# Draft Agreement Template for the Delegation of Official Control Sampling to Third Parties

The Best Practice Guidance for Local Authority Delegation of Official Control Samples for Shellfish Site Classification to Third Parties should be read before using this template.

## Introductory Note

This agreement template has been prepared for use by Local Authorities when delegating the collection of official control bivalve shellfish samples to a third party. This template can be adapted to suit the needs of an individual Local Authority. There is also the option to use a Sample Gathering Notice (SGN) to provide more prescriptive detail on the sampling requirements. Where text is highlighted in yellow the Local Authority will need to insert or remove specific information.

**Agreement for the Provision of Samples for the Microbiological Monitoring and the Algal Toxin Monitoring Required by the Official Controls for Live Bivalve Molluscs**

Reference Number: [insert agreement reference number]

Agreement between

Third party/Food Business Operator: [insert details including named individual responsible for delivery]

and

Local Authority: [insert details including named Local Authority Officer]

**Background**

1. In England and Wales, the Food Standard Agency (FSA) is the competent authority with overall responsibility for microbiological and biotoxin monitoring programmes. The Centre for Environmental, Fisheries and Aquaculture Science (CEFAS) has been contracted to coordinate these programmes. Local Authorities (LAs) are responsible for the collection of shellfish samples from the designated harvesting areas and sending these to the designated Official Control Laboratory for analysis. LAs are permitted to delegate this sampling to third parties including industry representatives.
2. This Agreement relates to the respective roles of the third party/Food Business Operator (FBO) and the LA for the collection, processing and transport of live bivalve mollusc samples for the microbiological and biotoxin monitoring programmes, and/or water samples for the phytoplankton monitoring programme.

**Official Control sampling covered by this agreement**

1. This Agreement governs the collection and delivery of Official Control samples by a third party/FBO on behalf of the LA required for the site classification of shellfish production sites.

1. The third party/FBO is responsible for the collection of [shellfish and/or water samples[[1]](#footnote-1)] required for the monitoring of shellfish production sites.
2. The Third Party/FBO is expected to
3. [provide the gathered samples directly to the LA officer for packaging and processing
4. wash and pack shellfish samples and deliver to the LA officer
5. wash and pack the shellfish samples and process and pack the water samples, and deliver to the LA officer.
6. Wash and pack the shellfish samples and process and pack the water samples, and deliver to an agreed courier and/or Royal Mail for onward delivery to the designated Laboratories.]
7. Any non-conformance with the requirements of this Agreement may lead to the bed becoming declassified which in turn will prevent commercial harvesting of shellfish at the site.
8. The third party/FBO is responsible for meeting the costs of collecting the samples and any associated risk assessment or Health and Safety requirements. The LA is responsible for the cost of sample transport to the Official Control Laboratories and subsequent analysis, and will provide the equipment for any processing and packaging of the samples.
9. This agreement is valid from the point of signature and will remain in force for [insert timeframe[[2]](#footnote-2)].

**Location**

1. [Insert a brief description and map of the location of the FBO designated harvesting areas and representative monitoring points (RMPs)]

