

AUDIT  
REPORT

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

**CORRECTIVE ACTION PLAN**

JULY 2014 (UPDATE JULY 2018)

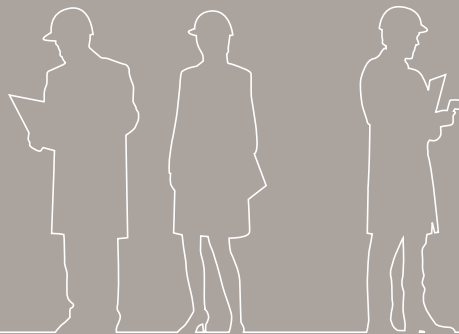


# AUDIT REPORT

Audit of SFPA Official Controls  
in relation to Biotoxin and  
Microbiological Monitoring of  
Live Bivalve Molluscs (LBMs)

## **CORRECTIVE ACTION PLAN**

JULY 2014 (UPDATE JULY 2018)



## **CORRECTIVE ACTION PLAN**

This corrective action plan describes audit findings requiring corrective action, documents responsibility for addressing the findings and describes progress on the close out of actions.

<b>Audit:</b>	Audit of SFPA Official Controls in relation to Biotxin and Microbiological Monitoring of Live Bivalve Molluscs (LBMs)
<b>Official Agency:</b>	Sea Fisheries Protection Authority
<b>Organisational Level:</b>	SFPA Headquarters (Central Level) and Port Offices (Regional Level)
<b>Date of Audit:</b>	Q3 2013

**Audit of SFPA Official Controls in relation to Biotoxin and Microbiological Monitoring of Live Bivalve Molluscs (LBMs)**

JULY 2014 (UPDATE JULY 2018)

	To be completed by FSAI			To be completed by Agency		To be completed by Agency & FSAI through Service Contract Liaison process		
	Report Ref.	Finding Requiring Corrective Action	Relates to	Proposed Corrective Action	Proposed Completion Date	Update	Status	
							Open	Closed (include date closed out)
1.	4.2 & 4.4	<p><b>Coordination and Planning of Official Controls</b></p> <p>In two Port offices (i.e KB &amp; DE POs), formal meetings with staff did not take place on a regular basis. The audit team were informed that for one port office (i.e. the KB PO) that informal discussions were favoured, which were not documented.</p> <p>Consequently there was a general lack of evidence to demonstrate that official control priorities and activities are discussed, monitored and reviewed formally with staff, as part of the management of regional official control activities.</p>	<p>SFPA</p> <p><u>Regional Port offices:</u></p> <p>DE – PO</p> <p>KB – PO</p>	Meetings will be held at an agreed frequency in ports; records of such meetings will be maintained in the ports.		.		Closed 30/08/16
2.	4.3	<p><b>SFPA Documented Procedures to Review Effectiveness</b></p>	SFPA	During quarter 4 of 2013 external consultants were employed by SFPA to				Closed 31/10/16

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		<p>A system to review the effectiveness of official controls is not in place within SFPA.</p> <p>Procedures to review the effectiveness of SFPA official controls in order to meet the requirements of article 8.3 (a) and (b) of Regulation (EC) No. 882/2004, were not in place at the time of the audit.</p>	<u>Central Level</u>	verify effectiveness of official controls.				
3.	4.4.1	<p><b>Microbiological Monitoring of LBM Production Areas</b></p> <p>Classification/Shellsan samples were often being taken from a number of different sampling locations within the production area, and did not relate to the specific sample point grid reference, as detailed within the SFPA Code</p>	<p>SFPA</p> <p><u>Central Level</u></p> <p>&amp;</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				Closed 19/9/17

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		of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012).	<u>Regional Port offices:</u> DG – PO DE – PO KB – PO	samples are actually taken from within production areas.  A further amended copy of the Code of Practice was provided to the audit team. <sup>1</sup>				
4.	4.4.1	<b><i>Microbiological Monitoring of LBM Production Areas</i></b>  In one instance observed by the audit team, an investigation was not performed following an elevated microbiological result of 5400 most probable number (MPN) <i>E.coli</i> per 100g, although requested by the NSSC at central level, which did not comply with the requirements of the SFPA	SFPA  <u>Regional Port office:</u> DE – PO & <u>Central Level</u>	A tender document is being prepared by the SFPA to employ the services of an external consultant to carry out an agreed number of internal audits on behalf of the SFPA in accordance with Article 4.6 of Regulation 882/2004.  In addition the SFPA will continue to implement				Closed 30/11/17

<sup>1</sup> Note: The effectiveness of these procedures could not be verified as they were received post completion of FSAI on-site audit activities.

