

**Shellfish
Supplementary Sampling
Guide**

A Guide on Food Business Operators' Supplementary Sampling In Support of the Official Microbiological Monitoring of Shellfish Production Areas (England and Wales)

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Glossary

Bivalve molluscs	Shellfish with a two-part shell that filter feed, such as oysters, mussels, clams, cockles, scallops
Cefas	Centre for the Environment, Fisheries and Aquaculture Science
Competent Authority	The central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred.
EQA	European Quality Assurance
FBO	Food Business Operator
FSA	Food Standards Agency
LFA	Local Food Authority, e.g. Local Authorities or Port Health Authorities
RMP	Representative monitoring point
UK-NRL	UK National Reference Laboratory (In this document, this refers to the UK-NRL for bacteriological and viral contamination of live bivalve molluscs)
UKAS	United Kingdom Accreditation Service

1. Introduction

This document has been produced for shellfish harvesters and Local Food Authorities (LFAs) in England and Wales. It follows requests from shellfish harvesters (referred to as food business operators (FBOs) in this document) who have expressed an interest in submitting samples to the Food Standards Agency's (FSA) official control microbiological monitoring programme for classified shellfish production areas in England and Wales.

The legal requirement for the use of harvesters' samples is set out in Annex II of Regulation (EC) No. 854/2004¹. It permits the Competent Authority (the FSA in the UK) to consider results from FBOs' sampling to supplement those from official control sampling in order to determine the classification, opening or closure of shellfish production areas following a protocol agreed by the Competent Authority and the FBO.

FBO samples are therefore intended to supplement official control samples (in addition) to those taken by the LFA. **They would be considered as part of the dataset to assess classifications, opening and closing of production areas. They may also be used to trigger action states.** An increase in available microbiological data from a production area may increase the knowledge of microbial contamination (and trends in water quality) in the area and possibly benefit compliance with regulatory limits.

The procedure must be agreed to ensure that FBO supplementary sampling and analysis is conducted under conditions comparable to sampling and analysis for official controls and is as representative as possible of the area being monitored. The procedure also creates an audit trail to help verify the authenticity and provenance of samples.

For supplementary samples to be considered, the FSA (as the Competent Authority) must have designated the laboratory carrying out the analysis. In addition to this, the sampling and analysis must have taken place in accordance with an agreed protocol.

This document describes the conditions that FBOs, LFA's and official control laboratories involved in the analysis would need to meet in cooperation with the FSA so that the results of FBOs' supplementary samples can be incorporated into the official control microbiological monitoring programme in England and Wales.

2. Requirements for use of supplementary samples submitted by FBOs

The following points summarise the steps that FBOs should follow in order to participate:

¹ Regulation (EC) No,854/2004, Annex II, part F

- The FBO makes an application in writing to their relevant LFA to initiate the process (**see Schedule 1**).
- The FBO and the laboratory enter into an agreement by completing a memorandum of understanding (MoU) with the LFA, so that their respective responsibilities are clear (**see Schedule 2**). All required information in the MoU, including the sampling plan must be completed and signed off by relevant parties at this stage.
- The LFA sends a copy of the agreement to the FSA as a means of formal notification. Any changes made to the MoU at a later date must also be forwarded by the LFA to the FSA with a brief explanation of the reasons.
- Samples are taken in accordance with predefined sampling requirements (**see Schedule 3**).
- Samples are analysed by laboratories (designated by the FSA) accredited for, and using, the official reference method (Most Probable Number, ISO TS 16649, part 3) or alternative methods accepted by the FSA (including the impedance method for the enumeration of *E. coli* in live shellfish using the BacTrac 4300 Analyser) with respect to bivalve molluscs. (Results obtained using other methods and from non-designated laboratories cannot be accepted for the purposes of classification, opening or closure of production areas).
- A sampling plan is agreed between the FBO and LFA (**see Annex A to Schedule 2**). To maximise the benefits from FBO sampling in terms of additional data, official control sampling and FBO supplementary sampling should take place at different times. Sampling should be consistent with the sampling plan used by the LFA for taking official control samples. This is to ensure that supplementary FBO samples are taken in the same way and from the same representative monitoring point as the LFA.
- Harvesters should aim to take all samples specified in the sampling plan. Results should be provided by the laboratory within agreed times and using the format specified in the sampling requirements (**see Schedule 3**). Any agreed changes to the sampling plan and/or sampling requirements should be sent to the FSA as soon as possible.
- The agreed sampling processes are to be made available for auditing by the Competent Authority (relevant LFA and/or FSA) if required.

