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Developing Scotland's Shellfish Water monitoring programme

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Abbreviations

CEFAS	Centre for Environment Fisheries and Aquaculture Science
EA	Environment Agency
FSA	Food Standard Agency
FSS	Food Standard Scotland
SAMS	Scottish Association for Marine Science
SEPA	Scottish Environment Protection Agency
SG	Scottish Government

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Contents

Appendices are available in a separate document.

This document is accompanied by a database linking FSS shellfish *E. coli* and readily available catchment data for all SWPAs in Scotland. This database was compiled during the course of the project and has been delivered to FSS.

Executive Summary

KEY RESEARCH QUESTIONS

- How well are the current approaches to monitoring and classification of Shellfish Production Areas (SPAs) by Food Standard Scotland (FSS) working? What improvements are feasible?
- Is SPA monitoring approach suitable for the classification of Shellfish Water Protected Areas (SWPAs) by the Scottish Environment Protection Agency (SEPA)? If not, what are the options?

KEY FINDINGS

- A review of current practices on shellfish water monitoring and classification in Scotland in the context of governance frameworks and research evidence in the EU and internationally showed that the current approaches are in line with regulatory requirements but have not addressed research evidence and best practice.
- Full sanitary surveys are essential to design monitoring in both SWPAs and SPAs. Sanitary surveys can provide the information to identify a robust, evidence-based, sampling plan at the SPA-scale within or outwith a SWPA. They can also help to assess the interplay of catchment and coastal sources of faecal contaminants in spatially variable SWPAs, which can inform decision-making on where catchment-based sources of faecal pollution must be controlled.
- Classification of SPAs alone cannot protect public health. Compliance with A class, i.e. no post-harvesting treatment of shellfish before placing onto market, does not guarantee that the shellfish harvested are negative for pathogenic enteric viruses. Therefore, both classification grading and the assessment of risk from faecal pathogen contamination based on sanitary surveys are required to inform classification in SPAs by FSS.
- FSS applies different sampling regimes for the classification of SPAs: 10 weeks' worth of data to provisional classification; one year' worth of data for annual classification; and three-years' worth of data for established classification; thus, some SPAs are granted a classification grade with considerably smaller number of samples than others.
- SEPA classifies SWPAs without accounting for species- or site-specific factors. Specifically, pooling *E. coli* data from all SPAs and species within a SWPA is not a fit-for-purpose approach because of differences in faecal organism accumulation rates by different shellfish species. Where all SPAs within a SWPA are harvested for the same species, pooling *E. coli* data from all SPAs may misinform the River Basin Management Planning (RBMP) by misrepresenting local risks from faecal contamination and spatially variable seawater dilution and mixing processes.
- FSS has not developed robust procedures for the recording and storage of data from routine monitoring. As a result, the available databases (one for routine monitoring and one for each year's sampling plan of classified SPAs) have discrepancies regarding sampling location and recording of the type of classification, making data use by SEPA time-consuming and challenging.
- In consultation with FSS and SEPA, the report identified the strengths of current approaches and opportunities for improvements (see Recommendations) to inform future discussions with Scotland's shellfish industry. Recommendations for Standard Operating Procedures (SOP) for sanitary surveys are also provided.

BACKGROUND

SPAs and FSS. *Regulation (EC) 854/2004* lays down the requirements for the organisation of official controls for live bivalve molluscs from classified SPAs, where commercial harvesting of bivalve shellfish is allowed. Prior to classification on the basis of shellfish *E. coli* concentrations, FSS must undertake full sanitary surveys before granting a classification grade. Instead, it identifies a provisional RMP through pRMP desktop assessments, until a revised approach is developed.

SWPAs and SEPA. The *Directive* 2000/60/EC establishing a framework for the Community action in the field of water policy, known as the Water Framework Directive (WFD), requires Member States to establish a register for "areas designated for the protection of economically significant aquatic species", including shellfish, since 2013. Accordingly, the Scottish Government (SG) designated 85 SWPAs and identified microbiological shellfish water quality standards for their classification to inform RBMP. SEPA must classify SWPAs as Good, Fair or Insufficient. In practice SEPA's classification is currently based on FSS monitoring data from SPAs overlapping with SWPAs, because both FSS and SEPA use the shellfish *E. coli* standard. However, for a number of SWPAs there is no monitoring data by FSS because no commercial harvesting for shellfish species is practised therein.

RESEARCH UNDERTAKEN

The project reviewed both peer-reviewed and grey literature. The project team developed a catchment-shellfish *E. coli* database to analyse the effect of catchment-based faecal sources on shellfish *E. coli* contamination. National-scale data on shellfish *E. coli* were examined in relation to data on catchment indicators of faecal contamination (i.e. livestock

density, number of septic tanks, population, rain) in SWPA source-catchments. Trial desk studies were undertaken in four trial SWPAs prioritised by the shellfish industry (priority SWPAs: Cat Firth, Cromarty Bay, Loch Ryan and Loch Creran), as a proxy to the desk study and the overall assessments included in a typical full sanitary survey report. National-scale and trial desk studies assessed data from: FSS, SEPA, SG, MetOffice, Edina AgCensus and pre-2015 sanitary survey reports by the Centre for Environment Fisheries and Aquaculture Science (CEFAS).

RECOMMENDATIONS

Overall, FSS and SEPA must apply *The Guide to Good Practice* in *Microbiological monitoring of Bivalve Mollusc harvesting areas*[1] and account for international evidence on shellfish species-specific factors when defining their monitoring strategy and classification approach.

Recommendations to FSS

- Include the following tasks in the revised (full) sanitary surveys see Figure 1a): a desk study, sampling of shellfish *E. coli* and salinity and field (shoreline and catchment) observations, analysis of shellfish microbiological data in the context of the desk-based data, a report, and GIS-linked database of the data collected during the sanitary survey accompanying the report.

- Tailor monitoring strategy to the risks and type of pollution sources identified in the sanitary survey. Areas predominantly influenced by farmland runoff can be monitored under the random strategy. Worst-condition (e.g. rainstorm events, ebb-phase of the tidal cycle) strategy is fit for areas influenced by point sources of human sewage discharges. A combination of both strategies (i.e. hybrid strategy), can be also applied depending on the findings of sanitary surveys.

- Collect seawater salinity and temperature samples in tandem with shellfish *E. coli* concentration during sanitary surveys and routine monitoring for classification.

- Gather and record field observations at the time of sampling (e.g. tidal phase, wildlife, pets, domestic sewage outflows, grazing livestock, recreational boating, wind direction and rain).

- Make a rule that all classifications are based on at least 24 samples regardless of whether they are based on six months', one year' or three years' worth of data.

Recommendations to SEPA

- Undertake sanitary surveys in SWPAs where no sanitary survey has been undertaken on behalf of FSS and there are not any currently classified SPAs (see Figure 1b).

- Classify SWPAs based on data from commercial aquaculture bivalve shellfish species, i.e. from SPAs.

- Classify each shellfish species from different SPAs within a SWPA separately in SWPAs where more than one species is commercially harvested, unless these SPAs are classified for the same species and can be grouped into a single, homogeneous area influenced by the same faecal pollution risks and processes on the basis of the results of a sanitary survey.

- In SWPAs where no commercial harvesting is practised, the options are as follows:

    - No monitoring until commercial harvesting begins.

    - Monitoring of shellfish *E. coli* from species deployed in bags in areas at risk from faecal contamination to inform the RBMP process; or at sites prioritised by the shellfish industry.

    - Monitoring of shellfish *E. coli* from naturally occurring (not commercially harvested) species found in the area. The species or the locations may be selected in consultation with the shellfish industry to inform on the potential for development of commercial harvesting.

- Undertake supplementary monitoring within or outwith the boundaries and the RMP of currently classified SPAs in order to provide "supplementary" information on the risk from faecal contamination in relation to specific catchment-based faecal sources of pollution or hydrographic parameters within the SWPA.

- Apply investigative monitoring for faecal indicators and to account for the presence of human pathogens in shellfish and water in areas where commercial harvesting has not yet started; and in areas potentially influenced by human sewage discharges and/or agricultural land runoff.

- Use the developed catchment-shellfish *E. coli* database to verify linked catchment-hydrodynamic models on faecal indicator inputs and transport (once the models are developed).

- Add stream *E. coli* monitoring data in source-catchments draining to priority SWPAs into the catchment-shellfish *E. coli* database in order to link source-apportionment with shellfish data.

[1] EURL-CEFAS. (2017a).

- Support the development of hydrodynamic (process-based) modelling to SWPAs where:
    - o Shellfish *E. coli* results do not match the desk-based assessment of pollution sources.
    - o There is a large bivalve shellfish production.
    - o Shellfish *E. coli* levels frequently exceed the classification grade granted to production areas.
    - o There is a potential link between bivalve shellfish harvested and a disease outbreak.

- Support and promote the development of linked catchment-hydrodynamic models to inform the RBMP process and the integrated management of shellfish waters in collaboration with Marine Scotland, FSS as well as research institutes and universities in Scotland and the UK.

Recommendations for integrating FSS and SEPA programmes

- Consider the benefits for Scotland of the French paradigm, whereby the requirements of the *Regulation (EC) 854/2004* and the WFD have been fully integrated enabling complete alignment of sanitary surveys, monitoring and classification and the RBMP process for SPAs and SWPAs.

- Share data from each sanitary survey undertaken at the SWPA- and SWPA source- catchment scale between FSS, SEPA and local authorities (LAs). In SWPAs where there are SPAs and applications for new SPAs, both FSS and SEPA will have write-access (Figure 1a). In SWPAs where there are not any SPAs, SEPA will have write-access (Figure 1b).

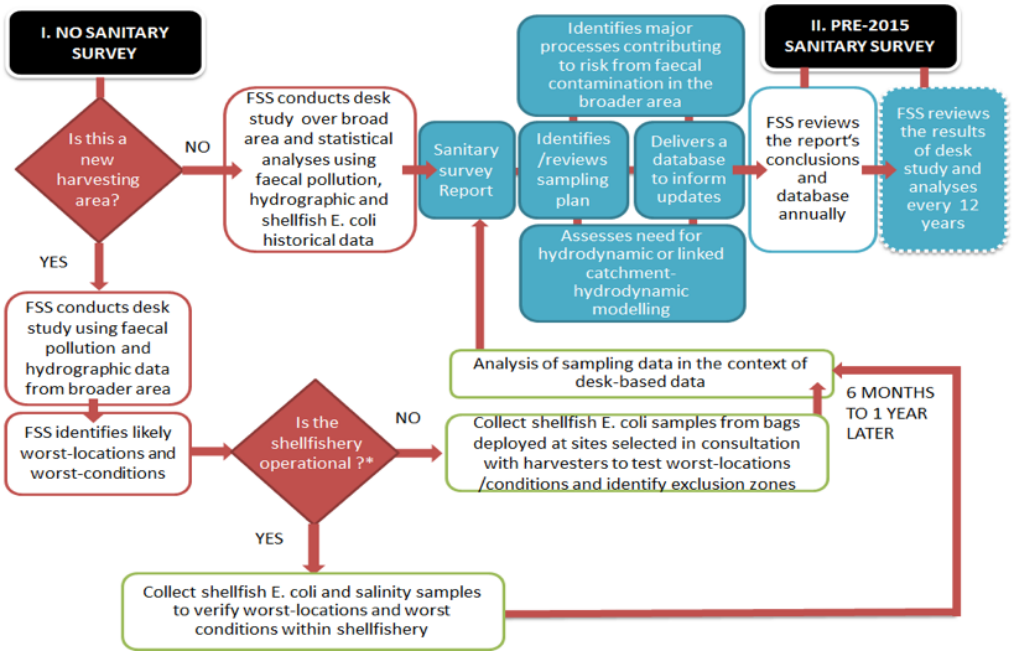

Figure 1a. Decision-tree for sanitary surveys in SPAs by FSS. *Operational: ready for harvesting.

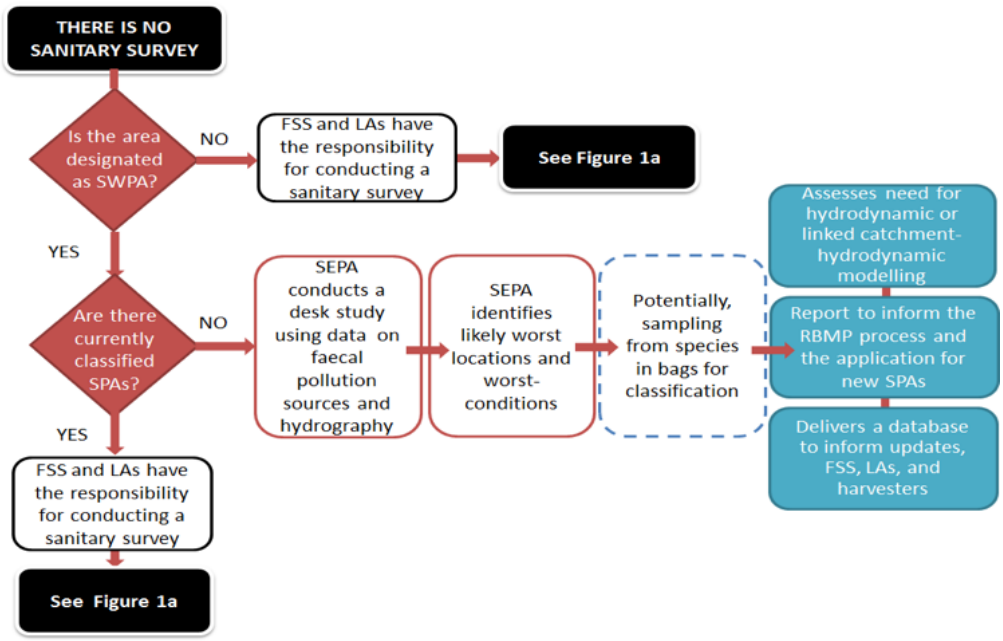

Figure 1b. Decision-tree for undertaking sanitary surveys in SWPAs where no sanitary surveys have been undertaken in the past.

1.0 Introduction

A scientifically robust, mutually beneficial and cost-effective programme for sanitary surveys and microbiological monitoring is required to inform Food Standard Scotland (FSS) and Scottish Environment Protection Agency (SEPA) programmes for the classification of Shellfish Production Areas and Shellfish Water Protected Areas respectively. The aim of this project is to assess current practices with a view to developing recommendations for feasible improvements.

The technical and scientific terms used in this report are explained in Appendix I.

1.1 The problem

1.1.1 Identifying a sampling plan for the classification of Shellfish Production Areas

Regulation (EC) 854/2004 lays down the requirements for the organisation of official controls for live bivalve molluscs from classified Shellfish Production Areas (hereafter reported as SPAs) where commercial harvesting of bivalve shellfish is allowed[2]. Prior to granting a classification grade (A, B, or C) based on MPN counts of Escherichia coli[3] (*E. coli*) per 100g of bivalve shellfish flesh and intravalvular liquid (FIL) specific for each grade, EU Member States are required to undertake a number of tasks, collectively known as sanitary surveys. Specifically, Annex II: Chapter II, Part A: par. 6 of *Regulation (EC) 854/2004* stipulates that if the competent authority decides in principle to classify a production or relay area it must:

- Make an inventory of the sources of pollution of human and animal origin likely to be a source of contamination for the production area (par. 6a).
- Examine the quantities of organic pollutants in relation to seasonal variations of both human and animal populations in the catchment area, rainfall, waste-water treatment and area-specific relevant factors (par. 6b).
- Determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area (par. 6c).
- Establish a shellfish sampling programme based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered (par. 6d).

In Scotland, sanitary surveys were undertaken since 2007 and until 2015 by the Centre for Environment Fisheries and Aquaculture Science (CEFAS) on behalf of the Food Standard Agency in Scotland (FSAS)[4]. These sanitary surveys, hereafter reported as full sanitary surveys, involved a desk study to identify pollution sources; a shoreline (field) survey to confirm the findings of the desk study; a bacteriological survey, as part of field investigations; hydrographic surveys; assessment of historical microbiological data, if any; and overall evaluation of existing information (CEFAS n.d.).

The outcome of each Scottish full sanitary survey was a report detailing the sources of pollution and environmental factors such as rain, wind, tides and bathymetry potentially influencing the broader area surrounding one or more SPAs (CEFAS n.d.). Each report assessed the findings of the areaspecific survey and concluded a microbiological "sampling plan" specific for each commercially harvested bivalve species in the broader area. As a rule of thumb, the sampling plan proposed collection of shellfish *E. coli* samples: (i) within the boundaries of areas characterised as homogeneous in terms of faecal pressures and contamination processes; (ii) outwith the direct influence of point sources of faecal or chemical contamination; (iii) from a sampling point (known as representative sampling point-RMP) and depth that is representative of the greatest impact of all faecal sources on a shellfishery ; and (iv) at dates that capture the random, bias-free (i.e. not avoiding unfavourable conditions for classification) variability of faecal contaminants at the RMP.

Typically, the full sanitary survey process from receipt of application for a new harvesting area to finalisation of the sampling plan may take over a year (e.g. Kershaw et al 2012). Next, FSS collects shellfish *E. coli* data over a period of time to assign a species-area classification grade (A, B, C), which determines the type of post-harvest treatment required, if any, before placing shellfish on the market for human consumption. FSS reviews classification grades annually based on the most recent three years' worth of data collected according to the sampling plan identified in the sanitary surveys.

Since 2015, no full sanitary surveys in new harvesting areas (or their reviews) have been undertaken because FSS considered the full sanitary survey process unsustainable[5]. Instead, FSS undertakes desk-based assessments[6], pending a full review, which will inform the development of a

[2] In Scotland, only small quantities of bivalve shellfish from non-classified areas are currently sold directly by producers onto the local market.

[3] E. coli is a faecal bacterium. It is found in the intestines of healthy humans and animals and is part of the normal bacterial gut flora. It is often used as a faecal indicator organism (FIO) to indicate the potential presence of pathogens associated with wastewater or sewage sludge or faecal inputs from warm blooded animals (i.e. livestock, pets, wildlife). Only specific strains of E. coli are pathogenic (European Food Standards Agency-EFSA 2014; World Health Organisation-WHO 2018).

[4] On 1 April 2015, SG through FSS assumed responsibility for functions carried out by the FSA in Scotland. However, in line with UK policy, the direct UK contact point in relations with the EU on food and feed matters will be FSA, as mentioned in the Memorandum of Understanding (MOU) between FSS and FSA (MOU 2015).

robust and cost-effective sanitary survey process. These assessments, hereafter reported as pRMP assessments, identify a provisional RMP (pRMP) and a frequency for the collection of samples for classification. Undertaking only pRMP assessments has substantially reduced the cost of the sanitary survey process and helped to apply a fast-track approach to classification, with initial (aka "provisional") classification granted upon receipt of 10 weekly samples. The question arises whether these practices comply with the requirement of the *Regulation (EC) 854/2004* to "establish a shellfish sampling programme based on the examination of established data" and, if not, what can be done to align the FSS monitoring programme with scientifically-based good practice.

1.1.2 Monitoring and classification of Shellfish Water Protected Areas by SEPA

The EU *Directive 2000/60/EC* establishing a *framework* for the Community action in the field of *water* policy, known as the Water Framework Directive (WFD), requires Member States to establish a register for "areas designated for the protection of economically significant aquatic species[7]" (WFD: Annex IV.1.ii). Accordingly, the Scottish Government (SG) has designated[8] 85 Shellfish Water Protected Areas, hereafter reported as SWPAs, for the protection or development of economically significant shellfish production (Water Environment and Water Services (Scotland) Act 2003; SG Designation Order 2013; 2016). Under the SG Directions (2015; 2016) for classification and environmental objectives, SWPAs must meet the objectives set under the River Basin Management Planning (RBMP) process by SEPA. SEPA must also classify SWPAs as Good, Fair or Insufficient based on the shellfish water quality standards set for each class in the SG Directions (2015; 2016). As of 2014, 47 out of 85 designated SWPAs were classified as Fair or Insufficient. This indicates that SEPA must assess where and whether measures to control point and diffuse sources of faecal pollution in the source-catchments, i.e. the catchments draining to SWPAs, can improve SWPA classification.

SEPA uses shellfish *E. coli* data collected from the SPAs sitting within SWPAS. This is because both the *Regulation (EC) 854/2004* and the SG Directions (2015; 2016) stipulate the monitoring of *E. coli* MPN counts per 100g of FIL for classification. However, in a number of cases, large parts of the designated SWPA lie outwith the area covered by a single or many classified SPAs. Therefore, it remains uncertain which of these RMPs identified for each small and homogeneous[9] SPA is representative of the greatest impact from all faecal sources in a much larger and potentially spatially heterogeneous SWPA. In addition, in a number of SWPAs no monitoring data have been collected by FSS because there are not any commercially harvested shellfish species therein, thereby questioning how, where and what shellfish species should be monitored for the classification of these SWPAs to inform the RBMP process. In the context of SWPA classification, the question arises whether FSS monitoring data is appropriate for the requirements of SWPA classification.

1.2 Objectives

The objectives of this project (as set out in the specification of the project) are to:

- Review the current approaches used to inform the development of SWPA monitoring plans.
- Review the current approaches used for data analysis and their application within classification programmes.
- Explore opportunities for improved delivery of Shellfish Harvesting classification under food hygiene legislation.
- Assess the fitness-for-purpose of existing programmes and propose revised robust, efficient and cost-effective approaches.
- Compare the Scottish SWPA programme with those used by other Member States and UK administrations and suggest alternatives or improvements that could increase the robustness of the programme and where possible reduce costs in monitoring.
- Review the existing approach used for undertaking sanitary surveys (including reviews) and propose a revised approach, which is scientifically robust, efficient, cost-effective and compliant with the relevant legislative requirement.
- Make recommendations for a future approach to delivery of sanitary surveys (including reviews).
- Prepare a written protocol or standard operating procedure for undertaking sanitary surveys and survey reviews, including mechanisms for defining a frequency of reviews and format of reports.

[5] In 2016/17, the overall annual budget for all pRMP assessments was £60K (FSS consultation 2017); in 2012-2015, the estimated average cost of a sanitary survey was £35K.

[6] Commissioned to SAMS.

[7] Economically significant shellfish species in Scotland refer to species commercially harvested within designated SWPAs, such as the species commercially harvested within SPAs (Joyce Carr, SG –pers. com.).

[8] Part 4 of the Aquaculture and Fisheries (Scotland) Act 2013 (asp 7) on the Protection of Shellfish waters specifies that the Scottish Ministers may by a "designation order" designate an area of coastal water or transitional water as a shellfish water protected area only if the Scottish Ministers consider it necessary or desirable to do so for the protection or development of economically significant shellfish production.

[9] Each SPA refers to the commercial harvesting of one species by a specified method in a specified area.

1.3 Structure of the report

This report is structured as follows:

- Section 2 outlines the research undertaken.
- Section 3 reviews current governance and management frameworks and best practice.
- Section 4 reviews evidence on the factors required for robust shellfish quality sampling.
- Section 5 reviews the current practices for the classification of SPAs and SWPAs in Scotland.
- Section 6 provides provisional recommendations.

2.0 Methods

2.1 Literature review

Both peer-reviewed and grey literature was reviewed. Computerised searches for peer-reviewed literature were performed using web-based search engines such as ScienceDirect (SD 2018); Google Scholar (GS n.d.); Web of Science (WoS n.d.); the legislative database of the Food Agricultural Organisation-FAO, FAOLEX (FAOLEX n.d.); and the Official Home of UK legislation (n.d.). Evidence was also extracted by searching the web sites of the organisations involved in the governance and management of shellfish waters. The following terms were searched, alone and in combination: shellfish; "shellfish water*"; "shellfish water protected area"; "register" "*Escherichia coli* monitoring"; "shellfish water monitoring"; "*Escherichia coli* sampling"; "*Escherichia coli*" OR Bacter* OR microb* NOT virus; "water framework directive" OR WFD"; "sanitary survey*" OR sanitary profil*; "Regulation 854/2004" OR "production area classification".

2.2 Analyses of shellfish *E. coli* and catchment data

Appendix II details the GIS and statistical methods applied to collate, analyse and assess the data from the FSS microbiological sampling plan, the catchment data from SEPA, the SG, MetOffice (n.d.) and Edina AgCensus (n.d.), the National Statistics data for population (n.d.), the Land Use/Land Cover data (2007), and the information presented in sanitary survey reports (CEFAS 2018). Hereafter, these analyses are collectively reported as a trial desk study and are considered as a proxy to the desk study and the overall evaluation of existing information for an area included in a typical sanitary survey report. The purpose of the trial desk study was to:

- Understand the degree and patterns of spatial overlap between SPAs and SWPAs.
- Assess the availability of data on catchment-based sources of faecal contamination such as rain, livestock, sources of sewage effluent, population, wildlife and land use (catchment indicators).
- Develop and deliver a catchment-shellfish *E. coli* database combining the historical shellfish *E. coli* data collected in the SPAs within SWPAs with all available GIS-linked data on catchment indicators.
- Explore the effect of catchment indicators, sampling month and bivalve species on shellfish *E. coli* data from all SWPAs and in four trial SWPAs (Cat Firth, Cromarty Bay, , Loch Ryan, Loch Creran).
- Demonstrate how the trial desk study can be tied in with the sanitary survey process and the assessment of catchment-based risk from faecal contamination in the four trial SWPAs.
- Assess the resources (e.g. time, expertise) required to build the catchment-shellfish *E. coli* database and carry out the trial desk study, as a proxy to the resources required for the desk study, the assessment and the report writing under the revised approach to sanitary surveys.

2.3 Data from (pre-2015) full sanitary surveys

CREW contacted CEFAS[10] to explore the availability of the data collected during sanitary surveys. It emerged that these data is not available in a comprehensive digitised format. The bathymetric, tidal and hydrographic data and the output of hydrodynamic modelling are not anymore available because they were obtained from other organisations (i.e. SAMS, UKHO, NAFC, SeaZone) on the basis of licensing contracts. Data from fish farm assessments by SEPA have been stored on a case-by-case basis by CEFAS; their extraction is time-consuming and their use requires permission.

3.0 Current regulatory frameworks in the EU and internationally

The overarching legislation applying on commercial shellfish harvesting and economically significant shellfish species in Scotland has been generated in the EU. Therefore, this section reviews the current EU governance (i.e. legislation, rules, policies, best practice) on shellfish harvesting in SPAs (Section 3.1 to 3.3 and Appendix III.1 to III.3) and in SWPAs (Section 3. 4). Section 3.5 compares governance and management arrangements for SWPAs between EU Member States, presenting the practices applied in France in detail (Appendix III.4). Practices applied in the USA and New Zealand are briefly reviewed in Section 3.6 to provide the wider context of international best practice. The findings are summarised in Section 3.7.

3.1 Governance framework for SPAs

The need to standardise market rules for shellfish and establish food hygiene safety equivalency between EU Member States and their trading partners led to *Regulation (EC) 854/2004,* which is the overarching legislation for the governance of SPAs in the EU. *Annex II of Regulation (EC) 854/2004* (as amended by *Regulation (EU) 2015/2285*) specifies the official controls (OCs) concerning live bivalve molluscs[11] from classified production areas (SPAs). Classification grade criteria and health standards are given in Table 1. For a review of the OCs required under the *Regulation (EC) 854/2004* and the requirements for monitoring, see Appendix III.1).

The competent authority must define a review period for sampling data from each production and relaying area in order to determine compliance with the microbiological criteria of Table 1. The microbiological sampling plan should include periodic and regular monitoring to check the microbiological quality of live bivalve molluscs in each classified production area taking particular account of the likely variation in faecal contamination and the results of the sanitary survey in such a way as to ensure that shellfish *E. coli* results are representative of the production area. No further specification is given for minimum requirements for the number of samples used for the review period, the monitoring frequency or the meaning of the term "representative".

The type of competent authorities for the implementation of the *Regulation (EC) 854/2004* varies by country with implications on their ability to undertake sanitary surveys and investigative monitoring in-house (see Appendix III.2). In countries where the responsibility for the organisation of the OCs is shared between government bodies and public (government) research organisations, such as in France, decision-making and management are integrated (Appendix III.2).

Class	Microbiological criteria and health standards[3]	Post-harvest treatment required[1]
A	Samples of live bivalve molluscs from these areas must not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of FIL. The remaining 20 % of samples must not exceed 700 *E. coli* per 100 g of FIL[3]	None
B	Live bivalve molluscs from these areas must not exceed, in 90% of samples, 4,600 MPN *E. coli* per 100g of FIL. In the remaining 10% of samples, live bivalve molluscs must not exceed 46,000 MPN *E. coli* per 100 g of FIL[3].	Purification, relaying or cooking by an approved method
C	Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution MPN test of 46 000 *E. coli* per 100 g of FIL[6].	Relaying or cooking by an approved method

[1] The competent authority has the power to prohibit any production and harvesting of bivalve molluscs in areas considered unsuitable for health reasons.
[2] These are laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No 853/2004.
[3] Regulation (EC) No 854/2004, as amended by Commission Regulation (EU) 2015/2285.
[4] *Regulation (EC) 854/2004* as amended by Regulation (EC) 1021/2008.

[10] Contact person: Michelle Price-Hayward (CEFAS).
[11] It also applies, by analogy, to live echinoderms, live tunicates and live marine gastropods.

3.2 Community Guide to Good Practice

An EU expert working group has produced a Guide to Good Practice for the Microbiological Monitoring of Bivalve Mollusc Harvesting Areas-Technical Application (hereafter reported as the Guide), authored by the European Reference Laboratory (EURL) and CEFAS (EURL-CEFAS 2017a). The purpose of the Guide is to assist competent authorities in implementing scientifically based OC programmes. The recommendations identify good practice in the application of the sampling plan and sanitary surveys in order to meet the requirements or intent of the *Regulation (EC) 854/2004* (EURL-CEFAS 2017a and previous versions). The Guide covers sanitary surveys, sampling plan, review period, sample transport, laboratory testing, data handling and storage and interpretation of data. For example, reviews should be undertaken annually or more frequently on a rolling basis, using data from the most recent three years. The guide's recommendations for the minimum number of shellfish *E. coli* samples for each type of classification are summarized in Table 2. Table 3 summarises key recommendations for the components of sanitary surveys procedures required to identify a robust sampling plan.

Table 2. The Guide's recommendations for the minimum number of samples for classification of SPAs. Source: EURL-CEFAS 2017a; b.

Classification	**Guide's recommendations for minimum number of samples**
Initial	At least 12 samples for six months at least weekly during "worst-season"
Annual [1]	12-24 at least fortnightly samples for a year after initial classification
Established	At least 24 monthly samples year-round for three years
Seasonal	· At least 24 monthly samples for each season for three years but higher frequency for SPAs where exceedance of class A criteria are likely · Sampling for classification should start at least one month prior to the harvesting season for class A areas and two months prior to the season for class B areas

[1] Reported as primary established classification in the Guide.

Table 3. The Guide's recommendation for the tasks in sanitary surveys. Source: EURL-CEFAS 2017a. See also Section 1.1 and Appendix III.3.1.

Sanitary survey task	**Description and purpose**
Desk based study to identify pollution sources	This involves: · Characterisation of the production area · Identification of actual and potential pollution sources related to: o Sewage discharges: continuous, rainfall dependent, emergency o Land use o Livestock o Other pollution sources such as wildlife and ships and boats
A shoreline survey	This is a field investigation (visual/sampling) to confirm initial findings of the desk-based study and whether all significant sources of contamination have been revealed by the desk-based study
A bacteriological survey	This is to explore and identify the worst-location and the worst- condition (i.e. rain or tidal stage, worst-season) to account for increased risk of faecal contamination (see also Table 4)
Analysis of historical microbiological data	Where such data is available for the species-area SPA, this analysis should supplement and not override the other elements of the sanitary survey
Hydrographic survey and hydrodynamics	This involves the use of nautical /tidal charts and hydrodynamic modelling in order to help interpret the information on sources of faecal pollutants obtained for the sanitary survey
Salinity monitoring	Whether as part of the shoreline or bacteriological survey or routine monitoring, this is prescribed to help interpret data on sources of pollution associated with fresh water inputs and inform water quality measures
Data assessment	This may involve assessment of · the effect of each faecal pollution source to the SPA based on available data and maps · the combined shellfish contamination risk on from all faecal pollution sources · hydrodynamic modelling to predict microbial load in water column around the SPA
Report	This should describe (including maps) and interpret all data. Its major output is the microbiological sampling plan (see Table 4)
Data handling and storage	This refers to storing the data in a secure, well-organised and easily accessible, GIS-linked database to enable proper validation and access by all interested parties and subsequent analyses of the data

Appendix III.3.1 details the Guide's prescription for sanitary surveys and Appendix III.3.2 presents evidence on the varying degree of uptake of the Guide's recommendations by the EU Member States.

The Guide also provides detailed recommendations for the components of the sampling plan. The sampling plan refers to: boundaries and location of SPAs, Site Name/ Identifier, the species commercially grown, the location and number of RMPs and the variance tolerated around these locations[12], the depth of sampling, the frequency of sampling, the monitoring strategy, the harvesting method, and the authorised sampler. Table 4 describes the scientifically-based recommendations in the Guide for identifying boundaries, the RMP, the sampling frequency and the monitoring strategy. It must be noted that the Guide refers to production areas, i.e. SPAs. However, the scientific principles for identifying the sampling plan also apply to the monitoring of SWPAs, which, by definition, refer to commercially (economically) important species.

Table 4. Recommendations in the Guide for the sampling plan for collecting shellfish E. coli data to classify SPAs. Source: EURL-CEFAS 2017a.

Sampling plan	**Guide recommendations**
Boundaries and extent of SPAs and relay areas – Closure (aka Exclusion) zones	(i) The identification of the boundaries should take into account the outcome of sanitary surveys and any historical microbiological monitoring (ii) Each SPA should ideally be homogeneous with respect to access, production, species and operations, hydrography and circulation of faecal pollutants. Homogeneity is essential to select the appropriate worst-location RMP, to apply a bias-free sampling frequency and strategy and to enforce the classification result. (iii) The following areas should not be used (designated) as SPAs: · Areas with active harbours and marinas; areas within inactive or seasonally active harbours and marinas should be tested for microbiological and chemical contamination before applying for harvesting · Areas with continuous or intermittent sewage or animal slurry discharges (or the mixing zone of these)# · Areas influenced by outfall containing industrial wastes · (In SPAs classified as A or B class) Zones of 300m radius around the entrances to harbours or marinas or any outflows from these, unless there is no impact. (iv) Buffer zones around point sources where bivalves are exported to the USA**.
Bivalve species	Option 1: The sanitary survey should identify a species-area specific sampling plan Option 2: The sanitary survey could identify one or more indicator species for the SPA if parallel monitoring has shown that the indicator species yields results at least as high as those of the other species it represents (i.e. worst-species approach)
Geographical location (grid reference and/ or latitude/longitude) and number of sampling points	(i) Each RMP should be at a fixed geographical location with an accuracy of at least 10m. A virtual RMP is suggested for offshore SPAs (i.e. >5km away from the shore), because uniform faecal contamination can be assumed. (ii) Selection of RMP should be based on the outcome of sanitary surveys (iii) RMP should represent the location at the highest risk of faecal contamination within the boundaries of the classified SPA (i.e. worst-location approach). (iv) Every RMP must produce sufficient specimens for testing
Tolerance	(i) All sampling points must be recorded at the time of sampling to check for tolerance (ii) For hand-picked or raked samples, tolerance should be within a maximum of 50m of the RMP (iii) For dredged samples, tolerance should be within a maximum of 250m of the zone referring to the RMP
Depth and timing of sampling (if relevant)	(i) Identifying worst-depth and worst-timing for sampling at the RMP presupposes sampling at different depths and states of currents and tidal movements during sanitary surveys and hydrographic assessments of the area. (ii) For bivalves grown on ropes or bouchots: the depth yielding the worst shellfish *E. coli* results must be sampled (i.e. the worst-depth approach). This will depend on currents and the tidal stage therefore the worst-depth will represent the worst-timing for sampling. (iii) For bivalves grown in experimental/investigative bags instead of the normal (native or cultivated) harvested stock: the bags must be placed at the worst-depth for the stocks.
Frequency of sampling	(i) This depends on the type of classification (initial or established); see Table 2. (ii) A higher frequency is recommended for areas with less than three-years' worth of data and coarser frequencies for areas with stable classification results over a period longer than three years. Options include: · Weekly, or 24 samples for a period of six months · Fortnightly, or 24 samples per year · Monthly, or 24 samples in three years. · Bimonthly (six times per year) or less than 24 samples per year
Monitoring strategy	Option 1 (Randomised sampling): Sampling should be on as random a basis as possible to avoid introducing any bias into the results. If sampling has been affected by factors such as rain or tidal stage due to safety or accessibility considerations, the sanitary survey should include an assessment as to whether there is any bias towards an incorrect result. In this case, interpretation of data and classifications should take account of the bias in order to provide the equivalent level of public health protection. Option 2 (Worst-case conditions sampling-aka adverse pollution condition (APC strategy): Sampling should be undertaken under conditions known to produce the highest shellfish *E. coli* results[1]. Worst-conditions must be identified during sanitary surveys and may include, depending on area: tidal stage, rain, wind, season, currents, and any condition or activity related to disposal of faecal contaminants.

*Terms are explained in Appendix I. ** See Section 5. #This refers specifically to SPAs classified as Class A and B.

[12] A sanitary survey report may conclude that there are areas that must be delineated within separate boundaries and monitored at RMPs that are representative of each separate area.

3.3 Caveats related to the implementation of the Regulation (EC) 854/2004

A number of caveats were raised regarding the efficiency and feasibility of the OCs for commercially harvested bivalve shellfish as described in the *Regulation (EC) 854/2004* and further clarified in the Guide. Appendix III.4 discusses these caveats in the context of evidence. A summary of the key remarks is provided below.

Caveats related to predicting public health risk

- Classification, as a post-harvest strategy for the mitigation of faecal contamination, is instrumental in protecting consumers from the risk of foodborne disease but this depends on the ability of historical shellfish *E. coli* data to predict the risk of faecal contamination in the future.
- Classification under the *Regulation (EC) 854/2004* is reliable only when the sampling plan and the classification programme have accounted for the presence of pathogens such *Norovirus* (NoV). Accounting for pathogens requires proper identification of all sources of faecal pollution during sanitary surveys to enable exclusion of areas unsuitable to harvesting.
- Sanitary surveys combined with pathogen monitoring, or microbial source tracking (MST), may yield a better prediction of health risk than classification alone.
- The most effective public health measure to control human NoV infection is to produce shellfish from areas that are not faecally contaminated.

Caveats related to practical issues such as undertaking of sanitary surveys and monitoring

- It is not always feasible to identify "seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc" as required by the *Regulation (EC) 854/2004* for the sanitary surveys. Some information (e.g. livestock data) may be accessible to one agency but not to the agency doing the sanitary survey due to confidentiality issues. Best practice may involve developing open access databases and enabling data-sharing procedures.
- Hydrography (i.e. depth, density, salinity and tidal data) and hydrodynamics (i.e. river, tidal and wind forcing on water circulation in an area) influence the fate (i.e. transport and survival) of faecal contaminants in production areas. However, this information may not be available for all coastal areas and, where available, it may not be freely accessible or affordable for a competent authority. Nautical and tidal charts can help in discussions on how hydrography may modify circulation in the area but hydrodynamic modelling is required to predict areas where contaminants tend to accumulate or persist.
- Data on actual river flows and the microbial content of sewage discharges is rare and therefore it is not always feasible for a competent authority to obtain the data required by the Regulation (EC) 854/2004.
- Sampling during worst-case conditions in relation to rainfall and tidal stage, wind direction, current speed or season is not always feasible for reasons of safety or convenience or, simply because there would be very few potential dates and times referring to all interacting factors coinciding to produce the highest shellfish *E. coli* results at the RMP.
- Historical shellfish *E. coli* data are useful for assessing faecal contamination risk and informing classification only if they have been collected from points representative of the greatest impact from faecal sources to a production area, i.e. they have been collected from the RMP identified in the sanitary survey.

3.4 Governance framework for SWPAs in the EU

EU legislation and policy makers have acknowledged that there are interactions between shellfish hygiene legislation and legislation laying down requirements for controlling the land-based sources of sewage and livestock inputs to shellfish waters. Such requirements have driven sewage treatment improvement and, to a lesser extent, diffuse pollution mitigation programmes (Murray and Lee 2009). Until recently, the overarching legislation referring explicitly to shellfish was the Shellfish Directive (*Council Directive 79/923/EEC*) on the quality required of shellfish waters. The Shellfish Directive was applied to those coastal and brackish waters designated by the Member States as needing protection or improvement in order to support shellfish (bivalve and gastropod molluscs) life and growth and thus to contribute to the high quality and edibility of shellfish products.

In 2013, Article 22 of the WFD repealed the Shellfish Directive. Generally, the WFD requires EU Member States to maintain the same level of protection of designated areas under repealed Directives through their designation as Protected Areas. EU Member States are required to apply the necessary environmental objectives and measures to Protected Areas under the RBMP process and the Programmes of Measures (PoMs). Normally, the environmental objectives set for Protected Areas are beyond the objective of the Good Ecological Status because more stringent objectives have been set for those areas in the repealed Directives (WFD Reporting Guidance 2016). However, it has been suggested that the WFD has not paid as much attention to the SWPAs as compared with Drinking Water and Bathing Water Protected Areas (WFD Reporting

[13] The EURL Recommendations refer to need for at least 50 samples before statistical analyses can be performed to assess the various states of each environmental factor.

Guidance 2016). Therefore, it is worth carrying out a review of the standards and requirements set in the repealed Shellfish Directive to enable a better understanding of the benefits and drawbacks of WFD for shellfish management.

Monitoring and standard criteria for classification of designated shellfish growing waters under the Shellfish Directive (*79/923/EEC*). The parameters applicable to the waters designated by the Member States included: pH; salinity; temperature; suspended solid; dissolved oxygen; organic compounds (i.e. petroleum hydrocarbons, organohalogenated substances); heavy metals (e.g. arsenic, cadmium, chromium, lead); saxitoxin; and Faecal Coliforms (FC) in shellfish FIL. *Directive 79/923/EEC* laid down requirements for the minimum levels of these parameters, which had to be met (i.e. "mandatory" standards), or endeavoured to be met (i.e. "guide" standards). It also set a minimum sampling frequency of these parameters, which ranged from half-yearly (e.g. for heavy metals) to quarterly (e.g. for FC) or monthly (e.g. for salinity). Member States also had to establish programmes to reduce pollution in these areas and ensure that the designated areas comply with the standards set.

Directive 2006/113/EC. *Directive 79/923/EEC* was repealed by *Directive 2006/113/EU*, which required that "References made to the repealed Directive 79/923/EEC shall be construed as being made to this Directive" (Article 1614)[14]. Many parts of the two directives are identical on an article to article basis, except in timescales of programmes to reduce pollution in designated shellfish waters and compliance with the standard. For example, whereas Annex I in *Directive 79/923/EEC* required Member States to comply with the mandatory standard of ≤300 FC per 100ml in FIL in shellfish designated areas, Annex I of *Directive 2006/113/EC* required Member States to endeavour to achieve this FC standard as a "guide" standard.

Shellfish and the WFD. The microbiological standards set in the repealed Shellfish Directive are not included in Annex V of WFD, which refers to the quality standards and parameters and their monitoring to determine waterbody and Protected Area status. A report produced for the UK Shellfish Industry Development Strategy concluded that the WFD fails to deliver in respect of shellfish waters because it fails to retain the microbiological standards that are vital for maintaining and improving the quality of these waters (Andrews 2008). More recently, the WFD Reporting Guidance (2016, p.214)[15] stated that "*microbiological standards are essential for the quality of shellfish waters*", but these are not part of the definition of ecological status; therefore, "*it is requested to report if these standards have been set (or maintained from the Shellfish Directive) and if they are met*".

It must be also noted that the Shellfish Directive or simply the term shellfish is not explicitly mentioned in the WFD, creating further uncertainty as to how or whether SWPAs must be monitored and classified. For example:

- The list of Protected Areas in Annex IV does not explicitly refer to bivalve shellfish but to "areas designated for the protection of economically significant aquatic species" (WFD:Annex IV.1.ii).
- No reference to the Shellfish Directive or to the areas designated for the protection of economically significant aquatic species is included in WFD:Annex VI.A, which lists the Directives whose measures are to be included within PoMs implementing the WFD.

3.5 Management and classification of SWPAs in the UK and the EU

The review of legislation transposing the WFD regarding the repeal of the Shellfish Directive delivered limited evidence on how EU Member States monitor and classify SWPAs. This may be partly attributed to the language used for the searches, i.e. English or French. In addition, it was observed that the relevant legislation was not always online. However, the findings from UK, France and Ireland (see Sections 4.1 to 4.3 and Appendix III.4) also show that, to a certain extent, this paucity of information reflects: (i) the absence of specification on any microbiological standards for the classification of SWPAs in the WFD and (ii) the reliance of data for SWPA classification on ongoing monitoring for SPAS.

3.5.1 UK: General approach, Scotland, England and Wales and Northern Ireland

3.5.1.1 Advise from the UK Technical Advisory Group (UK TAG) on shellfish water standards

In view of the repeal of the Shellfish Directive by the WFD, the UK TAG (2010) acknowledged that most of the chemical and physical water quality standards for the Shellfish Directive are covered by the standards and procedures of the WFD, thus providing the same level of protection before and after the repeal. UK TAG recognised that the WFD does not address protection of shellfish waters from microbial contamination but suggested that water column standards would be useful to inform setting of discharge consents.

[14] Article 22 of the Water Framework Directive (2000/60/EC), which refers to the directives repealed by WFD, mentions Directive 79/923/EEC and not Directive 2006/113/EC.

[15] Article 18 of the WFD requires the European Commission to publish assessment reports on the implementation of the Directive and to submit them to the European Parliament and to the Council. The assessment is based on information reported by Member States, comprising the published RBMPs and accompanying documentation required according to Article 15, the electronic reporting

Applying a water standard is in line with an interim standard of 110 FC per 100ml in water (as a geometric mean), which has been adopted by the respective agencies in the UK to assist discharge consenting (UK TAG 2010). UK TAG (2010) recommended water *E. coli* as the future microbiological standard in the UK for designated SWPAs. This water standard "would better tie in with the standards of the Revised Bathing Water Directive". However, UK TAG (2010) recognised that a shellfish *E. coli* standard would match better with the criteria for the classification of SPAs under the Regulation (EC) 854/2004.

3.5.1.2 Scotland

The SG Directions (2015; 2016) identify standards and criteria to be applied for the classification of shellfish water quality (Table 5), adopting the shellfish *E. coli* in FIL standard. Accordingly, shellfish water quality means the quality of a SWPA assessed in accordance with the shellfish water quality standards (criteria) for SWPAs (SG Directions 2015; 2016).

Table 5. Shellfish water quality standards in Scotland (SG Directions 2015, 2016).

Most probable number of *E. coli*/100g of FIL as a 90th-percentile standard[1]		Most probable number of *E. coli*/100g of FIL as 90th percentile standard
SWPAs classified as GOOD	SWPAs classified as FAIR	SWPAs classified as INSUFFICIENT
≤230	≤4,600	>4,600

[16] A standard that is failed if the MPN of E. coli/100g is greater than the standard for 10% or more of the assessment period (SG Directions 2015; 2016).

It must be noted that no further specification is given as to whether shellfish *E. coli* data should come only from (commercially harvested) classified SPAs or only/also from intertidal (usually not commercially harvested) mussel beds, which used to be sampled by SEPA to test compliance with the Shellfish Directive standards (SEPA 2011). However, following the repeal of the Shellfish Directive, a consultation in 2013 on "Delivering Scotland's River Basin Management Plans: next steps in implementing an integrated approach to the protection of shellfish growing waters" was held to inform the SG designations (SG 2013a). In line with the consultation outcome, the designations aimed to identify large areas of shellfish waters as SWPAs so that prospective shellfish producers could have confidence to establish shellfish farming there (SG 2013b). In this respect, the designated SWPAs were aligned with existing **shellfish aquaculture** areas in 2013, i.e. areas including SPAs classified for the commercial production of mussels and Pacific and native oysters, which are the key shellfish aquaculture species in Scotland (Munro and Wallace 2017). In this context, areas including SPAs classified only for wild stocks such as razors and common cockles were not designated as SWPAs.

The SG Regulations (2013) provide specifications for the setting of environmental objectives, the preparation of PoMs and the content of the RBMP process with regard to SWPAs, and also identify the content of the monitoring programmes (Box 1). The way the SG Directions (2015; 2016) and the SG Regulations (2013) are applied is reviewed in Section 5.3.

BOX 1. Content of monitoring programme in SWPAs in Scotland, as stipulated in the SG Regulations (2013)

Paragraph 8 of the SG Regulations (2013) on "Shellfish Water Protected Areas: Environmental Objectives etc." stipulates that the monitoring programme prepared by SEPA must

"1 (a) cover monitoring of the quality of the area;
(b) enable a reliable assessment of –
(i) the shellfish water quality of the area;
(ii) the extent to which each environmental objective set for the area […] has been, or is likely to be, achieved; and
(iii) any risks to the achievement of those environmental objectives; and
(c) enable the area to be classified by reference to its shellfish water quality in accordance with any relevant directions given to SEPA by the Scottish Ministers […]"

3.5.1.3 England and Wales

Designations, general monitoring directions and the environmental objectives for SWPAs are specified in The Water Environment (WFD) (England and Wales) (Amendment) Regulations 2016 and in the Water Environment (WFD) (England and Wales) Regulations 2017 (hereafter reported as E&W WFD Regulations 2017), which update the regulations transposing the WFD to domestic law (i.e. the WFD (England and Wales) Regulations 2003) According to the E&W WFD Regulations 2017, shellfish means any bivalve and gastropod mollusc (Reg. 2). The appropriate authorities, i.e. the Environment Agency (EA) in England and the National Resources body for Wales (NRW), may designate any area of coastal or transitional water within a river basin district as a SWPA by including it in the relevant list of SWPAs and review each designation at intervals not exceeding six years (Part 3: Reg. 9 of

through the Water Information System for Europe (WISE) in predefined formats agreed by the Water Directors, and any additional, supporting background documents that the Member States consider relevant.

E&W WFD Regulations 2017). EA and NRW must also maintain a monitoring programme for the purposes of enabling a reliable assessment of whether the shellfish water objectives have been or will be achieved in the designated SWPAs (Reg. 11 of E&W WFD Regulations 2017). The environmental objectives for SWPAs apply to the surface water bodies in which they are located and refer to objectives that are necessary or desirable to improve or protect the SWPA in order to support shellfish life and growth and to contribute to the high quality of shellfish products suitable for human consumption as the appropriate authority may direct (Reg. 13 of E&W Regulations 2017). .

A report to the House of Commons (Priestley 2015) mentions that draft action plans have been developed for each of the 98 SWPAs designated in England. The most recent SWPA list includes 96 areas in England and 13 areas in Wales (DEFRA 2016). Of the areas listed as SWPAs by EA in England (DEFRA 2016) at least 36 are not listed as currently classified SPAs by the FSA (CEFAS 2018). Of the areas listed as SWPAs by NRW in Wales (NRW 2016) at least five are not listed as currently classified by the FSA (CEFAS 2018).

The Shellfish Water Protected Areas (England and Wales) Directions 2016 (hereafter reported as E&W Shellfish Directions 2016) revoke the Surface Waters (Shellfish) Directions 2010 and implement the requirements of the WFD with regards to monitoring and classification of SWPAs. These regulations specify that the microbial standard is 300 or fewer colony forming units of *E. coli* per 100ml of shellfish FIL (Reg. 3 of E&W Shellfish Directions 2016). A SWPA complies with the microbial standard if all shellfish samples are collected at least at quarterly intervals from commercially harvested areas and 75% of the samples taken within any period of 12 months is equal to or below the specified microbial standard (Reg. 4 of E&W Shellfish Directions 2016). This shows discrepancies between the E&W Shellfish Directions 2016 and the *Regulation (EC) 854/2004* as well as the SG Directions (2015; 2016).

3.5.1.4 Northern Ireland

Designations and monitoring in SWPAs are regulated under The Water Environment (WFD) (Northern Ireland) Regulations 2017 in line with the WFD, i.e. without explicit guidance as to the repeal of the monitoring requirements of the Shellfish Directive. However, The WFD (Classification, Priority Substances and Shellfish Waters) Regulations (Northern Ireland) 2015 (hereafter reported as NI Regulations 2015) specify the classification programme in SWPAs. Schedule 5. Part 1 of the NI Regulations (2015) identify shellfish water mandatory standards for temperature, pH, silver and salinity; a guideline standard for salinity; and a guideline microbiological standard of shellfish *E. coli* , which should not exceed the value of 230 cfu/100ml in FIL. Quarterly shellfish *E. coli* monitoring is prescribed as a minimum sampling frequency. Schedule 5, Part 2.2(2) of the NI Regulations 2015, mentions that the microbiological standard "which may be ignored".

It is also interesting to note that SWPA designation before the repeal of the Shellfish Directive was decided upon evidence on shellfish production data in an area with a minimum class B awarded by the FSA in NI, or a Class C, if heat treatment was included in the business model for an area (Department of Environment of NI-DOENI 2016). Following the repeal of the Shellfish Directive, designation will have to be compatible with cost implications for NI Water and the farming industry, in line with WFD requirements for considering disproportionate costs of remediation mentioned in WFD Art 4(5) (DOENI 2016).

3.5.2 Ireland

Shellfish aquaculture activities (i.e. SPAs) are located in areas designated as shellfish waters under *Council Directive 79/923/EEC*, adopted into Irish Law as S.I. No. 268 of 2006 and amended by). This is now repealed but reports of monitoring data show that monitoring under the repealed Shellfish Directive is still in place with the aim to protect or improve the quality of waters where shellfish are grown for human consumption and establish pollution reduction programmes for each designated area (National Strategic Plan 2015).

Because of the protection status afforded to SWPAs through the pollution reduction programmes, the National Strategic Plan (2015) supports the designation all classified SPAs as SWPAs. This will further enhance the protection of human health and the environment. However, as mentioned in National Strategic Plan (2015), this approach presents a challenge for local authorities as maintenance and improvement of classifications in the SPAs-SWPAs can require significant investment to improve the performance of wastewater treatment plants. However, it is believed that the integration of SWPA programmes with the *Directive 2008/56/EC* (Marine Strategy Framework Directive-MSFD) will contribute positively to the licence decision procedures in the long run.

Overall, it remains unclear whether the Environment Protection Agency (EPA) in Ireland use the standards and monitoring of the repealed Shellfish Directive to classify SWPAs or have modernised the standard. Interestingly, the Code of Practice (COP) developed by the Sea Fisheries Protection Authority (SFPA) for shellfish monitoring in SPAs mentions that the desk studies undertaken as part of the sanitary survey process use catchment data collected under the Shellfish Directive (SFPA 2017).

3.5.3 France

In France, shellfish means bivalve and gastropod molluscs, echinoderms and tunicates. By reference to the French Government's Registry of designated Protected Areas under the requirements of the WFD, SPAs and SWPAs are integrated, i.e. existing SPAs were designated as SWPAs (Registre 2015). Specifically, there are two types of designated areas referring to SWPAs (Registre 2015):

1. "Professional SWPAs", which refer to all SPAs classified and controlled under the Regulation (EC) 854/2004. SPAs must meet quality standards, determined by microbiological and physico-chemical controls in shellfish waters and FIL under the *Regulation (EC) 854/2004* transposed into French Law by the Decree of 6 November of 2013. This Decree specifies that SPAs cannot include areas influenced by harbours or known pollution sources. In each local authority, an order of the Prefect defines the geographical extent of the SPAs and their classification in three zones (A, B, C). SPAs are monitored under the network for testing the microbiological quality of shellfish, known as REMI. The monitoring network is organised into two types of monitoring: regular (i.e. planned) and outbreak, which involves both bacteriological and virological monitoring.
2. "Recreational SWPAs", which refer to natural shellfish beds, where there is no professional exploitation. The reason for the designation of non-commercially shellfish harvested areas is that recreational collection of shellfish can generate a significant tourist activity locally, which may justify the inclusion of recreational areas in the "protected economically important aquatic species" registry. Recreational SWPA are not covered by *Regulation (EC) 854/2004*. Nationally, only a notice of the Superior Council of Public Health recommends increased monitoring of effluent discharges in these areas to prevent any public health risk from recreational shellfish harvesting. In practice, OCs in Recreational SWPAs have been modeled on those imposed in SPAs. The competent authority (see Appendix III.2) may perform inspections and classify selected Recreational SWPAs, whereby collection of live shellfish for human consumption can be practiced only when natural shellfish beds are classified as A or B.

Classification. Under article 2 of the Decree of 6 November 2013, classification of professional SWPAs is granted for a group and not a species of shellfish. **A different classification may be established for the same SPA for each group of shellfish species present.** Specifically, three biological groups of shellfish are distinguished in terms of their physiology and particularly their ability to accumulate contaminants and purify:

(a) Group 1: gastropods, echinoderms and tunicates
(b) Group 2: burrowing bivalves (e.g. cockles, razor clams, carpet clams)
(c) Group 3: non-burrowing bivalves (e.g. mussels, oysters, scallops)

A driver for this integration between *Regulation (EC) 854/2004* and WFD may have been the long-established French governance framework for commercial and recreational harvesting. Competent authorities comprise central and local government food and environmental authorities and marine research institutes (IFREMER). These were involved in the undertaking of sanitary surveys and investigative monitoring before the repeal of the Shellfish Water Directive in 2013.

Further information on the undertaking of sanitary surveys and monitoring in SWPAs-SPAs in France is given in Appendix III.5.

3.6 Key components of the governance and management frameworks outwith the EU

A review of the regulatory literature showed that the OCs for commercially harvested bivalve shellfish species in Canada, New Zealand and Australia draw on the governance and management paradigm developed in the USA, especially with respect to standards, monitoring, classification, sanitary surveys and extent of production areas. Further, New Zealand has developed a governance system, which in terms of monitoring and classification combines the EU and USA approaches. Therefore, both the USA and New Zealand frameworks are reviewed here to provide further insight into best practice. Details on sanitary surveys under the US and New Zealand approaches are summarised in Appendix III.6; see Also Appendix III.2 for the roles of competent authorities in the USA and New Zealand.

3.6.1 The USA approach[17]

In the USA, OCs are enforced at Federal and State level through the National Shellfish Sanitation Programme (NSSP 2015). The prime agency regulating seafood is the US Food and Drug Administration (FDA). To minimize the risk of illness to the public, federal and state agencies both under the Clean Water Act (1996) and the NSSP administer coordinated water quality and public health protection programmes to advise the public, restrict use of shellfish in the case of outbreak, and restore and maintain good water quality. To reduce and eliminate the need for shellfish harvesting restrictions, federal and state agencies administer programmes under the Clean Water Act to improve and protect surface water quality on a catchment scale. Federal and state agencies conduct shoreline surveys and

[17]Information for this section has been sourced from NSSP 2015.

monitoring to determine whether the specified standards are being met, and to identify actual and potential sources of contamination. Where waters fail the standards, the States and the EPA are required to develop pollution budgets, which are used for controlling the amount of faecal indicator organisms (FIO) in sewage effluent discharged to shellfish growing waters and FIO export from diffuse pollution sources through best management practices. Overall, this approach bears a great degree of similarity with the WFD approach.

The basic components of the NSSP (2015) are:

- A public health sanitary survey of the shellfish catchment area as a written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a shellfish growing area. A full sanitary survey must be conducted and completed at least once every twelve years (preceded by annual or triennial updates of toxicological and heavy metal data). Clear instructions on reporting and creating a database to facilitate updates are also included. It may take a couple of years before harvesting can commence in a new harvesting area because the sanitary survey identifies the sampling plan and the classification of the area.
- Water sampling to classify areas based on FC or total coliform (TC) criteria. Classification may be:
  - Approved and conditionally approved (when the areas meet the criteria for approved classification except certain conditions indicated by the sanitary survey) (Table 6a).
  - Restricted and conditionally restricted ((when the areas meet the criteria for approved classification except certain conditions indicated by the sanitary survey) (Table 6a).
- Controlled harvest times through conditional management. For example, there may be defined harvest closures due to adverse pollution conditions such as high boating activity in an area during the summer, or due to high land run-off and emergency sewage overflows following a storm-event.
- Labelling of shellfish so that consumers know the origin of the product.
- A specified minimum number of samples at a specified frequency over a three-year period is required for granting and reviewing a classification grade. When a new growing area is under classification, evaluation across a minimum of 30 samples must be undertaken. There are also mandatory requirements with respect to the monitoring strategy (see also Table 6b):
  - If an area is affected by point sources (e.g. a wastewater treatment discharges, emergency sewage overflows), sampling must ensure that adverse pollution conditions related to this source are targeted. If an area is not impacted by point sources, sampling can be random throughout the year.

3.6.2 The New Zealand approach

The basic components of the sanitary survey and monitoring programme applied in New Zealand are similar to the NSSP components, as described in the regulatory document by the New Zealand FSA (NZFSA 2006; 2017). The major addition to the US approach refers to collecting shellfish *E. coli* for classification (Table 6a and b). Both water and shellfish sampling stations must be placed so as to allow the effective evaluation and routine monitoring of all actual and potential pollution sources that may have an impact on the microbiological quality of the production area. For example, water sampling stations can be placed between the production area and a source, as in the US, but shellfish sampling stations must be within the production area. Shellfish sampling stations should also address the spatial and depth variability that may occur in the microbiological content of each commercial shellfish species, i.e. sampling for classification is pollution source- and species-specific.

In addition to water FC and shellfish *E. coli*, the monitoring programme includes the so-called critical measurements referring to parameters such as salinity, temperature and rainfall, which are used to assist conditional management (NZFSA 2006; 2017). Areas with point sources are also monitored under the APC strategy, as in the USA; however, a hybrid strategy is also applied in areas with known point and diffuse sources of faecal contamination. This is to enable collection of the minimum number of samples required for classification using both APC sampling and some samples under the random monitoring strategy (NZFSA 2006; 2017).

3.6.3 Remarks on monitoring and classification programmes in USA and New Zealand

- Training is offered to sampling officers to ensure reliable data recording and monitoring.
- Seasonal classification does not exist in USA and New Zealand. Instead, there is conditional classification to denote areas where the standard for approved or restricted classification (which requires treatment before marketing of shellfish) is not met year-round.
- In areas where samples are collected according to the random sampling strategy, classification must be based on the estimation of the 90-percentile to reflect the variation due to intermittent pollution events. The rationale for this approach is that if data collected following pollution events, which cause higher levels of contamination, are combined with data collected under normal/background conditions, variation in the data is increased. It has been shown that datasets displaying greater levels of variation will consequently exhibit an elevated estimated 90-percentile. The percentile approach has the potential to correct for the inherent variation in data when used with a normally (or log-

normally) distributed data set. The percentile evaluation of the log normal probability density function of microbiological data acquired, aka the FDA method, is the same with that mentioned in "The guidelines for assessment under the Bathing Water Directive and reporting under the 2016 bathing season" (Globevnik et al 2016) in the EU.

3.6.4 Remarks on prohibited classification - exclusion areas - buffer zones in the US and New Zealand

Harvesting is not permitted in growing areas classified as prohibited (NSSP 2015; NZFSA 2006). Growing areas must be classified as prohibited when the sanitary survey determines that they are located adjacent to a sewage treatment plant outfall or other point-source outfall of public health significance; or where inputs of faecal or toxic contaminants are unpredictable or unacceptably high. Areas where there is no complete sanitary survey (or a review) are also classified as prohibited.

Table 6a. Microbiological criteria for classification of shellfish growing waters in USA and New Zealand. FC=Faecal Coliforms G.M.=Geometric Mean; *100gr of FIL. Source: NSSP 2015; NZFSA 2006; 2017.

Classification	Area Classification Standard		
	USA *FC /100ml water*	*New Zealand* *FC/100ml water and Shellfish E. coli /100gr* per species*	
Approved or Conditionally Approved	Water G.M. ≤14/ 100ml 90%-ile≤43/100ml	Water G.M. ≤14 100ml 90%-ile≤43 100ml	Shellfish G.M.≤230/100gr* 90%-ile≤700/100gr*
Restricted or Conditionally Restricted	Water G.M. ≤88/100ml 90%-ile≤260/100ml	Water G.M. ≤88/100ml 90%-ile≤260/100ml	Shellfish G.M.≤4,600/100gr* 90%-ile≤14100/100gr*

Table 6b. Sampling strategy for classification in shellfish growing waters in USA and New Zealand. FC=Faecal Coliforms G.M.=Geometric Mean; APC=Adverse pollution conditions. Remote areas: Areas without known or likely faecal inputs. Source: NSSP 2015; NZFSA 2006; 2017. *per species

Type of Classification	Type of Pollution Sources	Sampling Strategy	Minimum number of samples per station for Classification		
			USA Water FC	New Zealand Water FC	New Zealand Shellfish E. coli*
Initial classification	None	Random	15	Not specified	
	Point/ Diffuse	Random	30	Not specified	
Approved/Remote	None	APC	15	15	15
Approved	Point	APC	15	15	30
Approved	Diffuse	APC	15	15	15
	Diffuse	Random	30	30	15
Restricted	Point	APC	15	15	30
	Diffuse	APC	15	15	15
	Diffuse	Random	30	30	30

3.7 Summary of findings on governance frameworks

- Examination of the EU, USA and New Zealand shellfish programmes showed three general approaches on how to predict and prevent the likelihood of foodborne disease due to consumption of shellfish contaminated by pathogenic microorganisms:
  - The EU approach, which has historically used the shellfish *E. coli* levels in FIL as the primary tool to control commercial shellfish harvesting. The EU requires the undertaking of sanitary surveys, but it has not stipulated their role in controlling commercial shellfish harvesting and has not specified how sanitary surveys and shellfish *E. coli* monitoring can be linked to the RBMP process to protect and improve water quality in areas where shellfish production is economically important.
  - The USA approach, which relies on both the undertaking of the sanitary surveys, with clearly specified tasks, and the routine monitoring of faecal (or total) coliforms in the overlying waters in order to control commercial shellfish harvesting and, where sanitary surveys and monitoring indicate water quality impairment, to inform improvement measures.
  - The New Zealand approach, which combines the EU and USA approaches requiring sanitary surveys, and water and shellfish microbiological monitoring as well critical measurements (such as rain, salinity or tidal stage) to control harvesting.
- EU legislation for designated SWPAs has not provided any specification on microbiological standards for the classification of the water quality of these areas. Review of available information shows that at least four SWPA governance models are implemented across the EU:
  - The approach of Scotland, where WFD requirements for SWPAs have been transposed into National Law, with areas designated as SWPAs aligned with SPAs classified for aquaculture bivalve species, Microbiological shellfish water quality standards (shellfish *E. coli*) for the classification of SWPAs to inform the RBMP process are similar to the microbiological criteria specified for SPAs under Regulation (EC) 854/2004.
  - The approach of England and Wales, where WFD requirements for SWPAs have been transposed into National Law identifying as shellfish any bivalve and gastropod mollusc. Microbiological standards (shellfish *E. coli*) for the classification of SWPAs to inform the RBMP process are different from the microbiological criteria specified for SPAs under Regulation (EC) 854/2004.
  - The approach of N. Ireland, where WFD requirements for SWPAs have been transposed into National Law and SPAs above class B were designated as SWPAs (at least in the past), the cost required for catchment improvements being the key criterion for SWPA designations.
  - The approach of France, where WFD requirements for SWPAs have been transposed into National Law designating classified SPAs as Professional SWPAs and areas of economically important recreational shellfish harvesting as Recreational SWPAs. This regulatory integration provides, potentially, the greatest level of efficiency and cost-effectiveness in terms of overall monitoring cost.

4.0 Factors contributing to faecal contamination in shellfish

The research evidence on the environmental factors influencing FIO[18] contamination in shellfish and shellfish waters is reviewed in Appendix IV. The purpose of this review was to provide scientific context to the evaluation of current approaches in Scotland. The review provided evidence on: the effect of each type of faecal pollution source (Appendix IV.1); FIO transport and dispersion processes (Appendix IV.2); FIO survival in shellfish waters (Appendix IV.3); FIO accumulation rates in shellfish (Appendix IV.4); catchment FIO export and source-apportionment modelling (Appendix IV.5); coastal water FIO modelling (Appendix IV.6); linked catchment and hydrodynamic modelling (Appendix IV.7); the principles on transforming and handling monitoring data (Appendix IV.8); and criteria on identifying exclusion zones (Appendix IV.9).

The findings of the literature review are summarised below:

- The risk from faecal contamination depends on the presence of faecal material of animal or human origin discharged from (i) catchment-based sources directly to shellfish waters or indirectly to the streams discharging to shellfish waters or in their vicinity; and (ii) marine-based sources within or near shellfish waters. Animal sources are related to livestock farming and wildlife; human sources refer to treated and/or untreated sewage effluent.

- Overboard waste disposal from recreationaland fishing boats can be an episodic-intermittent, marine-based source of raw sewage to shellfish waters, which has been linked to non-compliances and disease outbreaks.

- Pets and wildlife can be important sources of faecal contamination from a number of pathogens. Risk from

[18] This section uses the term FIO in order to account for FC, *E. coli*, enterococci, and bacteriophages and all other faecal indicator microorganisms described in the research articles reviewed here; see also Appendix I.

pets is associated with built up areas; wildlife effects increase with their density.

- The emerging science of Microbial Source Tracking (MST) has the potential to introduce more reliable indicators for routine monitoring of viral faecal pollution. This can substantially help to identify, isolate and potentially control the sources of human contamination in shellfish waters.

- Under dry weather conditions:

    - Streams transporting diffuse pollution fluxes from livestock exhibit very low FIO concentrations.
    - The treated sewage effluents are often the dominant source of FIOs to streams and coastal waters, their FIO content depending on level of treatment and type of system.

- During storm events

    - Even pristine streams draining woodland and livestock areas, with little or no human sewage inputs, can exhibit FIO concentrations similar to those observed in a dilute sewage effluent from a combined sewage overflow (CSO).
    - Treated sewage effluent may exhibit very different FIO concentrations following rainfall events, from reductions due to dilution to increases due to increased waste water treatment plant (WwTP) loadings. Therefore, generalizations are inappropriate.
    - The effluent of CSOs and storm tank overflows (STOs), which discharges to rivers or directly to the coast, may represent a considerable flux of FIOs during the early part of the storm event.

- Faecal contamination in shellfish waters depends on both terrestrial (catchment) and coastal transport processes and pathways. These processes must be studied because they determine:

    - When faecal inputs enter the environment.

    - How fast faecal contaminants travel from sources to receiving shellfish waters before natural die-off.

    - Where and when "hot spots" of high faecal concentrations in coastal waters can be observed.

    - How long faecal microorganisms survive before they are flushed out of a coastal area.

- Tides influence levels of FIOs in shellfisheries via dilution during the flood (incoming phase), through transport of microorganisms from reservoirs during the ebb- (outgoing) phase and through tidal currents, which control the flushing time and mixing processes.

- Coastal water parameters such as salinity, light exposure, turbidity and temperature determine FIO die-off in coastal waters and FIO accumulation rates by shellfish.

- Bacterial release into the water column via sediment resuspension may be an important factor affecting shellfish quality in shallow, low-energy, depositional environments. However, a number of studies found no or a weak relationship between sediment and shellfish FIO.

- Exposure of catchment-derived faecal microorganisms to saline waters causes osmotic shock and thus enhances die-off rates. Faecal bacterial concentrations are usually highest in inlets impacted by low salinity agricultural and urban runoff, intermediate in semi-enclosed bays exposed to both freshwater runoff and seawater and lowest in coastal bays.

- Salinity is a good tracer of short-term variations of FIO contamination in shellfish waters.

- Water temperature is positively correlated with FIO concentrations in coastal waters that are not significantly influenced by freshwater/livestock inputs and sewage discharges.

- Adsorption (binding) of microorganisms on sediment particles and turbidity can provide "protection" against the harmful effects of solar UV radiation, thus prolonging their survival.

- The absolute concentrations of FIOs in shellfish may increase at higher temperatures due to higher FIO levels in the water during the warmer period or due to higher accumulation rates.

    - Native and Pacific oysters increase filter feeding activity with temperature.

    - Mussels are able to ingest food particles and grow during typical winter conditions.

- The effect of salinity on feeding activity is shellfish species-specific.

    - Pacific oysters are euryhaline (i.e. can tolerate and feed under a wide range of salinity values).

    - Native oysters prefer subtidal habitats with a relatively narrow salinity range (e.g. 16-28 psu).

    - Mussels accumulate contaminants faster in more saline waters.

    - Scallops and razor clams are very intolerant of salinities lower than 30psu.

- Generally, cockles and mussels exhibit the highest FIO accumulation rates and n. oysters the lowest. **These differences do not support the application of a single water quality standard for shellfish protected areas where**

more than one species are commercially harvested[19].

- Predicting catchment FIO export and understanding source-apportionment, i.e. the proportions of the FIO flux derived from all potential inputs from human (sewage) and livestock sources during both low and high flow conditions, is essential to prioritise and target FIO mitigation measures. However, it is resource intensive. It requires high-frequency in-stream and effluent FIO sampling and information on land use and land cover, preferably on a waterbody or farm-scale.

- Catchment source-apportionment alone does not address the processes influencing the fate and transport of faecal contaminants in the coastal/estuarine environment and the highly dynamic nature of terrestrial FIO fluxes. Further, it does not take account of marine-based FIO sources.

- Coastal water FIO models are classified into statistical and process-based models.

    - Statistical models, such as regression models predicting the effect of environmental parameters on shellfish FIO concentrations, can be used for developing early warning systems based on real-time data on rain, salinity, or turbidity, as proxies of FIO concentrations.

    - Process-based models require three sub-models: a hydrodynamic model predicting current circulation and vertical mixing; a dispersion model predicting FIO transport; and a FIO decay model in relation to solar radiation, salinity, temperature and sediment in coastal waters.

- Coastal water FIO modelling suggests that when flushing time is very long, factors influencing FIO die-off and shellfish FIO accumulation rates (i.e. salinity, turbidity, solar radiation) are more important than physical dilution in determining spatial distribution of shellfish FIO concentrations. However, in areas influenced by strong tidal currents, processes related to currents, dilution and dispersion characteristics determine the distribution of shellfish FIO levels.

- In areas where the intention of monitoring is to inform the design of sewerage infrastructure, seasonal confounding of monitoring results can be avoided by targeting FIO monitoring to storm events.

- In areas where the greatest amounts of FIOs are discharged during short-term storm events, compliance FIO data in water and shellfish is biased and potentially misleading, because a routine (random) sampling programme of FIO levels (in-stream or coastal water or in shellfish) may systematically under-represent storm events.

- Shellfish microbiological data is often highly right-skewed, i.e. few high values. Assuming that data is lognormally distributed, percentile criteria for shellfish classification can be estimated using logarithmically transformed data (parametric approach). Using percentages of non-transformed data (nonparametric approach) requires no such assumption[20]. Data transformation and fitting a lognormal distribution will give a better estimate of the 80th or 90th percentile criteria for classification when a small number of samples is available.

- Building a database and establishing procedures for data input and storage are important steps in ensuring the accuracy and reliability of shellfish monitoring data.

- Exclusion zones can be identified on the basis of (i) distance from a known pollution source; (ii) dilution analysis to delineate areas within and adjacent to marinas/harbours; (iii) the interaction of time for reactive management in the event of a WwTP malfunction or a spill with dilution to delineate areas around a WwTP; (iv) shellfish NoV monitoring.

5.0 Review of current approaches in Scotland

5.1 Overview of the shellfish industry in Scotland

Bivalve shellfish production is a pillar of many coastal and rural communities in Scotland (Alexander et al 2014). It is predominantly comprised of small-scale operations, although there are larger operations in Shetland, the Western Isles and at Loch Fyne (SG 2015a). Blue mussel and Pacific oyster production dominate the shellfish farming (aquaculture) sector but king scallops, queen scallops and native oysters are also cultivated at a small number of sites (Munro and Wallace 2017). The wild catch sector mainly comprises bivalve species fished by dredging or trawling such as scallops, razor clams and cockles; cockles may be also collected by hand in some intertidal areas (SG 2015b). Other bivalves occasionally harvested in Scotland include the sand gapers, the Islandic Cyprine, the carpet clams, the Venus clams, the rayed Artemis, and the surf clams (FSSb n.d.; SG 2015c; SNH 2017; Marine Life Information Network-MARLIN n.d.). Gastropod species are harvested on a limited scale: whelks are fished with baited traps and periwinkles are collected by hand (SG 2015c).

[19] See also Kershaw et al 2013.

[20] For example, SEPA uses the parametric approach, whereas FSS uses the non-parametric approach.

The shellfish farming industry is estimated to contribute a gross value added (salaries and profit) of over £5m and as much as £17m in turnover across the Scottish supply chain including downstream logistics and processing opportunities as well as research (Alexander et al 2014). As of 2016, the Scottish shellfish farming industry had an estimated worth of approximately £11.7 million at first sale value, with mussels and P. oysters being the main species produced in terms of value and tonnage (Munro and Wallace 2017). This refers to a production of 7,732 tonnes of mussels and 3,534 of P. oysters for the domestic market (Munro and Wallace 2017). Prospects for the growth of bivalve shellfish farming are positive and the SG supports through the policy objectives set in Scotland's National Marine Plan the target of the shellfish industry for a production of 13,000 tonnes sustainably by 2020 (SG 2015a). There is a presumption that further sustainable expansion of shellfish farms should be located in designated SWPAs "if these have sufficient capacity to support such development" (SG 2015a, p. 50).

5.2 Review of current processes applied in SPAs by the FSS

In Scotland, the implementation of the requirements of the *Regulation (EC) 854/2004* is the responsibility of the FSS at the national scale[21] and of the local authorities at the local scale (Appendix V.1). The OC programmes for sanitary surveys, monitoring and classification are defined and organised by FSS and detailed in the FSS protocol (2017). A brief summary of the key components of this protocol is given in Appendix V.2 for providing the context for the review.

The current process for granting a classification grade to a new harvesting area, so as commercial harvesting can commence, includes the following steps (FSS 2017):

1. FSS receives application for a new production area (SPA). The application must be completed by the Applicant Harvester in conjunction with the Environmental Health Officer from the relevant Local Authority (LA). Applicant Harvester and LA must give information on the production area and identify the type of known or potential pollution sources impacting the production area (i.e. livestock, stable waste or slurry store, sewage treatment works, storm sewer outfalls, septic tank outfalls, wildlife, boating activity, or other).
2. FSS assesses the application and whether a full sanitary survey has already been undertaken in the same or broader area (for the same or another species). If not, a pRMP assessment is undertaken to identify a provisional sampling plan (see Section 1.1); if yes, the sampling plan identified in the sanitary survey is applied.
3. FSS decides what shellfish *E. coli* sampling is needed to grant a classification grade so that harvesting can begin:
   (i) No sampling required. Preliminary classification is granted immediately on the basis of a sampling plan identified for a different SPA but in the same area.
   (ii) Collection of 10 weekly samples is required to grant provisional classification. Then commercial harvesting can begin.
   (iii) Collection of 10 monthly samples is required to grant annual classification. Then commercial harvesting begins.
4. (After granting a classification grade and harvesting begins) FSS undertakes ongoing monitoring according to the provisional sampling plan (or the sampling plan identified in a previous sanitary survey for a SPA in the same area) to review the classification grade.
1. Once a three-year dataset with at least 24 samples becomes available, an established classification (seasonal, part-year, or whole year) can be granted[22].
2. The pRMP (and the sampling plan) and the impact of pollution sources on the SPA will be reviewed later in the sanitary survey process as additional information becomes available.

The FSS protocol (FSS 2017) and the FSS web page on SPA classification (FSSa n.d.) lay out in detail governance aspects, such as application process, types of classification, standards and enforcement procedures. However, the practices generating the information required by the OCs are not specified in the FSS protocol. For example, there are no specifications for:

- The identification of known and potential pollution sources in the application form for a new production area. It remains uncertain whether the application form submitted to FSS is assessed on the grounds of evidence from existing full sanitary survey reports and any available desk-based data, or some other evidence.
- The types of desk-based data required in the pRMP assessments.
- The structure and content of pRMP assessment reports.
- The method of percentile calculation for classification.
- The procedures for storing desk-based data for pRMP assessments, or for monitored data.
- The post-collection validation of shellfish *E. coli* data

Understanding and evaluating the management practices in place involved the examination of available data and consultations with FSS staff. The specific practices are evaluated below in the context of the findings of the review on governance frameworks in the EU and internationally (Section 3.0) and the research evidence on the factors influencing faecal contamination in shellfish (Section 4.0).

[21] The requirements of the Regulation (EC) 854/2004 were extensively discussed in Section 3; see comparative description of roles of competent authorities in EU and internationally in Appendix III.2.

[22] This classification is considered as "established" because it is based on three years' worth of data (see Table 2).

5.2.1 Review of the current sanitary survey process in SPAs

A fit-for-purpose approach for the sanitary survey process means to implement the tasks required by the *Regulation (EC) 854/2004* (see Section 1.1) in line with the Guide's recommendations, which tailor international best practice to the EU legislative framework.

5.2.1.1 Post-2015: pRMP assessments

The pRMP assessments undertaken post-2015 include some of the key tasks specified in the legislation and the Guide, i.e. desk studies on pollution sources and identifying a sampling plan. The data used for the pRMP assessments come from existing sources of publicly available information from SEPA, Scottish Water and SG and historic *E. coli* results. These data are not validated against more up-to-date or accurate sets of data held centrally by any third parties. Organisations providing data for rain, land use, livestock numbers or hydrographic data (e.g. bathymetry, tides) are not mentioned at all. A review of one example of a pRMP assessment by SAMS indicated that pRMP assessments described visual information from maps narrowly referring to the area around a SPA and made no use of already existing quantitative datasets available under licence for commercial use from sources such as Edina AgCensus for livestock, Metoffice for rainfall, National Statistics data for population or the Land Use/Land Cover (2007) data for identifying percentage of land use. The pRMP assessments can be described as an economical and fast-track approach identifying a sampling plan for new SPAs. However, every pRMP report states that the sampling plan should be reviewed after a sanitary survey is conducted (pers. com. Christopher Allen, SAMS, July 2018). **In the context of the regulatory requirements, the current pRMP assessment approach is not compliant.**

5.2.1.2 Pre-2015: Full sanitary surveys

Approximately 170 sanitary survey reports compiled between 2007 and 2015 are available on line (CEFAS 2018); see Annex V.3 for a detailed description on a task-by-task basis. These provide a useful source of practical information on how to carry out and interpret the data collected during sanitary surveys. The review showed that some sanitary survey procedures must be maintained in the revised approach whereas others must be improved or abandoned, as follows.

Area covered by surveys. Pre-2015, sanitary surveys focused on broader areas and not strictly on the area covered by a SPA. In many cases, the sanitary surveys refer to areas which are identical to the area covered by the designated SWPAS. Where monitoring data was available for more than one species or sites within the broader area, it was used and assessed to identify a sampling plan for each site and species. This is a cost-effective and scientifically robust approach because SPAs located in the same broader area, e.g. a loch, are subject to the same or interrelated catchment and hydrodynamic processes. It is recommended that undertaking sanitary surveys over broad areas and assessing local impacts on SPAs therein be applied in the revised approach.

Tasks undertaken. The tasks ensured the sanitary surveys met the requirements of the *Regulation (EC) 854/2004* (see Section 1.1) and aligned with the recommendations in the Guide (Table 3 in Section 3.2). It is recommended that these tasks are maintained in the revised approach. If historical shellfish *E. coli* data (from the same RMP as the one used for classification) are not available, then collecting a sufficient number of shellfish *E. coli* data prior to identifying the established sampling plan in new SPAs is recommended. For example, the currently undertaken sampling for provisional or annual classification can become part of bacteriological surveys under the revised full sanitary survey process.

Licenced desk-based data. The desk-based data (i.e. locations of pollution sources, land use, livestock numbers, and hydrographic data) were provided to CEFAS by a variety of relevant organizations in the UK under license agreements with CEFAS and is not available to FSS. This is a major limitation of the pre-2015 process and must be revised to enable FSS and LAs to control, reuse and update sanitary survey data. It is recommended that FSS and LAs use open-access data and, where this is not available, make the data license agreements and keep a record of the open-access and the licensed desk-based data collected for sanitary surveys.

Shoreline surveys. These provided visual qualitative observations and water *E. coli* data from potential faecal contamination sources in an area on the day of the survey. This data was not representative of the environmental conditions in an area. It is recommended that shoreline observations are collected on the same date and frequency as shellfish *E. coli* data for classification in order to improve understanding of the conditions influencing the results.

Exclusion zones. Delineation of exclusion zones or identification of buffer zones around sewage discharge points, marinas or other sources of pollution is not mentioned in the FSS protocol (2017). However, the sanitary survey reports have revised sampling plans established before the *Regulation (EC) 854/2004* came into force, to exclude these areas. It is recommended that FSS develops criteria for the delineation of SPA boundaries outwith the zone of influence of pollution sources discharging to the coast, which must be decided based on the shellfish *E. coli* data collected during the revised sanitary survey process.

Sanitary survey reports. These have generally been lengthy (over 80 pages) with many pages devoted to description of qualitative data and opportunistic (as opposed to systematic) observations during shoreline surveys. As a result, retrieval or assessment of the information therein is time-consuming and not straightforward. However, the "conclusion" was clearly reported and easy to retrieve. It is recommended that the reports of the revised sanitary survey process deliver an Executive Summary and a list of conclusions and recommendations on improvement of the process as a quick-read document for harvesters, LAs, FSS and SEPA.

Use of sanitary survey reports by Applicant Harvesters and LAs. Post-2015, it remains uncertain whether LAs or FSS have been using the information contained in the sanitary survey reports for "new" SPAs. It is recommended that Applicant Harvesters and LAs are required to explore whether a sanitary survey report is available for the area described in the application form and to use the evidence provided therein to inform the application forms for new SPAs.

Catchment data. Sanitary survey reports collected and assessed land use and pollution data referring to the immediate shoreline bordering the broader coastal area of interest. It is recommended that catchment data are collected at the scale of source-catchments in order to cover all potential sources of faecal contamination in the broader area encompassing one or more SPAs. This can be more easily achieved in collaboration with SEPA and with a view to implementing pollution control measures where needed to protect and improve shellfish microbiological quality in SPAs.

Database of data collected during sanitary surveys. There is no repository of the sampling data (i.e. shellfish *E. coli*; water *E. coli* in water column, streams or sewage effluent; and salinity, temperature or turbidity measurements at different water column layers) collected during sanitary surveys in relation to worst-locations or worst-conditions. It is recommended that sampling data collected during sanitary surveys is recorded in a GIS-linked database linking sampling data (i.e. result, date, location) with source-catchment-scale data on land use, livestock numbers, rain, sources of human sewage and any other relevant or available information. In addition, each sanitary survey report should be accompanied by this database.

To sum up, the pre-2015 sanitary survey approach was fit-for-purpose in the context of the *Regulation (EC) 854/2004* and in the context of SWPAs because it referred to broad-scale processes. However, catchment data was collected on a shoreline and not catchment scale. This is one of the key revisions required for the future approach undertaken for SPAs sitting within SWPAs.

5.2.1.3 Strengths-Weakness-Opportunities-Threats (SWOT) analysis for the sanitary survey process

Overall, the sanitary surveys undertaken in Scotland pre-2015 helped to:

- Identify the significance of the effects of rain and hydrography on shellfish and water *E. coli* variation using analyses of data collected during the surveys.
- Assess and confirm human and animal sources of microbial contamination through shoreline surveys and associated bacteriological (water and shellfish) sampling.
- Identify representative monitoring point or points (RMPs) near key inputs of point-source or diffuse faecal contamination in the SPA to ensure that shellfish most likely to be polluted are tested for initial and subsequent classifications.
- Identify SPA boundaries so they remain outwith areas at high risk from microbial or chemical contamination.

Major strengths

The full sanitary surveys undertaken pre-2015:

- Cover the majority of SPAs classified pre-2015 and, by extent many designated SWPAs (see Section 5.3).
- Have been undertaken on a broad-scale covering the catchment and hydrodynamic processes influencing the SPAs therein.
- Examined historical data on shellfish *E. coli*, showing that shellfish *E. coli* sampling is essential to understand the effect of faecal sources on shellfish microbiological quality.
- Provided thorough assessments of hydrodynamic processes.

Major weaknesses

- The data collected during the sanitary surveys undertaken pre-2015 have not been stored in a comprehensive GIS-linked database for subsequent reviews and updates; or, to help harvesters and LAs to identify pollution sources in the application for new production areas.
- The reports are detailed but lengthy, making it difficult to extract information.
- In the majority of surveys, sampling data and observations referred to the day of shoreline surveys and not to a systematic sampling of *E. coli* data or recording of concentrations.
- Catchment-based sources of faecal pollution have been examined in shoreline areas immediately bordering the coast and not on a source-catchment-scale.

Major opportunities for improvements in the revised sanitary survey approach

Overall, a practical and feasible sanitary survey programme can be developed on the basis of the tasks already undertaken in the pre-2015 sanitary survey process and in line with the recommendations in the Guide and international practice (see Table 3 in Section 3.2).

- The sanitary survey process for new production areas could be tied into the application process for a new production area.
- The sanitary survey process can be tied into the granting and reviewing of classification grade so as classification is based not only on shellfish *E. coli* monitoring but also on the overall assessment of the impact of pollution sources, in accordance with international practice.
- The sanitary survey process can use broad coastal (SWPA-scale) and catchment-scale data to enable its integration with the RBMP process implemented by SEPA.
- The sanitary survey process can be standardised by including the following broad tasks:
  - Desk study at the SWPA scale (if the SPA is located within SWPAs) or a broad (sea-loch) scale to identify and assess catchment and marine based faecal pollution sources and hydrographic information (bathymetry, currents, tides) based on nautical/tidal charts and research literature. The desk study can inform the preparation of an application for a new harvesting area by LAs and Applicant Harvesters and SEPA in SWPAs.

  - Sampling of shellfish *E. coli* and salinity and field (shoreline and catchment) observations to verify worst-location and worst-condition in new harvesting areas, where no historical shellfish *E. coli* data is available. Sampling must be systematic. Initially, sampling points can be located where the desk study indicated that the potential interaction between faecal discharges and tidal movements generates the greatest risk of shellfish *E. coli* contamination. Sampling must be weekly or fortnightly for six months to one year and include collection of sampling during August and September (see Section 5.4.4) or during the tourist season (if the area is affected by tourism). Detailed field surveys are required in areas where desk-based data on pollution sources are not available or are not up-to-date. Catchments surveys must be organised in consultation with SEPA.

  - Analysis of shellfish microbiological data from same production area. In new harvesting areas, this data will be from sampling during sanitary surveys. In areas where commercial harvesting is practised without having undertaken a sanitary survey in the past, this data will be the historical data used under preliminary, provisional and annual classification. In areas where a sanitary survey has been undertaken pre-2015, this data will be the historical data used for established classification.

  - A report analyzing and assessing available data, providing a conclusion and identifying the sampling plan. If between 12 to 24 shellfish *E. coli* samples have been collected during sanitary surveys, then the report can deliver an initial classification grade for the production area with the report. If 24 samples have been collected by the time the sanitary survey report is completed, then an established classification can be delivered.

  - A GIS-linked database of the data collected during the sanitary survey accompanying the report. This should be updated annually (regularly) to inform the Annual and Full Review of the primary sanitary survey report.

- Desk –based surveys can use:
  - Available quantitative data on livestock, rain and population.
  - GIS data on land use, locations of any sewage related sources, meteorological and hydrographic data.
  - The conclusions of the sanitary survey reports undertaken pre-2015.
  - Information from nautical and tidal charts.
  - Research evidence on generic information on FIO export coefficients or FIO content of sewage discharges.
  - Historical shellfish *E. coli* data used for classification can be included in the desk study.
- Shoreline surveys can be tied into the sanitary survey and routine monitoring to enable recording of observations on a systematic, routine basis.
- (If the current sanitary survey approach remains as is with undertaking only pRMP assessments) Shellfish *E. coli* data collected after granting preliminary classification and shellfish *E. coli* data collected to grant provisional and annual classification can be assessed against the desk study findings of pRMP assessments to verify or change the location of the RMP.
- FSS can obtain catchment data and SPA source-catchment boundaries from SEPA to support catchment-based sanitary surveys for SPAs outwith SWPAs.

Major threats

- For SPAs outwith SWPAs, it will be difficult to collect source-catchment data as part of the sanitary survey process and link the sanitary surveys to SEPA's plans to control faecal pollution.
- If only SWPAs are prioritised for further sustainable expansion of shellfish farms (SG 2015a), it will be difficult to prioritise funding for full sanitary surveys in new SPAs outwith SWPAs.

5.2.2 Review of the classification programme in SPAs

Under the FSS approach, classification for SPAs is tied in with the monitoring practice. The number of samples, frequency of sampling and monitoring strategy are evaluated in Section 5.2.2.1. The analyses used for classification are reviewed in Section 5.2.2.2. The recording and reporting of data used for classification are reviewed in 5.2.2.3. Opportunities for improvements are discussed in Section 5.2.2.4

5.2.2.1 Review of the monitoring programme in SPAs applied by FSS

Overall, FSS monitoring has provided a large amount of shellfish *E. coli* data, monthly collected since 1999. The current approach is not aligned with best practice with respect to monitoring under preliminary, provisional and annual classifications (Table 7). However, it must be recognised that the FSS dataset has the potential to inform improvements in the monitoring practice for both SPAs and SWPAs. This potential is assessed in relation to catchment indicators in the context of desk studies in Section 5.4.

Number of samples per type of classification. FSS protocol (2017) details the number of samples required for each type of classification and the review period. Alignment with the Guide's recommendations occurs only for established classification and the review period (Table 7). The number of samples for preliminary, provisional and annual classifications is below the minimum requirements recommended in the Guide or applied internationally. It is recommended that FSS aligns its monitoring regime for classification with the Guide's recommendations: e.g. annual classification should be granted upon receipt of at least 24 samples from a years' worth of data and.

Sampling Frequency. FSS applies weekly sampling for at least 10 weeks before granting provisional classification and then sampling for all other types of classification is monthly during the course of the harvesting season[23] (Table 7). A higher monitoring frequency would allow granting annual classification on the basis of a higher number of samples. In addition, combining monthly frequency with weekly or fortnightly frequency during worst conditions (e.g. tourist season) would better capture the range of random variability in an area, in line with the output of the sanitary survey. It is recommended that FSS aligns sampling frequency with the recommendation in the Guide applying a higher frequency (weekly or fortnightly) during the monitoring period for any initial type of classification and annual classifications.

Monitoring strategy. FSS perceives monitoring in SPAs exclusively in the context of the minimum requirements for the number of samples for each type and grade of classification for an existing or new production area. There is no consideration in relation to: the type of pollution sources in an area (e.g. human vs animal sources and event-driven vs regular inputs); the timing of sampling[24] (e.g. ebb vs flood tide and storm event vs non-storm event); and the season (e.g. tourist season vs winter). As a result, it is difficult to understand whether the shellfish *E. coli* results are bias-free, i.e. are collected without avoiding worst-conditions at the selected RMP and, therefore, underestimating faecal pollution pressures. In addition, seasonal confounding (i.e. low winter *E. coli* values) may eclipse the effect of storm event-driven human sewage discharges. It is recommended that FSS applies a sampling regime tailored to capture: (i) the random variability of faecal inputs in SPAs predominantly influenced by diffuse pollution sources, without avoiding worst-conditions (i.e. tourist season, storm-events[25] or ebb tide); (ii) worst-conditions as regards faecal inputs in SPAs predominantly influenced by point-source human sewage discharges (i.e. storm events and the tourist season). This requires that FSS undertakes monitoring during sanitary surveys to identify worst-conditions in an area as well as for classification purposes.

Investigative monitoring. FSS undertakes monitoring for test compliance with the microbiological criteria for classification. No investigative monitoring is applied to test the presence of pathogenic microorganisms to inform the application process or the sanitary survey process. It is recommended that investigative monitoring for pathogens is applied in areas with known human sewage discharges to explore their presence in relation to specific sources, events or processes, potentially in collaboration with other organisations such as SEPA and research institutes or universities in Scotland.

Species-area specific sampling plan. No pre-classification monitoring is required prior to granting preliminary classification. Ongoing monitoring in new SPAs granted a preliminary classification is based on the sampling plan identified for another or the same species within the same broader area in a sanitary survey, which may have been undertaken 10 years ago. It is recommended that no commercial harvesting is allowed in SPAs where there is

[23] The FSS protocol (2017) recognises that more samples may be required for a more robust determination.

[24] Sampling is always taking place outwith extreme weather events for safety reasons and when intertidal species (e.g. P. oysters) are exposed during low tide (pers. com. Kasia Kazimierczak, FSS 2018).

[25] It must be noted that the trial data described in Appendix V showed that, with regards to rain, current FSS monitoring strategy is bias-free and in line with the principles of the random strategy.

neither full sanitary survey nor historical data from a RMP representing greatest impact from faecal contamination for the species mentioned in the application for a new SPA.

Monitoring in de-classified SPAs. FSS does not monitor de-classified areas. Declassification may occur because harvesters decided to cease harvesting or because harvesting is prohibited for public health reasons. If the declassified areas that used to sit within SWPAs, there will be no monitoring data for SWPA classification, and hence, no information on whether or when the species classification improves. It is recommended that FSS consults with SEPA upon declassification of SPAs within SWPAs so as to enable SEPA decide whether monitoring should carry on in order to inform SWPA classification.

Table 7. Comparison between FSS monitoring practice and EURL Recommendations for monitoring in Shellfish Production Areas.

Type of classification	FSS sampling	Recommendations in the Guide
Provisional or initial classification	10 weekly samples	At least 12 weekly samples over at least a six-month period including the worst season.
Annual classification	A minimum of 10 monthly samples taken at least a month apart.	24 fortnightly samples for a year. Alternatively, monthly monitoring should be supplemented with additional sampling targeted at worst-case conditions (i.e. rain, river flows, tide, or sediment resuspension).
Established classification	At least 24 samples from three years' worth of data. A minimum of eight (8) samples per year for "B" or "C" and a minimum of 10 samples per year for "A" grade.	· (Generally) At least 24 samples from three years' worth of data. Ongoing monitoring must be at least monthly year-round. · (For remote areas): Bimonthly samples for three years. At least 12 samples. If sanitary survey indicates absence of human or animal faecal sources
Seasonal (established) classification	At least 24 samples from three years' worth of routine monitoring data showing a clear, seasonal trend[26]	24 samples per season. At least monthly samples year-round for three years for each season, preferably shown in statistical analysis
Review period for established classification	24 samples from most recent three years' worth of data	24 samples from most recent three years' worth of data

5.2.2.2 Review of the classification programme for SPAs

Under the FSS approach, classification for SPAs is tied in with the monitoring practice, which is reviewed in Section 5.2.2. This section reviews practices referring to the use of regulatory requirements under the (EC) 854/2004 in the calculation of classification grade.

Pathogens and *E. coli* compliances. Classification is based exclusively on shellfish *E. coli* data and not on any assessment of the type of the faecal pollution sources and the associated risk from pathogen (especially viral) contamination. Therefore, compliance with A, B or C class does not guarantee that the shellfish harvested are negative for pathogenic enteric viruses. It is recommended that classification of SPAs that may be influenced by human sewage is tested against pathogen monitoring results in relation to storm events, known malfunction of the treatment systems and the tourist season.

Method of calculating percentiles of shellfish *E. coli* data for determining classification grade. FSS uses a non-parametric method to calculate the 80% for class A and the 90% for class B. Hence, there is no need for transformation since a distribution is not being fitted to estimate the percentiles (as in a parametric method). Shellfish *E. coli* results collected under the random monitoring strategy are populated with many low concentrations and very few high concentrations, which reflect the effect of adverse pollution conditions. Whether the use of the non-parametric method based on percentages of the sample data yields a better estimate of

[26] However, the shortest seasonal classification grade awarded is for a period of three months and can be based on nine samples, i.e. three samples in each month over the three years. For example, to award a classification grade for the January-March season, FSS would look at monthly samples from January to March in 2016, 2017 and 2018 (pers. com. Kasia Kazimierczak, FSS, May 2018).

classification than fitting a lognormal distribution depends on the statistical distribution of the data and the number of samples that are available. It is recommended that the shellfish *E. coli* data is transformed for the calculation of classification if less than three years' worth of data are available for classification; the formulas described in Appendix IV.8: Calculation of percentiles can be used.

Terminology. FSS has developed a flexible classification protocol with many types/terms referring to classification. The terms such as provisional and preliminary are not reported in the Guide. In addition, the term "classified SPAs" refers to different types of classification granted with a different number of samples. Further, the database refers to classified SPAs which may be areas where sanitary surveys have been undertaken or to areas where sanitary surveys have not been undertaken. It is recommended that (i) FSS grants the types of classification in line with the Guide's recommendations, i.e. it uses the terms and sampling recommendations for initial, annual and established classification (see Table 2 in Section 3.2 and Table 7 in Section 5.2.2.1); and (ii) only SPAs with more than three years' worth of data are recorded as classified in the revised classification approach (unless it is demonstrated that classification with fewer years' worth of data is robust[27]).

5.2.2.3 Review of recording and reporting of monitoring data for classification of SPAs

FSS records classification grading per SPA for all classified SPAs in a given year in two comprehensive up-to-date databases:

(i) One linking the NGR of each SPA with: classification type, grade and status; the sanitary survey process (i.e. full sanitary survey or pRMP assessment); the sampling plan (boundaries, RMP or pRMP, tolerance, depth, frequency); and any other relevant information (e.g. biotoxin monitoring, local authority).

(i) The other linking the NGR of each shellfish *E. coli* data sampling point with: date of sampling, the SIN of the SPA, classification grade, shellfish *E. coli* concentrations, LA and harvester.

FSS databases. Keeping two databases allows for tracking, visualising, validating and assessing the shellfish *E. coli* data and classification of SPAs through time. It is recommended that this approach is maintained in the revised classification approach.

Data validation and storage. The FSS protocol (2017) gives no information on the use of specific methods for the validation and storage of available data for classification. However, it is clearly mentioned that "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 10 m". Both FSS databases are characterised by discrepancies and inconsistencies in the NGR recording of shellfish *E. coli* monitoring data. As a result, shellfish *E. coli* data cannot be readily used for GIS or statistical analyses or for the classification of SWPAs before corrections and georeferencing. It is recommended that (i) FSS identifies step-by-step procedures on validation and storage of available data for classification to ensure that all staff use the same method; (ii) staff and harvesters collecting shellfish *E. coli* samples are properly trained to use GPS and record the location of samples because the location of the sampling point is of quintessential importance in identifying classification grade; and (iii) shellfish *E. coli* sampling results are validated and projected on GIS maps soon after sampling and recording so that any discrepancies can be traced and potentially corrected.

5.2.2.4 SWOT analysis for the classification programme applied in SPAs by FSS

Major strengths

- The FSS classification programme is based on internationally accepted microbiological quality criteria under the clear-cut specifications in *Regulation (EC) 854/2004* (however see Section 3.3).
- Monitoring for established classification and the review period are both based on three years' worth of data in line with EU and international best practice.
- Shellfish *E. coli* monitoring data and each years' classified SPAs and their sampling plan are recorded in two separate databases, respectively. Both databases refer the location and date of sampling or year of classification grade, which can be updated and used by any interested parties.

Major weaknesses

- Preliminary, provisional and annual classifications are granted upon receipt of a smaller number of samples than that recommended in the Guide or applied internationally.
- The current monitoring strategy is not fit-for-purpose, as it does not address the worst-conditions in a SPA. In addition, in areas potentially influenced by human

[27] A classification can be considered as robust when it performs well even if the assumption about the distribution of the data (e.g. that the data is lognormally distributed) does not hold, and when it is not sensitive to outliers (i.e. high E. coli concentrations in response to worst-conditions).

sewage effluent from CSOs or STOs sample size is too low to include many samples taken during heavy or extreme rainfall events (i.e. rain intensity above 95th and 99th-percentiles of the whole rain data series from all source-catchments during 1999-2015, respectively; see also Appendix V.5.6).

- FSS has not developed robust procedures for the recording and storage of routine monitoring results. There are serious discrepancies regarding sampling location and SPA due to unreliable recording of the location where shellfish *E. coli* samples were collected from on behalf of FSS. As a result, the use of data for the review of sanitary surveys by FSS and for the classification of SWPAs by SEPA is challenging.

Major opportunities for improvements in the revised classification programme

- The classification grade can be based on the results of shellfish *E. coli* monitoring according to the sampling plan and risks from faecal contamination identified in a full sanitary survey.
- The random monitoring strategy can be applied in SPAs influenced by diffuse pollution sources to produce a bias-free classification of SPAs, i.e. a classification accounting for the mix of both favourable and worst-conditions in an area.
- The worst-condition strategy can be applied in SPAs influenced by point sources of human sewage discharges to produce a classification that does not underestimate the risk from pathogens. For example, and depending on the findings of the sanitary survey, samples may be collected: exclusively within two to seven days after a heavy or extreme rain event (see Appendix II: Identification of rare rainfall events); weekly or fortnightly during the tourist season or in August-September, which was shown in the trial studies to be a period of worst-conditions (see Section 5.4.4).
- If the number of samples collected is not sufficient for the review of classification (e.g. when under the worst-condition strategy there are fewer than 24 rainstorm events in the last three years), then the hybrid strategy can be applied. This involves both sampling under the random strategy (i.e. year-round at a monthly frequency) and sampling some heavy or extreme rainstorm events; or applying a higher frequency (e.g. weekly or fortnightly) during the tourist season or during August-September (see Section 5.4.4), if the area is influenced by tourism or recreational boating, always depending on the output of the sanitary survey.
- All types of monitoring should collect samples during the ebb-phase of the tidal cycle .
- The sanitary survey process can be tied in with the monitoring-classification programme. The sanitary surveys can identify the location and seasonality of sources posing a risk from pathogen, essential viral, contamination into production areas, regardless of shellfish *E. coli* classification results and thus inform when or where some areas must be excluded from harvesting or tested for pathogens.

Major threats

The major threat to improving the classification process is related to the legislative framework under the Regulation (EC) 854/2004, which although it has introduced the sanitary survey concept, it has not provided a clear control of its enforcement. Therefore, there is no obligation for FSS to use the sanitary survey findings and conclusions on pollution sources to assess the reliability of shellfish *E. coli* results. Nor is it obliged to apply the sampling recommendations reported in the Guide.

5.2.3 Currently classified SPAs

- Overall, 565 SPAs have been classified since 1999; of them, only 170 SPAs are currently classified (Year 2017/18).
- 134 out of 170 currently classified SPAs have been classified using monitoring data collected from a RMP identified through a full sanitary survey. Currently, four of these areas are dormant and are still monitored.
- 36 out of 170 currently classified areas are classified using monitoring data collected from a pRMP following a desk-top based assessment.
- 123 out of 170 SPAs have been graded as "A" for at least one season. Of these:
    - 105 have been classified using a RMP identified during a full sanitary survey.
    - 18 have been classified using a pRMP identified after a desktop pRMP assessment.

5.3 Review of current practices applied in SWPAs by SEPA

The documents related to SWPA classification focus on the practical aspects of generating information for classification. For example, extensive, step-by-step, in-house documentation of the procedures applied to extract

SWPA-specific data from FSS monitoring datasets has been developed (Denoon 2015; Pollard and Hern 2016). The SWPA classification programme was evaluated in consultation with SEPA in the context of the findings of the review on governance frameworks (Sections 3.4; 3.5; and 3.6) and the literature presented in Section 4.0.

5.3.1 Use and analysis of FSS monitoring data for SWPA Classification

Currently, SWPA monitoring data for SWPA classification may come from three different sources.

- FSS shellfish *E. coli* monitoring data in SPAs sitting within SWPAs (see section 5.3.2).
- Shellfish FC monitoring data collected until 2013 under the Shellfish Water Directive (*Directive 2006/113/EC*) in areas where SWPAs overlap with the designated Shellfish Waters. A 1:1 ratio has been used to transform shellfish FC to *E. coli* concentrations in the 2014 classification. This data may no longer be relevant to classifications based on three years' worth of data.
- Shellfish *E. coli* monitoring data at Loch Ryan[28] based on subtidal n. oysters and intertidal cockles.

The steps involved in the classification process for SWPAs by SEPA are as follows:

1. FSS and SEPA monitoring data are validated through map projection and "cleaned" through a rigorous and repeatable process that has addressed the presence of "<" or ">" qualifiers, inconsistencies with NGR recording in FSS recording, and duplicate and NULL values.
2. The 90th-percentile standard for *E. coli* MPN/100g FIL is calculated on log-transformed data.
3. Shellfish *E. coli* data from all different sampling points (i.e. RMPs from SPAs sitting within SWPAs and SEPA shellfish monitoring points) and monitored shellfish species (commercially harvested or not) within a SWPA are pooled from the most recent three years' worth of data to calculate the 90th-percentile standard and identify the classification grade.
4. Confidence of class is calculated to indicate when grading was based on a sufficient number of samples for a reliable face value classification, as follows:
    5. *High: when confidence in classification ≥ 95%.*
    6. *Medium: when confidence in classification ≥ 75%*
    Low: when confidence in classification <75%.
    7. *Very low: when < 10 samples are available.*

In 2014, there were 84 designated SWPAs. Water quality classification in these areas was as follows: "Good" in 28 areas; "Fair" in 48 areas; "Insufficient" in three areas; and Unclassified in five areas either because there were very few samples or no data at all. Some of these SWPAs were classified based on data from SPAs which were de-classified post-2014 by FSS, presumably because commercial harvesting ceased. It must be noted that any planned pollution control measures are implemented in SWPAs at Less than Good status and a High confidence. Additional monitoring may be planned for areas where classifications were based on sub-optimal sampling (i.e. less than three years' data) and low confidence classification (i.e. less than 10 samples).

5.3.2 Alignment between SPAs and SWPAs and implications for the classification of SWPAs

The degree of alignment between SWPAs and SPAs as of 2017 was investigated in ArcMap and was expressed as number of overlapping polygon layers. The spatial overlap between SWPAs and SPAs varies from zero to 100%. Currently, 122 out of 170 SPAs sit within 61 SWPAs. 65 out of 85 currently designated SWPAs sit within current or previously classified SPAs where full sanitary surveys (and reviews) have been undertaken. Therefore, there is no data for the classification of 24 SWPAs.
Spatial overlap between SPAs and SWPAs includes three arrangements.

- Full overlap with identical boundaries for SPAs and SWPAs.
- One SPA within a small or large part of the SWPA.
- Many small SPAs within a small or large part of the SWPA. Some SPAs may be favourable for commercial harvesting without need for post-harvest treatment year-round. Other SPAs may have seasonally fluctuating classification or be less favourable for the harvesting of a particular species (see also Section 4).

Priority SWPAs. From the standpoint of the shellfish industry, 21 out of 85 SWPAs have been flagged as a priority (priority SWPAs) for the development of shellfish farming operations. For four priority SWPAS (i.e. 11, 12, 26, 83) there is no sanitary survey report. However, SEPA reports (under the Shellfish Water Directive and until 2011) are available for all priority SWPAs. It is interesting to note that the species harvested currently (as of 2017/2018) or for some period in the past within the 21 priority SWPAs are as follows: mussels (11 SWPAs); P. oysters (five SWPAs); cockles (three SWPAs); n. oysters and carpet clams in one priority SWPA each.

[28] Supplementary monitoring of water E. coli and Intestinal enterococci (IE) is also taking place at Loch Ryan. Water microbiological monitoring is not relevant to SWPA classification but it is in line with specifications in Article 8.1.a of SG Directions (2015; 2016); see Box 1 in Section 3.5.1.2. However, it is uncertain how water E. coli and IE monitoring data should be used to inform the RBMP process.

5.3.3 Review of classification programmes for SWPAs by SEPA

Data handling and reporting. SEPA uses robust procedures for the validation and storage for data, in line with the experience gained under the Shellfish Water Directive collection of data, the WFD and the Bathing Water classification procedures. Reports under the Shellfish Water Directive can be characterised as mini-sanitary survey reports (SEPA 2011). It is recommended that the procedures for recording, transformations, storage and reporting are maintained by SEPA and applied by FSS to enable sharing of information and decision-making.

Data pooling and data from naturally growing shellfish species. SEPA pools the available SPA and SEPA data collected within each SWPA to grant area-based classification for SWPAs. It is recommended that data pooling is not applied in the revised approach to the classification of SWPAs and that data for SWPA classification come exclusively from shellfish species from farming operations. The reasons are explained below.

(i) Pooling data from different RMPs-SPAs classified for the same species may yield a classification unrepresentative of the locally important pollution sources and environmental conditions characterising a small, environmentally uniform SPA. Equally, using the SPA with the worst-classification to classify the larger SWPA, as in the "one out- all out" approach practised in WFD, is not accounting for local, more favourable, environmental conditions for the same or other species (see also Section 4.0).

(ii) Pooling data from different RMPs-SPAs classified for different species is incongruent with research showing that *E. coli* and pathogen accumulation rates depend on shellfish species and local conditions such as salinity, turbidity and temperature (see Section 4.0). Using an indicator species to classify a SWPA requires additional experiments, which are not always affordable. Pooling is also incongruent with international practice (see Section 3.0).

(iii) Using data from naturally growing shellfish species is outwith the remit of the SG designations for SWPAs (see Section 3.5.1.2; see also SG 2013a; b). Therefore, classifying SWPAs based on data from non-farmed shellfish species may misinform the RBMP process.

80th- vs 90th-percentile criteria for classification. Good classification for SWPAs is based on the 90th-percentile of data above 230 MPN of *E. coli*/100g of FIL; SPA class A is based on the 80th-percentile of data above 230 MPN of *E. coli*/100g of FIL. There is a small risk for 100% aligned SWPAs and SPAs to have a different classification based on exactly the same data. It is recommended that in SPAs within SWPAs when this difference in classification criteria causes downgrading of the established classification grade by FSS, SEPA use the stricter criteria, i.e. the 90th-percentile standard specified in the SG Directions, to inform the RBMP process.

SWPAs without commercial harvesting operations. Shellfish commercial harvesting is practised in the majority of designated SWPAs but not in all of them. If there is no commercial harvesting in a designated SWPA, FSS is not required to collect shellfish *E. coli* samples; therefore, these SWPAs cannot be classified based on FSS data, or indeed on sampling commercially farmed shellfish species. It is recommended that this be specifically addressed in consultation with FSS, LAs and Harvesters.

Classification of new SPAs and de-classification. The number of SPAs within SWPAs potentially changes on a year-by-year basis because of delineation of new classified SPAs and declassification of existing ones, mostly due to ceasing of commercial harvesting. Declassification will be a problem if this means that there is no other SPA in the SWPA. Data from new SPAs will accumulate to meet the criterion for using three years' worth of data for classification. It is recommended that SEPA use three years' worth of data and not less in order to generate a robust classification.

5.3.4 SWOT analysis on the classification process for SWPAs by SEPA

Major strengths

- The specified microbiological quality criteria have been specified based on standards and criteria for commercially harvested shellfish in the EU and internationally.
- The procedures applied by SEPA for handling the data (i.e. transformations, validation, storage) are robust and fit-for-purpose.
- Many SWPAs fully overlap with one or more SPAs, which is a fit-for-purpose approach for the protection of economically important production areas.

Major weaknesses

- SEPA has historically monitored intertidal populations of mussels, oysters and cockles, not always coming from shellfish farming operations. However, the use of data from naturally growing shellfish species is not a fit-for-purpose approach for the classification of SWPAs.
- Pooling of data to generate a single classification for a large, usually spatially heterogeneous SWPA, is not a fit-for-purpose approach because it misrepresents local risks and species-specific response to environmental

conditions.

- The classification of SWPAs without any SPAs, which are monitored by FSS, within their territory cannot be based on currently commercially harvested species.

Opportunities for addressing the identified weaknesses

- Addressing the problem of granting a single classification for a spatially heterogeneous area by pooling data from many SPAs for the same or different species, may involve the following the following actions-options:
  (i) SEPA may apply the microbiological criteria specified in the SG Directions (2015, 2016) for each SPA within SWPAs, separately. Practically, this means that (i) same procedures are applied for all arrangements of spatial overlap between SPAs and SWPAs and (ii) SEPA and FSS monitoring and classification programmes can be integrated (see below Opportunities).

  (ii) SEPA may wish to group SPAs for the same species (or shellfish feeding group) within a large SWPA, if and where these different SPAs can be grouped into an environmentally uniform area. This requires a new sanitary survey to investigate whether the grouped SPAs can be sampled from one RMP representative of greatest impacts in the area.

- Addressing the lack of data for SWPAs where no commercial harvesting is currently practiced, may involve the following actions-options for SEPA:

  (i) No monitoring until commercial harvesting begins.

  (ii) Monitoring of shellfish *E. coli* from species deployed in bags in areas at risk from faecal contamination to inform the RBMP process. The species for classification of these SWPAs could be selected in consultation with the shellfish industry, in order for classification to reflect the species-specific potential for economic investment.

  (iii) Monitoring of shellfish *E. coli* from naturally occurring (not commercially harvested) species found in the area. The species or the locations may be selected in consultation with the shellfish industry so as to reflect potential for development of a production area.

- Addressing the lack of sanitary surveys for SWPAs without any classified SPAs, may involve the following:

  (i) SEPA undertakes a desk study at the SWPA scale using data on marine-based and catchment-based faecal pollution sources and hydrographic data to identify likely worst-location and worst-conditions for a specific area.

  (ii) SEPA considers undertaking investigative monitoring to collect shellfish *E. coli* samples from experimental bags deployed in order to verify worst-location. Samples can be used for the classification of the SWPA with the caveat that the species tested in that area is not economically significant until its commercial harvesting is permitted.

  (i) The outcomes of the desk study and monitoring are described and assessed in a report and the data are stored in a database for subsequent updates and sharing with FSS and LAs. For example, the report should assess whether there is need for hydrodynamic or linked catchment-hydrodynamic modelling. The report should also inform the RBMP process and the applications for new SPAs in the designated SWPAs.

- SEPA may wish to undertake supplementary monitoring within or outwith the boundaries and the RMP of the SPA in order to provide "supplementary" information on the FIO content in water or in FIL of non-commercially harvested species in relation to specific sources of pollution or hydrographic parameters within the SWPA. However, this monitoring could not be used for generating a classification grade for the economically important shellfish farming operations within the SWPA.

- Opportunities for integrating FSS and SEPA use of monitoring data and classification may include:

  (i) Considering area-based (not species-specific) sanitary surveys in areas where SPAs sit within SWPAs. This implies assessing pollution effects using more than one monitoring points and species and is in line with the sanitary survey process applied pre-2015 by CEFAS.
  (ii) Applying consistent and robust procedures for data collection, recording, transformations, storage and sharing.
  (iii) Considering integration of the *Regulation (EC) 854/2004* and the WFD requirements, in line with the French and USA governance paradigms, to enable complete alignment of monitoring and classification procedures for SPAs and SWPAs.

Threats

A potential threat to improving the classification procedure for SWPA is related to the availability of FSS data from SPAs classified within SWPAs. FSS is monitoring only commercially harvested species in existing operations. If there are not any commercial operations in an area, FSS has no obligation to monitor. Therefore, any environmental or financial factors influencing commercial harvesting operations in SPAs sitting within SWPAs will result in changes in the available data for classification in SWPAs.

Yet to be explored is how SPAs outwith SWPAs can best be protected from faecal pollution, given that:

(i) FSS has no control on catchment-based faecal pollution risks to SPAs.

(ii) SEPA has no obligation to implement rural diffuse pollution control measures in catchments draining to these SPAs.

(iii) FSS has no control on whether the harvesters' applications refer to areas within or outwith the SWPAs.

5.4 Key findings from GIS and statistical analyses – Data from all SWPAs

The results of the GIS and statistical analyses and the findings of trial desk studies are detailed in Appendices V.5 and V.6, respectively. The key points are summarised below.

5.4.1 Effect of rain on shellfish E. coli results (Appendix V.5.4.4)

- The effect of two-day and three-to-seven-days antecedent catchment rain (i.e. rain prior to the date of sampling) was statistically significant.
- Two-day antecedent rain varied seasonally, with maxima in winter months and minima in June.
- The greatest shellfish *E. coli* results during the period 1999-2015 did not coincide with all heavy and extreme rainfall events in the two days prior to sampling.
- Very few heavy and extreme rainfall events (i.e. rain intensity above 95th and 99th-percentiles of the whole rain data series from all source-catchments during 1999-2015, respectively; see also Appendix V.5.6) were observed in the two days prior to shellfish *E. coli* sampling due to the low sample size.
- **Conclusion.** The significant effect of antecedent rain on shellfish *E. coli* results indicates that land runoff plays an important role in shellfish *E. coli* contamination. The effect of antecedent rain may be direct, when rain induces transport of faecal contaminants (animal or human) in runoff from catchment-based sources to SWPAs; and/or indirect, when freshwater inputs are influencing water circulation and mixing processes in lochs and semi-enclosed embayments. The reason rain cannot explain all exceedances in shellfish *E. coli* results may be related to the effect of other processes (e.g. discharge of treated effluent, overboard sewage disposal, and wildlife), which have the potential to contribute to background FIO contamination in shellfish waters. Random sampling may need to be supplemented by worst-condition monitoring during or two-to-seven days after heavy and extreme rainfall (i.e. rain intensity above 95th and 99th-percentiles of the whole rain data series from all source-catchments during 1999-2015, respectively; see also Appendix V.5.6) in order to capture more storm events.

5.4.2 Effects of livestock, number of septic tanks, human population on shellfish E.coli results

- The effect of the density of all livestock in a catchment on shellfish *E. coli* concentrations was not statistically significant. The only significant effect detected was for sheep density, whereby shellfish *E. coli* levels marginally increased with densities of sheep.
- Septic tank numbers and population were not found to have a statistically significant effect.
- SWPA source-catchments could not be categorised on the basis of the quantitative data on catchment indicators of faecal sources such as livestock density, septic tank numbers, human population, and catchment area.
- **Conclusion.** The effect of catchment indicators of faecal sources on the microbiological quality of SWPAs and SPAs sitting within SWPAs is area-specific.

5.4.3 FIO export in relation to land use

- Rural land use dominates SWPA source-catchments, with only three catchments having semi-urban areas. Based on generic models on the FIO export from catchments with rural land use, it can be assumed that the export of faecal coliforms from rural source-catchments to SWPAs is at the scale of 1.2 X 10^9 cfu/km^2/h at baseflow to 4.6 X 10^{10} cfu/km^2/h at high flow. This is one to two orders of magnitude higher than the FIO export from woodland dominated catchments.
- Waterbodies where improved or rough grassland exceeded 75% of land use were generally located upstream of the shoreline areas immediately bordering the SWPAs. A higher FIO export is expected from grassland waterbodies compared with arable and woodland areas. However, assessing whether these waterbodies will contribute to SWPA faecal contamination requires linked source-apportionment and hydrodynamic modelling (see also Section 4.0).

5.4.4 Effect of sampling month on shellfish E. coli results

- Shellfish *E. coli* concentrations varied according to sampling month and showed a marked seasonal pattern, with greatest levels observed for samples collected in August and September ("worst months") and lowest levels in April.
- Values above 4600MPN/100g of FIL were observed almost year-round.
- Annual average levels of shellfish *E. coli* concentrations slightly declined from 1999 to 2017.
- **Conclusion.** Any "worst-case condition" sampling (e.g.

during sanitary surveys or for granting classification for SPAs or SWPAs) should include sampling during "worst months". Further, year-round sampling would better capture the random variability in an area and the seasonal effects. It remains uncertain whether the interannual declining trend in shellfish *E. coli* results could be attributed to the implementation of measures for controlling rural diffuse pollution or discharges for WwTPs.

5.4.5 Effect of shellfish species on shellfish E. coli

- Shellfish *E. coli* concentrations varied by species. Cockles displayed the highest *E. coli* contamination levels. Mussels, carpet claps and razor clams displayed the lowest levels.
- The location of the shellfishery has influenced the shellfish species *E. coli* pattern.
- Shellfish *E. coli* levels in the commonly commercially harvested species in Scotland, i.e. n. oysters, P. oysters, cockles and common mussels, displayed a strong seasonal cycle, with greatest levels of contamination observed in late summer (August and September) and lowest levels in April and May.
- **Conclusion.** Both the shellfish species and the conditions in the growing area play an important role in determining the *E. coli* contamination patterns in shellfish species. The increase of *E. coli* contamination in late summer for all species may be related to both tourism and temperature.

5.5 Trial desk studies

5.5.1 Overall conclusion

- The findings from the trial desk studies are in line with peer-reviewed evidence on the importance of both catchment-based and coastal hydrodynamic processes in determining shellfish *E. coli* "hot spots" and the temporal patterns of faecal contamination in shellfish.
- Combining historical shellfish *E. coli* data with digitised GIS-linked catchment indicator data and examining the results in the context of hydrodynamic studies and the conclusions reported in the available sanitary survey reports was found to be an effective, fit-for-purpose, desk-based approach. This approach can be applied to:
  - Review existing primary sanitary surveys reports for SPAs within and outwith SWPAs.
  - Enhance the content of already completed pRMP assessments.
  - Inform the application process and primary sanitary survey reports for new harvesting areas.
- Using the results of hydrodynamic surveys and shoreline observations presented in available sanitary survey reports as part of the trial desk study showed that in some SWPAs, hydrodynamics, overboard sewage disposal, local issues with malfunctioning septic tanks and wildlife may be equally or more important determinants of faecal contamination than catchment-based sources and rain.
- Assessments of historical shellfish *E. coli* results in the context of catchment indicators and, where possible, the evidence presented in available sanitary survey reports were based on established RMPs or pRMPs. Therefore, the desk study cannot evaluate the location of the RMP (or pRMP) without data from other locations.
- Assessment of historical shellfish *E. coli* data under the desk study can help to evaluate the sampling frequency and the monitoring strategy (i.e. random versus worst-condition sampling) by examining the number of shellfish *E. coli* data collected per year and the type of faecal pollution sources in an area.
- The desk study showed that catchment and hydrodynamic processes interact locally and across broader scales (as when entire lochs are designated as SWPAs). The implication of this is that the sanitary survey process must identify local and broader scale processes influencing faecal contamination; however, the identification of the RMP depends on where natural shellfish beds or shellfish aquaculture operations occur.
- SWPA-wide sanitary surveys are critical to understand the interplay between catchment inputs and hydrodynamic processes.

5.5.2 Cat Firth

- Pattern of SPA-SWPA spatial overlap. Cat Firth represents a small area where the SPA classified for the commercial harvesting of mussels completely sits within the designated SWPA.
- Sanitary survey report. There is no sanitary survey report. Therefore, this trial desk study could be used as part of the revised sanitary survey process.
- Trial desk study. The desk study helped to map the rural land uses generating faecal contaminants, i.e. improved and rough grassland and septic tanks, and concluded a high confidence of class A or Good classification. The GIS and statistical analyses showed low risk from catchment-based sources of faecal contamination.
- Options for supplementary sampling by SEPA. As a caveat, the area is characterised by a relatively long flushing period; therefore, faecal microorganisms may survive for longer periods in the water column after episodic inputs, thus increasing the risk of shellfish contamination. An option for SEPA is to target (water or shellfish) sampling in periods immediately after episodic events (e.g. after rain, or any other catchment-based event) to take account of the time it takes to *E. coli* to depurate.

5.5.3 Cromarty Bay

- Pattern of SPA-SWPA spatial overlap. Cromarty Bay represents a case where the designated SWPA does not overlap with any classified SPAs. Therefore, there is no timeseries of historical shellfish *E. coli* data but there is some data based on samples from bags deployed to test the influence of hydrodynamic processes on shellfish *E. coli* contamination levels.
- Sanitary survey report. The available sanitary survey, which carried out hydrodynamic modelling, concluded that the major risks regarding faecal contamination are related to sources of human and wildlife faecal contamination within and outwith Cromarty Bay due to water circulation patterns and to likely increases in livestock and tourism during summer.
- Trial desk study. The desk study updated the catchment-based data described in the available sanitary survey report, but without historical shellfish *E. coli* data it was not possible to assess the effect of catchment indicators on the levels of shellfish contamination.
- Options for supplementary sampling by SEPA. The SWPA is spatially, and potentially temporally, heterogeneous, and the scope for supplementary sampling can be assessed once the location of aquaculture operations has been decided.

5.5.4 Loch Ryan

- Pattern of SPA-SWPA spatial overlap. Loch Ryan represents a case where approximately half of the designated SWPA overlaps with one relatively large currently classified SPA for the commercial harvesting of n. oysters; the other half has been declassified for razor clams by FSS.
- Sanitary survey report. There are two sanitary survey reports covering the entire SWPA. These reports detail the faecal pollution sources and the hydrodynamic processes influencing the currently harvested n. oyster bed as well as the declassified razor bed. The conclusion of the reports was that faecal contaminants from point sources of sewage effluent and catchment-based diffuse pollution sources are carried across the entire Loch by strong tidal currents.
- Desk study. The desk study assessed the catchment indicators and the available historical data as well as the evidence in the sanitary survey reports and recent monitoring data from SEPA. It concluded that the n. oyster bed of south Loch Ryan is at risk from faecal contaminants of both human and animal origin on a year-round basis.
- Sampling plan – monitoring strategy. Given the presence of point sources of sewage effluent, and in line with international best practice, Loch Ryan must be sampled under the worst-condition strategy. Worst-conditions can be heavy or extreme rainfall (i.e. storm events) in the two days prior to sampling and the tourist (summer) season. However, FSS has not collected samples during storm events and very few storm events occurred in the two days prior to sampling in historic sampling data. In addition, FSS has not collected samples during the summer season.
- Supplementary sampling by SEPA. SEPA's monitoring indicated that the RMP for the SPA is located in an area which has recently given lower water *E. coli* levels than other areas within the classified area. Therefore, this information must be accounted in the review of the sanitary survey report for n. oysters in Loch Ryan. An additional option for SEPA is to collect samples from the burns discharging and the water in the vicinity of the declassified natural razor bed within Loch Ryan.

5.5.5 Loch Creran

- Pattern of SPA-SWPA spatial overlap. Loch Creran represents a case in which five different SPAs sit within a large SWPA. The SPAs are classified for the commercial harvesting of three different shellfish species.
- Sanitary survey report. There are two sanitary survey reports: one for mussels and P. oysters within Loch Creran, which has been reviewed six years later; and one for cockles at Eriska Shoal. The sanitary surveys for Loch Creran concluded that tidal movement and circulation pattern plays an important role in keeping faecal contamination at high levels despite the observed low pressures from livestock and septic tank discharges. Other important sources include tourism and recreational boating in the summer months and potentially wildlife. The sanitary survey for Eriska Shoal concluded that there are no major sources of contamination other than wildlife feeding on the cockle bed but local sources in the immediate vicinity of the shellfishery (such as grazing cattle) may increase faecal contamination in cockles.
- Trial desk study. The desk study presented up-to-date information on rain and livestock and showed that there are low pressures from livestock and resident population in the catchment. However, the high confidence of class B or Fair classification suggests that local inputs (e.g. from septic tanks) and other sources such as overboard sewage disposal must be addressed and controlled. The trial also established that there are differences between species and locations for the same species. This reflects the spatial heterogeneity in hydrography described in the sanitary survey report. A potential implication of this is that a single classification for the entire SWPA is not representative of the local conditions, which may be more favourable in some areas than in others for the development of shellfish production within the SWPA.

6.0 Conclusions and recommendations

This report reviewed current practices on shellfish water monitoring and classification in Scotland in the context of governance frameworks and research evidence in the EU and internationally. This helped to better understand the strengths and limitations of the current practices and gain useful insights on the factors influencing shellfish *E. coli* monitoring results and, therefore, classification. It also helped to understand the limitations in sharing monitoring data between FSS and SEPA as well as the opportunities for developing an interactive and mutually beneficial approach. The key findings are provided below.

- A review of current practices on shellfish water monitoring and classification in Scotland in the context of governance frameworks and research evidence in the EU and internationally showed that the current approaches are in line with regulatory requirements but have not addressed research evidence and best practice.
- Full sanitary surveys are essential to design monitoring in both SWPAs and SPAs. Sanitary surveys can provide the information to identify a robust, evidence-based, sampling plan at the SPA-scale within or outwith a SWPA. They can also help to assess the interplay of catchment and coastal sources of faecal contaminants in spatially variable SWPAs, which can inform decision-making on where catchment-based sources of faecal pollution must be controlled.
- Classification of SPAs alone cannot protect public health. Compliance with A class, i.e. no post-harvesting treatment of shellfish before placing onto market, does not guarantee that the shellfish harvested are negative for pathogenic enteric viruses. Therefore, both classification grading and the assessment of risk from faecal pathogen contamination based on sanitary surveys are required to inform classification in SPAs by FSS.
- FSS applies different sampling regimes for the classification of SPAs: 10 weeks' worth of data to provisional classification; one year' worth of data for annual classification; and three-years' worth of data for established classification; thus, some SPAs are granted a classification grade with considerably smaller number of samples than others.
- SEPA classifies SWPAs without accounting for species- or site-specific factors. Specifically, pooling E. coli data from all SPAs and species within a SWPA is not a fit-for-purpose approach because of differences in faecal organism accumulation rates by different shellfish species. Where all SPAs within a SWPA are harvested for the same species, pooling E. coli data from all SPAs may misinform the River Basin Management Planning (RBMP) by misrepresenting local risks from faecal contamination and spatially variable seawater dilution and mixing processes.
- FSS has not developed robust procedures for the recording and storage of data from routine monitoring. As a result, the available databases (one for routine monitoring and one for each year's sampling plan of classified SPAs) have discrepancies regarding sampling location and recording of the type of classification, making data use by SEPA time-consuming and challenging.
- In consultation with FSS and SEPA, the report identified the strengths of current approaches and opportunities for improvements (see Recommendations) to inform future discussions with Scotland's shellfish industry. Recommendations for Standard Operating Procedures (SOP) for sanitary surveys are also provided.

Finally, the analyses of all shellfish *E. coli* data referring to designated SWPAs FSS and the undertaking of trial desk studies in four priority SWPAs enabled to recommend improvements in the monitoring and classification programmes for SPAs and SWPAs in line with up-to-date peer-reviewed research evidence. A list of recommendations is provided below.

Overall

FSS and SEPA must apply *The Guide to Good Practice* in *Microbiological monitoring of Bivalve Mollusc harvesting areas*[29] and account for international evidence on shellfish species-specific factors when defining their monitoring strategy and classification approach.

Recommendations to FSS

- Include the following tasks in the revised (full) sanitary surveys see Figure 1a): a desk study, sampling of shellfish E. coli and salinity and field (shoreline and catchment) observations, analysis of shellfish microbiological data in the context of the desk-based data, a report, and GIS-linked database of the data collected during the sanitary survey accompanying the report.
- Tailor monitoring strategy to the risks and type of pollution sources identified in the sanitary survey. Areas predominantly influenced by farmland runoff can be monitored under the random strategy. Worst-condition (e.g. rainstorm events, ebb-phase of the tidal cycle) strategy is fit for areas influenced by point sources of human sewage discharges. A combination of both strategies (i.e. hybrid strategy), can be also applied depending on the findings of sanitary surveys.

[29] EURL-CEFAS. (2017a).

- Collect seawater salinity and temperature samples in tandem with shellfish E. coli concentration during sanitary surveys and routine monitoring for classification.
- Gather and record field observations at the time of sampling (e.g. tidal phase, wildlife, pets, domestic sewage outflows, grazing livestock, recreational boating, wind direction and rain).
- Make a rule that all classifications are based on at least 24 samples regardless of whether they are based on six months', one year' or three years' worth of data.

Recommendations to SEPA

- Undertake sanitary surveys in SWPAs where no sanitary survey has been undertaken on behalf of FSS and there are not any currently classified SPAs (see Figure 1b).
- Classify SWPAs based on data from commercial aquaculture bivalve shellfish species, i.e. from SPAs. Classify each shellfish species from different SPAs within a SWPA separately in SWPAs where more than one species is commercially harvested, unless these SPAs are classified for the same species and can be grouped into a single, homogeneous area influenced by the same faecal pollution risks and processes on the basis of the results of a sanitary survey.
- In SWPAs where no commercial harvesting is practised, the options are as follows:
    - No monitoring until commercial harvesting begins.
    - Monitoring of shellfish E. coli from species deployed in bags in areas at risk from faecal contamination to inform the RBMP process; or at sites prioritised by the shellfish industry.
    - Monitoring of shellfish E. coli from naturally occurring (not commercially harvested) species found in the area. The species or the locations may be selected in consultation with the shellfish industry to inform on the potential for development of commercial harvesting.
- Undertake supplementary monitoring within or outwith the boundaries and the RMP of currently classified SPAs in order to provide "supplementary" information on the risk from faecal contamination in relation to specific catchment-based faecal sources of pollution or hydrographic parameters within the SWPA.
- Apply investigative monitoring for faecal indicators and to account for the presence of pathogens in shellfish and water in areas where commercial harvesting has not yet started; and in areas potentially influenced by human sewage discharges and/or agricultural land runoff.
- Use the developed catchment-shellfish E. coli database to verify linked catchment-hydrodynamic models on faecal indicator inputs and transport (once the models are developed).
- Add stream E. coli monitoring data in source-catchments draining to priority SWPAs into the catchment-shellfish E. coli database in order to link source-apportionment with shellfish data.
- Support the development of hydrodynamic (process-based) modelling to SWPAs where:
    - Shellfish E. coli results do not match the desk-based assessment of pollution sources.
    - There is a large bivalve shellfish production.
    - Shellfish E. coli levels frequently exceed the classification grade granted to production areas.
    - There is a potential link between bivalve shellfish harvested and a disease outbreak.
- Support and promote the development of linked catchment-hydrodynamic models to inform the RBMP process and the integrated management of shellfish waters in collaboration with Marine Scotland, FSS as well as research institutes and universities in Scotland and the UK.

Recommendations for integrating FSS and SEPA programmes

- Consider the benefits for Scotland of the French paradigm, whereby the requirements of the *Regulation (EC) 854/2004* and the WFD have been fully integrated enabling complete alignment of sanitary surveys, monitoring and classification and the RBMP process for SPAs and SWPAs.
- Share data from each sanitary survey undertaken at the SWPA- and SWPA source- catchment scale between FSS, SEPA and local authorities (LAs). In SWPAs where there are SPAs and applications for new SPAs, both FSS and SEPA will have write-access (Figure 1a). In SWPAs where there are not any SPAs, SEPA will have write-access (Figure 1b).

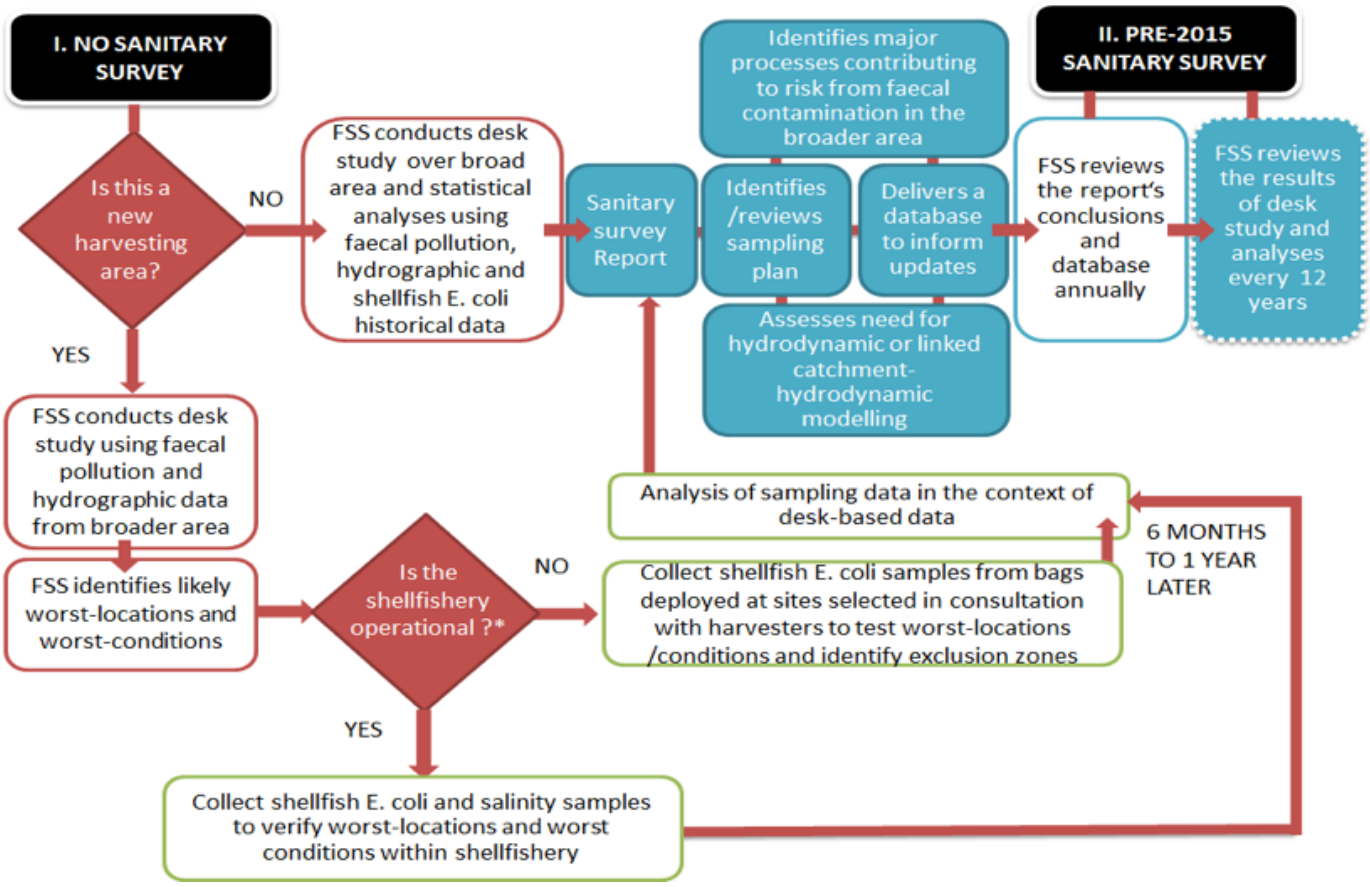

Figure 1a. Decision-tree for sanitary surveys in SPAs by FSS. *Operational: ready for harvesting.

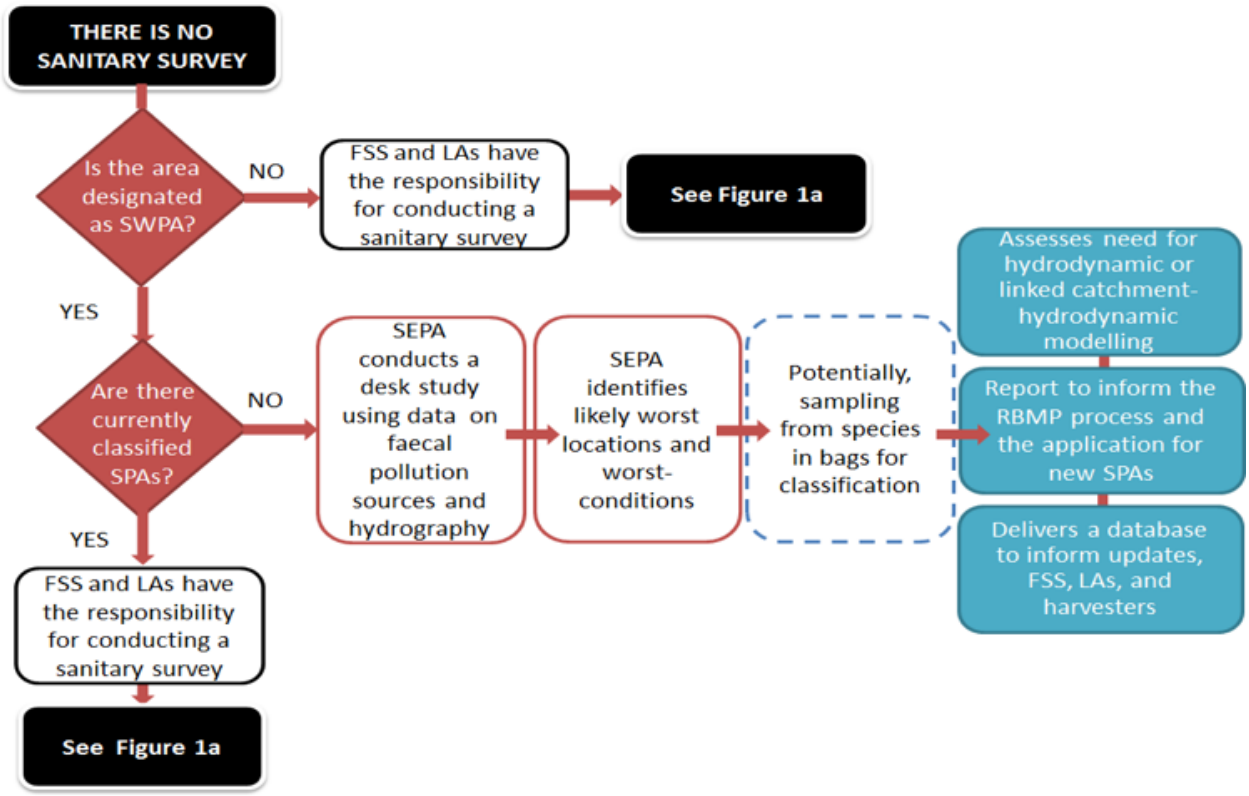

Figure 1b. Decision-tree for undertaking sanitary surveys in SWPAs where no sanitary surveys have been undertaken in the past.

An extended summary of the report detailing the findings from the literature review and the trial desk studies and presenting the full list of technical recommendations is provided in Appendix VII.

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