containing marine biotoxins in excess of legal limits are declared unfit for human consumption. The SFPA would also verify that disposal of such product is carried out in accordance with the relevant legislation (Regulation 1069/2009). A final revised version of the Establishment Inspection Checklist was provided at the FVO General Follow up Audit in December 12</p> <p>Following the General Follow up Audit, this recommendation was given status “Action taken” (appropriate measures to address the recommendation have been implemented by the competent authority) and therefore closed</p>	
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-15 To carry out appropriate official controls on periwinkles, whelks and abalone in order to verify compliance with the health standards laid down in Chapter V of 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.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = Satisfactory (27th July 2012)</p> <p>FVO Reassessment - Country Profile (CP)/General Follow Up (GFA) (December 2012) CP/GFA Mission Report 2012- 6418= Action Taken (August 2013)</p> <p>Extract: A summary of analysis (from 2010 until October 2012 – <i>same documents as provided before</i>) of Whelks Periwinkles Abalone), and Echinoderms (Sea Urchins) as part of the National Biotxin Monitoring programme was provided to the audit team.</p> <p>Response by Irish competent authorities (Sept. 2013) As part of the General Follow up Audit, data were provided on up to date testing of Gastropods (Whelks, Periwinkles, Abalone), and Echinoderms (Sea urchins) January 2010 to October 2012.</p> <p>Following the General Follow up Audit, this recommendation was given status “Action taken” (appropriate measures to address the recommendation have been implemented by the competent authority) and therefore closed.</p>	<p>FSAI Audit Conclusion: Action taken</p> <p>Progress has been made since the FVO Mission 2011-6007 and also since the FVO CP/GFA Mission 2012- 6418.</p> <p>CP/GFA Mission Report 2012- 6418= Action Taken (August 2013)</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674. Consequently based on the CP/GFA Mission report, the FSAI audit team’s view at the time of the audit is that action had been taken regarding this recommendation.</p>

Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-16 To ensure that only the EU analytical reference method for the determination of <i>E. Coli</i> (ISO TS 16649-3) is used in laboratories when carrying out official analyses for the monitoring of classified production areas and when verifying food business operators' compliance with EU requirements.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = <u>Satisfactory</u> (24th Feb. 2012) Response by Irish Competent Authorities (25th April 2012) FVO Response: = <u>Satisfactory</u> (27th July 2012) The actions you have proposed have been assessed as satisfactory. Response by Irish competent authorities (Sept. 2013) Following the FVO audit, the SFPA communicated to all inspectorate to ensure that the food business operators were complying with the EU analytical method for the determination of <i>E. coli</i> (ISO TS 16649-3) and the appropriate checklist was amended to reflect this. In addition since the audit, new contracts for determination of <i>E. coli</i> have been awarded following a re-tendering for services. Subcontract laboratories are required to use correct reference microorganism and this has been stipulated in the method as per reference method (ISO TS 16649-3). A sample contract is provided, where in Annex 1 (page 16) the use of correct reference material is clearly identified as a requirement. The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	<p>FSAI Audit Conclusion: Satisfactory FVO Response: = <u>Satisfactory</u> (27th July 2012) The actions you have proposed have been assessed as satisfactory. The FSAI audit team confirmed that the appropriate test methods were being used by food business operators at establishments visited during the FSAI audit in 2013. The FSAI however, did not visit private or official control laboratories during the course of the audit. Consequently, the FSAI audit team's view at the time of the audit is that this recommendation has been satisfactorily closed out.</p>

Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment /Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-17 To ensure that only laboratories that are accredited in accordance with specified European standards are designated to carry out the analyses of samples taken during official controls, as required in Article 12.2 of Regulation (EC) No 882/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Sept. 2013) All official analysis of biotoxins is now carried out in the Marine Institute; one laboratory is subcontracted by the Marine Institute to carry out on site preparatory work of samples. The Marine Institute is the designated National Reference Laboratory NRL and also has full accreditation under ISO 17025 for all tests (both phytoplankton and biotoxins) performed. (Accreditation Certification 130T VR20.</p> <p>The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities</p>	<p>FSAI Audit Conclusion: Satisfactory</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Consequently the FSAI audit team's view at the time of the audit is that this recommendation has been satisfactorily closed out</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674.</p>