If the requirements above are not followed, it is possible that the MoU may be terminated. This would lead to any data supplied not being taken into account for the microbiological monitoring programme.

3. The Application Process

FBO Application Form

All FBOs wishing to submit supplementary samples for classification, opening or closing of production areas should fill in an application form and send it to the relevant LFA. A standard application form can be found at Schedule 1.

Application Processing

On submission of a fully completed application form, the LFA will contact the FBO within 14 days of receipt to process the application. The LFA will also inform the FSA by email that an application form has been received and is being processed.

Memorandum of Understanding

Once the application form has been received and is accepted by the relevant LFA, the FBO, the laboratory and the LFA will sign a MoU to confirm agreement with the conditions of sampling and analysis outlined within this guide. The LFA will then send a copy of the signed agreement to the FSA. A template of a MoU is at Schedule 2.

4. Sampling Procedures

Training of FBOs

Before supplementary sampling can begin, it is important that all FBOs involved in collecting and submitting samples receive training on the sampling requirements (sample collection and packaging procedures) from an authorised sampling officer from the relevant LFA. This is because sampling and packaging can have unintended effects which might impact on the results and may even render them invalid. It is therefore necessary to ensure that all official control samples (taken by sampling officers and industry members) are collected and submitted according to the same protocol. Schedule 3 contains the requirements that all samplers should work to.

As working in a marine environment may be hazardous, we advise that training also includes health and safety components where necessary. The FSA and LFA cannot be held liable in the event of an accident.

Sampling Plan

Samples are to be collected in accordance with the sampling requirements in Schedule 3 and according to a sampling plan agreed with the LFA. It is recommended that the LFA agrees the proposed plan with the FSA to ensure that proposed sampling is consistent with the OC sampling plan and sanitary survey recommendations for the area. An example of a sampling plan is given in Annex A to Schedule 2.

With regard to the schedule for taking samples, it is recommended that FBOs' supplementary samples are taken at a time when they supplement rather than duplicate official control samples.

For instance, if the LFA plans to collect 8 samples in 12 months, the FBO could collect 4 samples at alternative times to increase the dataset.

All persons undertaking supplementary sampling and analyses for the monitoring programme should retain copies of the MoU and sampling plan for their reference.

Sampling plans are agreed so that official control and FBOs' supplementary sampling can help provide a valid picture of the bacterial contamination in a shellfish production area during the whole season of harvest. This is necessary because if one were to sample only at times when *E. coli* results are known to be lower, this would distort the picture and result in a classification that might be too favourable for a particular area and potentially place public health at risk. However, FBOs can opt out of submitting a sample when they have voluntarily ceased harvesting in the wake of operational or market constraints, or if events prevent harvesting or access to the harvesting area. FBOs should notify the LFA if they choose not to submit a sample so that a new sample submission date can be agreed.

Sample Submission Form

All samples sent to laboratories for analysis in the context of the monitoring programme should be accompanied by a completed sample submission form (Annex to Schedule 3). This ensures that all the necessary information regarding the sample is provided to the testing laboratory and logged. One copy of the submission form should be kept for the FBO's records. A testing laboratory may not accept a sample without a fully completed sample submission form. A copy of the form should be sent by the FBO to the LFA for their records.

5. Laboratory Requirements

FBO submitted samples can only be analysed in laboratories (designated by the FSA) accredited for, and using, the official reference method (Most Probable Number, ISO TS 16649, part 3) or alternative methods accepted by the FSA (including the impedance method for the enumeration of *E. coli* in live shellfish using the BacTrac 4300 Analyser) with respect to bivalve molluscs.

