

# **Food Standards Agency in Scotland**

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## **Report on the Focussed Audit of the Delivery of Official Controls for the Sampling of Shellfish**

### **Operations (Scotland)**

**02 - 04 June 2014**

**and**

**25 June 2014**

## Foreword

The primary purpose of Agency audits is to provide assurance that delivery of official controls for food and feed comply with EC and UK legal requirements and official guidance. Audit is defined as a systematic and independent examination to determine whether activities and related results comply with the planned arrangement and whether these planned arrangements are implemented effectively and are suitable to achieve objectives. The detailed guidelines for the conduct of audits of competent authorities are set out in an EC Decision of October 2006<sup>1</sup>.

Audits of the delivery of official controls are part of the Food Standards Agency's arrangements to improve consumer protection and confidence in relation to food and feed. These arrangements recognise that the enforcement of UK food law relating to food safety can often be carried out by the Central Competent Authority or their authorised Contractors or Internal Delivery Partners.

The audit programme sought to gain assurance that the Contractors and Internal Delivery Partners, so far as it relates to the delivery of official controls for the sampling of shellfish, are effective and comply with the contract in place, and also provides the opportunity to identify and disseminate good practice and provide information to inform Agency policy on food safety, standards and feeding stuffs.

It should be acknowledged that there will be considerable diversity in the way and manner in which official controls for a fully managed service for shellfish sampling are delivered reflecting the individual Contractors and Internal Delivery Partners' delivery arrangements.

For assistance, a glossary of technical terms used within this audit report can be found at Annexe C.

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<sup>1</sup>Commission Decision (October 2006): *'Guidelines laying down criteria for the conduct of audits under Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules'*.

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## 1.0 Introduction

- 1.1 This report records the results of an audit of Operations (Scotland) with regard to compliance with the Memorandum of Understanding (MOU) for the Provision of a Fully Managed Service for Shellfish Sampling in the regions of Dumfries & Galloway, North Ayrshire and South Ayrshire, which became effective from 01 April 2012. The audit focused on the Internal Delivery Partners arrangements for organising and delivering the management of sampling, and internal monitoring. The report has been made available on the Agency's website at:  
[www.food.gov.uk/enforcement/auditandmonitoring/auditreports](http://www.food.gov.uk/enforcement/auditandmonitoring/auditreports)

### ***Reason for the Audit***

- 1.2 The power to set standards, monitor and audit the delivery of official controls was conferred on the Food Standards Agency by Section 12 of the Food Standards Act 1999 and Regulation 7 of The Official Feed and Food Controls (Scotland) Regulations 2009. This audit of Operations (Scotland) was undertaken under section 12(4) of the Act, and Regulation 7(4) of the Regulations as part of the Food Standards Agency in Scotland (FSAS) audit programme.
- 1.3 There have been no previous FSA audits of Operations (Scotland) in relation to shellfish sampling; Local Authorities and a Contractor have been audited in the past on Shellfish matters,

### ***Scope of the Audit***

- 1.4 The audit covered the Internal Delivery Partners services for the delivery of official controls as detailed in the Memorandum of Understanding for the Provision of a Fully Managed Service for Shellfish Sampling (effective from 01 April 2012).
- 1.5 The Audit brief was sent to the Internal Delivery Partner in advance of the audit programme beginning and is available at  
<http://www.food.gov.uk/multimedia/pdfs/enforcement/enfs13005.pdf>
- 1.6 The audit examined the Operations (Scotland) local systems and procedures for the official controls on shellfish sampling and specifically the ability to meet and fulfil the Memorandum of Understanding for the Provision of a Fully Managed Service for Shellfish Sampling which specifically does not include any enforcement actions. This included verification checks with a Shellfish Sampling Officer to assess the effectiveness of official controls in relation to shellfish sampling implemented by the Internal Delivery Partner. The scope of the audit also included an assessment of the Internal Delivery Partners overall organisation and management, and the delivery and internal monitoring of shellfish sampling activities.
- 1.7 The audit examined systems and arrangements to determine that they were effective in supporting the official controls on shellfish and that local delivery was managed effectively. The on-site element of the audit took place at the Internal Delivery Partners office in Ayr and the reality checks were at various shellfish harvesting and storage locations within the Operations (Scotland) region of Dumfries and Galloway, North Ayrshire and South Ayrshire. The second part of

the audit took place in the FSAS office at St Magnus House, Guild Street, Aberdeen.

