

Use of Harvester's Own Results

Introduction

- 1.1 Regulation (EC) 2017/625 allows for the results of samples collected by harvester to be taken into account for the purposes of OC decision making. These results will only be considered if taken in accordance with an agreed protocol.
- 1.2 It is possible, therefore, for harvesters to supplement the Food Standards Scotland (FSS) OC *E. coli* monitoring results with their own results, including those taken as part of the harvester's end product testing regime, if:
 - Samples are taken in accordance with the protocol provided at Annex 4
 - Samples are taken from a nominated *E. coli* RMP only as agreed with FSS;
 - Harvesters ensure:
 - That samples are taken in accordance with an agreed timetable and that the timetable is met in full;
 - That the official reference method (ISO TS 16649 part 3) is used in analysis of such samples. Results obtained using other methods are not acceptable for classification purposes. The laboratory must be UKAS accredited for the method used;
 - that all results are provided to FSS by the laboratory;
 - that agreed timelines for submission of sample results are met (failure to do so could delay the classification process);
 - that sample result data is provided to FSS in an agreed and FSS compatible format (as set out in Annex 3);
 - to facilitate any potential audits of such agreed processes by LA officers;
 - that a MOU is agreed upon and signed (as set out in Annex 1).

Provision of samples by industry

- 1.3 Where, as allowed in Regulation (EC) 2017/625, it is decided to take into account results obtained by industry out with the official monitoring programme, the same considerations will be applied.

Harvester application form

- 1.4 An application form to apply for the use of own results must be completed in full and sent to FSS to allow the request to be processed. A standard application form for this purpose can be found in Annex 5

Main considerations

- 1.5 The locations(s) and timing of samples should adequately represent the level of contamination in the area. This will be assessed by FSS with respect to the outcome of any sanitary survey having taken place. Until such time as this has been completed, the samples must be collected from the current set RMP(s). Sampling and sample transport procedures should conform to protocols issued by FSS. The areas detailed below with respect to sample gathering and handling must also be complied with. Laboratory analysis must conform to those specified.
- 1.6 There must be a specific agreement entered into between FSS, the FBO and the testing laboratory to ensure that the sampling timetable and all results are provided in full.
- 1.7 An example agreement is shown in Annex 1.

Audit of sampling and transport procedures

- 1.8 Sample recording procedures should include verification procedures to ensure that appropriate aspects of the protocols (e.g. time-lag, temperature of sample) have been met. Physical audits of the sampling and sample transport procedures should be undertaken at least once a year, for each sampler, in order to ensure that the relevant protocols are being complied with. It is most likely that this will be carried out by the dedicated Sampling Officer. Deviations from the protocols should be rectified immediately.

- 1.9 Such audit procedures are necessary as *E. coli* levels measured in individual samples may be markedly affected by the location and timing of sampling, as well as other factors during the sampling and sample transport procedures. As these could impact on the overall classification awarded, it is essential that there is ongoing assessment of compliance with protocols. Some aspects can be checked at the data entry stage though further verification of these, together with other aspects, require physical audit of the sampling and sample transport procedures.

Best practice - sampling procedure for harvesters own results

Method of harvester's own sample collection

Wherever possible, species should be sampled by the method normally used for commercial harvesting. Where this is not possible, samples should be taken from the commercial harvest (prior to any grading, washing or processing) in order to ensure that the results of the monitoring programme, which may use a different means of sampling, are valid.

Size of individual animals

Samples should only consist of animals that are within the normal commercial size range.

Immature/juvenile bivalve molluscs, tunicates, echinoderms and marine gastropods may give *E. coli* results that are unrepresentative of mature stock that will be harvested for commercial sale/human consumption. **In circumstances where less mature stock is being commercially harvested for human consumption, samples of smaller bivalves may be gathered for analysis.**

Number of animals per sample

The sampling protocol as outlined in Annex 4 should be applied.