It is necessary that laboratories, involved in sample analysis for the official control monitoring programme, participate in UK National Reference Laboratory (UK-NRL) proficiency tests². They should also take part in the Public Health England's (PHE) Food External Quality Assurance (EQA) Shellfish Scheme and agree to the UK-NRL reviewing their performance in this. Laboratories must also be able to report results directly to the FBO, the relevant LFA, FSA Co-ordinators, and the Cefas Classification team (shellclass@cefasc.co.uk). Results above the classification limit for an area should be reported immediately. All other results should be reported within 3 -

² In a proficiency test, a large sample is divided among all participating laboratories who then analyse the sample as usual. Since all laboratories work on the same sample and should therefore produce comparable results, proficiency tests are a good way of detecting any problems that might adversely affect results and thereby classifications.

5 days of onset of analysis. For ease of communication, we suggest this is done by email.

A list of the Official Food Control Laboratories in the UK can be found at <http://www.food.gov.uk/enforcement/monitoring/foodlabs/foodcontrollabs>. A list of laboratories that have informed the NRL that they undertake microbiological examination of official control samples of bivalve molluscs can be found at <http://www.cefas.defra.gov.uk/nrl/laboratory-network.aspx>.

Any laboratory involved in the analysis of FBOs' supplementary samples for the official control microbiological monitoring programme should enter into an agreement with the relevant LFA and agree to ensure that results are provided to the right contacts using the required format within the required time-frame. The results of all supplementary samples submitted to the programme should be reported to the LFA and FSA and Cefas directly by the testing laboratory.

6. Costs of Sampling and Analyses

FBOs will meet the costs associated with the sampling and laboratory analysis of the samples they submit. The FSA is unable to reimburse FBOs for any expenditure that arises from FBO submitted samples to the official control monitoring programme. Samples taken by the LFA or on behalf of the LFA as part of the official control monitoring programme will continue to be paid for by the LFA, the latter subject to agreement.

7. Auditing of Sampling Procedures

In order to ensure that industry sampling is comparable with official control sampling and to verify sample provenance, FBOs providing supplementary sample results to the microbiological monitoring programme should make their procedures available for auditing by the LFA, if required. Audits may or may not be announced and could include checks on sample recording and sample collection procedures to ensure that all the necessary aspects of this protocol have been met. Physical audits of the collection of samples and sample transport procedures could also be undertaken. We advise that the LFA determines how frequently these audits should take place.

8. Data Assessment

Supplementary FBO samples will be used in conjunction with the official control samples collected by the LFA. Results will be incorporated into the dataset for the corresponding RMP and assessed in the same manner as results from the LFA's sampling to assess compliance and determine classifications (see Classification Protocol for England and Wales <http://www.cefas.defra.gov.uk/media/624728/201311%20classification%20protocol%20revised%20version%207.pdf>).

9. Voluntary Cancellation by the FBO

FBOs who no longer wish to submit supplementary samples may voluntarily cancel this agreement by giving appropriate notice to all contractual partners (different cancellation clauses may apply to the contracts held with laboratories). Voluntary cancellation of the agreement will not affect the data supplied thus far as all results will continue to be taken into account for classification purposes.

10. Enquiries

Enquiries relating to this guide, and operation and enforcement of the official control microbiological monitoring programme should be addressed in the first instance to the following contacts.