***Background***

- 1.8 The FSA is required to verify that official controls of bivalve molluscs and marine gastropods are organised and carried out in accordance with the relevant provisions of Regulation (EC) No 882/2004 of the European Parliament on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.
- 1.9 The Memorandum of Understanding, between The Food Standards Agency and Operations (Scotland), for the Provision of a Fully Managed Service for Shellfish Sampling is effective from 1 April 2012.
- 1.10 Operations (Scotland) do not deliver shellfish enforcement on behalf of FSAS. Any official controls after determination of sample results is passed to the relevant Local Authority for action.
- 1.11 The staffing allocation available to undertake shellfish sampling is 0.35 full time equivalent (FTE) Officer, as advised following the pre-visit questionnaire. The sampling duties are shared between 3 authorised officers based in one location in Ayr.

## 2.0 Executive Summary

- 2.1 The Internal Delivery Partner implements a Sampling Plan for 2014-2015, which is produced by the Food Standards Agency and is designed to cover the taking, at an appropriate frequency, of adequate numbers of samples of water for phytoplankton and shellfish flesh for marine bio-toxins, chemical contaminants and E. coli.
- 2.2 The Internal Delivery Partner had developed basic documented procedures relating to their shellfish sampling responsibilities. These documents were available to all Officers in electronic format on a central directory and hard copy in their office.
- 2.3 The Shellfish Sampling Officers have authorisation documents which do not follow the Internal Delivery Partners documented Scheme of Delegation. This scheme has authorised the Head of Operation Assurance to delegate authorisation to three named individuals, none of whom operate in Scotland and are not the signatory on the officer authorisation audited.
- 2.4 Authorisation documents do not include the power to take samples and the terminology used is inappropriate when describing the type of legislation covered by the authorisation.
- 2.5 Individual Officer training needs for shellfish sampling were included as part of the annual Personal Review and Development meeting. There were training records available for Shellfish Sampling Officers to demonstrate they had attended the FSA Shellfish Sampling Officers training course.
- 2.6 The Protocol for sampling and transport of shellfish for the purpose of official control monitoring was generally being followed with only the accuracy of the sampling location being a concern as the Representative Monitoring Point (RMP) was not accessible for the water sample.
- 2.7 Reality checks at three locations confirmed that the Internal Delivery Partner was generally completing sampling in accordance with the protocol and contract. However, it was noted that there was a high dependence on unverified samples which are provided by the Food Business Operator.
- 2.8 Discussion and review of qualitative internal monitoring procedures and practices indicated that the Internal Delivery Partner was not able to provide satisfactory evidence of active qualitative monitoring of many aspects of the work undertaken by Shellfish Sampling Officers.

### **3.0 Audit Findings**

#### **3.1 Sampling Plan**

- 3.1.1 The Internal Delivery Partner is provided with a sampling plan annually by the FSAS, which may be updated as new areas are classified for the production of shellfish. For water samples tested for phytoplankton and flesh samples tested for bio-toxin the plan indicates the required weeks in which the samples are to be taken. In case of E. coli in general the frequency is monthly and at least 10 samples in any calendar year are to be submitted. For chemical contaminants flesh samples are collected once a year between January and March.
- 3.1.2 The Internal Delivery Partner is generally following the requisite plan, allowing sample Key Performance Indicators (KPI) to be achieved. Samples are almost always taken on a Monday to Wednesday to allow suitable time for transport to the laboratory and testing to be complete by Friday afternoon.
- 3.1.3 The Shellfish Sampling Officer was aware of the sampling programme, plan and procedure for effective sampling which allowed them to sample, as required, within a designated geographic area. There is very limited flexibility to determine the location of shellfish to sample as Representative Monitoring Points (RMP) have been established to provide consistency and validation of the testing programme. Tidal conditions frequently dictated when samples were accessible and could be a factor in ensuring that random sampling times were chosen as required by the protocol.
- 3.1.4 The quantities of shellfish being sampled are defined within the Sampling Protocol. These were known to the Sampling Officer who followed these guidelines
- 3.1.5 The aim of water sampling is to collect samples of phytoplankton that are representative of the phytoplankton community in the water body being sampled. The water sample should be taken as close to the shellfish bed as possible and at the location from where shellfish samples for flesh testing are taken. This is determined by the Representative Monitoring Point (RMP) which can be moved if required.
- 3.1.6 The Shellfish Sampling Officer demonstrated his capability in shore line water collection by the bucket method which however was not fully in accordance with the Guidance provided by the Scottish Association for Marine Science (SAMS) as the RMP was inaccessible and the sampling point was not in the vicinity of the shellfish harvesting area. In this case the sample was taken a considerable distance from the RMP and the water sample was not a near surface sample, as sediment from the sea bed was present in the bucket of water.