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<p>2011-6007-18 To ensure that the recognised testing methods established in Article 3 of Regulation (EC) No 2074/2005 are used to determine marine biotoxins.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Sept. 2013) Recognised testing methods are used to determine marine biotoxins. The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities</p>	<p>FSAI Audit Conclusion: Not Reviewed</p> <p>This recommendation was not reviewed in detail by the FSAI audit team in 2013.</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674.</p>

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Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-19 To ensure that the recognised testing methods established in Article 3 of Regulation (EC) No 2074/2005 are used to determine marine biotoxins.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Sept. 2013) Following the FVO audit, analysis of Paralytic Shellfish Toxins by pre-column oxidation HPLC-FLD was accredited. This is the method "AOAC Official Method 2005.06 Paralytic Shellfish Poisoning Toxins in Shellfish. Prechromatographic Oxidation and Liquid Chromatography with Fluorescence Detection" and was successfully accredited by INAB to ISO 17025 in November 2011. Certificate of accreditation 130T VR20 is provided.</p> <p>The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	<p>FSAI Audit Conclusion: Not reviewed</p> <p>This recommendation was not reviewed in detail by the FSAI audit team in 2013.</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674</p>

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<p>2011-6007-20 To ensure that the testing of lipophilic toxins includes all the compounds described in Chapter III of Annex III to Regulation (EC) No 2074/2005.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012)</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Sept. 2013)</p>	<p>FSAI Audit Conclusion: Not Reviewed</p> <p>This recommendation was not reviewed in detail by the FSAI audit team in 2013.</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674</p>

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Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-21 To ensure that official controls of food business operators premises are carried out with the appropriate frequency defined by the competent authority as required by Article 3 of Regulation (EC) No 882/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011)</p> <p>FVO Response: = Unsatisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) The Official Control Plan 2012 stipulates that one full inspection must be carried out in each approved establishment. The SFPA will commit, within available resources, to meet target number of inspections as determined by a documented risk assessment and will prioritise high risk establishments. The SFPA will review risk assessments as required.</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Sept. 2013) A Control Plan is published annually by SFPA outlining official controls to be carried out regionally by the SFPA. Inspections are carried out on a risk basis and at a frequency deemed appropriate by the SFPA in accordance with a documented risk assessment procedure taking into account the requirements of Article 3 of Regulation 882/2004. The SFPA is committed, within available resources to meet target number of inspections as determined by the documented risk assessment and prioritises high risk establishments. The SFPA review risk assessments as required. The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>The FSAI audit team reviewed inspection frequencies, i.e. including the completion of full inspections as per SFPA procedures, in the three port offices visited during the course of the FSAI audit in 2013.</p> <p>The target risk based frequencies to be achieved for certain food business operator establishments, were in several cases not met, and also full audits had also, not always taken place as required. Refer to FSAI Corrective Action Plan No.12 & 13</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>

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<p>2011-6007-22 To ensure that official controls are carried out in accordance with the competent authority established documented procedures as required by Article 8.1 of Regulation (EC) No 882/2004 and that official controls include the verification of all requirements stated in Article 4 of Regulation (EC) No 854/2004.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) The SFPA has developed extensive documented procedures to enhance official controls, these will continue to be reviewed and communicated to inspectorate.</p> <p>The documented procedures relevant to routine (non-approval) inspections will be reviewed by the SFPA to ensure compliance, and this is likely to result in regularising the applicability of the relevant portions of the approval checklist to the routine inspections.</p> <p>FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) Documented procedures on official controls will continue to be reviewed on an ongoing basis and amended as necessary. The inspection checklist for Fishery Products and Live Bivalve Mollusc establishments was reviewed during Quarter 1 of 2012 to ensure it is in accordance with requirements of Article 4 of Regulation 854/2004. Please find the amended checklist in the response to Recommendation 14 above.</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Sept. 2013) The SFPA has developed extensive documented procedures to enhance official controls. These are available on an internal intranet system for all inspectorate to access. Documented procedures on official controls continue to be reviewed on an ongoing basis and amended as necessary. The inspection checklist for Fishery Products and Live Bivalve Mollusc establishments was reviewed during Quarter 1 of 2012 and again during Quarter 3 of 2013 to ensure it is in accordance with</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>The FSAI audit team verified that the SFPA has detailed comprehensive procedures in place.</p> <p>Although in many cases during the FSAI audit in 2013, SFPA inspections were carried out in accordance with requirements, in other instances however, they were not always adhered to. Refer to FSAI Corrective Action Plan No's 9-16</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>

	<p>requirements of Article 4 of Regulation 854/2004.</p> <p>The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of Action plan submitted by competent authorities.</p> <p>For information- please find current version of checklist and accompanying guidance document provided; this version has been in use since 1st September 2013.</p>	
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<p>2011-6007-23 To ensure that the requirements of Points 2 and 3 of Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004 regarding registration documents accompanying live bivalve molluscs are met.</p>	<p>Response by Irish competent authorities (3rd Nov. 2011) Comprehensive instructions and guidelines on the compilation of Shellfish Registration documents are already in place. There will be ongoing staff training to enhance official controls and inspectorate competencies to ensure that the requirements of Points 2 and 3 of Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004 regarding registration documents accompanying live bivalve molluscs are met.</p> <p>FVO Response: = Satisfactory (24th Feb. 2012)</p> <p>Response by Irish competent authorities (25th April 2012) Please find the following instructions and guidelines for harvesters additional instructions for Sea Fisheries Protection Officers. Training for inspectorate to enhance official controls will be carried out during Quarter 3 of 2012.</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>Response by Irish competent authorities (Oct. 2012) The Annual FSAI SFPA Regional Workshops were held during September and October 2012 and 39 SFPA officers attended. Live bivalve molluscs official controls were covered in a workshop presentation and attendees were trained in the requirements and the correct completion of registration documents. See attachment R 2011-6007-23A & R 2011-6007-23B for details of workshop programme.</p> <p>Response by Irish competent authorities (Sept. 2013) There are comprehensive instructions and guidelines on the compilation of Shellfish</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>The FSAI audit team verified that in most cases gatherer's registration documents accompanied consignments of live bivalve molluscs. In one instance however during the FSAI audit in 2013, this was not the case. Several consignments of scallops had been harvested from an unclassified production area. For some of these consignments, no registration document accompanied these products.</p> <p>Additionally, copies of these registration documents were not on file in the Killybegs Port Office for this food business operator. Refer to FSAI Corrective Action Plan No 7</p> <p>Appropriate enforcement action was taken by the SFPA in the Killybegs Port Office as a result of non-compliances identified during the course of the FSAI audit in relation to this food business operator and also in relation to a local establishment receiving this product.</p>

	<p>Registration documents in place. As part of the response to DG (SANCO)/2011-6007 report IE provided the following documentation: instructions and guidelines for harvesters and additional instructions for Sea Fisheries Protection Officers. In addition the inspection checklist was revised to build in further checks, a copy of which was provided at General Follow up Audit in December 2012.</p> <p>The Annual FSAI SFPA Regional Workshops were held during September and October 2012 and 39 SFPA Officers attended. Live bivalve molluscs official controls were covered in a workshop presentation and attendees were trained in the requirements and the correct completion of Registration Documents.</p> <p>Details of workshop programme were given as part of General Follow up Audit</p> <p>Following the General Follow up Audit, this recommendation was given status “Action taken” (appropriate measures to address the recommendation have been implemented by the competent authority) and therefore closed.</p>	<p>Based on findings, the FSAI audit team’s view is that this recommendation was in progress at the time of the audit.</p>
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
Ref no. & Recommendation	Summary of Corrective Action Response/FVO Assessment/Further Updates Provided	FSAI Live Bivalve Molluscs Audit 2013 - Verification
<p>2011-6007-24 To ensure that only molluscs of the same species are purified in the same tank and that packages of purified live bivalve molluscs are only sent to dispatch centres with a label, as respectively required in Points A.4 and A.7 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004</p>	<p>Response by Irish competent authorities (3rd Nov 2011) Documented procedures will be modified and there will be ongoing staff training and communications to enhance official controls and inspectorate competencies to ensure that only molluscs of the same species are purified in the same tank and that packages of purified live bivalve molluscs are only sent to dispatch centres with a label, as respectively required in Points A.4 and A.7 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004. (No documentary evidence attached)</p> <p>FSAI response to final report (25th April 2012) The inspection checklist has been amended- relevant sections. See Page 22 of the amended inspection checklist in the response to Recommendation 14 above. (Documentary evidence –page 22 - attached)</p> <p>FVO re-assessment (27th July 2012) The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for Dec 2012.</p> <p>Response by Irish competent authorities (Sep 2013) The inspection check list was modified in March 2012 to enhance official controls, one of these amendments was to ensure that only molluscs of the same species are purified in the same tank and that packages of purified live bivalve molluscs are only sent to dispatch centres with a label, as respectively required in Points A.4 and A.7 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004. The inspection checklist has been amended; this amended inspection checklist was forwarded to the FVO in April 2012. The response to this recommendation was deemed satisfactory following FVO assessment in March and September 2012.</p>	<p>FSAI Audit Conclusion: Satisfactory</p> <p>FVO Response: = Satisfactory (27th July 2012) The actions you have proposed have been assessed as satisfactory.</p> <p>The FSAI audit team verified that in all cases molluscs of the same species and batch were only purified in the same tank, for the food business operators visited.</p> <p>Consequently, the FSAI audit team’s view at the time of the audit, is that in general, this recommendation had being satisfactorily addressed.</p>

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<p>2011-6007-25 To ensure that food business operators of purification centres can demonstrate that live bivalve molluscs are continuously purified for a period sufficient to achieve compliance with the health standards for microbiological contamination of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, as required in Point A.3 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004.</p>	<p>Response by Irish competent authorities (3rd Nov 2011) The SFPA will as part of its ongoing official controls in the purification/dispatch centres, ensure that the controls conducted by the food business operators robustly demonstrate that live bivalve molluscs are continuously purified for a period sufficient to achieve compliance with the health standards for microbiological contamination of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, as required in Point A.3 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004. (No documentary evidence attached)</p> <p>FVO re-assessment (27th July 2012) The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for December 2012.</p> <p>FVO country profile pre-mission (25th Sep 2012) For Verification Please provide evidence: 1. That the review of all purification centres was finalised; 2. About the training carried out and, 3. If the guidelines on best practice were developed by Quarter 2 of 2012, as indicated above.</p> <p>Update provided to FVO (Oct 2012) 1. Review of Purification Centres: During Quarter 3/early Quarter 4 a review of all purification centres was carried out to verify that all approved purification centres had an up to date validation and ongoing</p>	<p>FSAI Audit Conclusion: Satisfactory</p> <p>Country profile final report published (Aug 2013) In Progress</p> <p>The FSAI audit team verified that the purification centres visited demonstrated that live bivalve molluscs are continuously purified for a period sufficient to achieve compliance with the health standards for microbiological contamination of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, as required in Point A.3 of Chapter IV of Section VII of Annex III to Regulation (EC) No 853/2004.</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674.</p> <p>Consequently, the FSAI audit team’s view at the time of the audit is that in general this recommendation had being satisfactorily addressed.</p>

	<p>verification in place as part of the food safety management system. Official control samples were taken where necessary to verify that the operation of the purification system achieves compliance with health standards for microbiological contamination.</p> <p>2. Training: A live bivalve molluscs purification workshop was held 29th March 2012. See attached agenda (attachment R- 2011-6007-25A)</p> <p>3. Guidelines on Best Practice: A guidance note – “SFPA Guidance document for inspecting live bivalve molluscs Purification Centres has been developed. This guidance document aims to clarify and standardise procedures for Sea Fishery Protection Officers inspecting and approving live bivalve molluscs purification systems. It outlines what are considered best practices in the operation of live bivalve mollusc purification systems and may also be used as a guide to industry. This Guidance note was circulated to all Sea-Fisheries Protection Officers in June 2012.</p> <p>See attachment R 2011-6007-25B <i>(Documentary Evidence provided)</i></p> <p>Country profile draft report (11th April 2013) Action Taken A Guidance Note for inspecting live bivalve molluscs purification centres was completed and circulated in June 2012. This guidance document aims to clarify and standardise procedures for Sea-Fishery Protection Officers inspecting and approving live bivalve molluscs purification systems</p> <p>Training was provided on 29 March 2012. The review of the purification centres was started by the SFPA on August/September 2012 and was expected to be completed by the end of 2012 (90% were reviewed). Therefore, <u>progress was noted but the competent authority has not provided yet documentary evidence if:</u></p> <p><u>- The review of all purification centres was completed and,</u></p>	
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	<p>- <u>Verified that food business operator's purification centres comply with the health standards for microbiological contamination, as required under this recommendation</u></p> <p>Country profile final report published (Aug 2013) In Progress</p> <p>A guidance note for inspecting live bivalve molluscs purification centres was completed and circulated in June 2012. This guidance document aims to clarify and standardise procedures for Sea-Fishery Protection Officers inspecting and approving live bivalve mollusc purification systems.</p> <p>Training was provided on 29 March 2012.</p> <p>The review of the purification centres was started by the SFPA on August/September 2012 and was expected to be completed by the end of 2012 (90% were reviewed).</p> <p><u>Therefore, progress was noted but the competent authority has not provided yet documentary evidence if:</u></p> <ul style="list-style-type: none"> • <u>The review of all purification centres was completed and, if verified that food business operator's purification centres comply with the health standards for microbiological contamination, as required under this recommendation</u> <p>Update provided to FVO (Sep 2013)</p> <p>1. Review of Purification Centres: During Quarter 3/Quarter 4 2012 a review of all purification centres was carried out to verify that all approved purification centres had an up to date validation and ongoing verification in place as part of the food safety management system. Official control samples were taken where necessary to verify that the operation of the purification system achieves compliance with health standards for microbiological contamination.</p> <p>2. Training: A live bivalve mollusc purification workshop was held 29th March 2012.</p> <p>3. Guidelines on Best Practice: A guidance note – “SFPA Guidance document for inspecting live bivalve molluscs</p>	
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	<p>Purification Centres has been developed. This guidance document aims to clarify and standardise procedures for Sea Fishery Protection Officers inspecting and approving live bivalve molluscs purification systems. It outlines what are considered best practices in the operation of live bivalve mollusc purification systems and may also be used as a guide to industry. This Guidance note was circulated to all SFPOs in June 2012. (Documentary evidence provided)</p>	
<p>2011-6007-26</p> <p>To ensure that food business operators of processing establishments can demonstrate that processed bivalve molluscs undergo sufficient 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.</p>	<p>Response by Irish competent authorities (3rd Nov 2011) The permitted thermal treatments for live bivalve molluscs originating from Class B & C areas is very specific in the legislation (Regulation 853/2004 Section VII, Chapter II) without clear provision for more risk-based food safety management, Enforcement action has been taken and compliance has been brought about in Irish food business operators. (No documentary evidence attached)</p> <p>FVO assessment of proposed competent authority (24th Feb 2012) Unsatisfactory Please describe the actions that have been taken to enforce the legislation.</p> <p>FSAI response (25th April 2012) A Compliance Notice has been served on the relevant food business operator restricting current thermal treatment processing to Classification A product. The said food business operator is conducting in consultation with the relevant State agencies a validation trial for thermal processing of product from Class B areas. This will be verified by the SFPA. The amended inspection checklist for fishery products and bivalve molluscs has checks to ensure that food business operators carrying out thermal processing of bivalve molluscs from B areas are doing so in accordance with the legislative requirements & the processes are validated. See Page 23 of the amended inspection checklist in the response to Recommendation 14 above. (Documentary evidence attached)</p>	<p>FSAI Audit Conclusion: Satisfactory</p> <p>FVO Re-Assessment (July 27th 2012) Satisfactory</p> <p>The FSAI audit verified that for the establishments visited bivalve molluscs undergo sufficient treatment to eliminate pathogenic micro-organisms.</p> <p>The FSAI audit team was satisfied, i.e. for the establishments visited, that food business operators could demonstrate that processed bivalve molluscs undergo sufficient 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.</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674.</p>

	<p>FVO Re-Assessment (July 27th 2012) The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for December 2012.</p> <p>Update provided to FVO (Sep 2013) Following the FVO Live Bivalve Molluscs Mission in 2011, a Compliance Notice was served on the relevant food business operator restricting current thermal treatment processing to Classification A product. The said food business operator is conducted in consultation with the relevant State agencies a validation trial for thermal processing of product from Class B areas. This was verified by the SFPA and the SFPA is satisfied that thermal processing of live bivalve molluscs being carried out in this establishment is in accordance with the legislation requirements of Regulation 853/2004 (Point A.5 of Chapter II of Section VII of Annex III).</p> <p>In addition, the amended inspection checklist for fishery products and bivalve molluscs has checks to ensure that food business operators carrying out thermal processing of bivalve molluscs from B areas are doing so in accordance with the legislative requirements & the processes are validated. The response to this Recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	<p>Consequently, the FSAI audit team’s view at the time of the audit is that in general this recommendation had being satisfactorily addressed.</p>
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Close-out of FVO Live Bivalve Molluscs Mission Report 2011-6007 Findings STATUS OF RECOMMENDATIONS & CORRECTIVE ACTIONS		
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<p>2011-6007-27</p> <p>To ensure that the requirements established in Article 5 of Regulation (EC) No 852/2004 for HACCP based procedures are fulfilled by food business operators.</p>	<p>Response by Irish competent authorities (3rd Nov 2011)</p> <p>As part of ongoing official controls, SFPA inspectors of approved establishments will ensure that HACCP plans accurately reflect the processes, which the food business operator is approved to carry out. Official control documented procedures will be reviewed to clarify the requirements.</p> <p>FVO assessment of proposed competent authorities (24th Feb 2012)</p> <p>The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for December 2012.</p> <p>FVO re-assessment (July 27th 2012)</p> <p>The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for December 2012.</p> <p>Update provided to the FVO (Sep 2013)</p> <p>As part of ongoing official controls, SFPA inspectors of approved establishments ensure that HACCP plans accurately reflect the processes, which the food business operator is approved to carry out. Official control documented procedures were reviewed to clarify the requirements. The inspection checklist was amended in March 2012 to reflect the corrective action.</p> <p>The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>FVO Re-Assessment (July 27th 2012) Satisfactory</p> <p>Although in general, the requirements in Article 5 of Regulation (EC) No 852/2004 for HACCP based procedures were being fulfilled by food business operators, certain deficiencies were also noted during the course of the FSAI audit. Refer to FSAI Corrective Action Plan No 21</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>

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<p>2011-6007-28 To ensure that food safety criteria established in Chapter 1 of Annex I to Regulation (EC) No 2073/2005 are met by food business operators.</p>	<p>Response by Irish competent authorities (3rd Nov 2011) In 2011, the SFPA issued clear instruction to all inspectors emphasising the need to verify food business operator compliance with the requirement to utilise the legislatively-mandated microbiological method. Since the audit (September 2011) there has been Cross Agency FSAI/SFPA training delivered on the Microbiological criteria- Regulation 2073/2004 to all staff. The purpose of this training was to enhance official controls in the area of microbiological criteria. In addition some inspectorate attended a series of FSAI Micro Criteria Seminars held in May 2011. In May 2011 FSAI developed checklists to be used when assessing compliance with Commission Regulation EC (No) 2073/2005 samples. The SFPA have commenced using these checklists in conjunction with own SFPA checklist. A national guidance document on Micro Criteria is due to be published shortly. (No documentary evidence attached)</p> <p>FVO assessment of proposed competent authority (24th Feb 2012) Satisfactory Please provide a copy of the agenda of the training FSAI/SFPA and the FSAI Micro Criteria Seminars. Please provide a copy of the new FSAI checklist to be used when assessing compliance with Regulation 2073/2005. Please give an estimation of the date when the national guidance document on Micro Criteria is going to be published and provide a copy.</p>	<p>FSAI Audit Conclusion: In Progress</p> <p>FVO Re-Assessment (July 27th 2012) Satisfactory</p> <p>Refer to FSAI Corrective Action Plan No 17</p> <p>Based on findings, the FSAI audit team's view is that this recommendation was in progress at the time of the audit.</p>

	<p>FVO Re-Assessment (July 27th 2012) The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for December 2012.</p> <p>Update provided to the FVO (Sep 2013) In 2011, the SFPA issued clear instruction to all inspectors emphasising the need to verify food business operator compliance with the requirement to utilise the legislatively-mandated microbiological method. Since the audit (September 2011), there has been Cross Agency FSAI/SFPA training delivered on the Microbiological criteria-Regulation 2073/2004 to all staff. The purpose of this training was to enhance official controls in the area of microbiological criteria. In addition some inspectorate attended a series of FSAI Micro Criteria Seminars held in May 2011. In May 2011 FSAI developed checklists to be used when assessing compliance with Commission Regulation EC (No) 2073/2005 samples. The SFPA have commenced using these checklists in conjunction with own SFPA checklist. A national guidance document on Micro Criteria was also published. Please find relevant documentation provided:</p> <ul style="list-style-type: none"> • FSAI Seminars on Microbiological Criteria, (5 Seminars) May 2011 agenda, • FSAI SFPA Regional Workshops, (4 workshops) Sept 2011 agenda, • FSAI Checklist for assessing compliance with 2073/2005, • National Guides (FSAI Guidance Note 26 for Food Business Operators) • <p>The response to this recommendation was deemed satisfactory in July 2012 following the FVO assessment of action plan submitted by the competent authorities.</p>	
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<p>2011-6007-29 To ensure that molluscs placed on the market or intended to be placed on the market are adequately labelled or identified to facilitate their traceability, as required by Article 18.4 of Regulation (EC) No 178/2002.</p>	<p>Response by Irish competent authorities (3rd Nov 2011) The SFPA has documented systems in place to verify that molluscs placed on the market or intended to be placed on the market are adequately labelled or identified to facilitate their traceability, as required by Article 18.4 of Regulation (EC) No 178/2002. Article 18.4 is very general in its requirements. Incoming legislation implemented by DG-Mare (Regulation 1224/2009 and Regulation 404/2011) creates specific traceability obligations on operators handling all fishery products including aquaculture products including molluscs. A specific roll-out of those provisions far in excess of 178/2002 is envisaged by SFPA as they come into effect 01 Jan 2012.</p> <p>In the specific instance identified during the audit, the typographical error has been corrected by the food business operator and verified by the control authorities.</p> <p>FVO assessment of proposed competent authority (24th Feb 2012) Unsatisfactory Although the documented system was in place at the time of the FVO audit, deficiencies when carrying out the official controls were found. These deficiencies were not only those mentioned in the competent authority's action plan. The action taken does not address the recommendation. Please take action to address the recommendation.</p> <p>FSAI response to final report with further updates on recommendations included (25th April 2012) The SFPA has amended the relevant inspection checklist to ensure that official controls verify that molluscs placed on the market or intended to be placed on the market, are adequately labelled or identified to facilitate their traceability, as required by Article 18.4 of Regulation (EC) No 178/2002. Please find the amended checklist (page 7 - enclosed) in the response to Recommendation 14 above.</p>	<p>FSAI Audit Conclusion: Satisfactory</p> <p>FVO Re-Assessment (July 27th 2012) Satisfactory</p> <p>The FSAI audit team verified that molluscs placed on the market or intended to be placed on the market were in general adequately labelled or identified by food business operators to facilitate their traceability, as required by Article 18.4 of Regulation (EC) No 178/2002</p> <p>Consequently, the FSAI audit team's view at the time of the audit is that in general this recommendation had being satisfactorily addressed.</p> <p>The decision as to whether this recommendation has been addressed, should be considered when reviewing the results of the final published FVO Report to Mission DG(SANCO)2013-6674.</p>

	<p>(Documentary evidence attached)</p> <p>FVO re-assessment (July 27th 2012) The actions you have proposed have been assessed as satisfactory. Based on the information provided, it would seem that it may be possible to close a number of these recommendations following verification of actions taken during the next GFA, scheduled for December 2012.</p> <p>Update provided to the FVO (Sep 2013) Since the FVO Audit in 2011, the SFPA has amended the relevant inspection checklist to ensure that official controls verify that molluscs placed on the market or intended to be placed on the market are adequately labelled or identified to facilitate their traceability, as required by Article 18.4 of Regulation (EC) No 178/2002. The response to this recommendation was deemed satisfactory in July 2012 following FVO assessment of action plan submitted by competent authorities.</p>	
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