England

Shellfish Team
Food Standards Agency
Floors 6 and 7
Clive House
70 Petty France
LONDON
SW1H 9EX

Tel: 020 7276 8454/8167

Email: shellfish@food.gov.uk

Wales

Daniel Morelli or Jonathan Downey
Local Authority Delivery and Support Team
Food Standards Agency Wales
11th Floor Southgate House
Wood Street
Cardiff CS10 1EW

Email: lasupportwales@food.gov.uk and Food.Policy.Wales@food.gov.uk

Schedule 1 – Application Form

Application Form for the Consideration of Use of Food Business Operator Supplementary Sampling Results for the Microbiological Monitoring Programme

Applicant details	Local Food Authority details
*Applicant:	*Authority:
*Company:	*Enforcement Officer:
*Address:	*Address:
*Tel No:	*Tel No:
Mobile:	Mobile:
Fax No:	Fax No:
*Email:	*Email:
Harvesting details	Site details
*Species: (Common and Scientific name) 1. 2. 3.	*Location/Grid ref (OS lat/long)
	*Production area name:
	*Bed/Site name/Current classification:
	*Monitoring point identification number:
*Signature of Applicant:	
*Date:	

* Mandatory information

Please refer to the Supplementary sampling guidance - *on the use of food business operator submitted sampling results in the official control programme for microbiological monitoring of classified live bivalve mollusc production areas in England and Wales* to ensure that you are familiar with the full details of the requirements for use of your own results in the monitoring programme prior to submission of this form.

Schedule 2 – Template Memorandum of Understanding

Memorandum of Understanding for the Provision of Data for the Microbiological Monitoring Programme

Reference Number:

outlining the agreement between

Food Business Operator: _____

Local Food Authority: _____

Laboratory: _____

relating to the provision of data for the microbiological monitoring of [INSERT site identification number, bed name and monitoring point reference] located in [INSERT production area name] by way of samples of [INSERT species] taken from this site according to an agreed sampling plan.

Results will be used to supplement those from official control sampling in the microbiological monitoring programme for England and Wales, in accordance with Regulation (EC) No. 854/2004. By signing this memorandum of understanding, all parties agree to undertake the respective tasks listed below.

Food business operator

- All samples are collected and handled in accordance with the sampling requirements defined by the Food Standards Agency's (Food Business Operators' Supplementary Sampling Guide *for the official control microbiological monitoring of shellfish production areas in England and Wales*).
- All samples are submitted according to a sampling plan agreed with the LFA, using the template at Annex A. Modifications of the plan are notified to and agreed with the LFA.
- A completed sample submission form accompanies each sample sent to the laboratory.
- The results of all samples submitted to the programme are reported to the LFA and the FSA directly by the testing laboratory.

Laboratory

- All samples are analysed by designated official control laboratories (<http://www.food.gov.uk/enforcement/monitoring/foodlabs/foodcontrollabs>). accredited for, and using, the official reference method (Most Probable Number, ISO TS 16649, part 3) or alternative methods accepted by the FSA (including the impedance method for the enumeration of *E. coli* in live shellfish using the BacTrac 4300 Analyser) with respect to bivalve molluscs. Samples are handled according to the recommendations made

by the UK-NRL for monitoring bacteriological and viral contamination of live bivalve molluscs and in accordance with the relevant provisions in the Food Standards Agency's guide (*Food business operators' Supplementary Sampling Guide for the official control microbiological monitoring of shellfish production areas in England and Wales*).

- All results are reported to the food business operator, LFA and FSA at the same time and within 3-5 working days of completion of the testing. Results above the classification limit for an area must be reported immediately by telephone and followed by an email.
- Results are reported by email using the template suggested in Annex B. Other templates may be used provided all the information contained in Annex B is included.
- The laboratory must be accredited for the specified method(s) in accordance with ISO 17025.
- By signing this memorandum of understanding, the laboratory agrees to participate in UK-NRL proficiency tests and the Health Protection Agency's Food EQA Shellfish Scheme, with the UK-NRL reviewing its performance in the latter.

This memorandum of understanding can be annulled by all the undersigned after agreement with the FSA if legislative changes result in substantial changes in the existing conditions of the agreement. Food business operators may voluntarily cancel this agreement by giving appropriate notice to all parties if they no longer wish to submit their own samples (different cancellation clauses may apply to the agreement held with laboratories). The FSA and LFA will not be responsible for any expenses connected with the gathering, transporting, handling or analyses of industry samples or in the initial reporting of analytical results.

This agreement is valid after approval by the Competent Authority. A copy of this agreement should be sent to the FSA by the LFA.