#### **3.2 Sampling Management and Transport**

- 3.2.1 The appropriate version of the "Protocol for sampling and transport of shellfish for the purpose of Official Control Monitoring of classified shellfish production areas under Regulation EC 854/2004" was available.

Examples of documented Policies and Procedures were reviewed; these were very general in nature, had minor spelling mistakes and were imprecise in instructions. They were undated, un-numbered and had no apparent method of control.

These documents were available to all Officers in electronic format on a central directory.

Template documents for recording the collection of shellfish and water for examination were available for Officers to use on the shared drive of a computer. Completed copies of these were examined and found to be generally satisfactory.

- 3.2.2 Sampling equipment was being stored in the shared office within the Officers normal work place, resulting in significant potential for cross contamination as this was both an office, soiled laundry store and shared rest area for other staff (meat hygiene inspectors, veterinarian). The facility had no provision for hygiene controls and was not clean enough to ensure that the risk of cross contamination was adequately controlled.
- 3.2.3 Sampling equipment and collected samples were transported in the Officer's own car. The number of cool boxes involved, together with the other equipment required, were such that the car was very well stocked; however there was no sense of organisation and suitability to the way in which items were packed and accessed.

#### ***Recommendation***

3.2.4 The Contractor should:

Ensure that suitable facilities for the storing of all sampling equipment and materials is available;

Ensure that suitable transport arrangements are available for sampling officers to use, carry and store sampling equipment and accessories.

#### ***Verification Visits with Shellfish Sampling Officers***

- 3.2.5 During the audit, verification visits were undertaken with one Officer to three different sites and verified and unverified sampling was observed. The main objective of the visits was to assess the effectiveness of the Internal Delivery Partners delivery of the Shellfish Sampling Programme in accordance with the Sampling Protocols.
- 3.2.6 The specific assessments included the preparation for the sampling visit, the conduct of the sampling event and the adherence to the sampling protocols.



- 3.2.7 The Shellfish Sampling Officer was interviewed before the verification visits took place to explain the format and objectives of the visit. It also gave the Officer the opportunity to explain the sampling process, i.e. the preparatory work carried out prior to sampling and the general processes while on site, which included the adherence to the Internal Delivery Partners health and safety requirements and the bio-security requirements in the CEFAS Protocol.
- 3.2.8 The verification visits satisfied the auditors that the Officer had generally followed the sampling protocols. However there were a small number of operational issues noted during and after the sampling process. These included:
- The water taken for the phytoplankton testing had sediment present which was allowed to settle
  - The water sampling point was not close to the RMP
  - Disinfectant and fresh water was available throughout the sampling process to disinfect equipment and to implement bio-security precautions between sites although in a very limited quantity
  - Some samples collected from the FBO were unverified and contained labelled duplicates that were selected and sent for testing without being able to establish exactly where that sample had originated
  - The private car of the Sampling Officer was barely adequate to carry all the cool boxes, other equipment and documentation.

**Recommendation**

3.2.9 The Contractor should:

Verify its conformance with relevant centrally issued guidance and any documented procedures.

**Facilities and Equipment**

- 3.2.10 The freezer temperatures were not being recorded to verify by evidence that the cool blocks were frozen to minus 18 degrees centigrade.
- 3.2.11 An office based electronic thermometer used specifically for shellfish sampling had not been calibrated. The cool blocks used, however, are placed in the freezer for at least 48 hours before use and the laboratories have recorded that the samples are at a satisfactory temperature when received. Alcohol in glass thermometers were not in use as these have been replaced with electronic probe thermometers. It is recommended that thermometers are regularly calibrated and then used to ensure that freezers are working at minus 18 degrees centigrade.

**Recommendation**

3.2.12 The Contractor should:

Ensure that equipment is properly maintained and calibrated.

### 3.3 Reporting and Liaison

Regular liaison is taking place within the Internal Delivery Partners structure and with the FSAS.

Completion of sample forms and labels were found to be satisfactory and in accordance with the requirements of the Protocol.

### 3.4 Capacity

#### ***Officer Authorisation***

3.4.1 The Internal Delivery Partner has a scheme for delegating authority where the Head of Operation Assurance can delegate authorisation to three named individuals, none of which are the undefined signatory on the audited officer authorisation.

3.4.2 The Authorisation document in use for the Shellfish Sampling Officer refers to a list of five EC Regulations, The Food Safety Act 1990, The Food Hygiene (Scotland) Regulations 2006, The General Food Regulations 2004 and the Official Feed and Food Controls (Scotland) Regulations 2008 collectively termed as "The Regulations". This term is not a recognised one, as "The Hygiene Regulations" do not include Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, The Official Feed and Food Control Regulations, The Food Safety Act or the General Food Regulations named in the list.

Using the term "Regulations" to include an Act is not accurate.

3.4.3 The Authorisation document is not in accordance with Agency guidance that the specific powers available to officers should be listed or shown. Specifically the power to procure samples under Regulation 12 of the Food Hygiene (Scotland) Regulations 2006 is absent.

#### ***Recommendation***

3.4.4 The Contractor should ensure that:

The documented procedure for the authorisation of officers is in accordance with centrally issued guidance;

The authorisation and duties of Officers should be consistent with their training, and experience.

3.4.5 The Internal Delivery Partner was able to provide copies of qualifications and training certificates during the audit and evidence of Shellfish Sampling Officers training records was also available. The Food Law Code of Practice requires that authorised officers receive minimum on-going training which should be 10 hours per year based on the principles of continuing professional development (CPD).

- 3.4.6 Individual training needs for shellfish sampling duties are discussed at the annual Personal Review and Development meetings or the subsequent reviews. Records of these discussions were available. Periodic team meetings were not documented so cannot be used as justification for CPD.

### **3.5 Capacity Contingency**

- 3.5.1 There are 3 trained Shellfish Sampling Officers available at the location visited. Each one participates regularly in the taking of samples. This is considered as being satisfactory.

### **3.6 Continuous Improvement**

#### ***Internal Monitoring***

- 3.6.1 There is no Internal Monitoring Procedure for the performance and quality of the Internal Delivery Partners shellfish sampling activities. The performance indicators monitored relate only to the KPI's in the MOU and are quantitative ones and are reported regularly to the FSAS.
- 3.6.2 There is limited qualitative monitoring taking place during regular meetings with the Service Delivery Manager; however there were no records of internal monitoring as notes or minutes of these meetings are not made.
- 3.6.3 The Auditors were advised that little formal internal monitoring takes place due to the larger restructuring and resource issues. The Shellfish Co-ordinator within the team, however, works alongside the other 2 Sampling Officers and he assists in their work and informed the auditors he is constantly aware of the status of the sampling programme.
- 3.6.4 Weekly returns from the Internal Delivery Partner to the Agency and the reporting of results from the laboratories allow work plans and outcomes to be externally monitored and reported in relation to the KPI's.

#### ***Recommendation***

- 3.6.5 In relation to shellfish sampling:

A record shall be made of all internal monitoring. This shall be kept for at least 2 years.

### **3.7 Health and Safety & Biosecurity Advice**

The Agency requires the Internal Delivery Partner to take all measures necessary to comply with the requirements of the Health and Safety at Work etc Act 1974 and any other acts, orders, regulations and codes of practice relating to health and safety.

The Internal Delivery Partner has a generic Risk Assessment for Shellfish Sampling. This refers to a risk assessment for lone working and also driving at work. The lone working document of March 2014 does not appear to have been drafted with shellfish sampling being covered.

It was identified that the Sampling Officers had not completed any Basic Sea Survival courses even though they may be working alone around a harbour or be on a boat with a shellfish farmer.

Equipment for shellfish sampling is required to be fit for purpose and adequately maintained. The life jackets provided to Officers had recently been serviced.

- 3.7.1 The Sampling Officers had been provided with the necessary equipment detailed in the Protocol to allow them to perform their role. At each of the verification visits the Officer demonstrated compliance with the recommended minimum bio-security procedures as recommended by Marine Scotland who advise FSAS in supporting the Scottish Government's vision of having marine and coastal environments which are clean, healthy, safe, productive and biologically diverse.
- 3.7.2 The Cefas Protocol that supports the Shellfish MOU for official control monitoring details that "sampling officers must be mindful of the risks of introduction or transfer of shellfish pathogens to the areas being visited, through their sampling activities. Officers are asked to comply with minimum biosecurity measures such as cleaning and disinfection of equipment and shoes/boots between sites".
- 3.7.3 The Shellfish Sampling Officer had one litre of water to use to clean equipment and utensils between the 3 sites. This could easily be insufficient as it was observed that one site was very muddy and the waders used became very dirty. It is recommended that a suitable and sufficient supply of fresh water be provided at all times when sampling.

**Recommendation**

3.7.4 In relation to bio-security:

Suitable cleaning supplies and equipment to enable cleaning of shoes/boots between sites sufficient to allow the required disinfectant to be sprayed onto a clean surface should be provided and used.

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## ANNEXE A

Action Plan for Operations (Scotland)

Audit dates: 02 - 04 June and 25 June 2014

TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
<p>Ensure that suitable facilities for the storing of all sampling equipment and materials is available</p> <p>Ensure that suitable transport arrangements are available for sampling officers to use to carry and store sampling equipment and accessories.</p>	<p>30 Sept 2014</p> <p>01 April 2015</p>	<p>A redundant storage cabinet will be relocated from the FSA office in Aberdeen to the unit in Ayr for the storage of sample collection boxes and other equipment by the end of September 2014. We will also investigate the hire of a small van for the use of sampling officers to use, carry and store sampling equipment. However, as sampling only takes place on one day per week at present it is unlikely that this will be a cost effective solution unless the volume of samples substantially increases in this area. If a van is to be acquired it will be introduced from April 2015 as the demand for sampling with reduce during the coming winter months.</p>	<p>Storage cabinet sourced and now used for tidying away of sample collection boxes and other equipment.</p> <p>Reviewed transport arrangements and use of sampling officers own vehicles and arrangements are considered to be satisfactory with sampling equipment and goods stored in vehicles in organised manner.</p>	<p>A requisition for transport of the cabinet from Aberdeen to Ayr has been raised and a delivery date will be advised shortly.</p> <p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>Evidence of this is requested. Digital photographs showing the arrangements in place for both of the paragraphs in the “Recommendations “ column would be acceptable.</p> <p><b>FSS Update 23 Oct 2015</b> <b>Satisfactory evidence as requested has been provided by email on 24 September 2015.</b></p> <p><b>Recommendation closed.</b></p>

TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
<p>The documented procedure for the authorisation of officers should be in accordance with centrally issued guidance.</p> <p>The authorisation and duties of Officers should be consistent with their training, and experience and centrally issued guidance.</p>	01 Oct 2014	As authorisations issued by FSA in Scotland to shellfish sampling contractors have been deemed to be compliant, FSA in Scotland will initiate a reissue of authorisations for FSA Operations staff in Scotland.	Re- issue of FSS authorisation will be completed by end of July 2015. FSS ID cards require amendment Rita Botto to explore.	<p><i>The matter of non-compliant authorisations was referred to the Head of Operations Assurance on 8/8/14 and on 14/8/14 she advised that the best way forward would be for the Aberdeen office to issue the shellfish authorisations for the FSA MHIs. Scotland Operations have been provided with a compliant template 19/8/14</i></p> <p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>Evidence is requested to verify that a new and suitable procedure or scheme for delegation is in place. Copies of relevant documentation would be acceptable.</p> <p>Evidence of copies of the authorisation documentation for 3 sampling officers is requested</p> <p><b>FSS Update 23 Oct 2015</b>  <b>Satisfactory evidence as requested has been provided by email on 24 September 2015.</b>  <b>Recommendation closed.</b></p>

TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
Shellfish Sampling Officers should receive the ongoing training needed to be competent to deliver the technical and administrative aspects of the work in which they will be involved.	Oct 2014	Training and development discussions are an integral part of the performance management process and the next discussion in October 2014 will cover this matter as normal.	Completed February 2015. Deep sea survival training TBC by end September 2015.	<p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>Evidence of completion of relevant training should be provided to verify that 10 hours CPD per year is being achieved.</p> <p><b>FSS Update 23 Oct 2015</b> Satisfactory evidence as requested has been provided by email on 24 September 2015.</p> <p><b>Recommendation closed.</b></p>

TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
The Internal Delivery Partner should ensure that equipment is properly maintained and calibrated.	01 Oct 2014	The issue of the supply of calibrated thermometers has been referred to the FSAS shellfish unit as we have agreed that they should specify the supplier and methodology of calibration.	Paul McInnes SUPMHI will order new thermometer 20/07/15. Weekly check of freezer temperature will now be entered in electronic day book (OWS system)	<p><i>A log of daily freezer temperatures is now kept in the shellfish sampling day book.</i></p> <p><i>A replacement thermometer has been ordered from the Business Support Unit. If calibrated units are not available we will revert to alcohol in glass units.</i></p> <p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>Evidence (digital photographs, purchase order, recording logs or meeting notes etc) to verify that suitable thermometers are in use and are appropriately calibrated is required.</p> <p>A copy of the log for freezer temperatures covering the period 1<sup>st</sup> April to 31 August 2015 is requested.</p> <p><b>FSS Update 23 Oct 2015</b>  <b>Satisfactory evidence as requested has been provided by email on 24 September 2015.</b></p> <p><b>Recommendation closed.</b></p>



TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
The Internal Delivery Partner should verify its conformance with relevant centrally issued guidance and any documented procedures.	01 Sept 2014	The cluster SUPMHI will carry out regular routine inspections to verify procedures and will detail his activities and findings in the recently introduced shellfish sampling specific daybook.	Cluster SUPMHI will verify procedures weekly/monthly via electronic day book and physical checks will be made quarterly by SUPMHI.	<p><i>SUPMHI attended agreement review meeting in August and will commence duties in mid-August.</i></p> <p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>Copies of both the first two of these verification checks as well as the 2 most recent of these (so a total of 4 routine inspections) is requested together with a timeline summarising the management controls carried out since 1<sup>st</sup> December 2014 to 31<sup>st</sup> August 2015.</p> <p><b>FSS Update 23 Oct 2015</b> Satisfactory evidence as requested has been provided by email on 24 September 2015.</p> <p><b>Recommendation closed.</b></p>

TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
<p>In relation to shellfish sampling:</p> <p>A record shall be made of all internal monitoring. This shall be kept for at least 2 years.</p>	30 July 2014	<p>Internal monitoring has now been included on monthly team meeting agendas and a monthly report on shellfish sampling performance is now presented to the Operations management Team on a monthly basis.</p>	<p>Standing item on Team meeting agenda every 6 weeks.</p>	<p><i>The first report was presented on 30 July</i></p> <p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>Clarification on the frequency of internal monitoring is requested to verify the frequency of meetings.</p> <p>Evidence to verify that a monthly report is being produced and that any corrective actions are being implemented for any 3 consecutive month period is requested.</p> <p><b>FSS Update 23 Oct 2015</b> Satisfactory evidence as requested has been provided by email on 24 September 2015.</p> <p><b>Recommendation closed.</b></p>