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		Code of Practice on microbiological monitoring of bivalve mollusc production areas.  This should also have been picked up at by SFPA at central level, (i.e. as part of the verification of the effectiveness of official controls in accordance with article 8.3 (b) of Regulation (EC) No. 882/2004), in order to confirm that a follow up investigation had been satisfactorily carried out		recommendations of an external review of effectiveness of official controls and recent audits.				
5.	4.4.2	<b>Biotoxin Sampling, Monitoring and Verification of LBM Production Areas</b>  Biotoxin samples were in some cases being taken from a location/area within the	SFPA  <u>Regional Port office:</u>	National Action Point – A Trilateral meeting (between FSAI, SFPA and MI) is to be held on the 25 <sup>th</sup> February 2014 where the sampling	Ongoing			

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		production zone where harvesting was active, which did not correspond to the specific designated sample point grid reference, detailed within the SFPA Code of Practice on microbiological monitoring of bivalve mollusc production areas (Ver. 4: Sep 2012) and the Manual on Molluscan Shellfish Production Areas, Sample Points and Coordinates for Biotoxin and Phytoplankton Samples (March 2012)	DG – PO DE – PO KB – PO	programme including sampling points will be discussed. Following this meeting and agreed actions the relevant COPs will be amended accordingly				
6.	4.3 & 4.4.2	<b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas</b>  A number of deficiencies were observed in certain port offices visited relating to records to be kept and maintained, as part of the supervision of	SFPA  <u>Regional Port office:</u>	The Food Safety Control Plan 2014 has incorporated a section on File Management covering approved establishments, registered FBOs and approved fishing vessels, the purpose of which is	Ongoing			



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		<p>samplers/harvesters, which did not comply with the SFPA documented procedure requirements.</p> <p>One harvester/biotoxin sampler (i.e. for scallops), was not present on the KB PO list.</p> <p>The DE PO did not maintain a register/list of industry samplers and harvesters on file.</p>	<p>KB – PO</p> <p>DE – PO</p>	<p>improve and standardise record keeping.</p> <p>A list of industry samplers will be maintained in the ports and at central level.</p>				
7.	4.4.2 & 4.4.3	<p><b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</b></p> <p>Copies of registration documents for some food business operators were not available at the KB PO when requested by the FSAI audit team which consequently did not comply with records to be</p>	<p>SFPA</p> <p><u>Regional Port office:</u></p> <p>KB – PO</p>	<p>The Food Safety Control Plan 2014 has incorporated a section on File Management covering approved establishments, registered FBOs and approved fishing vessels, the purpose of which is improve and standardise record keeping.</p>				Closed 30/07/18

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		maintained within the Port Office as part of the SFPA FSCP 2012/13		<b><u>KB – PO</u></b> Update March 2014- General findings of the audit to be discussed at the next food safety port meeting and corrective actions will be discussed				
8.	4.4.2	<b><i>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas</i></b> Records of the training of samplers were not on file within the three port offices audited.	SFPA  <u>Central Level</u> & <u>Port offices</u> DG – PO DE – PO KB – PO	Records of training of samplers to be kept on file at ports; records of relevant regional/national training will be maintained at Central level.	Ongoing			

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9.	4.3 & 4.4.2	<p><b><i>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas</i></b></p> <p>The audit team confirmed that on two occasions, samples of Pectinidae (scallops) had been taken by SFPOs from the DG PO in order to check the toxicity levels of scallops for harvesting purposes (i.e. from two different locations). These samples were also shucked prior to being sent for analysis. In both cases samples were not recorded on the SFPA sample advice form, and/or the LBM Harvest Official Control Form (Ver. 3; FOC02; March 2012) and had not been entered on the SFPA WS4 worksheet for the recording of official control biotoxin samples. These samples had not adhered to the</p>	<p>SFPA</p> <p><u>Port office</u></p> <p>DG – PO</p>	<p><b><u>DG – PO</u></b></p> <p>Scallop (Pectinidae) sampling to adhere to Biotoxin Code of Practice, SFPA FSCP and the new Scallop protocol for biotoxin analysis (Ref 14/10/13).</p> <p>3 Biotoxin verification samples submitted in 2013 from production area</p>					<p>Closed 28/02/14</p>

