

Best Practice Guidance for Local Authority Delegation of Official Control Samples for Shellfish Site Classification to Third Parties

Purpose

The Food Standards Agency (FSA) has confirmed that the delegation of Official Control sampling for shellfish site classification to third parties, including industry representatives, is permissible. This guidance has been developed to operationalise this change in approach, outlining the processes and considerations required to enable Local Authorities to establish third party sampling programmes, and to ensure that the sampling meets the standards required for Official Controls. This guidance is further supported by an agreement template for the delegation of OC sampling to third parties.

Background

1. The health standards required for live bivalve molluscs are set out in Annex III of retained EU law Regulation (EC) 853/2004 and Articles 53, 54 and 55 of retained EU law Regulation (EU) 2019/627. The end product microbiological criteria for live bivalve molluscs specified in the retained EU law Regulation (EC) 2073/2005 must also be met.
2. In the implementation of these requirements, Local Authorities have responsibility for the collection of the Official Control samples. However, FSA has confirmed, via the Smarter Comms platform, that it is acceptable for Local Authorities to delegate the collection of these samples to third parties, including industry representatives (see also annex 1).

Scope of this Guidance

3. This guidance is for the official control sampling required to establish, monitor and maintain classified shellfish production sites only.
4. This guidance is **NOT** suitable for the delegation of Official Control sampling required for wild caught shellfisheries.

Delegating to a Third Party

5. When deciding whether to delegate Official Control sampling to a third party, it will be necessary to determine the functions that will be delegated, and the level of supervision or oversight required. This will be influenced to some extent by the established nature of the third party and any previous interactions with the Local Authority (LA).
6. When delegating Official Control sampling to third parties, the following matters should be taken into account:
 - a. The type of Official Control samples to be delegated. The samples required will depend upon which aspects of the Official Control sampling are to be delegated (microbial,

contaminant, biotoxin and/or phytoplankton monitoring). Will the third party be required to collect only shellfish or will water samples also be required?

b. Options for sample delegation.

- i. Gathering only. The third party collects the shellfish samples and hands to the LA Officer, who will need to be available to receive the samples.
 - ii. Gathering and packing Official Control samples. The third party collects the shellfish, washes and packs them ready for transport to the Official Control Laboratory. The samples are then handed to the LA Officer or left in an agreed secure location for collection by the LA Officer. If the samples are left in a secure location, then there also needs to be an agreed handover window to limit the amount of time that samples are left awaiting collection by the LA.
 - iii. Gathering, processing and possible submission of Official Control samples to designated laboratory. In addition to the collection, washing and packing of shellfish samples, if the delegated sampling includes water sampling, then a small level of processing will be required in order to preserve the sample. As part of the agreement, the third party sampler could also be tasked with delivering the samples to the courier and/or Royal Mail for transport to the relevant Official Control Laboratories.
- c. Practice and Experience: Is the third party an established business or a relatively new one? Has the third party been contracted previously and successfully undertaken work for the LA? Has the third party committed to train staff if required?
- d. Delegation of costs and responsibilities will need to be formalised as part of the agreement to ensure the scope of each party's responsibilities and the personal expenditure are understood prior to committing to a formal sampling program.

Establishing an Agreement for Delegation of OC sampling to Third Parties

7. When a decision to delegate the Official Control sampling to a third party has been made, it will be necessary to establish an agreement between the parties involved to ensure that the legal requirements for the sampling are met. An agreement template can be found in Annex 2. This takes a flexible approach and can be adapted to meet the needs of the LA. In addition to the Agreement template, there is the option to also include a Sample Gathering Notice (SGN) to provide more prescriptive detail on the sampling requirements (see Annex 3).
8. The responsibilities and expectations of the different partners (including costs) should be clearly articulated. This should include a named representative with responsibility for undertaking the third party Official Control sampling and ensuring that the samples meet the legal requirements.
9. The Official Control sampling must be undertaken by a person that has received appropriate training. Regulation 2017/625 requires that this training ensures the Official Control sampler is familiar with the applicable legislation and the obligations for sample collection, storage and transportation. The need for refresher courses at regular intervals is also considered necessary.