For the food business operator	For the laboratory
Date:	Date:
Signed:	Signed:
Printed:	Printed:
Position:	Position:
For the Local Food Authority	
Date:	Printed:
Signed:	Position:

Annex A to Template Memorandum of Understanding

Example sampling plan for the collection of live bivalve molluscs

This sampling plan is agreed between [INSERT name of food business operator], [INSERT name of Local Food Authority], [INSERT name of laboratory] in accordance with Reference No. [XXX]. Samples of [INSERT species] will be taken only from the designated monitoring point [INSERT monitoring point reference number and grid reference] in [INSERT bed name and production area] at an agreed frequency (example shown below).

Samples should be submitted to [INSERT name of laboratory] as previously agreed with the LFA and FSA within 48 hours of sampling. Laboratory results will be provided to the FBO, LFA, FSA and Cefas in the agreed manner within 3 - 5 days of onset of analysis. Results above the classification limit for the area must be reported immediately. Failure to comply with these timeframes may affect the acceptability of sample results. A copy of the completed plan must be sent to the FSA.

FBOs can decide not to submit a sample when it is due, for example when they voluntarily cease harvesting. In this case, the LFA and FSA should be notified in advance of the planned collection date, so that the sampling plan may be adjusted.

The sampling plan below can be adapted to the agreed frequency of sampling. FBOs can sample more than once per month if they so wish, but ideally at intervals with the LFA sampling in order to maximise the benefits from these extra samples in terms of the amount of environmental information available for the harvesting area.

Period [INSERT Year]	Sample	Sample Reference Number
January week [X]	1 sample of [INSERT species] from [INSERT MPR]	XX1
February week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX2
March week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX3
April week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX4
May week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX5
June week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX6
July week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX7
August week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX8
September week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX9
October week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX10
November week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX11
December week [X]	1 sample of [INSERT species] from [INSERT RMP]	XX12

Terms to cancel contractual agreements may vary across different labs. It is therefore recommended that appropriate cancellation notice periods are discussed and included in the MoU.

For the food business operator	For the laboratory
Date:	Date:
Signed:	Signed:
Printed:	Printed:
Position:	Position:
For the Local Food Authority	
Date:	
Signed:	
Printed:	
Position:	

Annex B to Template Memorandum of Understanding

Form for reporting analytical results to the Food Business Operator,
Local Food Authority, FSA and Cefas

Agreement number	
Name of Food Business Operator	
Local Food Authority	
Production area	
Bed name	
Monitoring point reference number	
Grid reference (lat/long)	
Species	
Sampling method/ Method of harvesting	
Sampling date and time	
Temperature at time of sampling (air/water)	
Date and time of receipt at laboratory	
Temperature at receipt at laboratory (air/water)	
Temperature at time of analysis (air/water)	
Date and time tested	
Result (<i>E.coli</i>/100 g shellfish flesh)	
No. of analytical report	
Laboratory seal and accreditation number	

For the laboratory	
Signed:	Date:
Printed:	Position:

Schedule 3 – Sampling Requirements

This Schedule contains the requirements that all samplers – industry and official – have to work to. It covers the collection, transport and submission of samples of live bivalve molluscs from classified production areas for testing at designated laboratories. The results of analyses of industry samples are used to supplement data from the official control microbiological monitoring programme.

Sample species and method of collection

Each species in a production area should be sampled separately, unless otherwise indicated from the outcome of a sanitary survey (i.e. the official sampling plan). On each sampling occasion, species should be sampled from an established monitoring point, as agreed with the LFA, by the method normally used for commercial harvesting and in accordance with the memorandum of understanding.

Size of individual animals

Samples must consist of mature live bivalve molluscs only. The local inshore Fisheries and Conservation Authority (IFCA) catch size limits are species specific and should be used as a guide to determine mature size.

Sample size

Individual bivalve molluscs of the same species sampled at the same site at the same time can have different *E.coli* content. Increasing the number of animals per sample will help to get a clearer picture of the current *E.coli* load at the site. The recommended sample sizes below allow for this and ensure that sufficient shellfish flesh and fluid is available for the test procedures.