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		requirements of the Code of Practice on biotoxin and phytoplankton monitoring and the SFPA FSCP for 2013. Scallops are also required to be tested at the approved processing establishment level, where they are in general shucked prior to dispatch, and not at the harvesting stage.						
10	4.3 & 4.4.2	<b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas</b>  Biotoxin verification samples and inspections were not recorded on the SFPA WS4 worksheet in the DE PO and KB PO, which was not in accordance with the SFPA FSCP requirements for 2013.	SFPA  <u>Port office</u>  DE – PO  KB – PO	<b>DE – PO</b>  New Database to address				Closed 19/06/18

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11.	4.3 & 4.4.3	<p><b><i>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; establishments</i></b></p> <p>In relation to biotoxin verification sampling at LBM establishments i.e. dispatch/purification centres these were not in general being taken on a quarterly basis in accordance with SFPA requirements as per SFPA HQ instructions. (Reference NSSC e-mailed instructions to Port Offices - 4th December 2012 &amp; 15th May 2013).</p>	<p>SFPA</p> <p><u>Port office</u></p> <p>DG – PO</p> <p>DE – PO</p> <p>KB – PO</p>	<p><b><u>DG – PO</u></b></p> <p>Bio toxin verification samples to be taken on a quarterly basis from the LBM establishment</p> <p>Bio toxin verification samples submitted from the LBM establishment for the remainder of 2013</p> <p><b><u>DE – PO</u></b></p> <p>Sampling requirements now part of officer premises scheduled visits</p> <p><b><u>KB – PO</u></b></p> <p>To be done from 2014</p>	Q3 2018			

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12.	4.3 & 4.4.3	<p><b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</b></p> <p>Although inspections were generally taking place at establishments falling within the scope of the FSAI audit in some cases the minimum frequencies to be achieved were not fully met in 2011, 2012 and 2013.</p>	<p>SFPA</p> <p><u>Port office</u></p> <p>DG – PO</p> <p>DE – PO</p> <p>KB – PO</p>	<p>The SFPA, within fluctuating and restricted resources continues to strive to meet risk based targets. Inspection data will be monitored at central and port level.</p> <p><b><u>DG – PO</u></b></p> <p>Minimum inspection frequencies to be observed.</p> <p><b><u>DE – PO</u></b></p> <p>On target to complete in 2013, then Priorities Fisheries Control for Q4</p> <p><b><u>KB – PO</u></b></p> <p>Not achieved because of diminished human resources. Explained to audit team at time.</p>	Q1/2019			

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13.	4.3 & 4.4.3	<p><b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</b></p> <p>In certain cases full audits had not taken place at approved establishments on an annual basis which was not in accordance with the requirements of the SFPA FSCP 2012/13.</p>	<p>SFPA</p> <p>Port office</p> <p>DG – PO</p> <p>DE – PO</p> <p>KB – PO</p>	<p><b><u>DG – PO</u></b></p> <p>Annual full audits to be conducted at approved establishments on an annual basis in accordance with SFPA FSCP.</p> <p><b><u>DE – PO</u></b></p> <p>Full audits now prioritised for 2013 onward</p> <p><b><u>KB – PO</u></b></p> <p>During 2014 a full audit per establishment will take place.</p>					Closed 19/06/18

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				Risk assessments of establishments to be reviewed and revised if necessary.				
14.	4.3 & 4.4.3	<p><b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</b></p> <p>Certain audits were recorded incorrectly <i>i.e. some referred to as full audits</i>, where in fact they were routine audits/inspections on the intranet system.</p>	<p>SFPA</p> <p><u>Port office</u></p> <p>DE – PO</p>	<p><b><u>DE – PO</u></b></p> <p>Role out of Database (i.e. OAPI) &amp; inspecting officer to input</p>				Closed 19/06/18
15.	4.3 & 4.4.3	<p><b>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</b></p>	<p>SFPA</p> <p><u>Port office</u></p>					Closed 19/06/18



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		SFPA intranet worksheet entries are not fully maintained e.g. worksheets are not entirely reflective of completed official controls carried out	DE – PO  KB – PO	KB – PO The new database OAPI which will be in use during Quarter 1 of 2014 will address this.				
16.	4.3 & 4.4.3	<b><i>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</i></b>  It was not possible to fully verify the thoroughness of certain official controls conducted as they were not auditable/ verifiable due to the lack of detailed information being recorded on certain inspection checklists/ records used and the fact that in certain cases no contemporaneous notes had	SFPA  <u>Port office</u>  DG – PO    KB – PO	<b><u>DG – PO</u></b> Detailed information to be recorded on all inspection checklists. Any contemporaneous notes to be retained.  <b><u>KB – PO</u></b>				Closed 19/06/18

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		<p>been kept and/or were available</p> <p>Additionally evidence used to generate an outcome/conclusion of satisfactory compliance for establishments as part of SFPA inspections conducted, was not always recorded. SFPAs verification of food business operator own checks, frequently did not specify the evidence being relied upon as confirmation of the food business operator's satisfactory compliance with requirements.</p>	DE – PO	<p>Check lists now held on file</p> <p><b><u>DE – PO</u></b></p> <p>Guidance for officers as part of revised standard operating procedure as to what level of detail required</p> <p><b><u>DG – PO</u></b></p> <p>Any evidence used to generate outcomes and conclusions to be recorded. Food business operator evidence of own checks to be specified in reports.</p> <p><b><u>KB – PO</u></b></p> <p>Official control samples used to verify compliance</p>				

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17.	4.3 & 4.4.3	<p><b><i>SFPA Documented Procedures &amp; Biotoxin Monitoring and Verification of LBM Production Areas &amp; Establishments</i></b></p> <p>SFPO inspections had not identified that some food business operators were not using the appropriate sample plans in order to comply with the requirements of Regulation (EC) No. 2073/2005 e.g. <i>Salmonella</i> testing in LBMs</p>	<p>SFPA</p> <p><u>Port office</u></p> <p>DE – PO</p> <p>KB – PO</p>	<p><b><u>DE – PO</u></b></p> <p>Use of guidance document when sampling.</p> <p><b><u>KB – PO</u></b></p> <p>General findings of the audit to be discussed at the next food safety port meeting and corrective actions will be discussed.</p>					Closed 19/06/18

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18.	4.5	<p><b>Monitoring, Review and Evaluation of the Effectiveness of Official Controls Performed</b></p> <p>At the time of the audit, there was a general lack of evidence of reviews of the performance of official controls at both central level and within the port offices visited, which was not in accordance with the requirements of Regulation (EC) No. 882/2004 (and in particular article 8.3 a) as part of the verification of effectiveness of official controls carried out</p>	<p>SFPA <u>Central Level</u></p> <p><u>Port offices</u></p> <p>DE – PO</p> <p>KB – PO</p> <p>DG – PO</p>	<p><b><u>DE – PO</u></b></p> <p>New database to provide clarity re acceptable / unacceptable results and appropriate follow up.</p> <p><b><u>KB – PO</u></b></p> <p>Status review beginning 2014</p> <p><b><u>DG – PO</u></b></p> <p>Reviews of performance of OCs to be recorded by SPO. Establishment files to have individual review sheets to be completed by SPO.</p>					Closed 19/06/18

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19.	1.7	<p><b><i>Monitoring, Review and Evaluation of the Effectiveness of Official Controls Performed</i></b></p> <p>Internal audits for assessing performance of official controls (i.e. in order to comply with the requirements of Article 4.6 of Regulation (EC) No. 882/2004) were not taking place at the time of the FSAI audit.</p>	<p>SFPA</p> <p><u>Central Level</u></p>	<p>National Action Point- During quarter 4 of 2013 external consultants were employed to look at the area of verification of official controls by the SFPA. A planned follow up action to this is to look again at the area of internal audits during 2014 and take account of the recommendations of the report and recent audits.</p>				<p>Closed</p> <p>01/10/15</p>

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20.	4.7	<p><b>Approval of Establishments</b></p> <p>The audit team observed as part of the paperwork review establishment files within the port offices and at central level, that while approvals at the time of the audit were in general reflective of LBM activities and operations, a number of exceptions were also identified.</p>	<p>SFPA</p> <p><u>Central Level</u></p> <p><u>Port offices</u></p> <p>DE – PO</p> <p>KB – PO</p> <p>DG – PO</p>	<p><b><u>DE – PO</u></b></p> <p>Premises activities v approved activities now part of the checks on full audit</p> <p><b><u>DG – PO</u></b></p> <p>Approval Certificates reviewed – recommendations and amendments sent to SFPA HQ 2/9/13.</p>					Closed 19/06/18

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21.	5.0	<p><b>Food business operator Controls performed in accordance with Regulations 178/2002, 852/2004 &amp; 853/2004</b></p> <p>The non-compliances identified as part of the on-site verification activity should be closed out by SFPA in conjunction with the food business operators.</p>	<p>SFPA</p> <p>Port offices</p> <p>DE – PO</p> <p>KB – PO</p> <p>DG – PO</p>	<p><b><u>DE – PO</u></b></p> <p><b><u>KB – PO</u></b></p> <p>Closed out (Oct 2013)</p> <p><b><u>DG – PO</u></b></p> <p>All identified non-compliances closed out in conjunction with food business operator. (22/11/13)</p>					Closed 31/10/16








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