Shellfish Supplementary Sampling Protocol

A protocol on the use of Food Business Operators' own sampling results in the official control programme for microbiological monitoring of classified live bivalve mollusc productions areas in Northern Ireland

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Glossary

Bivalve molluscs	Shellfish with a two-part shell that filter feed, such as oysters, mussels, clams, cockles, scallops
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.(In this protocol, this refers to the Food Standards Agency (FSA)).
EQA	European Quality Assurance
FBO	Food Business Operator (In this protocol, this refers to shellfish harvesters.
FSA	Food Standards Agency
NIPHL	Northern Ireland Public Health Laboratory
RMP	Representative monitoring point
UK-NRL	UK National Reference Laboratory (In this protocol, this refers to the UK-NRL for bacteriological and viral contamination of live bivalve molluscs)
UKAS	United Kingdom Accreditation Service

1. INTRODUCTION

This protocol has been produced for shellfish harvesters (food business operators (FBOs) in Northern Ireland. It follows requests from FBOs who have expressed an interest in submitting their own samples to the Food Standards Agency's (FSA) official control microbiological monitoring programme for classified shellfish harvesting areas in Northern Ireland. A similar protocol has been produced by the FSA in England and Wales for FBOs in GB.

The legal requirement for the use of harvesters' samples is set out in Annex II of Regulation (EC) No. 854/2004[1]. 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 harvesting areas following a protocol agreed by the FSA and the FBO.

FBO samples are therefore intended to supplement official control samples (in addition) to those taken by the FSA. **They would be considered as part of the dataset to assess classifications, opening and closing of harvesting areas.** An increase in available microbiological data from a harvesting area may increase the knowledge of microbial contamination (and trends in water quality) in the area.

FBO supplementary sampling and analysis must be conducted under conditions comparable to sampling and analysis for official controls and is as representative as possible of the area being monitored.

For supplementary samples to be considered, the FSA must have designated the laboratory carrying out the analysis. In addition to this, the sampling and analysis must have taken place in accordance with FSA's official control sampling and transport protocol.

This protocol describes the conditions that FBOs 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 Northern Ireland.

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 FSA in NI to initiate the process (**see Schedule 1**).

- The FBO, designated laboratory and FSA in NI enter into an agreement by completing a memorandum of understanding (MoU), 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 all parties.

- Samples are taken in accordance with FSAs official control sampling and transport protocol, available at: http://www.food.gov.uk/sites/default/files/sp-transport-of-samples-flesh_0.pdf

- Samples are analysed by laboratories (designated by the FSA) which are 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 harvesting areas).

- A sampling plan is agreed between the FBO, FSA in NI and designated laboratory (**see Annex A**). 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 FSA 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 FSA.

- FBOs should aim to take all samples specified in the sampling plan. Results should be provided by the laboratory within agreed times and using an agreed format. Any agreed changes to the sampling plan and/or sampling requirements should be sent to FSA in NI as soon as possible.

- The agreed sampling processes are to be made available for auditing by the 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 harvesting areas should fill in an application form and return it to FSA in NI (contact details provided in section 10). A standard application form can be found at **Schedule 1**.

Application Processing

On submission of a fully completed application form, FSA in NI will contact the FBO within 14 days of receipt to process the application.

Memorandum of Understanding

Once the application form has been received and is accepted, the FBO, the laboratory and FSA in NI will sign a MoU to confirm agreement with the conditions of sampling and analysis outlined within this protocol. A template of a MoU can be found 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 FSA official control sampling officer. 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 FSA sampling officers) are collected and submitted according to the same protocol.

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

Sampling Plan

Samples are to be collected in accordance with the sampling requirements set out in the agreed sampling plan between the FBO, FSA in NI and designated laboratory. An example of a sampling plan can be found at **Annex A**.

It is recommended that FBOs supplementary samples are taken at a time when they supplement rather than duplicate official control samples.

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 FSA in NI and the designated laboratory if they choose not to submit a sample so that a new sample submission date can be agreed.

Sample Submission Form

All FBO samples sent to the designated laboratory for analysis should be accompanied by a completed sample submission form. 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. The testing laboratory may not accept a sample without a fully completed sample submission form.

An FSA official control sampling submission form is available at: http://www.food.gov.uk/sites/default/files/shellfish-sampling-form.pdf

5. LABORATORY REQUIREMENTS

FBO submitted shellfish 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 tests[2]. They should also take part in the Health Protection Agency's Food External Quality Assurance (EQA) Shellfish

[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.

Scheme and agree to the UK-NRL reviewing their performance in this. Laboratories must also be able to report results directly to the FBO and FSA in NI within 1 working day of completion 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 FSA 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 FSA in NI 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.

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 FSA, 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.

8. DATA ASSESSMENT

Supplementary FBO samples will be used in conjunction with the official control samples collected by the FSA. Sample results will be publically available and published alongside FSA official control monitoring results on the FSA's website. Results will be incorporated into the dataset for the corresponding RMP and assessed in the same manner as results from the FSA's sampling to assess compliance and determine classifications (see Classification and microbiological monitoring of production areas protocol for

Northern Ireland, available at: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/micro-harvest-ni.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 protocol and operation and management of the Northern Ireland official control microbiological monitoring programme should be addressed in the first instance to the following contact.

Debbie Sharpe
Local Authority Policy and Delivery Team
Food Standards Agency in NI
10A-10C Clarendon Road
Belfast
BT1 3BG

Email: debbie.sharpe@foodstandards.gsi.gov.uk
Tel: 028 90 417703

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 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/SIR/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 Northern Ireland* 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.

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

Reference Number:

outlining the agreement between

Food Business Operator:_____

Laboratory: _____

and FSA in NI: _____

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 Northern Ireland, 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 outlined in the FSAs official control sampling and transport protocol, available at: http://www.food.gov.uk/sites/default/files/sp-transport-of-samples-flesh_0.pdf

- All samples are submitted in accordance with a sampling plan to be agreed by FBO, the designated laboratory and FSA in NI, using the template at **Annex A**. Modifications of the plan are to be notified to and agreed with FSA in NI and the designated laboratory.

- A completed sample submission form accompanies each sample sent to the laboratory.

- All sample labels must indicate that the sample is being submitted to the FSA microbiological monitoring programme in accordance with the MoU Ref XXX

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 this protocol.

- All results are reported to the FBO and FSA in NI at the same time and within1 working day 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. FBOs 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 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 (FSA).

For the food business operator	**For the laboratory**
Date:	Date:
Signed:	Signed:
Printed:	Printed:
Position:	Position:
For FSA in NI	
Date:	Printed:
Signed:	Position:

Annex A

Example sampling plan for the collection of live bivalve molluscs

This sampling plan is agreed between [INSERT name of FBO], [INSERT name of FSA], [INSERT name of designated 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 designated laboratory] within 24 hours of sampling. Laboratory results will be provided to the FBO, FSA in NI within 1 working day of completion 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 FSA in NI.

FBOs can decide not to submit a sample when it is due, for example when they voluntarily cease harvesting. In this case, FSA in NI 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 official control 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 [INSERTRMP]	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 very across different laboratories. 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 FSA in NI	
Date:	
Signed:	
Printed:	
Position:	

Annex B

Form for reporting analytical results to the Food Business Operator and FSA

MoU Agreement number	
Name of Food Business Operator	
Local Authority	
Production area	
Species	
Site name - SIR	
Monitoring point co-ordinates (lat/long)	
Sampling method	
Sampling date and time	
Temperature at time of sampling (air/water)	
Storage temperature by sampling officer (if app.)	
Date and time of receipt at laboratory	
Temperature at receipt at laboratory	
Storage temperature by laboratory (if app.)	
Date and time tested	
Result (*E.coli*/100 g shellfish flesh)	
No. of analytical report	
Laboratory seal and accreditation number	

For the laboratory	
Signed:	Date:
Printed:	Position:

Annex C

Contact details for parties

Food Business Operator

Name of FBO:	
Contact:	
Telephone:	
Email:	

FSA in NI

Contact:	
Telephone:	
Email:	

PHL

Contact:	
Telephone:	
Email:	