Protocol for Classification of Shellfish Production Areas

1.0. Introduction

1.1. Regulation 854/2004 lays down the official control (OC) requirements for the Competent Authority (CA) concerning Live Bivalve Molluscs (LBMs, shellfish). These controls include the classification and monitoring of shellfish production and relaying areas, from which the CA authorises the harvesting of LBMs. The classification of a production area determines the treatment required before the molluscs may be marketed:

1.2. Table 1 - Shellfish classification categories and permitted levels of *E. coli* /100g flesh:

Category	Classification criteria	Action
A	**80 % of samples collected during the review period ≤ 230 E. coli/100 g of flesh and intravalvular liquid. The remaining 20% of samples ≤ 700 E. coli/100 g of flesh and intravalvular liquid.**	**May go directly for human consumption if end product standard met**
B	**90 % of samples collected during review period ≤ 4 600E. Coli/100 g of flesh and intravalvular liquid. The remaining 10% of samples ≤ 46 000 E. Coli/100 g of flesh and intravalvular liquid.**	**Must be subject to purification, relaying in Class A area (to meet category A requirements) or cooked by an approved method.**
C	**Samples ≤ 46,000 E coli/100g of flesh and intravalvular liquid**	**Must be subject to relaying for a period of at least 2 months or cooked by an approved method**
	Any value exceeding 46,000 E coli /100g of flesh and intravalvular liquid	**Prohibited. Harvesting** not **permitted**

1.3. It should be noted that routine *E. coli* sample analysis methodology in Scotland means that results can only be quantified up to 18,000 *E. coli* /100g. For any 'C' result labelled '>18,000', a further OC sample must be taken as soon as possible for further dilution testing, to determine whether the levels of *E. coli* present are over the statutory maximum (46,000 *E. coli* /100g).

1.4. As the CA, if Food Standards Scotland (FSS) decides to classify a production or relaying area, it must first establish the location, fix the boundaries of the area to be classified, assess the area for likely sources of contamination and identify a representative monitoring point (RMP). This is achieved through a sanitary survey being undertaken. As part of the sanitary survey process, for new areas a Provisional report will be carried

out in order to establish an appropriate monitoring point for the purposes of gathering indicative data on the hygiene status of the fishery. The faecal coliform indicating bacteria, *E. coli* is used to establish the degree of contamination within areas where shellfish are to be harvested. Classifications are awarded by FSS according to the degree of contamination in samples of LBM flesh (Table 1). Types of classification are shown in section 2.0 and details of the classification process are outlined in section 3.0.

2.0. Types of Classification

Shellfish production areas may be awarded a preliminary, provisional, annual, seasonal or part-year classification.

2.1. Preliminary classification

May be considered for any area which is currently classified for another species or has been declassified within the past 2 years. Furthermore, a Preliminary Classification may also be considered when the area has been subject to a sanitary survey and/or where existing or historic monitoring data allows water quality assessment.

2.2. Provisional Classification

May be considered for new areas where there is no existing monitoring data and where no sanitary survey has been undertaken. A sanitary survey of the new production area will then be undertaken and completion of a specified sampling plan will be required before Provisional Classification is awarded. If harvesting is planned in the forthcoming year, following receipt of a minimum of 10 samples taken at least a week apart, monthly sampling will follow prior to an annual classification being awarded. Transition from provisional to Annual Classification will occur after receipt of 10 monthly samples.

2.3. Annual Classification

May be considered for new areas where there is no existing monitoring data and where no sanitary survey has been undertaken. A sanitary survey of the new production area will then be undertaken and completion of a specified sampling plan will be required before annual Classification is awarded. Following receipt of a minimum of 10 monthly samples, taken at least a month apart, annual classification will be considered. For existing classified areas, annual classification can be maintained by submitting 8-10 monthly samples, where historic and current results allow for an annual classification to be awarded.

2.4. Seasonal Classification

May be awarded when at least 3 full years' worth of routine monitoring data shows a clear, seasonal trend. The production area may be classified as an 'A' or 'B' for one period of the year and 'B' or 'C' for the other.

2.5. Part-Year Classification

May be awarded when harvesting is restricted to a stipulated period in a year and where current and historical results allow for a straight 'A', 'B' or 'C' classification to be awarded.

For more information on the types of classifications, see item 6.0

3.0. Getting Classified

For a production area to be considered for classification, an application form must be completed by the applicant and submitted in conjunction with the Environmental Health Officer (EHO) with responsibility for shellfish from the relevant local authority (LA) area.

3.1. All applications should be submitted to:
***Email*:** shellfish@fss.scot
***Post*:** Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL

3.2. On receipt of the application, FSS will consult with all relevant interested parties to verify the classification application can be processed and will initiate a sanitary survey, if required.

3.3. Application forms and guidance can be found here: http://www.foodstandards.gov.scot/e-coli-protocol

3.4. Applications should only be made where there is stock in the production area for commercial harvesting, or a plan is in place for active harvesting. Applications for annual classification, with no preceding preliminary or provisional classification request, is intended for harvesters who have longer term classification goals. In this case, harvesters should aim to apply around 14 months in advance of intended harvesting date.

3.5. Harvesters involved in commercial razor fishing must ensure that their vessel is licenced by Marine Scotland. Therefore, applications for classification of razor production areas should only be submitted by those carrying an appropriate licence. More information on razor licencing can be found at this link: http://www.gov.scot/Topics/marine/Licensing/FVLS/razorlicence

3.6. FSS has no enforcement ambit in this area, but will not proceed with any razor classification application without evidence of the applicant possessing a razor licence. FSS will continue to share weekly sampling plans, as well as new classification applications to Marine Scotland Compliance (MSC) and LA as a matter of course.

3.7. On receipt of each individual species application, FSS will allocate a unique Site Identification Number (SIN). The SIN is provided to each harvester and LA upon receipt of a classification application form. The SIN consists of 2 letters (LA ID), 3 numbers (production area ID), 3 numbers (site ID) and 2 numbers (species code ID). This specific SIN must accompany all classification samples annotated on all future sample submission forms. The SIN should also be referenced in any area correspondence. SINs are allocated in order to identify and manage the classified areas effectively and each area's number can be found within the current year's *Classification of shellfish harvesting areas document*.

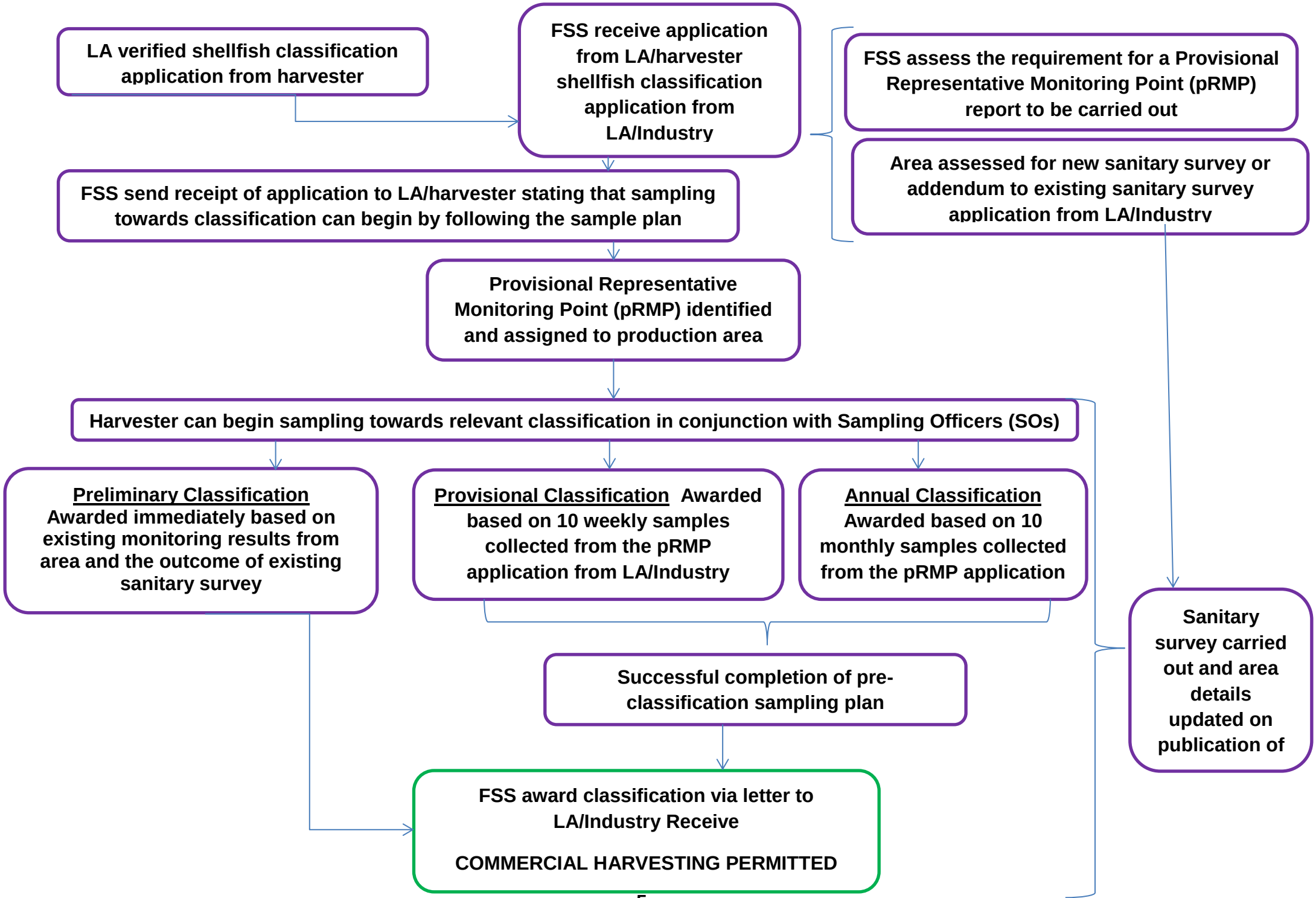
3.8. Classification awards are species specific and classified production areas can encompass several sites of the same species. Shellfish harvesters who have submitted applications for multiple species classifications in a single production area, should ensure that samples of **each** species are submitted for analysis from the nominated *E. coli* RMP.

3.9. It must be noted that a SIN is representative of a production area, rather than an individual harvester. An individual may harvest in more than one production area or LA and a production area may also change ownership, or be subject to itinerant gathering. When a change of ownership of a production area occurs, the harvester and/or LA should notify FSS in writing, stating the appropriate details.

3.10. Samples should not be submitted until an RMP has been determined and a sampling plan has been provided by FSS. Agreeing on the monitoring points, area boundaries and the sampling plan itself is part of the sanitary survey process detailed below.

3.11. TREE 1:

FLOW DIAGRAM DETAILING THE PROCEDURES FOR CLASSIFYING NEW AND EXISTING PRODUCTION AREAS


LA verified shellfish classification application from harvester
FSS receive application from LA/harvester shellfish classification application from LA/Industry
FSS assess the requirement for a Provisional Representative Monitoring Point (pRMP) report to be carried out
Area assessed for new sanitary survey or addendum to existing sanitary survey application from LA/Industry
FSS send receipt of application to LA/harvester stating that sampling towards classification can begin by following the sample plan
Provisional Representative Monitoring Point (pRMP) identified and assigned to production area
Harvester can begin sampling towards relevant classification in conjunction with Sampling Officers (SOs)
Preliminary Classification
Awarded immediately based on existing monitoring results from area and the outcome of existing sanitary survey
Provisional Classification Awarded based on 10 weekly samples collected from the pRMP application from LA/Industry
Annual Classification
Awarded based on 10 monthly samples collected from the pRMP application
Sanitary survey carried out and area details updated on publication of
Successful completion of pre-classification sampling plan
FSS award classification via letter to LA/Industry Receive
COMMERCIAL HARVESTING PERMITTED

4.0. Sanitary Surveys

4.1. Sanitary surveys are a regulatory requirement for new shellfish production areas prior to classification. The surveys provide a thorough assessment of microbiological pollution sources that may affect the new production area and help to develop the appropriate sampling plan towards classification.

4.2. More information on sanitary surveys can be found at the links below:
FSS Industry advice fish and shellfish

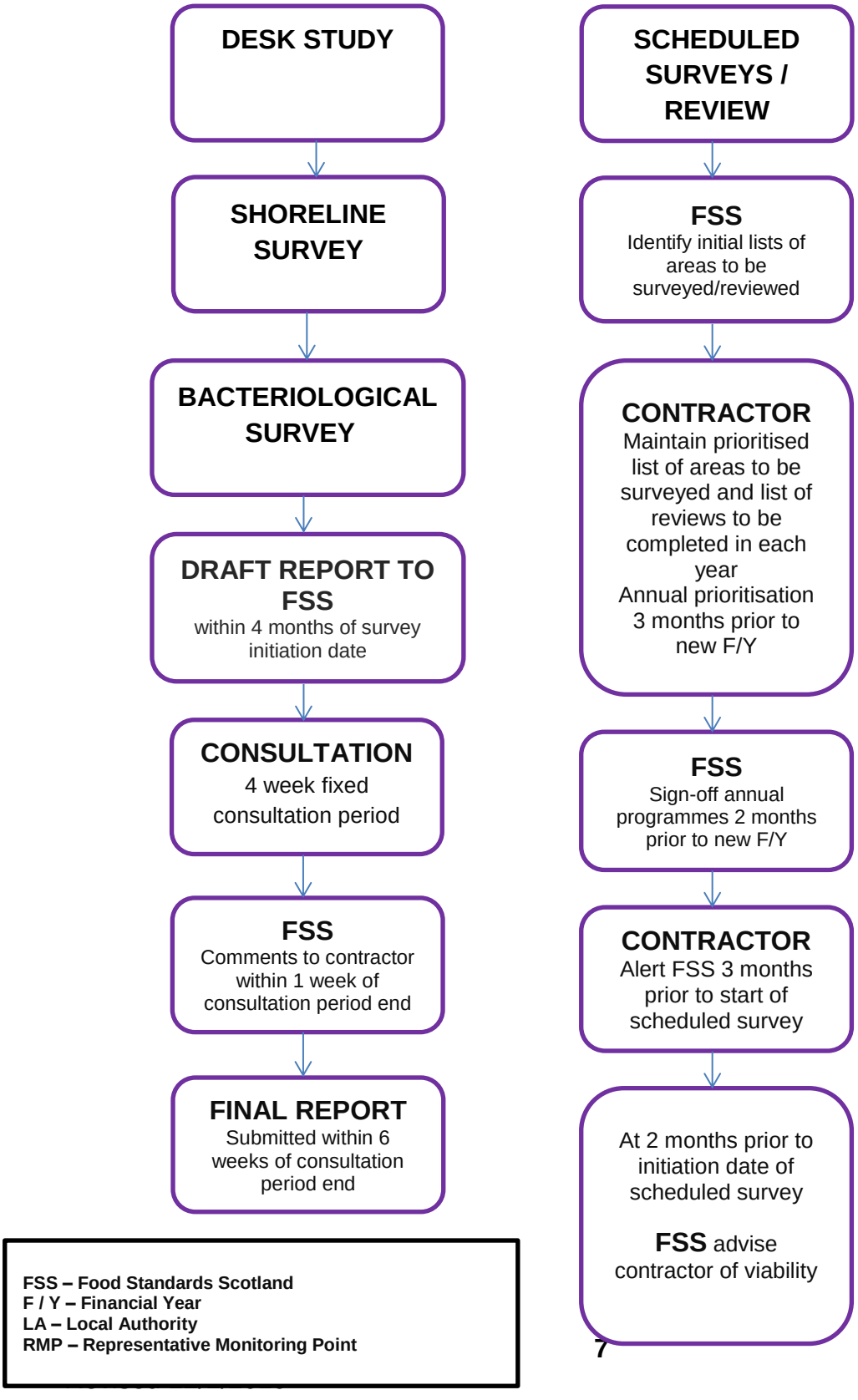
https://www.cefas.co.uk/cefas-data-hub/food-safety/sanitary-surveys/scottish-sanitary-survey-reports-2007-2012/

https://www.cefas.co.uk/nrl/information-centre/eu-good-practice-guide/eurl-good-practice-guide-issue-5/

4.3. On receipt of all shellfish classification applications, FSS will determine whether a sanitary survey is required for the production area. If a sanitary survey is required, FSS will initially carry out a Provisional Representative Monitoring Point (pRMP) assessment whilst awaiting the completion of the sanitary survey. This will identify a production area boundary and a monitoring point to allow sampling to begin as soon as possible.

4.4. TREE 2:

FLOW DIAGRAM DETAILING THE PROCESS FOR CARRYING OUT SANITARY SURVEYS



FSS – Food Standards Scotland
F / Y – Financial Year
LA – Local Authority
RMP – Representative Monitoring Point

5.0. Provisional Representative Monitoring Point (pRMP) Assessment

5.1. The pRMP assessment process takes the form of a desktop survey of the area to facilitate the classification process and allow classification sampling to begin as soon as possible.

5.2. As much relevant information as possible is obtained from existing sources of publicly available information. Records from the Scottish Environmental Protection Agency (SEPA), Scottish Water (SW) and Scottish Government (SG) are utilised, as well as historic official control *E. coli* results.

5.3. The key difference between a pRMP report and the results from a full desk top survey provided by a Sanitary Survey report, is that the data used for pRMP purposes will not have been validated against more current or accurate lists held centrally by any third parties.

5.4. The pRMP assessment report will:

- Detail provisional co-ordinates for the production area boundary;
- Detail provisional *E. coli* RMP(s) for the production area;
- Detail the number of samples to be taken from each *E. coli* RMP as part of a provisional sampling plan;
- Be reviewed later in the sanitary survey process as additional information becomes available.

Further information

6.0. Preliminary classifications

6.1. If a production area has been previously classified (within two years of new application), is currently classified for another species, and a sanitary survey has been carried out where there is sufficient data in order to make a robust assessment, then it may be possible to award an immediate preliminary classification to facilitate early harvesting.

6.2. Such classifications will be awarded based on the precautionary principle, to ensure public health is not jeopardised. The area will receive an immediate 'B' classification at best, with the classification subject to review or declassification due to any unfavourable results. Immediate preliminary A classifications will not be awarded. Therefore, a previously classified 'A' area may receive an immediate 'B' classification which may be upgraded, or downgraded according to received sample results.

6.3. Information contained in any sanitary survey report already carried out in the production area will be used in the process of awarding the preliminary classification.

6.4. Following the award of a preliminary classification and progressing towards a provisional classification, a total of 10 samples are required to be collected from the production area. These samples should be submitted at least a week apart for *E. coli* analysis and where more than one species is to be harvested within the same production area, the microbiological status of all species must be separately determined.

6.5. An assessment of the sample results will then determine whether the sampling plan derived from the previous sanitary survey is appropriate for the production area's new species classification and a provisional classification awarded. If the sampling plan is considered appropriate, the newly classified production area will be represented by the given RMP. However, if the sampling plan is considered inappropriate, a pRMP assessment of the production area will be carried out (see *5.0*) and monitored independently.

General Notes:

Preliminary classifications are subject to review if samples show unfavourable results compared to the areas given classification.

The applicant may wish to bypass preliminary classification, if 'B' classification proves unfavourable and collect ten samples (at least a week apart) to obtain a provisional classification.

7.0. Provisional classifications

7.1. For new harvesting (or relaying) production areas, and for which no previous data exists, a sanitary survey is required.

7.2. For production areas that have been awarded a preliminary classification, or in order to award a new provisional classification, a minimum of 10 samples (taken at least a week apart) are required for microbiological analysis. More samples may be required in order to assist in providing a more robust determination. Where more than one species is to be harvested, the microbiological status of all species must be determined separately.

7.3. Sample results returning prohibited levels (>46,000) of microbiological contamination (after extra dilution test has been carried out) during initial monitoring towards provisional classification, may result in the area being designated as 'prohibited' and the classification application rejected at that time. Harvesting cannot commence without the appropriate biotoxin monitoring in place.

General notes:

Provisional classifications are subject to review if samples show unfavourable results compared to the area's given classification.

8.0. Relaying areas

8.1. The Regulations require relaying areas to be classified and monitored in a similar manner to production areas. They must be designated by the FSS. Furthermore, relay areas must have clearly identifiable boundaries marked by the use of poles, buoys or other fixed means and they must operate on a batch basis i.e. 'all in all out' system. Batches and species may not be mixed at any one time.

9.0. Annual classifications

9.1. Following the award of the provisional classification, routine OC sampling will be carried out by FSS on a monthly basis (or alternative frequency as recommended by the sanitary survey). The results of the samples collected from the established RMP(s) will contribute to the production area's annual classification.

9.2. Annual classification can be requested at application stage, with no preliminary or provisional classification proceeding annual classification. This is intended for harvesters who have longer term classification goals and do not require access to a quicker classification process. Annual classification reviews are also routinely carried out for well established areas – see section [15] for details.

9.3. Within the calendar year, a minimum of 8 monthly sample results are required to award and maintain annual 'B' and 'C' area classification. Whereas, to award and maintain 'A' classification status, a minimum of 10 monthly sample results are required. Inability to meet the minimum sample requirement stated in the classification protocol will result in no classification being awarded, the production area being awarded a dormant status or even de-classified by FSS. (see 11.0 – 12.0)

10.0. Seasonal classifications

10.1. At least 3 years' worth of data showing a clear seasonal trend is necessary for a seasonal classification to be awarded. Seasonal classifications must comprise of at least 3 consecutive months and the data for each season must be significantly different. Each classified area can have only 2 separate seasons per year. Routine monthly monitoring should continue throughout the full calendar year. A minimum of 8 samples are still required for classification (B or C) and a minimum of 10 samples in the calendar year, for a seasonal A.

General Note

Please note that until FSS issues a formal letter of classification for a production area, the status of the area remains unclassified.

11.0. Dormant Status

11.1. For classified production areas that become commercially inactive for a period of time (between 6 months and two years), FSS may remove the classification and award a 'dormant' status.

11.2. Dormant status will allow classified production areas to quickly resume harvesting activity following a period of inactivity. Harvesters/LAs are required to inform FSS of their temporary inactivity to enable the dormant status to be awarded and implement reduced monitoring.

11.3. During this period, a reduced frequency of (quarterly) monitoring may be agreed between FSS and the shellfish harvesters, provided there is sufficient stock to continue sampling.

11.4. To remove dormant status, the harvesters/LA must inform FSS of the intention to re-commence commercial harvesting. Routine monthly monitoring will then be required to resume one month before harvesting begins. The production area's classification will be re-instated, provided the quarterly monitoring results are compliant with the EU classification criteria. If there is insufficient stock to continuing sampling, the production area may then be de-classified by FSS. (see below).

11.5. If the production area is still inactive after 2 years of dormancy, it will be de-classified, placed on the de-classified list for up to two years and monitoring will cease.

11.6. Dormant status will be implemented if:

- *E. coli* levels in shellfish flesh are >18,000/100g (and susequently between 18,000/100g and <46,000/100g after extra dillution testing), within a specific production area for an extended period of time;
- Shellfish harvesting is no longer occurring at a specific area/site and declassification is requested;
- Areas have been identified where no harvesting has taken place for two years or more;
- Where a specific request regarding verified sample numbers has not been met. (Verified samples are those samples collected from the RMP directly or corroborated to be from the RMP by an authorised sampling officer).

12.0. <u>De-classification</u>

12.1. Classified production areas that are unable to submit the required number of sample results within the calendar year, or where there is insufficient stock for sampling, the production area will be de-classified. The production area will be placed on the de-classified list for up to two years and will no longer be monitored.

12.2. Sites that have been de-classified will remain on the de-classified list for two years. If a classification request is made within the two year period, a preliminary classification may be considered (see 6.0). If after two years there is no request to classify the production area again, it will be removed from the de-classification list.

12.3. Any request to classify the production area after the two year period, would require submission of a new classification application to FSS.

13.0. <u>Classification sampling and number of samples</u>

13.1. Sample collection for a new production area will be undertaken by authorised sampling officers, in conjunction with the harvester, who are issued with the agreed sampling plan.

13.2. After FSS has provided the applicant with a receipt of application, the harvester should liaise with the authorised sampling officer to arrange sample collection towards classification.

Once a classification has been awarded, FSS authorised sampling officers will collect samples on a monthly basis (or at a frequency recommended by the sanitary survey) over a calendar year. To maintain classification status, a minimum of 8 samples are required to achieve a 'B' or 'C' classification and a minimum of 10 samples are required to achieve an 'A' classification. Mature stock should be collected, as samples should be representative of the product being placed on the market.

General Notes

Unless 10 samples are received in any calendar year, an area cannot be awarded an A classification

A minimum of 8 samples is required to award a classification B/C in any calendar year.

Reduced sampling may be considered for areas which may have historically achieved A or A/B classifications, but for which sufficient sample numbers have proved difficult to collect (for example in some wild shellfish sites). In such cases, a 'B' or 'C' classification may be awarded. However, under **no** circumstances will an 'A' classification be awarded unless minimum sampling requirements are met.

13.4. All samples are required to be collected in accordance with the sampling protocol (see link below)

13.5. The quantity of product required to carry out the microbiological analysis of the sample is set down in the sampling protocol. It is vital that the sampling protocol is followed as any samples arriving at the laboratory out-with the specified temperature range (2-10º) will not be accepted (with the exception of local samples delivered to the laboratory within 4 hours of collection).

13.6. Samples must be accompanied by a correctly completed sample submission form, showing the relevant SIN and accurate grid reference point to within an accuracy of 10m (unless otherwise specified by FSS). Classification samples must arrive at the testing laboratory within 48 hrs of original sampling collection, otherwise they will be rejected.

13.7. Details of the sampling protocol, including minimum sample collection numbers can be found at:

Shellfish and water sampling protocol:
https://www.cefas.co.uk/media/201509/h-website-c7715-industry-shellfish-water-sampling-protocol-version-2-final.pdf

Protocol for the collection by industry of shellfish samples from classified areas:
https://www.cefas.co.uk/media/201509/h-website-c7715-industry-shellfish-water-sampling-protocol-version-2-final.pdf

13.8. FSS has developed a shellfish sampling Best Practice DVD. This can be found at: https://www.cefas.co.uk/cefas-data-hub/food-safety/the-shellfish-partnership/guide-to-shellfish-sampling-protocols/?REDIRECTMESSAGE=TRUE

13.9. The most up to date list of classified areas in Scotland can be found at: http://www.foodstandards.gov.scot/shellfish-classification-document

14.0. Sample analysis

14.1. OC samples are analysed by contractors in designated OC laboratories, on behalf of FSS. All actionable results are reported to FSS immediately and all other results are routinely reported on a weekly basis. On receipt of the results from the laboratory, FSS immediately forward them to all LAs and harvesters, with actionable results being immediately reported to the specific LA and harvester, with follow up correspondence from the FSS incidents team. All sample results are published on the FSS website on a weekly basis at: http://www.foodstandards.gov.scot/food-safety-standards/advice-business-and-industry/shellfish/shellfish-results

14.2. All testing undertaken by the OC laboratory is in accordance with the agreed EU reference method. Results obtained using other methods are not acceptable for classification purposes. The OC laboratories are UKAS accredited for this method and take part in the Health Protection Agency's External Quality Assessment (EQA) Shellfish Scheme and UK National Reference Laboratory (NRL) ring trials.

15.0. Annual Classification Review

15.1. Classified shellfish production areas are monitored by FSS to ensure the classification award for each site is compliant with the EU legislative criteria and protective of public health. The classification of the production area is determined by the OC sample results from FSS *E. coli* monitoring programme.

15.2. Classifications are awarded based on the OC data received for each species specific production area, applying the requirements set down in (EC) 854/2004. Details of the requirements can be found in Table 1.

15.3. In January each year, FSS carry out a review of all classified shellfish production area classifications within Scotland. Using the previous three year data-set from the production areas (or all data if less than 3 years), this informs classification award decisions for the coming classification year. This process is in accordance with guidance issued by the European Union Reference Laboratory (EURL) Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice. This guidance can be found by following this link: https://www.cefas.co.uk/nrl/information-centre/eu-good-practice-guide/eurl-good-practice-guide-issue-5/

15.4. Consideration will also be given to the most recent complete year's results if there is evidence to show that water quality has improved or deteriorated over the past 12 months.

15.5. OC microbiological results and shellfish classifications are also monitored on an on-going basis throughout the year. Any exceptional or high results will be acted upon in accordance with the FSS protocol for dealing with 'out-with' results (sample results above the production area's given classification). Production area classifications may be revised or prohibited at any point in year, depending on the outcome of 'out-with' investigations.

15.6. Following the production area classification review, FSS will produce a draft *Classification of Shellfish Harvesting Areas in Scotland document* in January of each year, covering the period from April to the following March. FSS will provide this document to LAs who will distribute to harvesters in each LA area.

15.7. A two week period is given for harvesters to request a review of their classification. Review requests will be assessed by an independent panel and on completion of the review process, the final annual document will be published by FSS and distributed electronically to all relevant stakeholders. This information is also published on the FSS website and can be accessed at the following link:
http://www.foodstandards.gov.scot/shellfish-classification-document-2015-16

15.8. A review request lodged against classification decisions on the basis of insufficient sample numbers (i.e. less than 8 for B/C, or less than 10 for A) will not be considered valid. Therefore, the review will not progress.

15.9. This list will be updated on the FSS website on a monthly basis.

15.10. A flow diagram of the classification process can be found at (3.11)

15.11. Provisional classification awards are not eligible for review.

16.0. Continual review of classification

16.1. In Scotland, the LA is advised by FSS of any actionable results. When a result has been received that is out-with classification, FSS has procedures in place to deal with these high *E. coli* results from classified production areas. In these instances, the LA may consult with other parties including:

- The harvester
- FSS
- Testing laboratory
- Local industry
- SEPA
- Scottish Water (SW)
- Scottish Fisheries Protection Agency (SFPA).

16.2. The LA should ensure that the FBO continues to supply product in compliance with the health standards when results out-with classification are found. In addition, the LA may wish to put in place plans to investigate the cause of any unusually high results. This is further outlined in **Annex 1**; 'Local Action Groups' (LAG) and 'Local Action Plans' (LAP).

16.3. It should be noted that routine *E. coli* sample analysis methodology in Scotland means that results can only be quantified up to 18,000 *E. coli* /100g. For any C result labelled '>18,000', a further OC sample must be taken as soon as possible for further dilution testing, to determine whether the levels of *E. coli* present are over the statutory maximum (46,000 *E. coli* /100g).

16.4. The LA and harvester may wish to agree a voluntary closure on the area pending the results of further analysis, in the interests of public health. If further analysis indicates the result is over the statutory maximum, the area must be closed by the LA under a Temporary Closure Notice (TCN).

16.5. For the TCN to be revoked, the LA will carry out a risk assessment, determine a sampling plan and make a decision on the status of the TCN based on supplimentary sampling results.

Annex 1

Local Action Group and Local Action Plan

Introduction

In Scotland, there are procedures in place to deal with high *E. coli* results from classified production areas.

This involves introducing two levels of 'alert states', investigative and incident (see below for details). These 'alert states' facilitate a more risk-managed approach when high contamination results occur, which allows a more open and transparent system of enforcement. The two alert states also provide a rapid response facility when levels exceed pre-defined *E. coli* trigger levels.

Role of Local Action Groups (LAGs)

This system will operate by means of LAGs set up to deal with results out-with classification above pre-determined levels. The work will range from providing advice, to more extensive incident investigations. This may result in a temporary downgrade/closure of the affected production area, following the identification of a potential risk to public health. Each LAG is responsible for developing a Local Action Plan (LAP) and laying down investigation procedures.

The LAG will consist of Officers from the LA, local SEPA Officers and the harvester. FSS will provide the LA with results out-with classification, as is currently the case. Where necessary, the group will be involved in activities such as gathering data pertinent to local factors and/or conditions that may affect test results. The LA will hold the contact details for their LAG.

The LAG is intended to centralise communication and information sharing, while aiding in the investigation of unusual results. The exchange of information will be on an electronic basis, thus the impact on resource is expected to be minimal. The LAG encourages the sharing of expertise on specific local issues.

Classification

The LAG will not be able to overturn classification results, or remove them from the classification data set. However, FSS will take note of any such recommendations that the LAG wishes to present. The decision on whether to act on this evidence-based recommendation will remain with FSS, with advice where necessary obtained from the laboratory and the UK NRL.

Results out with classification

The two 'alert states' of response for results out-with classification will be essential to ensure that the monitoring and reporting procedures are rapid. The criteria for action and implementation of the LAG and LAP are as follows:

- Incident State
- Investigative State

Investigative State
This state will apply only to A and B production areas and is the first alert action level for results slightly out-with classification (but below the "Incident State" trigger levels).

Table 2- Investigative State Definitions

When an area is classified as:	Then a result in the range :	Activates an :
Class A	231 – 1000 *E. coli* /100g flesh	nvestigative State
Class B	4601 – 9100 *E. coli* /100g flesh	nvestigative State

The LA would initiate an investigation in consultation with the harvester, SEPA and FSS, if required. In instances where there is no apparent reason for the high result (e.g. heavy rainfall preceding the sample) some assistance from the LAG would be expected under the LAP in identifying a cause for the high level.

The LA will need to decide what control measures are needed, but temporary closure/restrictions are not expected unless it is deemed otherwise. Further details on decisions following monitoring results can be found in the Food Law Code of Practice and Practice guidance sections relating to shellfish.
http://www.foodstandards.gov.scot/food-law-code-practice-2015

Incident State
This state applies to Class A, B or C production areas, where *E. coli* results are as follows :

Table 3- Incident State Definitions

When an area is classified as:	Then a results in the range :	Activates an
Class A	1001 *E. coli* /100g flesh and above	Incident State
Class A/B	9101 *E. coli* /100g flesh and above	Incident State
Class A/B/C	18,000 *E. coli* /100g flesh and above	Incident State and Immediate TCN should be considered pending 'extra dillution' testing.

An "Incident State" is activated by the LA who notifies the relevant LAG. The LAG is required to implement the LAP to assist the authority in providing appropriate control measures. The LA should implement the necessary control measures.

For any result above 18,000 *E. coli* /100g flesh, the LAG should consider an immediate closure of the area whilst extra dilution test is being carried out.

If high results continue for 3 months or more, classification status is to be reconsidered by FSS.

Establishing a Local Action Group (LAG)
All relevant LAs with classified shellfish areas are required to establish a LAG and LAP, as all will be subject to alert states if and/or when results for Class A, B or C production areas exceed levels specified above.

The LAG will provide LAs with assistance in investigations of unusually high *E. coli* results under "Incident State" investigation. The LAG should develop LAPs specific to local areas (with laboratory/FSS input), contributing data and local knowledge to ensure effective and

timely information exchange. Electronic exchange of information is expected rather than formal meetings and is not expected to be resource intensive.

Formulating a Local Action Plan (LAP)
In order to facilitate this process, it is recommended that the LAG set up and maintain a LAP. This should clarify the process of data collection and exchange, as well as identify what measures are to be put in place or removed when an "Incident State" occurs. A template for a LAP is provided at Annex 8.

The effectiveness of the LAP relies on it being tailored to specific local needs, to enhance existing measures of public health protection. Therefore, all members of the LAG should be involved in the development of the LAP and be aware of its function and scope within the two alert states as described in tables 2 and 3. LAPs should consider the appropriate action and investigations that may be required when *E. coli* results are out with classification and should take into account likely pollution scenarios in these circumstances. The swift implementation of the LAP is of prime importance and must contain contact details for the LAG members, FSS and other relevant personnel.

All outputs from the investigation undertaken by the LAG upon implementation of the LAP should be provided to FSS.

In general terms the LAP should:

- Be sent to FSS for review and approval indicating the LA responsibilities as co-ordinator;
- Be ready for use prior to contamination events occurring. They should cover all *E. coli* RMPs over which the LA has responsibility;
- Detail methods and scope of communication;
- Allow for shared responsibilities with other Authorities while giving a clear indication of who takes the lead as the co-ordinator;
- Indicate who should receive information internally and externally;
- Clarify how and in what format this information will be fed back to FSS;
- Indicate criteria for lifting control measures, ending investigations and time scales for reporting of the outcome.

Checklist for the setting up LAGs and LAPs

- Contact SEPA representative to discuss preferences and identify other authorities;
- Contact harvesters to discuss preferences for being part of the group;
- Invite relevant bodies/associations with interests to be member of LAG e.g. SW representative;
- Formulate LAP based on template and recommendations in conjunction with members of the LAG;
- Notify and agree plans with FSS, who should be informed by the LAG at all relevant points.

Annex 2

FSS Contact Details		
Caroline Thomson	Operations Manager	☎ 01224 285378 Caroline.Thomson@fss.scot
Graham Ewen	SLAs and Contracts	☎ 01224 285190 Graham.Ewen@fss.scot
Madeleine Bowie	Shellfish technical admin	☎ 01224 285190 madeleine.bowie@fss.scot>
Jennifer Howie	Policy	☎ 01224 285157 Jennifer.Howie@fss.scot
Kelly White	Annual Classification Awards	☎ 01224 285111 Kelly.White@fss.scot
	Incidents	☎ 01224 285156 ☎ 24hrs - 07881516867 Incidents@fss.scot

Shellfish Partnership Contact Details		
Cefas	Biotoxin, *E. coli*, Phytoplankton & Chemical Contaminants Monitoring	☎ biotoxinmonitoring@cefas.co.uk ecoliscotland@cefas.co.uk
Hallmark	Sampling Officers	julie.duncan@hmmh.co.uk