**Sampling Protocols**

1. Samples shall be collected and handled in accordance with sampling requirements in line with instructions from the LA and in accordance with the principles of the following protocols:
2. FSA’s Protocol for sampling and transport of shellfish for the purpose of Official Control Monitoring of classified shellfish production areas under Commission implementing Regulation (EU) 2019/627
3. FSA’s Protocol for sampling and transport of water samples for the purpose of Official Control Monitoring of classified shellfish production areas under Commission implementing Regulation (EU) 2019/627
4. FSA’s Guide on Food Business Operators’ Supplementary Sampling In Support of the Official Microbiological Monitoring of Shellfish Production Areas (England and Wales) Wales [or Northern Ireland]
5. [Hard copies of these protocols have been provided to the third party/FBO].
6. Sampling carried out in accordance with these protocols is aimed at protecting public health. Samples collected in default of these protocols may lead to a public health event and the declassification of the bed. Further details on how the monitoring results are utilised can be found in the following protocol:
7. FSA’s Protocol for Classification of Shellfish Production Areas, England and Wales [or Northern Ireland]
8. Samples should be collected in accordance with the outline sampling plan agreed with the LA Officer. The LA Officer will ensure that as far as practically possible sampling intervals and frequencies will adhere to the sampling plan as required by FSA and CEFAS.
9. It is recognised that sampling dates may need to deviate from those outlined in the plan (e.g. due to weather conditions). When modifications to the sampling plan are required, these should be agreed with the LA Officer as far in advance as is practicable. Where a sample cannot be taken in the predefined period, a re-sampling date will be agreed with the LA Officer.
10. The third party/FBO will be required to respond in a reasonable and timely manner to the LA officer’s requests for additional investigative sampling.

**Training**

1. Before Official Control sampling can begin, it is important that the third party/FBO named responsible person and any other third party/FBO personnel involved in collecting and submitting samples receive appropriate training on the sample collection and packaging procedures.
2. This requires completion of an appropriate training course[[3]](#footnote-3) and/or any specific on-site training required by the LA officer.
3. This training will need to be refreshed [insert timeframe[[4]](#footnote-4)]
4. Working in a marine environment can be hazardous. It is expected that the third party/FBO will make sure all relevant risk assessments have been undertaken and that health and safety requirements are adhered to. This includes ensuring that any vessel used to collect samples is seaworthy and piloted by a suitably qualified person, and that it is insured against the usual risks including damage to the vessel, personal injury and public liability. The FSA and LA cannot be held liable in the event of an accident.

**Sampling Plan**

1. Because sampling and packaging can have unintended effects which might impact on the results and may even render them invalid, it is important that the samples are collected and packaged competently. It is therefore necessary to ensure that all official control samples (taken by LA Officers and third parties/FBOs) are collected and submitted according to the same protocol.
2. Samples will be taken only from the designated representative monitoring points (RMPs). These are currently:

 [insert RMP latitude and longitude locations]

1. The samples shall be provided at mutually agreed dates [and times if appropriate] for packing, processing and transportation to the courier and Post Office.
2. Adhering to the required timeframes is essential as sample analysis is expected to begin within 24 hours of collection. By agreement, this can be extended to 48 hours where necessary (e.g. due to the remoteness of the site and associated transport times). Late delivery may mean the sample is rejected for analysis.
3. Laboratory results will be provided to the LA, FSA and CEFAS in the agreed manner within 3 - 5 days of onset of analysis. The LA will then forward the results to the FBO.
4. The FBO can decide not to submit samples when they are due, for example when they voluntarily cease harvesting. In this case, the LA and FSA should be notified in advance of the planned collection date, so that the sampling plan may be adjusted and CEFAS notified.

**Sampling Frequency**

1. New bivalve production sites will be awarded a provisional classification once certain criteria have been met. Established sites are awarded an annual (or full) classification.
	1. Provisional classification: awarded to new shellfish areas where there is no existing monitoring data and where no previous sanitary survey has been undertaken. Once a minimum of ten classification samples have been taken, a provisional classification is awarded and commercial harvesting can begin.
	2. Annual classification: awarded to an area after a full 12 months of routine monthly monitoring has been undertaken.
2. Provisional Classification Sampling
	1. Comprising: 10 classification samples for [insert species]. This will commence on [insert start date] and continue, with a minimum interval of 7 days between samples from each of the designated RMPs, until the sampling requirement is met.
	2. Biotoxin sampling and phytoplankton monitoring will require 2 additional shellfish samples and 2 water samples from each shellfish bed collected at least 7 days apart before any commercial harvesting can take place.
3. Annual Classification Sampling
4. Shellfish samples will be required on a monthly basis. This comprises of two samples of [insert species] from each RMP. One for microbial analysis by the Official Control Laboratory and one for biotoxin sampling by CEFAS.
	1. Water samples will be required for phytoplankton monitoring on a [insert frequency of sampling as required[[5]](#footnote-5)].
5. Note that for sample results indicating elevated levels of biotoxin causing algae in the water sample or toxin in the shellfish flesh, if there is a contamination event or *E.coli* levels trigger an action state, additional samples may be required. The third party/FBO will be notified of such requirements by the LA Officer.
6. Periodic sampling of shellfish for chemical contamination will also be required. These samples must be collected between January and March prior to the onset of spawning. The LA Officer will advise the third party/FBO when these are required.

**Sampling Notification**

1. Where it has been agreed that the LA officer will collect the Official Control samples from the third party/FBO for processing and delivery to the courier, the third party/FBO will notify the LA giving as much notice as possible and a minimum of 24 hrs of their intention to sample. A telephone or email response will be provided by the LA to acknowledge the proposed sampling date.
2. Email contact details for the LA [insert name and email address]
3. Phone contact details for the LA [insert phone number]
4. The third party/FBO should make every effort to adhere to the agreed sampling plan/frequency. Where a sample cannot be taken in the predefined period, the LA must be notified as soon as possible and agree a re-sampling date with the LA Officer.

**Shellfish Sample Preparation**

1. Sample Size.
	1. Samples should only consist of animals that are within the normal commercial size range. Immature/juvenile animals may provide results that are unrepresentative of mature stock[[6]](#footnote-6). Although not a requirement, there is some indication that animals that are not of commercial quality may also return unrepresentative results.
	2. Microbial Classification: [insert number of live animals required for species being sampled].
	3. Biotoxin: [insert number of live animals required for each species] (to provide min 200g flesh).
2. Wherever possible the shellfish should be sampled by the method normally used for commercial harvesting. Where this is not possible, samples may be taken by other means (e.g. hand-picked). The method of collection must be clearly stated of the sampling form.
3. Sample Transfer to LA Officer.
	1. The third party/FBO will provide samples to the LA officer by [insert time] at [insert location].
	2. The agreed drop off arrangements shall be that the samples are either:
		1. Directly handed to an LA officer, or
		2. Left in [insert secure location]. [Confirmation that the drop off has taken place will be required. Contact details for the LA officer Insert name, email address and phone number]

**Sample transfer to OC Laboratory**

1. Samples will be taken directly by the [LA Officer or third party/FBO] to the courier for transit to the designated Official Control Laboratory for microbial testing, and via Royal Mail Special Delivery for CEFAS Weymouth and Lowestoft for biotoxin testing and phytoplankton monitoring.

**Costs associated with sampling**

1. The third party/FBO will be responsible for any expenses connected with the gathering and transporting of samples to the point of landing. This includes where samples fail to arrive at the laboratories in time, where samples are received above the temperature required for analysis and for any repeat or investigative sampling required.
2. The LA will be responsible for the samples from the point of landing. This includes materials for processing and packaging of the sampling, and the costs associated with transportation, analysis and any subsequent action required.
3. The cost of formal training course and any required refresher training will be borne by the third party/FBO. The cost of any on-site training and oversight will be covered by the LA.

