Food Standards Scotland

For safe food and healthy eating

Protocol for classification of Shellfish Production areas

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Version control

Version	Date	Last review carried out	Next review date	Comments
2.0	11	2019		
3.0	May 2025			Reviewed to add details on SMC and 4 dilution testing. Also updated for accessibility

Acknowledgements

Contact information

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At Food Standards Scotland (FSS), we have a unique role, working independently of Ministers and industry to provide advice which is impartial, and based on robust science and data.

Our remit covers all aspects of the food chain which can impact on public health – aiming to protect consumers from food safety risks and promote healthy eating.

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1. Abbreviations

CA	Competent Authority
EHO	Environmental Health officer
FBO	Food Business Operator
FSS	Food Standards Scotland
LA	Local Authority
LAG	Local Action Group
LAP	Local Action Plan
LBM's	Live bivalve molluscs
OC	Official control
MD	Marine Directorate
MSC	Marine Scotland Compliance
pRMP	Provisional Representative monitoring point
RMP	Representative monitoring point
SEPA	Scottish Environmental Protection Agency
SW	Scottish Water
SIN	Site Identification Number
TCN	Temporary Closure Notice

2. Introduction

Regulation 2017/625 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.

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

Category	Classification	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 is met.
B	90 % of samples collected during review period ≤ 4 600 *E. 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.
X	Any value exceeding 46000 *E. coli* /100g of flesh and intravalvular liquid	Prohibited. Harvesting not permitted.

2.1 It should be noted that in areas which have low risk of prohibited results are quantified up to 18000 E.coli /100g flesh. For an areas returning a >18000 E.coli 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).

2.2 As CA, if FSS decides to classify a production or relay area, it must first establish the location, fix boundaries of the are to be classified, assess the area for likely sources of contamination and identify a representative monitoring point (RMP). This is achieved Initially by a provisional representative monitoring point (pRMP) assessment in order to establish an appropriate monitoring point for the purpose 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 harvested. through a sanitary survey. Later a full sanitary survey will be carried out. 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 3, with additional information in sections 7-11.

3. Types of Classification

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

3.1 Preliminary classification
If an area has been classified for a different species, or has been declassified within the last 2 years, it may be considered for a preliminary classification. Furthermore, a preliminary classification may also be considered when an area has been subject to a sanitary survey and/or where existing historic monitoring data allows for a water quality assessment.

3.2 Provisional classification
If there is no existing monitoring data, and no sanitary survey has been undertaken, a provisional classification may be considered. A pRMP of the new production area must then be undertaken and completion of a specified sampling plan is 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 7 days apart is required. Monthly sampling will follow prior to annual classification being awarded. If a sample is taken more than a month apart from previous or subsequent samples, classification may need to re-start. This will be reviewed by FSS on a case-by-case basis. Transition from provisional to annual classification will occur after receipt of 10 monthly samples.

3.3 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.

3.4 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 then be given a split classification of A/B, A/C or B/C depending on the interpretation of the available data.

3.5 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 classification see sections 7–11.

4. Getting Classified

4.1 For the production area to be considered for classification, an application form must be completed by the applicant and submitted to FSS via the Shellfish Monitoring and Classification (SMC) system

4.2 SMC provides the ability to apply for provisional and annual classification only. If you wish to enquire about a preliminary, seasonal, or part year classification, please contact shellfish@fss.scot to highlight this as part of your application process.

4.3 For any other enquires regarding your application please also contact shellfish@fss.scot

4.4 On receipt of the application, all relevant parties will be consulted via SMC, to verify the classification application can be processed. If successful, a pRMP report will then be progressed, if required.

4.5 Applications should only be made where there is stock within 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.

4.6 Harvesters involved in commercial razor fishing must ensure that their vessel is licenced by Marine Directorate (MD), as part of the on-going razor electrofishing trial. 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: Sea fisheries management - Sea fisheries - gov.scot

4.7 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 MD and LA as a matter of course.

4.8 When each individual species application progresses past consultation stage, FSS will allocate the new area with a unique Site Identification Number (SIN). The SIN consists of 2 letters (LA ID), 4 numbers (production area ID), 4 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, as SINs are allocated in order to identify and manage the classified areas effectively.

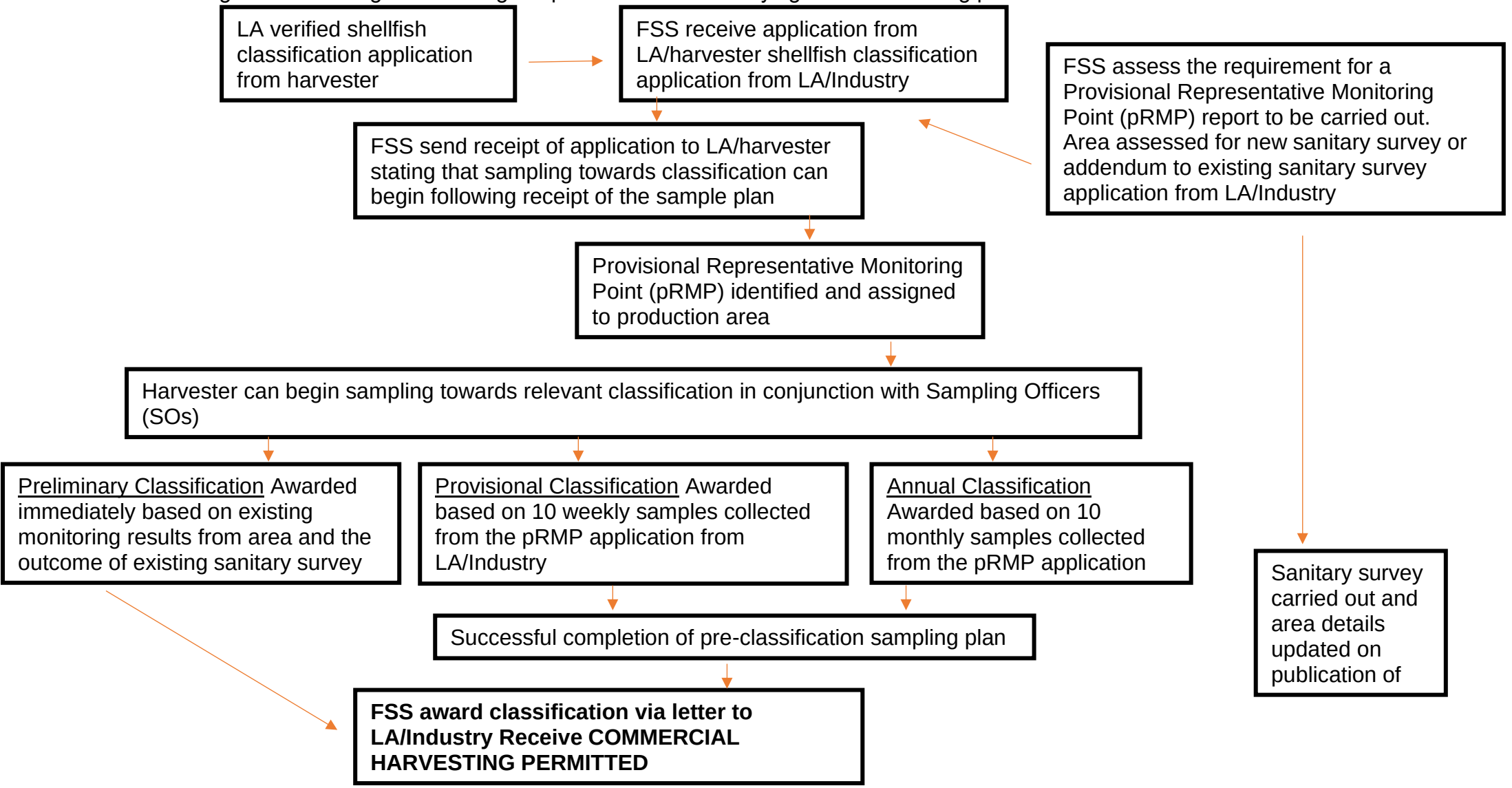
4.9 Classification awards are species specific and harvesting areas can encompass several sites of the same species. Therefore, for classification purposes, multiple species applications within a single production area will be treated separately. Applicants should ensure that samples of each species are submitted for analysis from the nominated E. coli RMP.

4.10 It must be noted that a SIN is representative of a production area & site, 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 via shellfish@fss.scot, stating the appropriate details.

4.11 Samples should not be submitted until a SIN has been created, a RMP has been determined and a sampling plan has been issued by FSS. Agreeing on the monitoring points, area boundaries and the sampling plan itself is part of the pRMP/sanitary survey process detailed below.

4.12 Figure 1 Flow diagram detailing the procedures for classifying new and existing production areas



5. Sanitary surveys

5.1 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.

5.2 More on sanitary surveys can be found here: Food standards Scotland shellfish monitoring

Sanitary surveys carried out between 2007-2012 can be accessed here: Scotland - Cefas (Centre for Environment, Fisheries and Aquaculture Science)

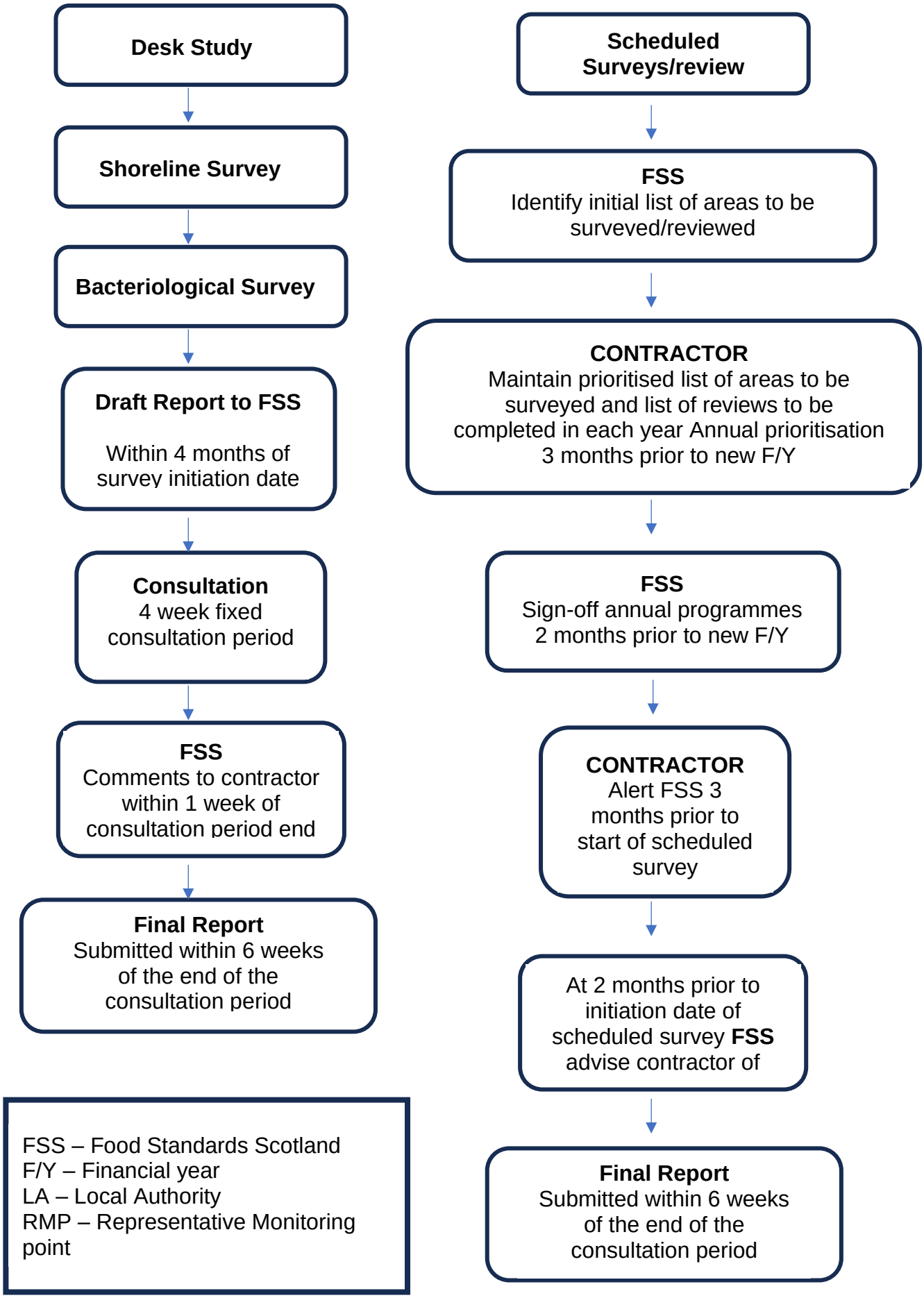
Sanitary surveys carried out post 2012 can be accessed on request to FSS via shellfish@fss.scot

5.3 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 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.

5.4 Areas requiring a sanitary survey are reviewed annually and the programme is provided to the contractor before the start of the financial year.

5.5 Sanitary surveys consist of a desk study, a shoreline survey, a bacteriological survey and consultation to produce the report.

5.6 Figure 2. Flow diagram of the process for sanitary surveys


Desk Study
Shoreline Survey
Bacteriological Survey
Draft Report to FSS
Within 4 months of survey initiation date
Consultation
4 week fixed consultation period
FSS
Comments to contractor within 1 week of consultation period end
Final Report
Submitted within 6 weeks of the end of the consultation period
Scheduled Surveys/review
FSS
Identify initial list of areas to be surveyed/reviewed
CONTRACTOR
Maintain prioritised list of areas to be surveyed and list of reviews to be completed in each year Annual prioritisation 3 months prior to new F/Y
FSS
Sign-off annual programmes 2 months prior to new F/Y
CONTRACTOR
Alert FSS 3 months prior to start of scheduled survey
At 2 months prior to initiation date of scheduled survey FSS advise contractor of
Final Report
Submitted within 6 weeks of the end of the consultation period
FSS – Food Standards Scotland
F/Y – Financial year
LA – Local Authority
RMP – Representative Monitoring point

6. Provisional representative monitoring points

6.1 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

6.2 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.

6.3 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.

6.4 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.

7. Preliminary Classification

7.1 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.

7.2 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.

7.3 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.

7.4 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 7 days 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.

7.5 An assessment of the sample results will then determine whether the classification from previous data is still appropriate for the production area's new species classification and a provisional classification awarded.

7.6 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 7 days apart) to obtain a provisional classification.

8. Provisional classification

8.1 For new harvesting production areas, and for which no previous data exists, a sanitary survey is required.

8.2 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 7 days 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.

8.3 Sample results returning prohibited levels (>46,000) of microbiological contamination during initial monitoring towards provisional classification, may result in the area being designated as 'prohibited' and the classification application rejected at that time. Furthermore, harvesting cannot commence without the appropriate biotoxin monitoring in place and must be agreed with FSS in advance.

8.4 Provisional classifications are subject to review. If samples show unfavourable results compared to the areas given classification, the classification may be downgraded, or removed.

9. Relaying Areas

9.1 The Regulations require relaying areas to be classified and monitored in a similar manner to production areas. Therefore, relaying areas must be designated by the FSS, with 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.

10. Annual classification

10.1 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.

10.2 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 16 for details.

10.3 Within a calendar year, the minimum of 8 monthly sample results are required to award and maintain an annual ‘B’ and/or ‘C’ area classification. Whereas, to award and maintain an ‘A’ classification status, a minimum of 10 monthly sample results are required. Inability to meet the minimum sample requirement stated within 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 sections 12 & 13 for more details.

11. Seasonal classification

11.1 At least 3 years’ worth of data showing a clear seasonal trend is necessary for a seasonal classification to be awarded. Seasonal classifications will 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 to consider B or C classifications and a minimum of 10 samples are required within the calendar year for a seasonal A to be considered.

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

12. Dormant status

12.1 Where classified production areas become commercially inactive for a period of time, FSS may remove the classification and award a ‘dormant’ status. This status will only be considered for a period of time between 6 – 24 months.

12.2 Dormant status will also be implemented if:

- E. coli levels in shellfish flesh are >18,000/100g (and subsequently between 18,000/100g and >46000/100g after extra dilution 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.
- 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).

12.3 Dormant status will allow classified production areas to quickly resume harvesting activity following the period of inactivity. Harvesters and/or LA are required to inform FSS of the temporary inactivity, to enable the dormant status to be awarded and a reduced monitoring programme to be implemented.

12.4 During this period, a reduced frequency of quarterly E. coli monitoring may be agreed between FSS and the shellfish harvesters, provided there is sufficient stock to continue sampling. If the area also has biotoxin/phytoplankton sampling responsibilities, alternative RMPs will be identified at this stage for the period of dormancy.

12.5 To remove dormant status, the harvesters and/or LA must inform FSS of the intention to recommence commercial harvesting in advance. Routine monthly

monitoring will then be required to resume one month before harvesting begins. The production area's classification will be reinstated, provided the sample taken to remove dormant status and quarterly monitoring results are compliant with the required classification criteria. If there is insufficient stock to continuing sampling, the production area may then be de-classified by FSS. See section 13.

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

13. Declassification

13.1 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, will be de-classified and no longer monitored. .

13.2 Sites that have been de-classified will remain on the de-classified list for two years. If a classification request is made within that two year period, a preliminary classification may be considered – see section 7. If after two years there is no request to classify the production area again, it will be removed from the de-classification list.

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

14. Classification sampling and sample numbers

14.1 Sample collection for a new production area will be undertaken by authorised sampling officers, in conjunction with the harvester. The required sample plan is accessed via SMC, where sample collection is scheduled on a weekly basis.

14.2 After the consultation process has passed, the pRMP has been carried out and FSS has provided the applicant with confirmation to proceed, the harvester should liaise with the authorised sampling officer to arrange and commence classification sample collection from the designated RMP.

14.3 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.

14.4 Reduced sampling may be considered for areas that 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 will be awarded, as under no circumstances will an 'A' classification be awarded unless minimum sampling requirements are met.

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

Shellfish and water sampling protocol:
c7715-sampling-officer-shellfish-sampling-and-transport-protocol-scotland-version-7-accessible-300824.pdf

Protocol for the collection by industry of shellfish samples from classified areas:
c7715-industry-collection-shellfish-water-sampling-protocol-scotland-version-4-accessible-300824.pdf

14.6 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). 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.

14.7 The most up to date list of classified areas in Scotland can be found on Shellfish Monitoring and Classification Scotland - Classifications

15. Sample Analysis

15.1 OC samples are analysed by contractors in designated OC laboratories, on behalf of FSS. All actionable results are reported to FSS immediately via automated SMC alerts. All other results are available to all on the SMC platform, as soon as they are uploaded by the testing laboratory. All sample results are available at: Shellfish Monitoring and Classification Scotland - Sample Results

15.2 Low risk areas are tested using the 3 dilution method which has a quanification limit of 18000. Higher risk areas that are likely to produce >18000 results are analysed using a 4 diltion MPN method with a quantification limit >46000. All areas are assessed annually prior to the high risk period for inclusion in the high risk testing group.

15.3 All testing undertaken by the OC laboratory is in accordance with the agreed EU reference method. FSS also recognise the alternative pour plate method which can be found at Shellfish E.coli pour plate method. This method has been validated as a suitable alternative and to the reference method and harvesters own data produced using this method will be considered when reviewing evidence of possible anomalous results.

15.4 The OC laboratories are UKAS accredited for the reference method (ISO 16649-3) and take part in the Health Protection Agency's External Quality Assessment (EQA) Shellfish Scheme and UK National Reference Laboratory (NRL) ring trials.

16. Annual Classification Review

16.1 Classified shellfish production areas are monitored by FSS to ensure the classification award for each site is compliant with the 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.

16.2 Classifications are awarded based on the OC data received for each species specific production area, applying the requirements set down in (EC) 2017/625. Details of the requirements can be found in Table 1.

16.3 Around December each year, FSS begin a review of all classified shellfish production area classifications within Scotland. Analysing a 3 year dataset from each production area (or all available data if we hold less than 3 years), a classification status is awarded for the upcoming classification year

16.4 In making a decision on the classification status, 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.

16.5 On completion of the production area classification review, FSS will publish the draft Classification decisions via SMC, for the upcoming classification year (April until March the following year)

16.6 Thereafter, a two week period is given for harvesters to review their classification and submit an appeal if they do not agree with the given classification award, or have supplementary data/evidence to support a more favourable classification status. Appeal requests are assessed by an independent panel of experts. Upon completion of the appeals process, the final annual classification decisions are made available via SMC at:

Shellfish Monitoring and Classification Scotland - Classifications

This information is also published on the FSS website and can be accessed at the following link:

Shellfish safety and sanitation | Food Standards Scotland | Food Standards Scotland

16.7 To note - an appeal request lodged against an unfavourable classification decision due to insufficient sample numbers (i.e. less than 8 for B/C, or less than 10 for A) will not be considered valid. Therefore, the appeal will not progress to the panel for review.

16.8 Any area with a sample result of >46000 within its data-set will be assessed on a case by case basis and may be considered for a part year classification if the prohibited level sample results are confined to a particular part of the year.

16.9 Provisional classification awards are not eligible for review in the annual review process. These areas will maintain their provisional classification status until

sufficient sample numbers have been submitted to allow a standard classification to be awarded. At that point, the area will be eligible for annual review.

16.10 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.

17. Continual Review of Classifications

17.1 In Scotland, FSS advises the LA of any actionable OC results as soon as the result is made available by the laboratory via SMC. On receipt of this notification from FSS, the LA may consult with a number of other parties to ensure the level of risk is dealt with adequately. This may include:

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

17.2 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).

17.3 It should be noted that E. coli sample analysis methodology in Scotland means that for the majority of areas tested under the OC monitoring programme, results are only quantified up to 18,000 E. coli /100g (3 dilution testing). A select number of higher risk areas are quantified up to 46,000 using a 4 dilution method. Whether an area is initially quantified up to 18000 or 46000 E.coli /100g is determined on a risk assessment caried out each year. Therefore, for any C result labelled '>18,000', a further OC sample must be taken as soon as practicably possible for further 4 dilution testing, to determine whether the levels of E. coli present are over the statutory maximum (46,000 E. coli /100g).

17.4 During the resample period, 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.

17.5 If initial 4 dilution analysis, or subsequent re-sample analysis indicates the result is over the statutory maximum (prohibited status), the area must be closed by the LA under a Temporary Closure Notice (TCN).

17.6 For the TCN to be revoked, the LA will first carry out a risk assessment and liaise with FSS. Once satisfied there is no underlying issue in the area, FSS require 2 sample results <RL (supplied at least 7 days apart) before the TCN is revoked.

18. Annexe 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
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

Area Classification	Result Range	State activated
A	231 – 1000 *E. coli* /100g flesh	Investigative
B	4601 – 9100 *E. coli* /100g flesh	Investigative

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.

Food Law Code of Practice (Scotland) | Food Standards Scotland | Food Standards Scotland

Incident 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)

Area Classification	Result Range	State activated
A	1001 *E. coli* /100g flesh and above	Incident State
A/B	9101 *E.coli*/ 100g flesh and above	Incident State
A/B/C	18000 *E. coli* / 100g flesh and above	Incident State and Immediate TCN should be considered pending ‘extra dillution’ testing if testing limit was 18 000 *E. coli* / 100g flesh
A/B/C	46000 *E. coli* / 100g flesh and above	Immediate TCN

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, where this was the limit of the test, the LAG should consider an immediate closure of the area whilst extra dilution test is being carried out. If the result is >46000 a TCN should be issued. 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 18 Revised 22/1/2019 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.. 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.