10. The types of samples to be collected as well as the location (i.e. the representative monitoring points [RMPs]) and frequency of sampling need to be clearly identified.
11. The duration of the agreement should be outlined. This might be shorter for new operations (e.g. 12 months) and longer for well established businesses (e.g. 3-5years).
12. On occasion, it may not be possible for the third party to collect the Official Control sample (e.g. poor weather conditions prevent access to the RMP). Contingencies for such events need to be agreed between partners so that the minimum number of Official Control samples required to maintain the site classification are obtained. For reference these are:
 - a. A minimum of 10 samples are required to award an A classification in any classification year.
 - b. A minimum of 8 samples are required to award a B or C classification in any classification year.
 - c. These minima also apply to seasonal classifications.
13. The agreement needs to outline the partner responsibilities in the event of an above threshold result being returned. This should consider the requirements and costs for investigative sampling, as well as any required engagement in Local Action Group processes.
14. The agreement should consider the level of monitoring required to ensure that the delegation is effective and successful, as well as any action to be taken if this is not the case. The agreement should include provision for LA officers to occasionally accompany the third party during sample collection to ensure collection is in keeping with the protocol and training.

Implementing the Agreement

15. Regulation 2017/625 requires that internal audits are undertaken to ensure compliance with the Official Control sampling requirements. These audit processes must be transparent and suitable for independent scrutiny.
16. Once an agreement has been put in place, it will be necessary to develop and implement a mechanism for monitoring the Official Control sampling being undertaken by the third party.
17. This monitoring should confirm that the samples have been collected from the right location (e.g. photos/GPS recording of position), and that sample handling, washing and any packing and processing required are completed to the required standards.
18. For auditing purposes, it may be necessary for the LA Officer to accompany third party at regular intervals to ensure that the required standards for sample collection, washing, packing and/or processing are being met.
19. Regular liaison with the Official Control Laboratories will also ensure that the quality of the samples being provided meet the necessary standards.

20. The frequency of this monitoring should be agreed.

Supporting documents and other relevant materials:

- [Food Standards Agency Scotland video on OC shellfish sample collection](#)
- [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](#)
- [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](#)
- [Protocol for Classification of Shellfish Production Areas, England and Wales](#)
- [Protocol for Classification of Shellfish Production Areas, Northern Ireland](#)

Annex 1: FSA Clarification on the requirements for delegating official control sampling of live bivalve molluscs.



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For food law enforcement, and port health authorities in England.

Clarification of requirements for delegating official control sampling of live bivalve molluscs

Summary: Clarification of sampling live bivalve molluscs (LBMs) as part of the official monitoring programmes in England. This clarifies that competent authorities may delegate the collection of official control samples from classified production and relay areas and the requirements in the legislation that must be fulfilled in order to do so.

The purpose for sharing this information is to support local authorities. This information may be shared with interested parties.

Dear Colleagues,

The Food Standards Agency (FSA) has been asked to clarify our advice in relation to the delegation of shellfish official control sampling. Retained Regulation 2017/625 on official food and feed controls and other official activities (the OCR) outlines the framework for all official controls required to ensure compliance with food and feed law.

This regulation permits competent authorities to delegate certain official control tasks, providing the conditions in Articles 28, 29 and 30 are met. This includes sampling of LBMs from classified production and relay areas for the official control monitoring programmes.

In accordance with the OCR, a competent authority may choose to delegate sampling to any third party which can comply with requirements including limited companies, food

businesses, shellfish harvesters and other public bodies. As competent authorities responsible for sampling and enforcement in your areas, any delegation must be with your agreement, and once you are satisfied a third party can fulfil the relevant obligations of the OCR.

You may wish to consider the [Food Law Code of Practice](#) (Chapter 3), the [Competency Framework](#) as well as your own service level agreements when considering arrangements for effective delegation. You may also wish to consult your legal teams on the scope of the delegated activities, and other aspects of the delegation agreement.

There are no changes to classifications, sampling plans or sampling methods as a result of this clarification.