TO ADDRESS (RECOMMENDATION INCLUDING STANDARD PARAGRAPH)	BY (DATE)	PLANNED IMPROVEMENTS	PROGRESS	ACTION TAKEN
<p>In relation to bio-security:</p> <p>Suitable cleaning supplies and equipment to enable cleaning of shoes/boots between sites sufficient to allow the required disinfectant to be sprayed onto a clean surface should be provided and used.</p> <p>Shellfish Sampling14/Ops/08</p>	<p>30 Sept 2014</p>	<p>Receptacle for holding up to 10l of water will be sourced and FSAS shellfish unit have provided a list of disinfectants. BSU will be asked to supply in the first instance</p>	<p>Actioned and completed 30/09/2014. Sufficient supply of disinfectant stored and arrangements in place for maintain an adequate supply.</p>	<p><i>Recommended list of disinfectants has been sourced and referred to BSU for supply. Local sources of potable water at various sampling locations have been identified.</i></p> <p><b>FSS Request for evidence – 03 Sept 2015</b></p> <p>A digital photograph of the details of the disinfectant used together with a link to the supplier/manufactures website to verify the chemical is requested.</p> <p>Any documentation that has been produced or is in use to ensure that suitable cleaning and disinfection of boots or other equipment is required is requested.</p> <p>Digital photographs of any receptacles used to transport the clean water supply are requested.</p> <p><b>FSS Update 23 Oct 2015</b>  <b>Satisfactory evidence as requested has been provided by email on 24 September 2015.</b>  <b>Recommendation closed.</b>  November 2014</p>

## ANNEXE B

### Audit Approach/Methodology

The audit was conducted using a variety of approaches and methodologies as follows:

#### *(1) Examination of policies and procedures.*

The following policies, procedures and linked documents were examined before and during the audit:

- MOU for the provision of: A fully managed service for Shellfish Sampling
- CEFAS Protocol for sampling and transport of shellfish for the purposes of Official Control Monitoring of classified shellfish production areas under Regulation EC 854/2004
- Liz Olney Authorisation document (L:\DPU\delivery\Authorisations-13.35\Current Authorisations\Appointment letter 160310.doc
- Phytoplankton Sampling
- Biotxin Sampling
- E. coli sampling
- Equipment list
- Personal Location Beacon registration
- Shellfish PPE list
- Generic risk assessment – shellfish sampling
- Sampling schedules
- Shellfish sampling coding guidance
- Admin duties summary
- Shellfish financial weeks 2014/15

#### *(2) File reviews*

The following file records were reviewed during the audit:

- Training files & Qualifications
- Sample returns summary March April 2014
- Sampling performance April – June 2013-14

### *(3) Officer interviews*

The following Officers were interviewed:

- Audit Liaison Officer
- Authorised Officers who carried out the most recent sampling visits at the sites selected for a verification visit.
- Service Delivery Manager

Opinions, comments and views raised during Officer Interviews remain confidential and are not referred to directly within the report.

### *(4) Verification visits:*

Verification visits were made with one Officer to 3 shellfish harvesting sites. The purpose of the verification visits was to assess the shellfish and water sampling methodology in accordance with the “MOU for the Provision of a Fully Managed Service for Shellfish Sampling”, and to verify that the terms of the MOU were being fulfilled.

**ANNEXE C****Glossary**

Audit	Audit means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Authorised Officer	A suitably qualified Officer who is authorised by the Agency to act on its behalf in, for example, the enforcement of legislation.
E. coli	<i>Escherichia coli</i> microorganism, the presence of which is used as an indicator of faecal contamination of food or water. <i>E. coli</i> O157:H7 is a serious food borne pathogen.
Food hygiene	The legal requirements covering the safety and wholesomeness of food
Food Standards Agency	<p>The Food Standards Agency is an independent Government department set up by an Act of parliament in 2000 to protect the public's health and consumer interests in relation to food.</p> <p>Everything we do reflects our vision of Safe food and healthy eating for all.</p>
Full Time Equivalents (FTE)	A figure which represents that part of an individual Officer's time available to a particular role or set of duties. It reflects the fact that individuals may work part-time, or may have other responsibilities within the organisation not related to food enforcement.