**Conditions of the Agreement**

1. The LA Officer will oversee and audit sampling operations at regular intervals to ensure compliance with the requirements of this Agreement.
2. The third party/FBO shall not transfer, assign or sub-contract directly or indirectly, any part of this Agreement.
3. The LA may terminate this Agreement with immediate effect if:
4. the LA has no evidence that there is ongoing commercial interest in the classified bed defined in the FBO application.
5. the third party/FBO commits or permits any serious breach of the terms of this Agreement including samples of inadequate quality and/or
6. an act of bankruptcy, allows a receiver of its assets to be appointed, enters into compulsory or voluntary liquidation (otherwise than for the purpose of reconstruction or amalgamation), makes any arrangement with its creditors or allows distress to be levied or threatened upon a container or any other property of the LA.
7. If any condition of this Agreement is declared by any judicial or other Competent Authority or considered by the parties to be void, voidable, illegal or otherwise enforceable:
8. the parties shall amend that provision in such reasonable manner as mutually agreed; or
9. at the discretion of the parties, it may be severed from the contract and the remaining conditions of this agreement shall, except where otherwise provided, remain in full force and effect unless otherwise terminable.
10. Neither party shall be liable for failure to perform its obligations under this Agreement if such failure results from circumstances beyond the party’s reasonable control.
11. The LA reserves the right to change the terms of the Agreement for legal reasons or for operational efficiency provided that reasonable notice is given. Where variations to the terms of this Agreement are required, the signed written agreement of both parties will be required to ensure any changes are clearly articulated and understood.
12. This agreement is valid once signed by the LA and the third party/FBO.

**For the Third Party/FBO For the Local Authority**

Date: Date:

Signed: Signed:

Print name: Print name:

Position: Position:

**Draft Sample Gathering Notice**

**Introductory Note**

This draft Sample Gathering Notice (SGN) has been prepared as an optional addition to the Agreement. The SGN can be used to provide more prescriptive detail on the sampling requirements specific to a particular site. Where text is highlighted in yellow the Local Authority will need to insert specific information.

**SAMPLE GATHERING NOTICE**

Sample gathering agreement number: [insert SGN number]

Third Party/Food Business Operator (FBO) [insert name]

Classified bed name/location [insert name]

Vessel name/ID [insert if relevant]

1. Location of representative sampling point

[Insert grid references for representative monitoring points (RMPs)]

1. Sampling frequency: [insert sampling frequency expected, usually monthly]

1. Location for handover of samples by the third party/FBO to LA Officer

 [insert handover location and/or secure location if samples are to left for collection].

1. Other arrangements which may impact on the sampling process, not mentioned above.

[insert any further arrangements that need to be considered]

**NOTICE**

This notice applies to the agreement number and classified bed referred to in this notice. By signing and submitting this notice the third party/FBO agrees that all the terms and conditions of the Agreement are incorporated into this notice by reference and will apply to this notice and the execution of the sample gathering.

Signed………………………………

Date …………………………………

Print name, address, email address and contact telephone number:

1. This sampling could relate to the collection or gathering of shellfish samples for microbial testing, collection or gathering of shellfish for biotoxin testing, and/or the collection of water samples for phytoplankton monitoring. [↑](#footnote-ref-1)
2. It is suggested that a shorter timeframe (e.g. 12 months) would be more appropriate for new operators while a longer timeframe (3-5 years) could apply to established businesses. [↑](#footnote-ref-2)
3. Seafish have developed a Shellfish Official Control Sampling course. [↑](#footnote-ref-3)
4. Whilst Regulation 2017/625 does not explicitly require that the training is refreshed, DG SANTE audits have highlighted the need for this but did not set specific timeframes. Therefore, this requirement to repeat the training could vary from an annual requirement to a longer timeframe depending on the competence and experience of the personnel undertaking the Official Control sampling. [↑](#footnote-ref-4)
5. Phytoplankton monitoring usually occurs more frequently between April – September (e.g. fortnightly) than between October – March (e.g. monthly). This may however vary depending on the level of perceived risk. [↑](#footnote-ref-5)
6. There is anecdotal evidence to suggest that immature or juvenile shellfish may give rise to *E.coli* results that are unrepresentative of the mature stock harvested for commercial sale or human consumption. Such individuals may have a higher levels of *E.coli* present in their flesh which could be impact on the site classification. Similarly, there is anecdotal evidence that individuals of commercial size but not quality may also return unrepresentative higher *E.coli* results that could influence the site classification. [↑](#footnote-ref-6)