The following sample sizes relating to mature stock are recommended:

Species	No. of animals/sample
Oysters (<i>Crassostrea gigas</i> and <i>Ostrea edulis</i>)	12-18
Hard clams (<i>Mercenaria mercenaria</i>)	12-18
Horse mussels (<i>Modiolus modiolus</i>)	12-18
Sand gapers (<i>Mya arenaria</i>)	12-18
Razor clams (<i>Ensis spp.</i>)	12-18
King scallops (<i>Pecten maximus</i>)	12-18
Queen scallops (<i>Aequipecten opercularis</i>)	18-35
Manila clams (<i>Tapes philippinarum</i>)	18-35
Palourdes (<i>Tapes decussates</i>)	18-35
Mussels (<i>Mytilus spp.</i>)	18-35
Cockles (<i>Cerastoderma edule</i>)	35-55
Thick trough shells (<i>Spisula solida</i>)	35-55

Each sample must be sent to the designated laboratory as soon as possible to ensure that it is tested within **48 hours of collection**. Samples must be accompanied by a completed Sample Submission Form (see Annex to this schedule). Failure to complete all sections may result in rejection of the sample.

Sample preparation

Equipment used for sampling should be kept only for that purpose and be clean.

After taking the bivalve molluscs from the water, wait for them to close and then remove any mud and sediment adhering to them by rinsing with clean seawater or fresh water of potable quality to avoid contamination. If this is not available, the seawater from the immediate area of sampling may be used instead. **Do not immerse bivalve molluscs in water whilst washing them** as this may cause them to open and become contaminated. Allow the bivalve molluscs to drain before placing them in the specified sample collection container. Do not include dead bivalves or those with open, gaping or damaged shells.

Record the temperature of the surrounding seawater at the time of sampling on the sample collection form. Where intertidal shellfish are sampled dry, the temperature of the shellfish sample should be recorded immediately after collection. Measure the temperature by placing the thermometer or probe in the centre of the bagged shellfish sample to ensure good contact with shell surfaces.

It is important to keep the bivalves alive and to avoid potential contamination of the sample from sediment, algae and microorganisms at all times. Samplers should therefore be careful to use the appropriate equipment and to clean the sample well. Since the animals are alive, they might also open and start filter feeding again. This should not be allowed to happen as it might result in contamination of the sample. To give a true picture of the conditions at the harvesting area, the bivalves should reach the laboratory in the same condition they were in when taken out of the water and must not exceed the acceptable temperature range of 1-10 °C

Sample transport

Each sample must be sealed in a food grade plastic bag that has a permanently marked waterproof label attached to it. This bag may be placed inside a second bag or other container. Separate samples must be placed in separate bags to avoid cross-contamination.

The label on the sample bags must have the following information:

- sample reference number agreed by the LFA
- date and time of sampling
- a sentence indicating that “this sample is submitted to the microbiological monitoring programme according to the memorandum of understanding Ref XXX”

Laboratories may reject samples that are submitted without a correctly completed label.

Once the sample bags have been sealed they should be transported to the laboratory in a suitably chilled cool box. The LFA will be able to advise on the most appropriate cool boxes to use. Incorrect storage and insufficient temperature control during transport will affect the quality of the sample which in turn might have negative effects for the reported results. Therefore, it is important to achieve good temperature control.

Temperature control

Samples should be packed into the cool box together with cool packs which should not come into contact with the samples. Samples should not be frozen at any stage because frozen samples cannot be tested. The internal air temperature of the cool box should be recorded by the laboratory on receipt.

A temperature less than 10°C should be achieved within 4 hours and maintained for at least 48 hours. The number and arrangement of cool packs and the sample packing procedure shown to be effective during the validation procedure of the relevant type of cool box should therefore be followed (see the UK-NRL's advice in Appendix A of the following document at: <http://www.cefas.defra.gov.uk/media/680082/201404%20cefas%20classification%20sampling%20protocol%20for%20local%20authorities.pdf>). Again, the LFA will be able to advise on the effective packing of the cool boxes they recommend.