Variation in *E. coli* content of individual bivalve molluscs, of the same species, sampled at the same site, at the same time can be large. Increasing the number of animals per sample will help to average out this variation. The recommended sample sizes allow for this as well as the need to have enough animals to ensure that sufficient flesh and intravalvular fluid is available for analysis. See Annex 4 for details.

Avoidance of contamination

Equipment used for sampling should be kept clean and used only for that purpose. Suspension of sediment should be avoided – where possible, samples should be taken upstream of any potential disturbance (such as the sampler). After the bivalves have been removed from the water and have closed, any mud and sediment adhering to them should be removed by rinsing/scrubbing with clean seawater or fresh water of potable quality. If these are unavailable, the seawater from the immediate area of sampling may be used instead. Do not totally re-immerses the shellfish in water as this may cause them to open. Allow to drain.

Sampling of bivalve molluscs, tunicates, echinoderms and marine gastropods needs special care from the sampler, since the animals may continue filter feeding until they are taken out of the water. Potential contamination before, during and after sampling should be avoided at all times. Ways to avoid contamination include using appropriate equipment and ensuring suitable cleaning of the sample. Bivalve molluscs, tunicates, echinoderms and marine gastropods covered with dirt, sediment, algae and organisms may be contaminated inside the storage bag (post sampling). Therefore the procedures should include the requirement of cleaning work.

Sample bags and containers

Each sample should be placed in a separate, intact food grade plastic bag. A permanently marked waterproof label should be affixed to each sample and should contain the following information: sample reference number, sample date and time of collection, seawater and/or sample temperature, grid reference point accurate to 10 m (if appropriate) and any other relevant information (e.g. species). An alternative method of permanently labeling the sample bag may be agreed with the Sampling Officer and the testing laboratory. This bag should be placed inside a second bag or other container. Testing laboratories will not accept unlabelled samples.

Placing samples in appropriate bags, protects them from contamination and prevents them from cross-contaminating other samples and the transport containers. The use of proper labelling procedures ensures traceability.

Best practice- continued.

Temperature control during transportation

Seawater and/or sample temperature should be recorded at the time of sampling. Samples (in the bags) should be placed in cool boxes with cool packs. Samples should not come into direct contact with the cool packs and must not be frozen at any stage. Validation should be undertaken for specific cool box, cool pack and sample loading combinations and a temperature less than 8°C should be achieved within 4 hours and maintained for at least 24 hours. The number and arrangement of freezer packs, and the sample packing procedure, shown to be effective in the validation procedure should be followed during routine use. Where validation data ready exists for a specific combination, there is no need to undertake a local revalidation. On receipt in the laboratory, the internal air temperature of the coolbox will be checked and recorded.

Since sample areas are often situated in remote locations away from the laboratories, where logistics are sometimes poorly available, there is a challenge in ensuring temperature-controlled transportation of shellfish samples. However, as growth and mortality of microbiological components in foodstuffs are directly influenced by temperature, it is imperative to optimise the conditions during transportation of the samples. Temperatures should not be below 0° and not exceed 8°C.

Time lag between sampling and analyses

The maximum elapsed time between sampling and the start of the microbiological test should be 24 hours. In extremely remote areas in Scotland, up to 48 hours is permitted. The recommended time lag is well within the period during which a properly packed cool box system will maintain the recommended temperature of 8°C or less.

Sample submission form

It is important to use appropriate sample submission forms in order to prevent loss of data, and to ensure traceability.

The following should be recorded on the sample submission form: sample point identification number/grid reference point to a 10 m accuracy, name, time and date of collection, species sampled, method of collection (hand-picked, dredged, etc) and seawater and/or sample temperature. Any other information deemed relevant (e.g. unusual events, adverse weather conditions, etc.) should also be recorded. One copy of the submission form should be kept for the sampler's own records and another should accompany the sample to the testing laboratory. If electronic systems are used for this purpose, they should record the same items of information and allow information to be retrieved by both the sampler and the testing laboratory. A testing laboratory should not accept a sample received without a sample submission form.

Best practice- continued.

Sampling instructions

A set of instructions should be provided to, and available for reference by, all persons taking samples for the monitoring programme.

Incorrect sampling procedures can introduce additional variability into the results or may even invalidate the use of the results obtained. Use of standard procedures will reduce the risk of this occurring and these must be readily available to, and regularly referenced by, the staff involved in taking samples.

A method for ensuring that the sample is taken from the correct representative monitoring point to an accuracy of 10m, should be ensured (e.g. by use of a GPS device or by gathering the sample from a point marked by the authorised Sampling Officer).

Timetable for industry samples

- 1.10 Prior to accepting a harvesters own results, a timetable must be drawn up that is agreed between both parties. This timetable must specify:
- Number of samples to be taken over the 12 month sampling period;
 - Months and, where appropriate, the period within the month when samples are to be taken (see below);
 - RMP from where samples are to be taken;
 - Agreed depth where samples are to be taken from (if necessary);
 - Use of agreed sampling protocol;
 - Use of agreed sample submission form;
 - Use of laboratory that meets the specifications in section 1.100.
- 1.11 The harvester must agree to provide the timetable in full. Where a sample has not been taken due to unforeseen circumstances, e.g. weather, then FSS must be notified of this at the time and a waiver agreed. Where the timetable is not met and there are no valid reasons for this, then FSS will not be obliged to make use of the results provided. Audit of the sampling procedure will be carried out on an ad hoc basis by the OC Sampling Officer. An example of a timetable can be found at Annex 2.

- 1.12 It should be noted that a maximum number of own samples will be applied to this timetable. In general terms this will equal the number of official samples taken by the OC sampling officer, e.g. where a sample is taken every 4 weeks starting at week 1 by the sampling officer then it will be usual for the harvester sample to be taken every 4 weeks starting at week 3.

Method of sample analysis

- 1.13 Regulation (EC) 2017/625 specifies the use of a five-tube, three-dilution MPN method for the classification of class B and C areas while Regulation (EC) 2074/2075 identifies the use of ISO TS 16649-3 as the reference method. By cross-reference to Regulation (EC) 2073/2005, the same reference method applies for the classification of class A areas. This reference method was agreed for all *E. coli* monitoring of bivalve molluscs by the NRL network for Bacteriological and Viral Monitoring of Live Bivalve Molluscs. It is based on the method of Donovan *et al.* (1988) and is a two-stage, five-tube by three-dilution MPN method. The first stage of the method is a resuscitation requiring inoculation of minerals modified glutamate broth (MMGB) with a series of diluted bivalve mollusc homogenates and incubation at $37\pm 1^{\circ}\text{C}$ for 24 ± 2 hours. The presence of *E. coli* is subsequently confirmed by subculturing acid producing tubes onto agar containing 5-bromo-4-chloro-3-indoly- β -D glucuronide and detecting growth on the tryptone bile glucuronide agar (TBGA).

Laboratory requirements

- 1.14 Any laboratory involved in the analysis of harvester own samples for OC purposes in the FSS' (as CA) classification system must enter into an agreement with FSS to ensure that all results are submitted to FSS. This is in addition to the agreement with the harvester. The OC laboratory must take part in NRL ring trials and the HPA EQA scheme and agree to the NRL reviewing its performance in the latter. The laboratory must be UKAS accredited for the method described in section 1.100 above.
- 1.15 A combined MOU must be agreed between the harvester, laboratory and FSS. A model of such an MOU is shown in Annex 1.

Provision of results to FSS

- 1.16 Results being submitted to FSS must be compatible with electronic systems deployed. Results should be provided electronically by the testing laboratory on an agreed spread sheet which details all the relevant sample information and sample result/s. An example of the information required from the results spread sheet is detailed in Annex 3.

Local Authority Involvement

- 1.17 LAs should be involved in the process of acceptance of the harvester application for use of own results. The application form should be signed by an authorised officer of the LA. After the application process, FSS will provide a copy of the signed MOU to the LA for information and distribution to the harvester. Harvester results will also be provided to the LA for information.

Status of harvester's own samples

- 1.18 Under the MOU the harvester's own results are assigned OC status. This being the case, these results will be considered along with those OC samples taken by dedicated Sampling Officers.
- 1.19 The results will be used to assist in the classification of production areas and to trigger alert and action states as necessary.

Harvesters Own Results Frequently Asked Questions

Q. Why is FSS allowing the use of harvester own results within their official control monitoring programme?

A. Regulation (EC) 2017/625 allows FSS to consider the use of harvester own results where these are taken in accordance with an agreed protocol.

Q. How do I get started?

A. In the first instance please read the protocol in full. This will ensure that you are aware of what is required from you and your laboratory. If you feel that you are able to meet the protocol criteria you should complete the application form provided in schedule E and send this to FSS. If you wish any assistance in completing this application, FSS staff will be pleased to assist.

Q. How long will the application process take?

A. We will make every effort to contact you within 2 weeks of your fully completed application form being submitted to us. Thereafter, the time will depend on how quickly all parties can agree the timetable and the MOU.

Q. Will my samples be used to classify my site?

A. Yes. Your samples will be used in accordance with those taken by the Sampling Officer and will be used to classify your site.

Q. How many samples can I submit to the FSS programme in a year?

A. In general terms the number of samples permitted from the harvester will be similar to the number of official samples taken by the sampling officer. Therefore if a sampling officer gathers a sample in the first week of every month then the harvester would gather an official sample in the 3rd week of every month.

Q. What if my sample results differ from those that the sampling officer gathers for analysis?

A. There may be times when this is the case. However the samples will not be taken at the same time, since this is duplication of effort and does not add value to the

dataset. Differing results therefore are likely to indicate genuine variation and cannot be compared to sample results taken at other periods in time.

Q. Will my samples be used for any other purpose?

A. Your samples are assigned official control status and therefore may be used for the purposes of triggering action and alert states under the management of *E. coli* results system.

Q. Can I use any laboratory to analyse my samples under this programme?

A. You can use any laboratory provided that it meets the requirement for its method of analysis and quality systems and accreditation documented in the protocol.

Q. Will my LA be involved in the application and then the sampling process?

A. It is essential that your LA is involved in the process. We ask that they be aware of your application since they will have an involvement in verifying your procedures when they are on site for inspection duties. FSS will ensure that your LA has a copy of any MOU agreement and timetable. You may ask your LA for guidance in how best to gather samples and they may assist you in marking your sampling point where you require assistance in doing so.

Q. How can I ensure that I take my samples from the point specified in the MOU?

A. A GPS system allows accurate sample point identification. Where you have no access to such a device you may request your sampling officer to mark the sampling point using his GPS system for you. The point may be marked by a buoy or other device.

Q. What do I do if I cannot gather a sample specified on my timetable?

A. If you find that you are unable to gather your scheduled sample, please advise FSS as soon as possible. FSS will accept valid reasons for this, for example extreme weather conditions. We may verify these conditions where necessary via the sampling officer. FSS will only accept 10% failed sample submission without adequate reason.

ANNEX 1

Reference:

Memorandum of Understanding

Date
Reference
No.

Memorandum of Understanding between [harvester] and Food Standards Scotland (FSS) ('the parties') relating to the provision of data for *E. coli* (*Escherichia coli*) in [species] samples taken from [Grid ref], [production area] (Local Authority).

The parties herewith enters into an agreement relating to the provision of all *E. coli* results for the area mentioned above according to the agreed timetable as shown in Schedule A.

The agreement covers all samples taken and/or forwarded by [company/harvester] in relation to the analysis of the aforementioned bivalve molluscs for *E. coli* where the results of the analysis are used in connection with the classification of the production area as established by FSS in accordance with Regulation (EC) No 2017/625.

The Laboratory used for the analysis of these samples must be accredited in accordance with ISO 17025 to carry out the analysis for the presence of *E. coli* in bivalve molluscs in accordance with the methods named in food hygiene legislation. The Laboratory must agree to submit results in a format specified by FSS.

The Laboratory must follow the instructions, concerning the analytical methods, provided by FSS and by the UK National Reference Laboratory for Monitoring Bacteriological and Viral Contamination of Bivalve Molluscs.

The harvester must ensure that samples of bivalve molluscs are gathered and transported in accordance with requirements provided by the FSS sampling protocol. The Laboratory must ensure that samples of bivalve molluscs are handled and analysed in accordance with requirements given in EU Food Hygiene legislation and the recommendations given in the FSS and NRL protocols.

Laboratories should ensure that the analysis report provides information as to the accreditation status of the MICRO Laboratory, (meaning the seal of the accreditation body and the accreditation number), and reference to the analytical method used.

This agreement can be annulled by both parties with notice of 3 months and can be annulled with immediate effect if legislative changes result in substantial changes in the existing conditions of the agreement.

FSS will not be responsible for any expenses connected with gathering, transporting, receiving, handling or analysing of harvester's own samples or in the reporting of analytical results, **unless otherwise specified by FSS in writing**. These samples are monitoring samples only and should not be considered proof that any product harvested from this area is fit for human consumption. Food Business Operators are responsible for ensuring that only safe food is placed on the market.

For FSS	For the MICRO LAB *Check with FSS*	For The harvester/Food Business Operator	For the Local Food Authority
Signed :	Signed : *	Signed :	Signed:
Printed :	Printed :*	Printed :	Printed:
Date :	Date :*	Date :	Date:

E.mail confirmation, referencing this letter, will be considered sufficient proof of agreement by each party.

Annex 2 - Timetable for *E. coli* Sampling

The following timetable is agreed between (insert harvester FBO information) and FSS. The timetable will cover the classified shellfish production area of (insert name) Site of (insert name). Samples of (insert mollusc species) bearing SIN number (insert SIN) will be taken from the representative monitoring point/s at (insert grid ref/s) at the frequency shown below. A total of (insert total number of samples as dictated by sanitary survey requirements or FSS protocol) samples will be taken with results submitted on the agreed spread sheet within 48 hours of results being available. If for any reason a sample is not taken FSS must be notified immediately. Failure to submit at least 90% of samples without sufficient reason will render the agreement null and void.

Period	Sample
January week 3	1 sample of Common mussels from SI0123 0123
February week 3	1 sample of Common mussels from SI0123 0123
March week 3	1 sample of Common mussels from SI0123 0123
April week 3	1 sample of Common mussels from SI0123 0123
May week 3	1 sample of Common mussels from SI0123 0123 1 sample of Common mussels from SI0125 0125
June week 3	1 sample of Common mussels from SI0123 0123 1 sample of Common mussels from SI0125 0125
July week 3	1 sample of Common mussels from SI0123 0123 1 sample of Common mussels from SI0125 0125
August week 3	1 sample of Common mussels from SI0123 0123 1 sample of Common mussels from SI0125 0125
September week 3	1 sample of Common mussels from SI0123 0123 1 sample of Common mussels from SI0125 0125
October week 3	1 sample of Common mussels from SI0123 0123 1 sample of Common mussels from SI0125 0125
November week 3	1 sample of Common mussels from SI0123 0123
December week 3	1 sample of Common mussels from SI0123 0123

For FSS	For the MICRO LAB	For the Harvester/FBO	For the Local Authority
Signed :	Signed :	Signed :	Signed:
Printed :	Printed :	Printed :	Printed:
Date :	Date :	Date :	Date:

Annex 3 - Reporting Results Template

'Harvester's own' sample results must be populated on the attached reporting spread sheet template.



Microsoft Excel
97-2003 Worksheet

The harvester must email the completed spread sheet along with a copy of the original lab result report to:

shellfish@fss.scot

Annex 4 - Microbiological Sampling Protocol

Please refer to the following link:

<https://www.cefas.co.uk/cefas-data-hub/food-safety/classification-and-microbiological-monitoring/scotland-classification-and-monitoring/>



ANNEX 5 - Application for the consideration of the use of harvester's own results in the FSS Official Control Classification of Live Bivalve Mollusc Production Areas monitoring programme.

LOCAL AUTHORITY DETAILS	
Name of Local Authority:	
Environmental Health Officer:	
Address:	
Tel:	Fax:
Mob:	
Email:	
APPLICANT DETAILS	
Name of Applicant:	
Company Name:	
Address:	
Tel:	Fax:
Mob:	
Email:	
PRODUCTION AREA INFORMATION	
Production Area / Site name description:	
Site Identification Number (SIN)	

SPECIES TO BE HARVESTED		✓	Wild or Farmed?	Growing method (e.g. bed, trestle, rope)	Harvesting method (e.g. hand, dredged, dived)	Season (e.g. year round or specify season)
Shellfish species						
Pacific oyster	Crassostrea gigas					
Common mussel	Mytilus spp.					
Native oyster	Ostrea edulis					
King scallop	Pecten maximus					
Queen scallop	Aequipecten opercularis					
Razor clam	Ensis spp.					
Common cockle	Cerastoderma edule					
Surf clam	Spisula solida					
Sand Gaper	Mya arenaria					
Carpet Clam	Venerupis senegalensis					
Venus Clam	Chamelea gallina					
Rayed Artemis	Dosinia exoleta					
Other:						

Signature of applicant:

Date:



Important Information

Fully completed application forms should be posted to:

Graham Ewen
Food Standards Scotland
Operational Delivery - Shellfish
Pilgrim House,
Old Ford Road,
Aberdeen,
AB11 5RL

Or emailed to:

graham.ewen@fss.scot

On submission of a fully completed application form, FSS will contact you in order to process your application. We will do so within 14 days of receipt. Where submitted forms have details important to your application missing, then a delay in processing your application may occur. In extreme cases, missing details may result in return of the form so as to obtain clarification on relevant points.

FSS protocol for the use of harvester own *E.coli* results in the official control classification of shellfish Production Areas will provide you with full details of the requirements for use of your own results in the FSS programme. Please refer to this prior to submission of this form to ensure that you are aware of the requirements for use of your own results.

FSS staff will be able to assist you in completion of this application form if necessary.

Should you require further information regarding your application or the process, please contact Caroline Thomson on 01224 288378 or Graham Ewen on 01224 285190.

Data Protection Statement

Food Standards Scotland complies with UK Privacy Laws, including the Data Protection Act 1998 and is registered as a data controller with the Information Commissioner (Reg nbr ZA109196). Any personal data that you provide to us will be used only for the purpose for which it was obtained. We will take all steps necessary to protect your personal data from unauthorised or accidental loss. We will also not pass on your personal data to others outside our organisation unless the Data Protection Act allows us to do. If you have any data protection queries please contact the FSA Data Protection Officer at:

Email: dataprotection@fss.scot Tel: 01224 285100

Schedule A

Timetable for *E. coli* sampling

The following timetable is agreed between [harvester] and Food Standards Scotland (FSS). The timetable will cover the classified shellfish production area of [insert]. Samples of Common Mussels bearing SIN number [insert] will be taken from the representative monitoring point at [Grid Ref] at the frequency shown below.

If for any reason a sample is not taken FSS must be notified immediately. Failure to submit samples without sufficient reason will render the agreement null and void and the original classification will stand.

Period	Sample
[insert month/week] (or by arrangement with sampling officer 7 days apart from OC sample in month)	1 sample of [species] from [Grid ref]
[insert month/week] (or by arrangement with sampling officer 7 days apart from OC sample in month)	
[insert month/week] etc below -	

For FSS	For the MICRO LAB	For the harvester/Food	For the Local Food
	Check with FSS	Business organisation	Authority
Signed :	Signed :	Signed :	Signed:
Printed :	Printed :	Printed :	Printed:
Date :	Date :	Date :	Date:

E.mail confirmation, referencing this letter, will be considered sufficient proof of agreement by each party.

Annex 6 - Application Process Flow Diagram