If there are any queries regarding this letter, please do not hesitate to contact the Shellfish Team at: Shellfish@food.gov.uk

Yours sincerely

Julie Moody

Head of Food Hygiene and Feed Official Controls Delivery
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Annex 2: Draft Agreement Template for the Delegation of Official Control Sampling to Third Parties

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 (see Annex 3). 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

3. 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.
4. The third party/FBO is responsible for the collection of [shellfish and/or water samples¹] required for the monitoring of shellfish production sites.
5. The Third Party/FBO is expected to
 - a. [provide the gathered samples directly to the LA officer for packaging and processing
 - b. wash and pack shellfish samples and deliver to the LA officer
 - c. wash and pack the shellfish samples and process and pack the water samples, and deliver to the LA officer.
 - d. 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.]
6. 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.
7. 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.
8. This agreement is valid from the point of signature and will remain in force for [insert timeframe²].

Location

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

Sampling Protocols

10. 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:
 - a. 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

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.

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.

- b. 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
 - c. 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]
11. [Hard copies of these protocols have been provided to the third party/FBO].
12. 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:
- a. FSA's Protocol for Classification of Shellfish Production Areas, England and Wales [or Northern Ireland]
13. 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.
14. 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.
15. 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

16. 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.
17. This requires completion of an appropriate training course³ and/or any specific on-site training required by the LA officer.
18. This training will need to be refreshed [insert timeframe⁴]

³ Seafish has developed a Shellfish Official Control Sampling course.

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.

19. 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

20. 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.
21. Samples will be taken only from the designated representative monitoring points (RMPs). These are currently:
[insert RMP latitude and longitude locations]
22. The samples shall be provided at mutually agreed dates [and times if appropriate] for packing, processing and transportation to the courier and Post Office.
23. 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.
24. 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.
25. 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

26. 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.
- 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.
 - Annual classification: awarded to an area after a full 12 months of routine monthly monitoring has been undertaken.
27. Provisional Classification Sampling

- a. 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.
- b. 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.

28. Annual Classification Sampling

- a. 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.
- a. Water samples will be required for phytoplankton monitoring on a [insert frequency of sampling as required⁵].

29. 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.

30. 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

31. 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.

- a. Email contact details for the LA [insert name and email address]
- b. Phone contact details for the LA [insert phone number]

32. 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

33. Sample Size.

- a. Samples should only consist of animals that are within the normal commercial size range. Immature/juvenile animals may provide results that are unrepresentative of

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.

mature stock⁶. Although not a requirement, there is some indication that animals that are not of commercial quality may also return unrepresentative results.

- b. Microbial Classification: [insert number of live animals required for species being sampled].
- c. Biotoxin: [insert number of live animals required for each species] (to provide min 200g flesh).

34. 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.

35. Sample Transfer to LA Officer.

- a. The third party/FBO will provide samples to the LA officer by [insert time] at [insert location].
- b. The agreed drop off arrangements shall be that the samples are either:
 - i. Directly handed to an LA officer, or
 - ii. 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

36. 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

37. 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.

38. 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.

39. 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.

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.

Conditions of the Agreement

40. The LA Officer will oversee and audit sampling operations at regular intervals to ensure compliance with the requirements of this Agreement.
41. The third party/FBO shall not transfer, assign or sub-contract directly or indirectly, any part of this Agreement.
42. The LA may terminate this Agreement with immediate effect if:
- a. the LA has no evidence that there is ongoing commercial interest in the classified bed defined in the FBO application.
 - b. the third party/FBO commits or permits any serious breach of the terms of this Agreement including samples of inadequate quality and/or
 - c. 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.
43. 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:
- a. the parties shall amend that provision in such reasonable manner as mutually agreed; or
 - b. 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.
44. 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.
45. 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.
46. This agreement is valid once signed by the LA and the third party/FBO.

For the Third Party/FBO

Date:

Signed:

Print name:

Position:

For the Local Authority

Date:

Signed:

Print name:

Position:

Annex 3: 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)]

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

3. 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].

4. 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: