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	Last updated by	Comments
2.0		2019		
3.0	May 2025			Reviewed to add details on SMC and 4 dilution testing. Also updated for accessibility
4.0	April 2026	May 2025	GE/KW	Updated following the 2025 EU audit recommendations. • Removes reference to 854/2004 • Removal of Preliminary classification • Removal of declassified as a classification status following dormancy • Addition of reference to pRMP as part of the sanitary survey process • Addition of reference to standard classification • Clarified the requirements for dormancy • Remove references to >18000 results and 3 dilution testing • Changes to Provisional classification replacing 10 weekly samples with fortnightly samples for 6 months to obtain classification. • Addition of buffer months to seasonal classifications • Change of trigger level for A class incident status

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FSS is the Competent Authority responsible for undertaking Official Controls to determine the safety of marine waters used for the harvesting of live bivalve molluscs (LBMs) in Scotland. LBMs include shellfish such as mussels, oysters, clams and cockles.

Retained EU Regulation 2017/625 along with its Delegated and Implementing regulations, establishes an integrated approach to official control requirements – Further Information can be found on the on the Official Controls Regulation (OCR) | Food Standards Scotland.

We're required to undertake an extensive programme of OC monitoring of LBMs and marine phytoplankton (algae) from LBM harvesting waters. The results of this programme are used to determine whether an area should be open or closed for harvesting depending on the levels of microbiological and chemical contaminants, including marine biotoxins.

For more information, please see the FSS website: Shellfish | Food Standards Scotland

Contents

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
OCR	Official control regulation
MD	Marine Directorate
pRMP	Provisional Representative monitoring point (Desktop assessment)
RL	Regulatory Limit
RMP	Representative monitoring point
SEPA	Scottish Environmental Protection Agency
SDP	Service Delivery Partner
SW	Scottish Water
SIN	Site Identification Number
TCN	Temporary Closure Notice

1. Introduction

1.1 Regulation 2017/625 lays down the official control (OC) requirements for FSS as the competent authority (CA) concerning Live Bivalve Molluscs (LBMs). These controls include the classification, monitoring and enforcement of safety standards within authorised LBM production and relaying areas.

1.2 As CA, if FSS receives an application to harvest and decides to classify a production or relay area, it must first establish the location, fix boundaries of the area to be classified, assess the area for likely sources of contamination and identify a representative monitoring point (RMP). This is initially achieved by undertaking a provisional representative monitoring point (pRMP) assessment, which establishes a representative monitoring point (RMP) for the purpose of gathering indicative data on the hygiene status of the fishery. A full sanitary survey of the harvesting area is carried out at a later date. (See section 4.0)

1.3 The faecal coliform indicating bacteria ‘E. coli’ is used to establish the degree of contamination within areas where shellfish are harvested.

1.4 Classifications are awarded by FSS according to the degree of contamination in samples of LBM flesh, following a pre-determined sample plan. The given classification of a production also determines the treatment required before the LBMs may be placed on the market. (See Table 1).

1.5 The types of classifications initially available to harvesters are shown in section 5.0, providing information on attaining provisional, standard and part-year classification. Further information on the types of classifications awarded during the annual classification review for more established areas can be seen in section 8.0

1.6 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.

1.7 The key purpose of classification sampling is to identify when there may be risks to water quality that could impact on shellfish safety, and a robust sample set is essential in enabling FSS to assess this

2. Attaining classification

2.1 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
Please note that you will have to register on the system to be able to access and submit an application.

2.2 SMC only provides the ability to apply for provisional and standard classifications at the initial application stage. If you wish to enquire about part-year classification, please contact shellfish@fss.scot to highlight this request as part of your application process.

2.3 For any other enquires regarding the application process, please contact shellfish@fss.scot

2.4 On receipt of an application, all relevant stakeholders will be consulted automatically via SMC to verify that the classification application can be processed and progressed. If successful, a pRMP assessment will then be requested and undertaken, if required. If unsuccessful, FSS will liaise with the applicant to discuss options.

2.5 Applications for initial classification should align with the harvester's plans for the area. (See section 5) For provisional classification, an application should only be submitted when there is stock within the production area for commercial harvesting and the harvester requires the quickest method of accessing the area. For standard classification, an application should be submitted where stock is present within the production area and available for sampling, and a plan is in place for forthcoming active harvesting, in the longer term.

2.6 **Important Note -** 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

2.7 FSS has no enforcement ambit in this area. However, we will not proceed with any razor classification application without evidence of the applicant being part of the MD electrofishing trial and in possession of a razor licence. Whilst the trial is ongoing, FSS will continue to share weekly razor sampling plans, as well as new classification applications to MD and LAs as a matter of course.

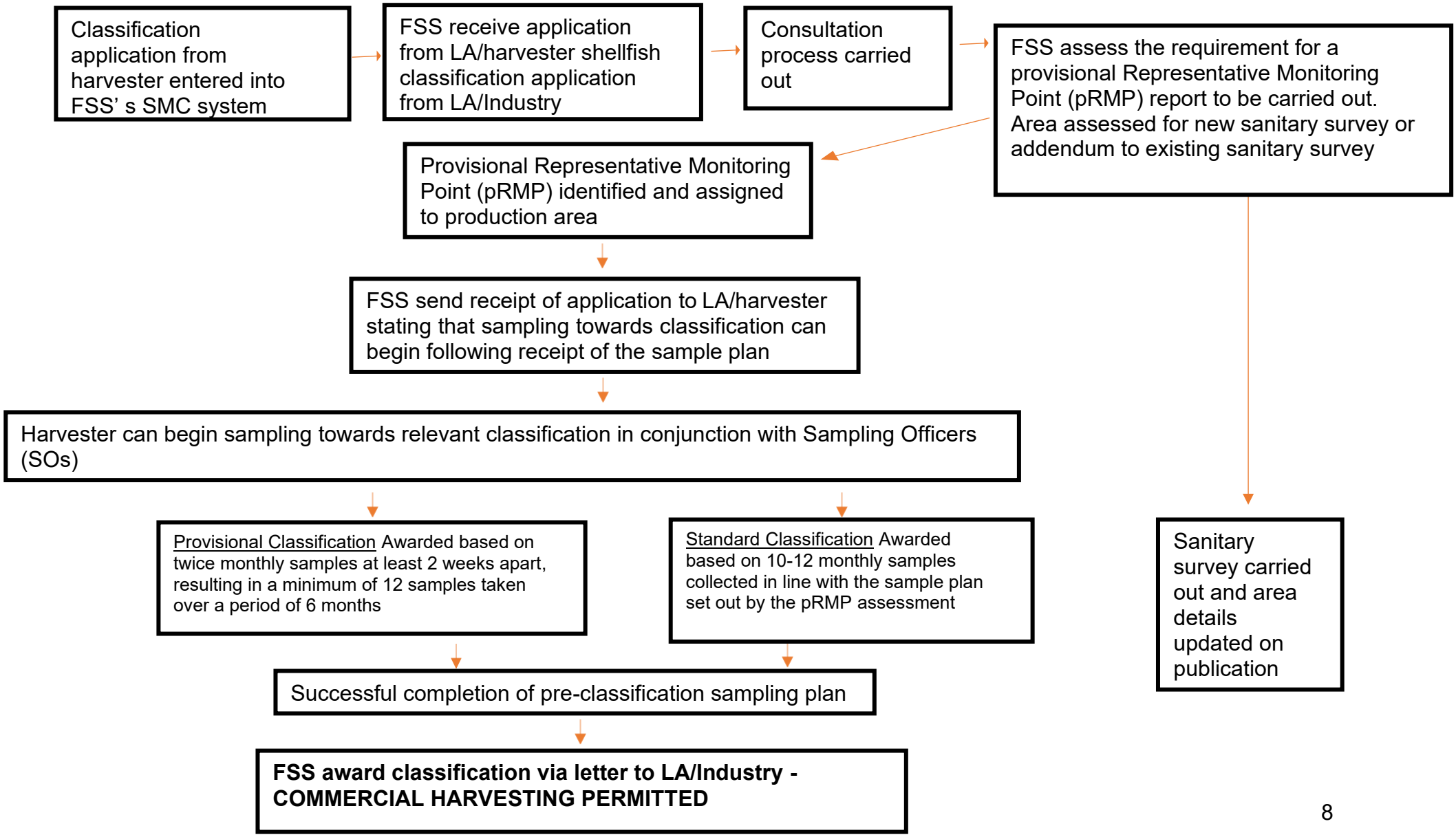
2.8 When each application progresses past consultation stage, FSS will allocate the new area with a unique Site Identification Number (SIN). The SIN consists of 2 letters (LA ID), 4 numbers (production area ID), 4 numbers (site ID) and 2 numbers (species code ID). This specific SIN must accompany all classification samples annotated on all future sample submission forms. The SIN should also be referenced in any correspondence relating to the area, as SINs are allocated in order to identify and manage the classified areas effectively.

2.9 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 as separate classification areas. Applicants should ensure that samples of each species are submitted for analysis from the nominated E. coli RMP. If there are any issues obtaining samples from the RMP, please contact FSS.

2.10 It must also be noted that a SIN is representative of a LA, production area, site and species, rather than an individual harvester. An individual harvester 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 as soon as possible, stating updated details.

2.11 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. The pRMP/sanitary survey process (see section 3) will determine the RMP, area boundaries and the sampling plan itself. Once these steps have been undertaken, FSS will alert the harvester and sampling towards classification may commence.

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



3. pRMP & sanitary survey process

3.1 FSS completes Sanitary surveys in a 2 stage process. An initial pRMP desktop assessment as described below, followed by the longer and more in depth sanitary survey which is carried out as soon as practically possible.

3.2 After receipt of a shellfish classification application and completion of the consultation process, FSS will initially carry out a pRMP assessment and will determine whether a full sanitary survey is required to be carried out for the production area at a later date.

3.3 The pRMP assessment consists of a desktop survey of the area, designed to inform the classification process and allow sampling towards classification to commence at the earliest opportunity.

3.4 In assessing each area, 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), Scottish Government (SG) and relevant LA are utilised, as well as any historic OC E. coli results.

3.5 The key difference between a pRMP assessment and the results from a full desktop survey provided by a Sanitary Survey report, is that the data used for pRMP purposes will not have been independently validated.

3.6 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 as part of the sanitary survey process, taking into account any additional information that becomes available.

3.7 Harvesters and LA officers should ideally be part of the initial pRMP process, but contact should be made to FSS if there are any concerns around the boundary recommendations and/or RMP placement as soon as practicably possible. The recommendations to FSS will be based on scientific data available, but there are also accessibility, shellfish stock and health and safety considerations to be taken into account when ensuring sampling in the area is both achievable and representative.

3.8 Following completion of the pRMP, the harvester and LA will be notified of the sampling plan, including sampling frequency required to work towards either provisional, part-year, or standard classification.

3.9 Although FSS carries out an initial pRMP assessment of each new area, sanitary surveys are a regulatory requirement for new shellfish production areas. The

surveys provide a more thorough assessment of microbiological pollution sources that may affect the production area.

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

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

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

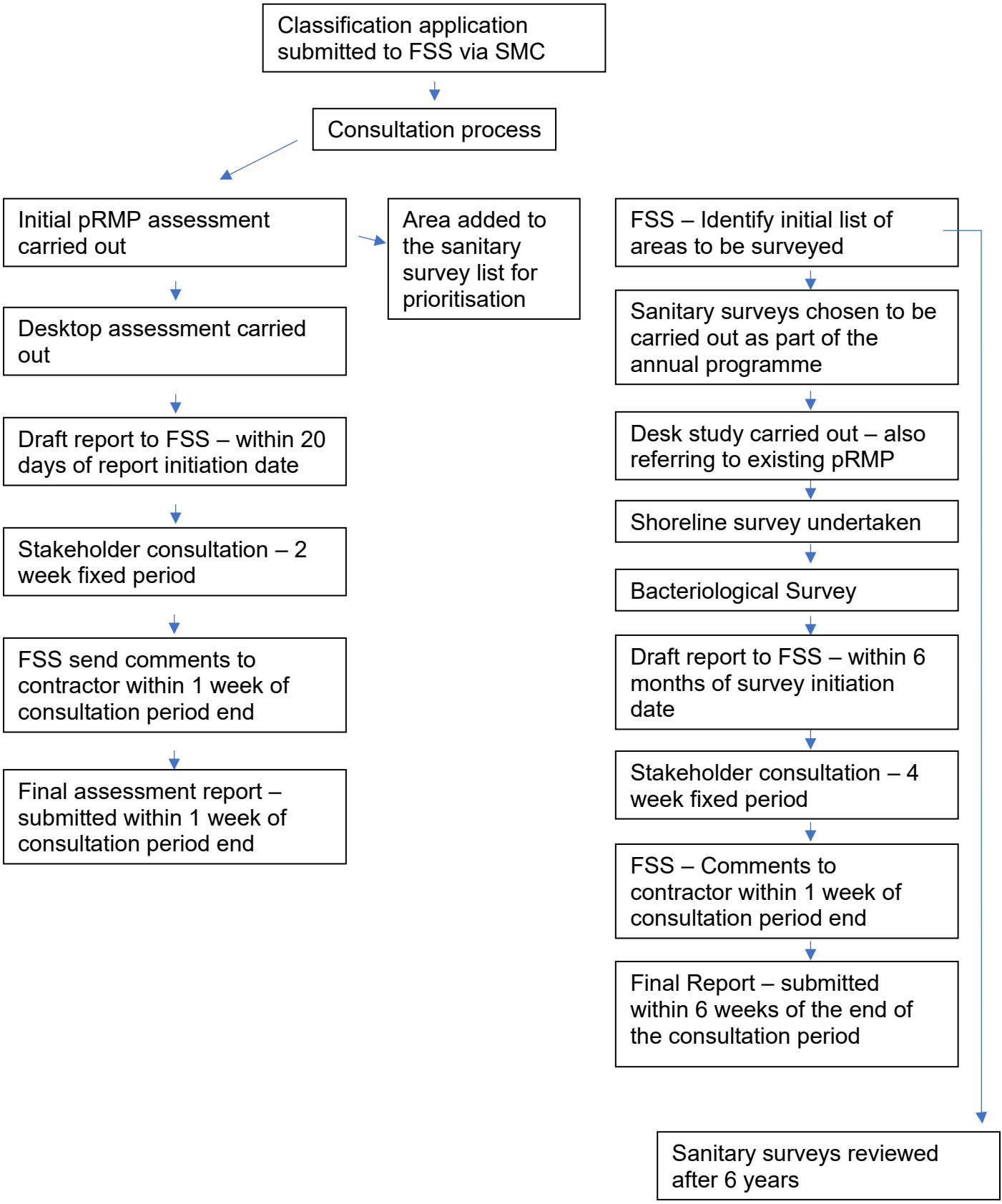
3.13 Areas requiring a sanitary survey are reviewed annually and a risk assessed priority list is used to plan FSS's programme of sanitary survey work each year. This workplan is agreed at the start of each financial year.

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

3.15 To note - Sanitary surveys carried out for long-line mussel production areas will incorporate sampling at multiple depths to assess variation in contamination throughout the water column. The outcomes of this sampling will be used to identify and justify the most representative sampling depth within each survey report.

3.16 Once a sanitary survey is carried out, it will be added to the review programme after a period of 6 years. The list of areas for review will be considered on a risk basis.

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



4. Classification sampling and sample numbers

4.1 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.

4.2 Sampling should follow the stated sample plans at all times, unless otherwise advised by FSS.

4.3 On successful completion of the application process, the harvester should then liaise with the authorised SO to arrange and commence sample collection from the designated RMP. Harvesters should maintain communications with their SO to ensure successful completion of the sampling plan.

4.4 Once a classification has been awarded, SOs will collect samples on a monthly basis (or at a frequency recommended by the pRMP report or a sanitary survey) throughout the calendar year. Mature stock should be collected, as samples should be representative of the product being placed on the market.

4.5 Details of the sampling protocols, 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

4.6 It is vital that the sampling protocol is followed at all times.

4.7 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 1 meter (eg. NB 01234 56789). Classification samples must arrive at the testing laboratory within 48 hrs of original sampling collection, otherwise they will be rejected.

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

5. Initial classification

5.1 As classifications are species specific, when more than one species is to be harvested, the microbiological status of all species must be determined separately, resulting in a separate classification award.

5.2 Following completion of the application process and a pRMP assessment being carried out, harvesters will then be notified that they can start submitting samples and now work towards one of the following types of classification:

5.3 Provisional classification

This option is recommended for harvesters aiming to obtain classification as soon as possible. If harvesting is planned in the forthcoming year, harvesters must provide twice monthly samples at least 2 weeks apart, resulting in a minimum of 12 samples taken over a period of 6 months. On completion of the initial sampling plan, monthly sampling will continue, with each sample being submitted within a separate calendar month, until sufficient samples have been submitted to allow standard classification to be awarded. Transition from provisional to standard classification will occur after receipt of 10 - 12 consecutive monthly samples. Any missed samples during this process will be considered on a case-by-case basis and may extend the time period required for classification.

5.4 Standard classification
This option is intended for harvesters who have longer term classification goals and do not require access to the quicker classification process. Standard classification requires a minimum of 10 monthly samples prior to classification award.

5.5 Part – year classification
This option is intended for harvesters who only wish to harvest during a certain period of the calendar year, with the minimum period of classification being 6 consecutive months. Harvesters must provide twice monthly samples at least 2 weeks apart, resulting in a minimum of 12 samples taken over a period of 6 months. On completion of the initial sampling plan, monthly sampling will continue. Harvesting can only take place within the classified months.Part-year classifications will be considered on a case-by-case basis in consultation with the applicant.

5.6 Please note: Any 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.

5.7 Furthermore, harvesting cannot commence without the appropriate biotoxin monitoring programme in place, with the testing frequency being provided by FSS in advance.

6. Relaying areas

6.1 The Regulations require relaying areas to be classified and monitored in a similar manner to production areas.

6.2 Therefore, relaying areas must be designated by 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.

7. Annual classification review process

7.1 Classified shellfish production areas are monitored by FSS to ensure the classification awarded to each site is compliant with the legislative criteria and protective of public health.

7.2 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

7.3 In December each year, FSS begins the process of reviewing all classified shellfish production areas around Scotland. The available dataset from each production area is analysed and a classification status is awarded for the upcoming classification year. The data set considered in this process will comprise of between 1 and 3 years of data, depending on how long the area has been classified and whether water quality in the area has improved or declined in the last 12 months. If the water quality has declined or improved in the last 12 months, this data will be prioritised when awarding the classification for the following year.

7.4 Any area with a sample result of >46000 within its dataset 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.

7.5 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 review.

7.6 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).

7.7 A production area's classification status may be revised or prohibited at any point in year, depending on the outcome of 'out-with' investigations.

7.8 To maintain a standard classification, 12 monthly samples should be submitted. To account for the possibility of samples being missed for reasons that were out-with the harvester's control, such as transport delays, 'A' classification can be maintained with the submission of 10 samples – depending on the sample results. However, every endeavour should be made to provide 12 samples to maintain a robust assessment of the microbiological risk of an area.

7.9 'B' and/or 'C' classification can be maintained with the submission of a minimum of 8 samples. Again, every endeavour should be made to provide 12 samples to maintain a robust assessment of the microbiological risk of the area.

7.10 On completion of the production area classification review, FSS will publish the draft classification decisions via SMC, during March for the upcoming classification year. At this point, harvesters can appeal the given classification (See section 10). The final classification decision will be published in line with the classification year, which runs from 1st April until 31st March the following year.

7.11 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-classification by FSS. See sections 9.2 & 9.4 for more details.

8. Types of classification

8.1 Standard classification

8.1.1 Standard classification may be awarded based on 12 monthly samples collected within a 12 month period, from the time of the initial sample being submitted.

8.1.2 Routine monthly monitoring should be on-going throughout the full calendar year.

8.1.3 A minimum of 10 samples are required within the calendar year for a seasonal A to be considered, whereas 8 samples are required to consider B or C classifications. Every endeavour should be made to provide 12 samples to maintain a robust assessment of the microbiological risk of the area.

8.2 Seasonal classification

8.2.1 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.

8.2.2 At least 3 years' worth of data showing a clear seasonal trend is necessary for a seasonal classification to be considered.

8.2.3 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.

8.2.4 Routine monthly monitoring should continue throughout the full calendar year.

8.2.5 'Buffer months' will be included when classification changes from B to A, C to A or C to B. For classifications changing in year from B to A or C to B, there will be a 1 month buffer period. For areas going from C to A there will be a 2 month buffer period. During the buffer period the microbiological water quality must meet the requirements of the better classification, but will be awarded the lower classification for those months. Product will be required to be treated in accordance with the classification given (See Table 1). For example, an area that has E. coli results meeting the requirements for A classification from January – June, C classification results from July to September and A classification results from October to December would be classified A January until June, C July until November and A in December. This is illustrated in Fig. 3.

Figure 3. Illustration of buffer months example

	E.coli results	Classification	
January	A	A	
February	A	A	
March	A	A	
April	A	A	
May	A	A	
June	A	A	
July	C	C	
August	C	C	
September	C	C	
October	A	C	Buffer months
November	A	C	
December	A	A	

8.2.6 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.

8.3 Part-Year classification

8.3.1 Harvesters may request a part year classification if there are specific months of the year that won't be actively fished. However, monthly sampling towards the OC monitoring programme is still expected within these months.

8.3.2 FSS must underline the importance of ensuring every effort is made throughout the year to submit sufficient samples in line with the stated sample plans. This will ensure compliance with the protocol and that there is a robust evidence base for classification.

8.4 Dormant status

8.4.1 Where classified production areas become commercially inactive for a period of time, FSS may temporarily remove the classification and award a 'dormant' status.

8.4.2 This status will only be considered for a period of time between 6 – 24 months.

8.4.3 Where an area has been awarded dormant status, it is illegal to harvest LBMs until the status has been lifted.

8.4.4 Dormant status may also be implemented if:

- 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).

8.4.5 Harvesters and/or LA's are required to inform FSS of area inactivity, which will enable the dormant status to be awarded and a reduced monitoring programme be implemented.

8.4.6 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.

8.4.7 If the area also has biotoxin/phytoplankton sampling responsibilities, alternative RMP's will be identified and activated for the period of dormancy. FSS will notify all those affected by this change to ensure there is no interruption to the OC programme requirements.

8.4.8 To remove dormant status, the harvesters and/or LA must first inform FSS of the intention to recommence commercial harvesting.

8.4.9 Routine monthly monitoring will then be required to resume one month prior to harvesting recommencing. The production area's previous classification will be reinstated, provided the samples taken to remove dormant status, along with the quarterly monitoring results are compliant with the required classification criteria. The classification status will then be subject to annual review once 10 consecutive monthly samples are submitted. At that point, if there is insufficient stock to continuing sampling, the production area may then be de-classified by FSS.

8.4.10 If the production area is still inactive after 2 years of dormancy, it will be de-classified and any monitoring will cease.

8.5 Declassification

8.5.1 Classified production areas that are unable to submit the required number of samples within the calendar year, or where there is insufficient stock for sampling, will be reviewed and possibly de-classified and no longer monitored. Taking the circumstances into account, each area will be reviewed on a case by case basis.

8.5.2 Any request to classify a production area after declassification will require submission of a new classification application to FSS, via the SMC system.

9. Annual appeals process

9.1 Within the month of March each year, a two-week period is set aside 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 the award of a more favourable classification status.

9.2 An independent appeals panel sits each year, chaired by FSS. These appeal requests are assessed by the independent panel of experts and the final classification decisions for each area are agreed by the panel and the recommendations presented to FSS. The panel only deal with appeals that meet a specific criterion. For example, any 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 by the panel for review. These appeals will be reviewed by FSS internally on a case-by-case basis, considering any supporting information provided, or circumstances that have resulted in an inability to provide the required number of samples.

9.3 Any complaint harvesters wish to submit to FSS regarding any aspect of the classification process can be sent via email to shellfish@fss.scot

9.4 Upon completion of the appeals process, the final annual classification decisions are made available via SMC at: Shellfish Monitoring and Classification Scotland - Classifications

9.5 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

10. Sample analysis

10.1 OC samples are analysed by contractors in designated accredited OC laboratories, on behalf of FSS. All actionable results are reported immediately to relevant stakeholders via automated email alerts sent by FSS's SMC system. All results are available to view 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

10.2 All shellfish areas within the OC monitoring programme are tested using the 4 dilution MPN method.

10.3 All testing undertaken by the OC laboratory is in accordance with the agreed EU reference method.

10.4 FSS also recognise the alternative pour plate method which can be found at Shellfish E.coli pour plate SOP 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.

10.5 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.

11. Continual review of classifications

11.1 In Scotland, FSS advises the relevant LA of any actionable OC results as soon as the result is made available by the laboratory via SMC email alerts. 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).

11.2 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).

11.3 If initial analysis, indicates the E. Coli result is over the statutory maximum (prohibited status), the area must be closed by the LA under a Temporary Closure Notice (TCN).

11.4 FSS have provided LA's with the delegated power to serve these temporary closure notices under OCR.

11.5 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.

12. Annex 1 – Local action group and local action plan

12.1 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.

12.2 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.

12.3 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”. 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.

12.4 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.

12.5 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.

12.6 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 – 700 *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

12.7 Incident State

This state will apply only to A and B production areas for results above the “investigative state” but below the “prohibited state” trigger level.

Table 3

Area Classification	Result Range	State activated
A	701 *E. coli* /100g flesh and above	Incident State
A/B	9101 *E.coli*/ 100g flesh and above	Incident State
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. 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.

12.8 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.

12.9 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.

12.10 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 point.