When the sample arrives at the laboratory four hours or more after sampling and the internal air temperature of the cool box is more than 10°C, laboratory staff will check the temperature between the shellfish. If this is at or below 10°C the sample is satisfactory. Samples above this temperature must be rejected.

When the sample arrives at the laboratory less than four hours after sampling, the air and contents will not necessarily have reached 10°C or less but should be less than the temperature at the time of sampling.

Note: It is important that sample temperatures at the time of sampling and at the time of receipt at the laboratory are reported to the FSA.

Time between sampling and analyses

There should be no more than 48 hours between sampling and the start of the microbiological test at the laboratory. Samples will not be accepted for classification purposes if the period elapsed between time of sampling and commencement of testing is greater than 48 hours.

Please note; transport and analysis should be undertaken as soon as practically possible and strict rejection criteria will be applied to any samples that arrive for analysis beyond the 48hr period and/or in breach of the 10 degrees Celsius maximum temperature.

Sample testing

Analyses of samples can only be undertaken by laboratories (designated by the FSA) accredited for, and using, the official reference method (Most Probable Number, ISO TS 16649, part 3) or alternative methods accepted by the FSA (including the impedance method for the enumeration of *E. coli* in live shellfish using the BacTrac 4300 Analyser) with respect to bivalve molluscs. The laboratories must be UKAS accredited for this method and must participate in the Health Protection Agency's Food EQA Shellfish Scheme and UK-NRL proficiency tests. Laboratories must also be able to report results directly to the relevant LFA, FBO and the FSA.

Results obtained using other methods, and/or from non-accredited/non-designated laboratories cannot be accepted.

Reporting results

The testing laboratory should provide results directly to the food business operator, FSA, Cefas and the relevant LFA in the timeframe agreed. All information requested in the agreed agreement should be provided.

Results above the classification threshold must be reported immediately. All other routine results are to be reported within 3 - 5 days of onset of analysis.

Note: The results of all samples submitted to the programme (including whether a sample has been rejected) must be reported to the food business operator, FSA and the LFA at the same time.

Sampling plan

Food business operators should make every effort to adhere to the agreed sampling plan. Where a sample cannot be taken in the predefined period, the LFA should be notified as soon as possible and a re-sampling date agreed, ideally at the first available opportunity after the missed sample.

Annex to Schedule 3 – Sample Submission Form

Bold type indicates mandatory information that must be provided.

A: TO BE COMPLETED PRIOR TO SAMPLE DISPATCH	
1. Site Name and Identification Number (SIN):	2. Laboratory of analysis: Address:
3. Harvester name: Address:	4. Local Authority: Address:
Tel: Fax: Email:	EHO: Tel: Email:
5. Production Area:	6. OS Grid reference of Monitoring point:
7. Sample species:	8. Method of commercial harvesting:
9. Method of sample collection:	10. Depth of sample:
11. Date of collection:	12. Time of collection:
13. Time of Next High Tide:	14. Tidal status:
15. Water appearance: Clear <input type="checkbox"/> Turbid <input type="checkbox"/>	Ebb <input type="checkbox"/> Spring <input type="checkbox"/> Flow <input type="checkbox"/> Neap <input type="checkbox"/>
16. Water temp. (°C) at time of sampling:	17. Weather conditions:
18. Wind direction:	
19. Sample source: Shore cultivation <input type="checkbox"/> Suspended cultivation <input type="checkbox"/> Bottom cultivation <input type="checkbox"/> Natural bed <input type="checkbox"/>	
20. Any other Relevant Information:	

B: TO BE COMPLETED ON RECEIPT AT LABORATORY	
Sample ID:	
Date of arrival:	Time of arrival:
Temp. (°C) on arrival:	Salinity:
Analysis date:	Analysts:
Result: <i>E.coli / 100g</i>	

<u>For the food business operator</u>	
Signed:	Date:
Printed:	Position: