AN t-ÚDARÁS UM CHOSAINT IASCAIGH MHARA | SEA-FISHERIES PROTECTION AUTHORITY

Code of Practice for the Classification and Microbiological Monitoring of Bivalve Mollusc Production Areas in Ireland

Version: 8.0

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General

1.1. Background and Introduction

EU regulations exist to control the public health risks associated with consumption of microbiologically contaminated shellfish. The risk of contamination of shellfish with bacterial and viral pathogens is evaluated by reference to:

- the sources and types of faecal contamination (human and animal) in the vicinity of the shellfish production areas and
- results obtained, based on levels of *E. coli* in shellfish samples taken in these areas.

Areas are classified following a full assessment of this risk based on *E. coli* monitoring and the classification given to an area determines whether shellfish harvested in that area require post-processing treatment and, where appropriate, the level of such treatment.

Ongoing monitoring establishes if the level of risk has changed and thus whether short-term controls need to be applied or if the classification status needs to be changed. This code of practice outlines the procedures for the official monitoring undertaken for these purposes.

There are three classifications, Class A, B and C. Bivalve molluscs from areas not meeting at least Class C requirements cannot be placed on the market regardless of any treatment applied and it is prohibited to produce LBMs for consumption from such areas. Requirements of each classification are as follows:

- **Class A** - 80% of samples ≤ 230, and all samples must not exceed 700 *E. coli* MPN (Most Probable Number) per 100g of flesh and intravalvular fluid. No treatment is required and molluscs can be harvested for direct human consumption.
- **Class B** - 90% of samples must not exceed 4,600 *E. coli* MPN per 100g of flesh and intravalvular liquid and no samples may exceed 46,000 MPN per 100g. Treatment required of purification/depuration, relaying in Class A area or cooking by an approved method.
- **Class C** - samples must not exceed 46,000 *E. coli* per MPN per 100g of flesh and intravalvular liquid. Treatment required of relaying for a long period or cooking by an approved method.
- **Prohibited** – samples are greater than >46,000 *E. coli* MPN per 100g of flesh and intravalvular fluid, i.e. they do not meet the requirements of a Class C classification.

Please see the *Further information Sources* section at the end of this CoP for information beyond this document's scope but relevant to shellfish food safety.

1.2. Aim

The primary aim of the Irish Shellfish Monitoring Programme is the protection of human health with the view to maintaining the excellent reputation and sustainability of the shellfish industry in Ireland.

This Code of Practice (CoP) draws on best practice in other European jurisdictions, published advice as well as statutory requirements. This CoP outlines procedures for:

1. Producing sampling plans and conducting sanitary surveys
2. Sample collection and testing
3. Classification of areas as Class A, B, and C including procedures for data interpretation
4. Communication with stakeholders regarding monitoring results and classification
5. Additional risk management including procedure for responding to high *E. coli* results, sewage pump failures, outbreaks etc.

1.3. Scope

The scope of this document covers procedures for shellfish samplers, Sea-Fisheries Protection Officers, the laboratories undertaking microbiological analysis of shellfish, and those charged with managing the information generated from the monitoring programme.

Note: Nothing in this document can be taken as overriding obligations under other regulations/legislation unrelated to food safety and/or shellfish classification. In any case where additional factors, outside of the scope of this document, come to light in the course of establishment or management/monitoring of a shellfish production area they may override requirements of this code of practice. Such issues will be dealt with on a case-by-case basis.

1.4. Stakeholders

Those stakeholders that contribute directly to the monitoring programme are listed below.

The Food Safety Authority of Ireland (FSAI) has the statutory function of co-ordinating the enforcement of food legislation at national level. The principal function of the FSAI is to take all reasonable steps to ensure that food produced, distributed, or marketed in the State meets the highest standards of food safety and hygiene, reasonably attainable and to ensure that food complies with legal requirements, or where appropriate with recognised codes of good practice.

The Sea-Fisheries Protection Authority (SFPA) is the Competent Authority for the enforcement of Seafood Safety Legislation on the island of Ireland and throughout Irish territorial waters. The SFPA is an Official Agency of the FSAI, operating under a Service Contract. The SFPA implements, manages and monitors the National Microbiological Sampling Program. SFPA Sea-Fisheries Protection Officers (SFPOs) are responsible for supervising assigned production areas, with all sampling in a port office area being under the supervision of the local SFPA Senior Port Officer (SPOs) acting as the local Shellfish Sampling Manager.

The Marine Institute (MI) is an Official Agency of the FSAI operating under a Service Contract and has been designated as the National Reference Laboratory (NRL) for the following elements associated with the monitoring of microbiological and virological contamination of bivalve shellfish. Namely: -

- *E.coli* (shellfish only)
- Microbiological Classification of LBM production areas
- Foodborne viruses (shellfish only)

The MI coordinates the activities of the national testing laboratories involved in the microbiological monitoring programme ensuring high quality standards for the relevant analysis are maintained. The MI also provides advice on monitoring programmes and a range of support services to the competent authorities.

The Irish Farmers Association Aquaculture Section (IFA Aquaculture) represents **Shellfish Producers** which have primary responsibility for ensuring the safety of food produced and, as such, are required to co-operate fully with the national monitoring programme. Producers have a defined role in certain areas to assist the SFPA with microbiological sampling. They also have a role in providing local information to support work on sanitary surveys.

Bord Iascaigh Mhara (BIM) provides technical advice and information on the sustainable development of the industry as well as a market perspective (both domestic and international).

The Loughs Agency is a cross-border body, exercising a statutory remit for conservation, protection and development across the catchment areas of Lough Foyle and Carlingford Lough. The Loughs Agency is responsible for the development and management of the shellfish resources in both Lough Foyle and Carlingford Lough. The Agency conducts shellfish sampling in the two loughs under a Memorandum of Understanding with the FSAI

Additional stakeholders in Ireland's microbiological classification and monitoring include the following:

The Health Service Executive is responsible for managing publicity and communications with the general public and consumers, and when necessary, product recalls or withdrawals. Checking and validation of shellfish suppliers is carried out routinely by Environmental Health Officers during programmed auditing of food premises. Microbiological sampling of shellfish from retail and catering outlets is undertaken periodically as part of a locally agreed, comprehensive food sampling programme. This combination of food safety measures also serves as a secondary check on the efficacy of production level controls.

Uisce Éireann (Irish Water) has sole responsibility for the cleaning and maintenance of the public sewer network, as well as operating a network covering the large majority of public Wastewater Treatment Plants across Ireland.

The Environmental Protection Agency (EPA) is responsible for protecting and improving the environment for the people of Ireland. As such, it is the organisation with overall responsibility for licensing, monitoring and enforcement in relation to wastewater, its treatment and related pollution events.

All the stakeholders listed above are represented as members of the Molluscan Shellfish Safety Committee (MSSC).

1.4.1 The Molluscan Shellfish Safety Committee (MSSC)

The MSSC was created, following Ministerial direction, to provide a partnership forum within which all stakeholders involved in the production, processing, development, analysis and regulation of shellfish can frankly express their views in the interests of collective learning. It facilitates the discussion of the safety of the product and the management of the industry from risk management and consumer protection perspectives. The MSSC is an open forum and any relevant stakeholders with matters to discuss are free to attend and participate, with the prior arrangement through the chair (FSAI).
The MSSC acts as a consultative body from which the CAs take advice in the context of their statutory roles. The Committee facilitates communication between the Irish CAs responsible for Official Control and industry representatives. The application of official controls as they apply to shellfish is the responsibility of the CAs specifically, the SFPA, the MI and the FSAI. In the context of European and National legislation, the SFPA is the CA for the production, harvesting, processing and placing on the market of live bivalve shellfish.

1.4.2 MSSC Terms of Reference

The MSSC has broad terms of reference. These are: -

- Protection of consumer health,
- Ensuring that Ireland complies with relevant food safety legislation regarding the placing of molluscan shellfish on the market,
- Ensuring consumer confidence in the safety of molluscan shellfish,
- Supporting the long-term sustainable development of the shellfish industry and to maximize its export potential,
- Ensuring that any changes in legislation are introduced into the monitoring programme in a co-operative and open manner.

Within these terms of reference, the MSSC can develop areas of work or projects, and can, in the light of risk profiles, recommend adjustments to sampling, monitoring and testing programmes to the CAs.

The MSSC can also delegate some of this work or some of its functions to sub-groups or sub-committees, constituted by members of the MSSC and others co-opted for membership of a sub-group or sub-committee.

1.4.3 Operation of the MSSC

MSSC meetings are convened and chaired by the FSAI who also provide secretariat support. There is a minimum of four meetings per year. In person meetings may be held regionally or meetings can be held virtually as appropriate.

The FSAI circulate draft minutes within three weeks of each MSSC meeting. The draft minutes will normally be approved at the next meeting, and the agreed Final minutes are posted on the FSAI website.

1.5. Legislation

Please see below the main EU & Irish Food Safety Legislation of relevance to this Code of Practice.

1. **Regulation (EC) No 178/2002 as amended** Article 2, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
2. **Regulation (EC) 852/2004 as amended** states that primary responsibility for food safety lies with the food business operator, includes a requirement for use of clean seawater to wash bivalves, as well as a definition of clean seawater.
3. **Regulation (EC) No 853/2004 as amended** laying down specific hygiene rules for food of animal origin, gives associated requirements for the industry.
4. **Regulation (EU) 2017/625 as amended** lays down rules for the organisation of official controls on products of animal origin intended for human consumption.
5. **Commission Implementing Regulation (EU) 2019/627** Title V. Specific requirements for official controls concerning live bivalve molluscs from classified production and relaying areas.
6. **Regulation (EC) 2073/2005 as amended** laying down the microbiological criteria for foodstuffs.
7. **The European Communities (Food and Feed Hygiene) Regulations 2020 (SI No 22 of 2020)** transpose the above regulations so far as they relate to Fishery products in Ireland.
8. **The Food Safety Authority of Ireland Act 1998, Number 29 of 1998.** An Act to provide for the establishment of a body to be known as the Food Safety Authority and to define its functions.
9. **Sea-Fisheries and Maritime Jurisdiction Act 2006 as amended.** Transposing of EU Sea Fishery legislation into Irish Law and the establishment of the SFPA, including making the SFPA an official agency, in lieu of the Minister, in respect of food safety law for the purposes of the Food Safety Authority of Ireland Act 1998.

Responsibility for developing and applying official monitoring programmes lies with the SFPA and monitoring requirements are given in Title V of Commission Implementing **Regulation (EU) 2019/627 as amended.** The DAFM are responsible for drafting and, transposing fisheries legislation, and food safety legislation for all fishery products.

1.6. Legislative Microbiological Standards

Table 1 (below) outlines the legislative[1] microbiological criteria for classification of bivalve mollusc harvesting areas, setting out the limits for E. coli levels detected in shellfish flesh and intravalvular fluid for each classification category.

[1] Commission Implementing Regulation (EU) 2019/627 Title V Art 53, 54 and 55, Regulation (EC) 853/2004 and Regulation (EC) 2073/2005

Table 1. Criteria for Classification of Bivalve Mollusc Harvesting Areas

Classification	Standard per 100g of LBM flesh and intravalvular fluid[2]	Treatment Required[3]
A	80% of LBM samples from these areas must not exceed 230 MPN *E. coli* per 100g; the remaining 20% must not exceed 700 MPN *E. coli*/100g.	None - molluscs can be harvested for direct human consumption
B	90% of LBM samples from these areas must not exceed 4,600 MPN *E. coli* per 100 g of flesh and intravalvular liquid. In the remaining samples, LBMs must not exceed 46,000 MPN *E. coli* per 100g of flesh and intravalvular liquid.	As per regulation • Purification in an approved establishment, or • following relaying in an approved relay area, or • treatment by an approved heat treatment method
C	All LBM samples 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 flesh and intravalvular liquid.	As per regulation • Relaying in an approved relay area, or • treatment by an approved heat treatment method
Prohibited	>46,000 *E. coli* per 100g of flesh and intravalvular fluid.	Harvesting not permitted

1.7. Harvesting: Legal Requirements

It is a principle of Irish Law that all food business operators: producers, manufacturers, distributors, retailers and caterers bear the primary responsibility, individually or, as appropriate, collectively, for the safety and suitability for human consumption, of any food placed on the market by them.

Furthermore, the parties mentioned above are required to take all reasonable steps to ensure, insofar as that party is concerned, the safety and hygienic standard of that food. Producers must, therefore, be familiar with relevant monitoring results and production area classification statuses.

Please note that the following legal requirements also apply:

1. Harvesting for placing on the market must only take place from classified production areas which have been classified for the specific species to be placed on the market.
2. Harvesting should only take place from classified production areas classified for that species which are not subject to temporary closures (e.g. due to pollution events) as per regulation[4]. Note that there are no areas currently classified for gastropod molluscs.
3. Harvesting should only take place from classified production areas that have an open status on the basis of biotoxin results (see: *Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins)*[5] and the Marine Institute's Harmful Algal Bloom monitoring website[6]).
4. All harvested live bivalve molluscs must be accompanied by a completed shellfish registration document in accordance with legislation[7].

[2] Commission Implementing Regulation (EU) 2019/627 Title V Art 53, 54 and 55, Regulation (EC) 853/2004 and Regulation (EC) 2073/2005
[3] Article 62 of EU Regulation 2019/627
[4] Article 62 of EU Regulation 2019/627
[5] https://www.fsai.ie/getmedia/c8f4d945-b1ee-4cb5-a906-f6546b0339ab/shellfish-monitoring-programme-code-of-practice.pdf
[6] https://webapps.marine.ie/HABs/
[7] Regulation (EC) 853/2004 as amended, specifically Section VII of Annex III

Before any processed shellfish are placed on the market, robust product recall and traceability procedures must be in place (see FSAI Guidance Note No.10 on Product Recall and Traceability[8]). Any product recall or withdrawal must be handled in accordance with this document.

Sampling Plans for Classified Shellfish Production Areas

Microbiological Sampling plans will be maintained centrally for all classified shellfish production areas and amended as necessary to record:

- bivalve species,
- sample location code,
- coordinates/position of sampling points and
- frequency of sampling.

Sampling plan details form the basis of the microbiological monitoring programme of classified shellfish production areas. In turn, the results of the monitoring programme are used to provide data to inform the annual review of shellfish production area classifications. The sampling plan must ensure that the results of the analysis carried out will be as representative as possible for the area considered, while in keeping with best practice guidance and legislative requirements.

2.1 Selecting Representative Monitoring Point Location

Sampling points, known as representative monitoring points (RMPs) should reflect the location at highest risk of faecal pollution within a classified production area[9]. To determine this, a sanitary survey of the area should be undertaken. A sanitary survey must be undertaken to determine the representative monitoring point and sampling plan for a new harvesting area prior to classification and must be carried out for all existing classified production and relaying areas where one has not been previously carried out[10].

2.2 Sanitary Surveys

Under Article 56 of Commission Implementing Regulation (EU) 2019/627, the SFPA must conduct sanitary surveys before classifying production areas and for all classified production areas where there has not been one previously carried out. These surveys identify and assess faecal contamination sources, evaluate how contaminants move through the area, and provide the scientific basis for selecting RMPs and establishing a monitoring programme for shellfish classification areas.
The SFPA will arrange for sanitary surveys to be undertaken for all such shellfish production areas and will establish a programme to conduct sanitary surveys for all existing classified shellfish production areas. This work may also involve collaboration with other agencies.

In order for an area to be included in the SFPA list of areas requiring sanitary survey the shellfish producer or fisher should complete and return the sanitary survey application form[11] formally requesting a sanitary survey for a proposed new shellfish classification, or to request that an existing classification awaiting sanitary survey be moved up the priority list. Note, all proposed wild bivalve fisheries are subject to the required steps under the Protocol for Opening a New Fishery for Bivalve Molluscs[12]. Any

[8] https://www.fsai.ie/publications/guidance-note-10-product-recall-and-traceability
[9] Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Implementing Regulation 2019/627
[10] Article 56 of Commission Implementing Regulation (EU) 2019/627 Title V
[11] https://www.sfpa.ie/Search/resource/2963
[12] http://www.fishingnet.ie/media/fishingnet/content/inshorefisheriesmanagement/Protocol%20for%20Opening%20a%20New%20Fishery%20for%20Bivalve%20Molluscs%202022%20081122.pdf

such proposed wild fisheries must have reached the specific step in the protocol requiring a sanitary survey before being considered by the SFPA for inclusion in the national sanitary survey schedule.

A sanitary survey **may involve** four elements:

1. A desk-based study to identify pollution source
2. A shoreline survey to confirm initial findings of the desk-based study
3. A bacteriological survey (If the best location for one or more representative sampling points for an area is not clear after doing the desk-based study, shoreline survey and historical microbiological data analysis.)
4. Data assessment

In order to meet requirements of defining a classified production area with precise geographical limits relative to the coastline and, where necessary, the open sea, a classified production area will ideally constitute a coherent entity based on the following:

1. Access
2. Production activity
3. Demarcation of boundaries
4. Hydrological Features
5. Characteristics of the circulation of microbiological pollutants.

Classified areas must constitute an enforceable entity, clearly defined as per the above parameters.

Figure 1 (below) visually presents the key steps involved in the sanitary survey process.

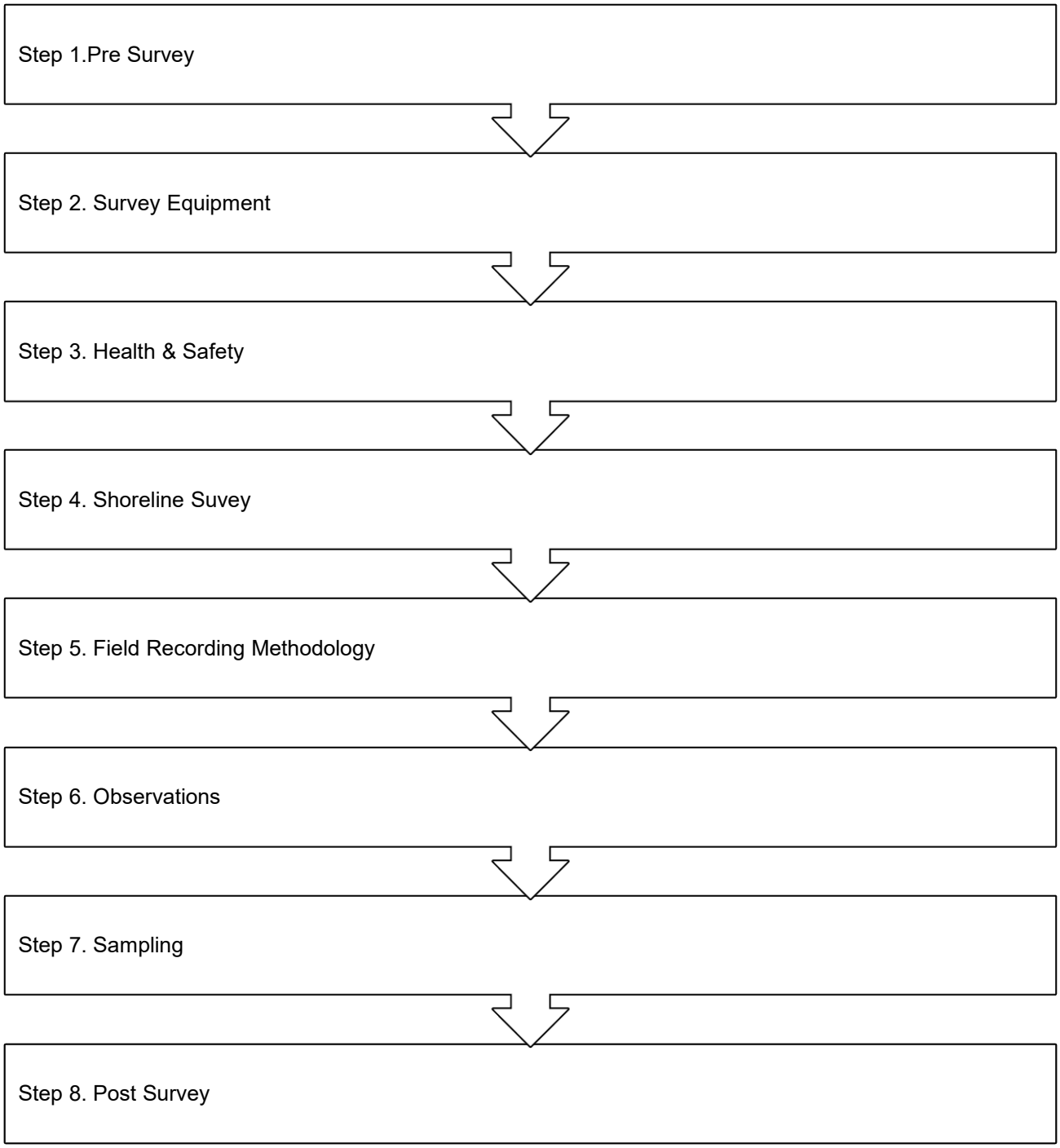

Figure 1. Sanitary Survey Steps

2.2.1 Desk Based Study

The following steps should be undertaken during the desk-based phase:

Characterisation of the fishery/production area

Through consultation with industry representatives, IFA Aquaculture, BIM and other relevant interested parties as well as scientific advisors such as the Marine Institute, the following characteristics should be identified and recorded for the aquaculture operations and any wild bivalve fishery(ies) in a production area.

1. Location and spatial extent.
2. Bivalve species.
3. Aquaculture or wild stocks.
4. Nature of area (whether it is a production or relaying area.
5. Seasonality of harvest.
6. Growth and harvesting techniques.
7. Any conservation controls (e.g. closed season) or other legal restrictions on harvest.
9. Existing classification data.

Identification of pollution sources.
An inventory of pollution sources of human and animal origin likely to be a source of contamination for the production area should be made. Where possible, information on the seasonal variation of quantities of such organic pollutants should be gathered. The information to be obtained and documented should include:

- **Sewage discharges:**
  a) Location and inventory of contamination sources
  b) Perceived Impact
  c) Treatment level (e.g. untreated, primary, secondary, tertiary, disinfected, septic tank, soakaway).
  d) Seasonal variation in pollution loading
  e) Maximum predicted flow rate (where data are available).

- **Rainfall-dependent sewage discharges (combined sewer overflows or storm tank overflow) and other rainfall-dependent discharges (storm water discharges):**
  a) Location.
  b) Measured or predicted spill frequency (per annum).
  c) Treatment level (if any).
  d) Maximum predicted flow rate (where data are available).

- **Emergency discharges:**
  a) Location. (Industrial discharges that have significant sewage content should also be assessed)
  b) Circumstances under which the discharge may operate.
  c) Maximum predicted flow rate (where data are available).

- **Land use:**
  a) Pastureland.
  b) Cattle.
  c) Sheep.
  d) Pigs.
  e) Poultry.
  f) Other livestock.
  g) Arable.
  h) Grassland.
  i) Horticulture.
  j) Forest/Woodland.
  k) Urban areas, roads, and other impermeable cover.

- **Other pollution sources such as:**
  a) Ships or boats.
  b) Wild animal such as birds.
  c) Spreading of bio solids on land.

2.2.2 Shoreline Survey

A shoreline survey should be undertaken by the SFPA or contractor designated by the SFPA. The survey will be conducted in collaboration with the local Sea-Fisheries Protection Officers and in consultation with the relevant shellfish producers. The shoreline survey purpose is to determine whether all significant sources of contamination have been identified during the desk-based study,

and whether previously identified sources are still present. The entire shoreline within the vicinity of the BMPA, influenced by the water catchment areas identified in the desk-based review, should be surveyed with the objective of identifying the pollution sources listed above.

A detailed procedure for conducting a shoreline survey is provided to SFPA personnel in order to standardise the shoreline survey process.

2.2.3 Bacteriological surveys

If the appropriate location for one or more RMPs within a BMPA is not clear following completion of the desk-based study and any shoreline survey, a bacteriological survey may be undertaken by SFPA.

2.2.4 Hydrography / Hydrodynamics

The circulation of pollutants may be determined based on current patterns, bathymetry and the tidal cycle in the production area. Existing available data should be utilised where practically possible and may include:

- Nautical charts (admiralty charts) either within a GIS or hard copy.
- Tidal Atlases, Mariners Handbook, Olsen's Nautical Almanacs or Sailing Directions
- Tidal charts/tidal stream software or simple hydrodynamic modelling.
- Complex hydrodynamic models.

Where available this information may be used to interpret the significance of the data gathered during the sanitary survey.

2.2.5 Compilation of Sanitary Survey Report

A standardised report format (**Appendix I**) should be prepared. The Sanitary Survey Report will be held centrally by the by SFPA. It will be made available to all stakeholders.

2.2.6 Assessment of Sanitary Survey Data and Selection of Sampling Locations

The data produced and recorded in the sanitary survey will be assessed to determine representative monitoring points within the production area, and appropriate boundaries for the production area. For each potential pollution source, an assessment should be made as to whether it will contribute to the microbial load in the production area. This assessment should consider the microbial load of the source, the distance from the fishery and associated dilution.

2.2.7 Review of Sanitary Survey

Periodic reviews of Sanitary Surveys will be undertaken by the SFPA to ensure that the environmental conditions have not changed and that the classifications are still valid.

Under Article 58 of 2019/627, the Competent Authority, i.e. the SFPA, is obliged to establish a procedure to ensure a sanitary survey is 'representative of the area' to which it refers.

To this end, review of sanitary survey reports will commence immediately once all existing production areas have had a sanitary survey carried out. Similarly, if during review of existing sanitary surveys it is decided through the sanitary survey planning process that a new production area, or areas, require sanitary surveying then these will be prioritised and the review process for existing sanitary surveys will be paused. When all areas have a sanitary survey in place, the sanitary survey review process will commence for areas based on their date of first publication, but with scope for prioritisation based on significant changes having been identified in any given production areas.

<u>Review of sanitary surveys can take place on one of three levels of detail/complexity:</u>

- Consultation with a production area's local SFPA Port Office to identify a requirement for sanitary survey update including any recommended updates that they have identified for the sanitary survey. Any updates identified as required should be incorporated into a revised sanitary survey addendum apart from when a more complete re-drafting of the sanitary survey is identified as required. In such cases, the review should progress to the next level (below).
- Where significant amendments, identified in the previous level of review, necessitate a more comprehensive re-drafting of the sanitary survey (for cases where the findings of the desktop review are not a true reflection of the current BMPA — e.g. significant increase or decrease in

pollution sources, changes in hydrodynamics, etc.) it will require an in-depth review and re-drafting of the desk-based elements of the full sanitary survey as well as the consultation in the point above. Any updates identified as required should be incorporated into a revised sanitary survey.

- Where identified as required under the previous two levels of review (above), a shoreline and bacteriological surveying of the production area may be required (where determined), as well as the elements in the previous two points above. Any updates identified as required should be incorporated into a revised sanitary survey.

2.2.8 Publication & Communication of Sanitary Survey

Sanitary survey reports will be published for public access on the SFPA website in PDF format.
Prior to publication, a notification will be issued to relevant internal SFPA stakeholders by the Shellfish Environmental Manager, advising them of the findings of the sanitary survey and outlining the next steps for the responsible Port (e.g. sampling requirements).

Following this, the Shellfish Environmental Manager will notify all relevant external stakeholders of the summary findings and provide a link to the full report. External stakeholders include:

- Food Safety Authority of Ireland (FSAI)
- Irish Farmers' Association (IFA) Aquaculture
- Bord Iascaigh Mhara (BIM)
- Marine Institute
- Local producers/Food Business Operators
- Environmental Protection Agency (EPA)
- Uisce Éireann
- Local Authority Waters Programme (LAWPRO)
- Inland Fisheries Ireland

Finally, the SFPA will extend an invitation to local producers/FBOs and bivalve fishers to attend a post-survey briefing. This session will communicate the findings of the report and provide an opportunity to address any questions relating to the sanitary survey.

2.2.9 Separate Sites in a Classified Production Area (CPA)

If an area is divided into separate sites, each capable of being classified at a different classification status or subject to short term closures, there must be at least one sampling point per site. Each sampling point should be at a fixed geographical location, identified by latitude/longitude reference to an accuracy of 10 metres. Samples should be taken within an identified distance of this location as per the following:

1. For hand-picked or raked samples, within a maximum of 100 metres.
2. For dredged samples this should be within a maximum of 250 metres.
3. For wild fisheries in offshore sites, a virtual sampling point may be identified at the centroid of the production area. Note, as per the Samp

2.2.10 Changes of RMP

Where there is a clear case for moving an RMP a risk assessment will be undertaken in consultation between the SFPA Shellsan team and local port office's Shellfish Sampling Manager/Senior Port Officer. Once a New RMP has been proposed and authorised by the SFPA there should be an immediate switch to the new sampling point in order to gather appropriate monitoring data at the earliest possible point in time. In any such instance where there is evidence of a clear risk the resulting from an RMP location, risk management action (determined on a case-by-case basis) may be implemented on the basis of risk assessment carried out by the SFPA based on available data and risk profile.
The RMP may be temporarily moved to a location when it is not possible to get samples from the usual RMP due to health and safety reasons, or other factors determined by the local SPO/Shellfish Sampling Manager. This should be undertaken following risk assessment conducted by the SFPA with technical support from the Marine Institute.

Any agreed changes to RMP locations resulting from the sanitary survey report will be noted in the sampling plan. If there are issues obtaining sufficient shellfish on repeated occasions from a particular

RMP, an alternative point may be identified in consultation with local industry. Where such a change is required, it should be done in consideration of, and may require update to, the sanitary survey report. Use of the previous RMP should then be discontinued. The selection of the sampling points and boundaries will be notified to the MSSC. Changes to sampling frequency, including reductions or increases, may also be considered on the basis of the sanitary survey findings.

Sampling and Sample Transport

For detailed information on the collection and transport of E. coli samples in keeping with the rules of this CoP, please refer to **Appendix II**, *Collection and Transport of Shellfish Samples for E. coli Testing*.

3.1 Selection of bivalve species to be monitored

In order to provide the highest standards of food safety, the Irish Shellfish monitoring programme aims to sample all harvested shellfish species within each production area as standard. Different bivalve species can vary in the levels of *E. coli* contamination and in the time of response to uptake and removal of faecal contamination.

However, where multiple shellfish species are present, one or more indicator species may be used to classify the area where parallel monitoring has shown that the indicator species yields results at least as high as those of the other species it represents.

The extent of parallel testing required before accepting a given species as an indicator species for another species or species group must be determined on a case-by-case basis in consultation between the FSAI, Marine Institute and SFPA. This will be dependent on fishery characteristics and risk factors identified in the sanitary survey. Any non-standard sampling procedures, such as initial parallel testing of proposed indicator species and subsequent use of indicator species must be on the instruction of, and recorded in writing by, the SFPA. The use of indicator species in sites will be approved by the SFPA. The Marine Institute will provide technical support to the SFPA as required to make such determinations.

3.2 Depth of sampling

Where bivalve species are grown on ropes, samples should be taken at the depth that generally yields the highest *E. coli* results if this is known from survey data. Where bagged bivalve molluscs are used for sampling instead of the normal harvested stocks, the bag should be located as near in depth to those stocks as possible.

3.3 Responsibility for sampling

It is the responsibility of the SFPA to make arrangements for the collection of samples for *E. coli* testing and it is the responsibility of all designated sampling officers to comply with this Code of Practice and the applicable sampling guidance (see **Appendix II**). Where sampling is carried out by someone other than an SFPO, it is the responsibility of the local SFPA personnel supervising sampling to ensure that the designated sampler has received sufficient training and information, and is sufficiently supervised, to ensure their adherence to the rules outlined in this CoP (see **Sections 3.7** and **3.8** of this CoP). All SFPOs receive training to ensure their competence in correct sampling processes for this official control.

3.3 Sampling frequency and minimum requirements for sampling.

In general, monthly sampling frequency is the normal requirement for classification sampling. Full details of sampling frequency requirements are outlined for each Classification Type in **Table 2**.

Table 2. Sample frequency/s data requirements for each shellfish area classification type.

Classification Type	Sampling Frequency / Data Requirements	Notes
Preliminary (Precedes all other classification types)	A minimum of 12 valid results not closer than fortnightly. Minimum period to obtain preliminary classification is 6 months.	Sanitary survey required for a new area prior to classification. Preliminary sampling may commence as soon as there is confirmation of the RMP locations. Producers may not under any circumstances move product from an unclassified area without prior consultation and approval from the SFPA.
Full Classification	Initial award of full classification, (following preliminary classification requiring 12 results) may take place once 30 monthly samples have been obtained over a three-year review period. Preliminary classification will be retained until full classification is awarded through the annual review process based on at least 30 samples over three years of data.	Sanitary Survey requirements as above for preliminary classification. Can include samples taken for preliminary classification.
Seasonal Classification	Three-year dataset with a minimum of 30 monthly samples representative of all seasons. Shows a clear seasonal trend.	The season classified as the least contaminated (better classification) must be preceded and followed by a buffer period. • Changing C to B 2 months. • Changing B to A one month Also, must be followed by a one-month buffer zone. Minimum period considered for seasonal classification is 3 months excluding the transition/buffer period. Period under consideration must show 100% compliance with proposed classification.
Short-Term Classification for wild fisheries.	For wild bivalve fisheries only. Fishers must submit a request to carry out initial collection of two samples not closer than two weeks apart before risk assessment is carried out by the SFPA and prior to approval or refusal of permission to fish in a given year. Regular monitoring required during fishing period, subject to a tailored sampling plan	Application to be made to SFPA for approval of fishing of wild bivalves under a short-term classification to facilitate commercial fishing. Application for consideration as a short-term classification may only be considered where there are ongoing issues in obtaining a full sampling dataset through an existing classification. Two initial samples required prior to risk assessment and approval or refusal to fish subject to adherence to tailored sampling plan. If, risk assessment, indicates potential approval for fishing in a given year, a sampling plan will be developed appropriate to the level of fishing

Classification Type	Sampling Frequency / Data Requirements	Notes
	and sufficient availability of local SFPA personnel for adequate supervision of this sampling plan. Decided on a case-by-case basis for these fisheries, with sampling plan issued following risk assessment if fishing is approved.	and assessed potential risk. Sampling plans will be subject to local SFPA approval due to their being contingent on availability of personnel for supervision of sampling. Out-of-range results for short-term classifications may necessitate management action more easily relative to classifications with a larger dataset (e.g. Full and Seasonal classifications) on the basis of risk assessment. This is in order to mitigate against risk associated with less-comprehensive monitoring datasets for short-term classifications. Note other regulatory/policy requirements may limit application of a short-term classification approach and any such issues will be considered on a case-by-case basis. New bivalve fisheries are subject to the process defined in the *Protocol for Opening a New Fishery for Bivalve Molluscs*[13] prior to consideration of any classification.
Dormant Classification	At least quarterly sampling, with samples taken not closer than fortnightly. Where no samples are submitted in a 24-month period the area may be deemed by the SFPA to require new classification, subject to risk assessment and consideration of the existing classification in place for the area.	To be applied to existing classifications where production is dormant and unlikely to recommence for at least a year. No harvesting may take place while the production area is dormant. Class A production areas will be reduced to class B while dormant. If sampling falls below quarterly frequency the production area will be at risk of being declassified. Following two years of dormant classification status classifications may be considered for declassification at the following annual review of classifications. To reactivate a dormant Class A site at an A classification level, at least 12 valid samples taken not closer than fortnightly, and less than 40 days apart are required. B classified areas will generally return to B classification status upon submission of two suitable microbiological sample results (taken not closer than fortnightly and less than 40 days apart). Note that an area that was formerly classified as A (before dormancy and becoming B classified), may reactivate as a B classified area following submission of two microbiological sample results (taken not closer than fortnightly and less than 40 days apart).

[13] Protocol for Opening a New Fishery for Bivalve Molluscs

Classification Type	Sampling Frequency / Data Requirements	Notes
		Any out-of-range or alert level results obtained during the dormant period and while on a reduced sampling frequency will be given consideration before reopening for production.
Notes on Data Review Requirements		In a given 3-year review period • 36 monthly samples form the standard requirement for full or seasonal classification. • 12 quarterly sample results are required for a dormant classification. • Generally, a minimum of 12 results are required for a 3-year period to be reviewed under the annual review of classifications (or a proportion of 12 such samples, where less than 3 years of data are available for a classification). • 12 results over a 3-year period corresponds with the minimum requirement for a dormant classification. If sufficient data are not available, for a given classification type the production area classification should be considered for: ○ Declassification, ○ Dormancy or ○ Changing to a different classification type with reduced data requirements relative to its current classification (e.g. short-term classification where appropriate).

3.4 Timing of sampling

For the protection of public health, sampling should be undertaken on a random basis where possible with respect to likely influencing environmental factors e.g. tidal state, rainfall, wind etc, so as to avoid introducing any bias to the results. Alternatively, sampling may be undertaken under conditions that have been identified as producing the highest levels of contamination. It is recognised that samplers are constrained by logistical considerations, and it may not be reasonably practical to undertake sampling on a fully random basis. A key principle is that every practicable effort should be made not to introduce bias to the sampling. With this in mind, where possible, sampling should be planned in advance according to availability of personnel, and contingent of meeting sampling requirements (e.g. tides) as well as health and safety considerations, rather than assessment of weather (which may have a subjective element). Classification samples should be taken at a frequency in keeping with requirements for each given classification type (as per **Table 2**, above) in order to be considered as part of the classification dataset (see more on this in **3.4.1 Follow-up sampling**, below)

3.4.1 Follow-up sampling

Please note that samples collected as follow-up samples in the period soon after an elevated result cannot be considered random, due to their relationship/dependence on the date of the initial, elevated result unless they have met a minimum interval threshold for inclusion in the classification dataset, 14 days (see **3.4 Timing of sampling**). This is in order to adhere to guidance that samples should not be

taken so closely together in time as to produce correlation between results[14]. For this reason, samples taken within 14 days of an elevated result are considered a food safety measure to ensure the safety of subsequently harvested product but cannot be included for consideration as part of a classified production area's classification monitoring dataset. Under the annual review process, any such datapoints will be removed from consideration regarding the classification level awarded, while being retained for the record of the classified area. Sampling SFPOs and Shellfish Sampling Managers/SPOs should note that in cases where a follow-up sample is taken within two weeks of a previous sample it will not be considered towards the annual total of samples to be taken and an additional sample should be taken, appropriately timed, after the follow-up sample in order to meet the subsequent monthly sampling requirement and to be included in the classification dataset.

3.5 Recording of the sampling plan

When decisions have been taken on sampling location, frequency, time and species sampled a sampling plan will be drawn up for each area. The plan will include the following information:

1. Production area name.
2. SFPA office responsible for sampling (including arrangements with industry e.g. wild fisheries)
3. Current classification status (A, B, C – Short-term, seasonal etc.)
4. Unique sampling point identifier.
5. Geographical location of each sampling point (latitude/longitude).
6. Frequency of sampling.
7. Species (including use of indicator species)
8. Depth of sampling
9. Other relevant information (e.g. duration or seasonality of the classification).

A record of the sampling plan will be held by the relevant SFPA port office and centrally by the SFPA HQ. Revisions to sampling plans should be notified to all relevant stakeholders as soon as reasonably possible and sampling plans are reviewed annually following the classification implementation meeting.

3.6 Sampling and sample transport protocols

All samples will be taken according to the sampling guidance (**Appendix II**).

- The maximum elapsed time between sampling and arrival at the laboratory must not exceed 48 hours. Samples received after this time may not be tested or if tested the results may not be used in the classification programme.
- The temperature on receipt in the laboratory must be ≤15˚C unless the transit time from sampling to arrival at the laboratory is <4 hours. Testing laboratories will record the temperature of the sample on receipt. Samples received above 15˚C and more than 4 hours after sampling may not be tested or the results may not be used in the classification programme.
- Where less than 4 hours have elapsed between collection from production area and receipt at the laboratory, sample temperature should be less than the air temperature recorded at the time of sampling.
- On receipt in the laboratory samples must be accompanied with a fully completed sample advice note. The sample advice note and sample labelling requirements should be checked against requirements outlined in the sampling guidance (**Appendix II**), ensuring inclusion of the following details:

    1. Sample point identification number and name.
    2. Temperature at sampling site (see above)
    3. Time and date of collection.
    4. Species.
    5. Method of collection (hand-picked, dredged, etc).

[14] Section 3.3.1, Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Implementing Regulation 2019/627

6. Any other information deemed relevant (e.g. unusual events, adverse weather conditions, Seawater temperature etc.) may also be recorded.

- Samples may be stored in the laboratory for up to 24 hours at <8˚C before analysis provided the total time between sample collection and commencing analysis does not exceed 48 hours.
- Sample collection and transport guidance (**Appendix II**) will be made available to all samplers.
- Only test laboratories contracted by the Marine Institute may be used for analysing samples for classification monitoring. Contact details can be obtained from the Marine Institute (see **Section, *Contact Details*** in **Appendix II**).

3.7 Training of samplers

All SFPO samplers must receive appropriate training to ensure compliance with this Code of Practice before commencing sampling under the monitoring programme. Requirements for training are stipulated in Article 5 (4) of Regulation 2017/625) and these requirements are met for SFPOs under their initial induction training programme with the SFPA, through a combination of class-based theory as well practical demonstration/work shadowing under the supervision of experience SFPOs/SPOs. All Samplers must have relevant sampling and safety equipment. All samples must be taken by SFPOs or under the supervision of SFPOs (see next, **Section 3.8** *Provision of Samples by Industry*).

3.8 Provision of Samples by Industry Under the Supervision of the SFPA

Where, as allowed in Article 65 of Commission Implementing Regulation (EU) 2019/627 Title V it is decided that members of the industry may provide samples, for example when sampling wild fisheries or for rope grown mussels and boat access by SFPOs is not possible, arrangements for industry sampling should be drawn up on a local basis, approved by the local SFPA local SPO/Shellfish Sampling Manager and notified to the SFPA National Shellfish Monitoring Manager (see SFPA *Contact Details* in **Appendix II**). In such cases arrangements must comply with all aspects of sampling requirements and this Code of Practice. Supervision and training of such samplers by SFPA should be maintained locally and documented under these arrangements. Once notified to the National Shellfish Monitoring Manager such industry sampling arrangements should be noted as part of the sampling plan and be locally monitored so that compliance ensured. In particular, as per guidance (see **Appendix II**), when collecting a wild-caught sample, e.g. from a fishing vessel, coordinates of the actual point from where the sample was fished must be obtained. Sampling officers should take additional steps available to verify fishing/sampling locations (e.g. monitoring of VMS or iVMS records or shore-based observations with binoculars). Training of locally approved industry samplers to meet the provisions of this Code of Practice must be approved by the local SFPA (SPO) in all cases where industry sampling is deemed required.

3.9 Audit of sampling and transport procedures

A programme of audits of sampling and transport procedures is carried out under the SFPA internal audit programme as well as being included in applicable FSAI audits of the SFPA and the Irish Shellfish Monitoring programme.

Microbiological Testing

The Marine Institute, as the Irish National Reference Laboratory (NRL) for *E. coli* (shellfish) testing is responsible for co-ordinating the activities of official testing laboratories involved in the classification monitoring programme. Only sample results provided by accredited laboratories recognised by the Marine Institute for the purpose of the Microbiological Monitoring Programme will be included in the classification monitoring dataset.

4.1 Methodology

All testing laboratories must use the five-tube three-dilution most probable number technique based on EN/ISO 16649-3 for detection of *E. coli.* All shellfish must be analysed within 24 hours of receipt in the laboratory and within the total time between sample collection and commencing analysis may not exceed 48 hours of sampling. Results of analysis will generally be reported to the Marine Institute, the SFPA SPO, National Shellfish Monitoring Manager and local area SFPO on the day, or as soon as practically possible thereafter, they become available.

4.2 Accreditation

All laboratories undertaking official testing of bivalve molluscs under for the classification monitoring programme must be accredited to EN ISO/IEC 17025 for the specific method used for *E. coli* in bivalve molluscs. The status and continued compliance of accredited laboratories is monitored by the Marine Institute through audits and quality assurance procedures.

4.3 Internal Quality Controls

Internal quality control procedures are specified in EN/ISO 166649-3 and must be complied with.

4.4 Comparative testing

All laboratories undertaking testing of bivalve molluscs for inclusion in the microbiological monitoring programme must participate in proficiency testing/ring trials for *E coli* in bivalve molluscs specified by the MI as the National Reference Laboratory. The MI evaluate laboratory performance in such proficiency testing and ring trials.

4.5 Sample condition

Samples not complying with sampling criteria outlined above will not be included in the classification dataset. The National Shellfish Monitoring Manager, sampling SFPO and local port SPO/Shellfish Sampling Manager must be informed on receipt of such non-compliant samples.

Classification

As the initial step, prior to new classifications, a sanitary survey needs to be carried out. Data gathered from the sanitary survey, sampling programme, other available data sources and local information from industry will be used. Data thus gathered will be used alongside interpretation of existing monitoring programme data, to decide on the boundaries of the classified area. The boundaries will be decided by the SFPA in consultation with the MI and local SFPA and industry.

Classification may also be considered for a new species in any area which is currently classified for another species but only where an existing sanitary survey has been carried out, and where any other required legislative steps have been completed may a new classification be put in place.
Furthermore, it may be considered if adjacent production area has had a sanitary survey (and the data supports this) and where existing or historic monitoring data allows for a robust risk assessment and immediate preliminary classification to be awarded.

The SFPA determine all classifications annually following review by the Implementation Team. Results from each monitoring point are reviewed on an annual basis, taking into account the last 3 years' data, or all data if there is less than 3 years of data available. These data are routinely monitored as sampling results are received, which can result in interim changes to classifications which will be notified as necessary via monthly updates. Classification will be determined on the basis of demonstrating compliance with the legislative criteria (see **Table 1**) and allowing for any anomalous results identified during the sampling programme which meet the requirements of the *Criteria for Discarding Results from the Classification Process* (**Section 5.5**, of this CoP). If significant changes in contaminating sources

(e.g. significant known changes in sewage discharge arrangements) have occurred within this period, then only the data obtained since the change(s) should be included in the review.

5.1 Delineation of classified areas

A classified production area is defined by precise geographical limits relative to the coastline and, where necessary, toward the open sea. An area can be classified as preliminary, full classification, short term, seasonal or dormant.

It will constitute an enforceable coherent entity based on consideration of the following:

1. Access
2. Production activity
3. Demarcation of boundaries
4. Hydrological features
5. Characteristics of the circulation of microbiological pollutants.
6. Sampling point locations determined by the sanitary survey

5.2 Classification Types

5.2.1 Preliminary classification

The results of 12 samples taken not closer together than fortnightly should be assessed against the criteria given in the legislation (see **Table 1**) and allowing for any anomalous results excluded under the defined criteria set out in this Code of Practice. This is in keeping with best practice as determined by other reviews of shellfish classification legislation[15]. Please also note that, as outlined in **Section 2.2** of this CoP, a sanitary survey must be completed prior to classification.

5.2.2 Full classification

A full classification established on the basis of results satisfying hygiene requirements as per **Table 1** and sufficient data/sampling as per **Table 2** (above), will normally last at least one year or until the next annual review of classifications. As the standard data requirement for review is for 36 monthly samples over a three-year period, with a minimum requirement of 30 samples in a three-year period for full classification, full classifications' review should not be undertaken if there are less than 12 results available for 3 years or the appropriate proportion of this if the period is less than 3 years. In such a cases insufficient sampling has taken place to meet sampling requirements for a dormant production area and consideration should be given to suspension or downgrading of the classification during the annual review until sufficient additional samples have been taken at the prescribed intervals. Any such consideration of suspension or downgrading will be carried out by the SFPA on a risk basis considering applicable data, in consultation with the MI.

5.2.3 Seasonal Classification

Where there are clear seasonal patterns to contamination demonstrated by sampling results in classified areas as interpretated during the annual review process, seasonal classification may be awarded.

At least 3 years' data showing a clear seasonal trend of *E coli* results is necessary to establish a seasonal classification. Similarly to full classifications, the standard data requirement is 36 monthly samples in a three-year review period. The minimum number of samples required will be 30 samples with monitoring samples taken during all seasons.

It is not possible to award a seasonal classification until at least 30 samples have been submitted full covering the full annual season (i.e. with samples collected in all four seasons in each of the three years of data under review).

The season classified as the least contaminated (better classification) must be preceded and followed by a buffer period. The intended transition must be preceded by 2 months satisfactory sample results

[15] Seafish Publication: Review of the application of the Official Control Regulations for shellfish production as they relate to microbial contamination.

when changing from class C to B and 1 month of satisfactory results when changing from class B to A. (i.e. the historical results during this period must also conform to the better classification category). The minimum period to be considered for a seasonal classification will be three months. In addition to the transition period from one classification to another, the microbiological results obtained from the microbiological monitoring programme for the period under consideration for seasonal classification must be 100% compliant with the higher classification. Additionally, the overall percentage compliance from the three-year dataset for the production area must be > 80% compliance with the higher classification. Reduced frequency (stable area) cannot be applied to production areas with a seasonal classification.

5.2.4 Short-Term Classification for Wild Fisheries

Under the short-term classification approach, shellfish monitoring may be considered for a reduced period of the year for wild fisheries with clear patterns of historical harvesting over short/seasonal durations, or where there are significant issues with obtaining and maintaining a year-round dataset (e.g. relating to sampling vessel access, weather, etc.).

Sampling for short-term classification high-frequency monitoring must commence immediately prior to, and during that given fishing period in order to ensure that the appropriate minimum data set is collected. If there is any possibility that harvesting could take place outside of the normal/traditional season for a classified production area, then monitoring must take place throughout the year and the classification can only be assessed with reference to Full Classification or Seasonal Classification criteria.

In cases where fishing under a short-term classification has been requested, the process outlined below must be followed strictly.

No fishing may commence under a short-term classification without following the process outlined below and following written request to, which has been approved by, the SFPA detailing proposed duration and timing of the fishery. SFPA will only award a short-term classification where all conditions below are met to ensure any increased public health risk is identified.

Where possible, full classification and seasonal classification (or preliminary classification for these standard classification types), are to be preferred to the short-term classification approach in order to minimise any possible risk because of the relatively reduced sampling/monitoring record for short-term classifications.

Please note the below detailed requirements for proposal, approval and subsequent fishing of a short-term classification in a given rolling 12-month period.

Authorisation to fish bivalves under short-term classification arrangements may be approved in order to regularise wild bivalve fisheries where provision of monthly samples throughout the year faces difficulty due to:

- Limited accessibility,
- Seasonal patterns of weather conditions inappropriate for fishing,
- Health and safety,
- A fishery's seasonality/pattern of commercial exploitation and/or
- Other factors that clearly limit sampling opportunities.

Short-term classification is a non-standard approach to classification of shellfish production areas which may be proposed as an alternative to full and seasonal classifications. As a non-standard approach, it is subject to differing sampling controls compared with full and seasonal classifications.

Approval to fish under a short-term classification is on the basis of risk assessment in advance of fishing under a short-term classification in a given 12-month rolling period.

Approval to fish under a short-term classification in previous years does not guarantee approval in subsequent periods and approval will be solely based on updated risk assessment carried out by the SFPA ahead of each proposed fishing period.

1. Bivalve fisheries seeking short-term classification should either have an existing classification (includes dormant, but not unclassified fisheries), or have completed all required steps from the Protocol for Opening a New Fishery for Bivalve Molluscs. Unclassified fisheries must be subject to all steps of this protocol before being eligible to consider for short-term classification.
2. Short-term classification should be for a minimum of one month, and a maximum of three continuous months, per rolling 12-month period. Where fisheries meet the short-term classification definition but have two distinct periods of the year where fishing activity could take place (due to access or market patterns), up to a maximum of two separate one-month periods may be authorised to be fished under short-term classification rules. Any additional request other than the maximum of three continuous months, or two separate (1-month) periods per rolling 12-month period cannot be considered. Any harvesting/fishing beyond two such short-term classification periods per 12-months will require award of a standard full classification or seasonal classification under the annual review process and will be subject to standard sampling plan requirements (i.e. 12, monthly samples per year).
3. The months of any requested fishing must be defined and communicated in advance of any classification and/or approval to sample or fish by the SFPA in a given period. The timing(s) of any short-term classification should be based on a fishery's history of commercial exploitation, where applicable, or on the period where sampling opportunities are maximised for other reasons (weather, etc.).
4. Any request to the SFPA for a fishery to be classified for fishing in a given 12-month period must be submitted by email to the SFPA detailing the intended fishing activity and timing (duration and expected frequency/days fished). The fisher (or their representative) must contact both the SFPA port office which oversees the production area in question and the SFPA Food and Fishery Support Unit (see ***Contact Details*** section, **Appendix II**) to seek approval to start initial sampling prior to fishing.
5. Once approval to start initial sampling is given, prior to SFPA consideration/risk assessment regarding approval of fishing in that year, two microbiological samples must be taken and submitted for analysis, more than 48 hours apart, and no more than 12 days apart. The sampling location (GPS or mobile phone location app) and time should be noted by the fisher when collecting these samples and where possible this will be verified by the SFPA using appropriate means of supervision (VMS, etc.).
6. At this point, the SFPA, in consultation with the Marine Institute where required for scientific advice, will carry out a risk assessment of the proposed fishery before providing feedback to the fisher/representative to allow or not allow fishing to proceed under the short-term classification rules for the requested period. SFPA will endeavour to carry out risk assessment within three working days of receiving the second preliminary sample's analysis result. In cases where further time is required to carry out such risk assessment, this will be communicated to the fisher at the earliest possible point. Risk assessment will be based on:
    a. any historical monitoring results available,
    b. any information provided by the fisher in requesting fishing approval,
    c. results of the initial two preliminary samples,
    d. any identified potential polluting sources
    e. sufficient availability of local SFPA personnel to facilitate supervision of envisaged sampling requirements.
7. If approval is given to commence fishing, the SFPA will provide this approval together with:
    a. that year's short-term classification level (e.g. Short-term A or Short-term B) and
    b. the fishery's sampling plan for that year (developed in consultation with the Marine Institute and the local SFPA Senior Port Officer/Shellfish Sampling Manager).
8. Short-term classification sampling plans will require significantly increased sampling frequency in order to mitigate risk associated with samples not being available for periods of the year when classifications are not fished/sampled. This, in turn, will require increased supervision during the fished/classified period, which is agreed in advance with the local SFPA Senior Port Officer/Shellfish Sampling Manager, prior to issuing the approval to fish or

the sampling plan. This ensures the fisher's local SFPOs' appropriate oversight on all microbiological sample collection.

9. Results of sample analyses relating to short-term classification may be provided to the harvesting fisher by the local SFPA following their receipt by the SFPA in order to allow active management of the fisher's harvesting activity.
10. The sampling plan issued must be strictly adhered to for the duration of the fished period in that year. A failure to adhere to the sampling plan may result in suspension of fishing, and/or a downgrade to the classification.
11. Note the short-term classification will be determine on the basis of the sampling prior to approval to commence fishing.
12. If the SFPA and supporting agencies (FSAI and MI) assess initial sampling results as indicating sufficient risk, permission to fish under a short-term classification may be refused on the basis of these initial sampling results.
13. If authorised in writing by the SFPA to commence fishing, all further samples must be submitted under SFPO supervision during the short-term classification period as per the sampling plan.
14. Due to the reduction in annual numbers of samples, relative to full and seasonal classifications, any out-of-range results obtained during the authorised fishing period, or non-adherence to stated sampling plan requirements will prompt immediate consideration of management action by the SFPA. This is to ensure consumer safety and the integrity of the microbiological monitoring program. Such management action may include:
    a. Temporary suspension of a short-term classified fishery pending further results/evidence indicating it is safe to fish, any such suspension will be under the normal legislative rules[16] for discontinuation of production, as outlined elsewhere in this CoP. Suspension of production will be on a risk basis of ensuring that shellfish are safe to harvest and providing results within the expected range of the short-term classification before harvesting may resume. Given the limited sampling data availability relative to standard classifications, the evidence required to reopen a fishery must provide significant confidence of the safety of harvested LBMs and must be on a clear risk basis, as determined by the SFPA in consultation with supporting agencies.
    b. Downgrading of Short-term A classifications to Short-term B classifications for that calendar year (please note that any such downgrading will be enacted from the date of the downgrading decision going forward, and not retrospective to previously completed fishing during the period) and/or
    c. Instruction to carry out a product recall in order to safeguard consumer safety where deemed required by SFPA personnel authorised to do so under food safety regulation[17]. For further information on product recall please refer to FSAI guidance[18]

15. Note, any decision to suspend or downgrade any such fishery will be on a risk-based basis in consultation between the responsible agencies (FSAI, Marine Institute and SFPA).

Please Note:

Only bivalve fisheries with existing classifications may be considered for a short-term classification. Unclassified fisheries must go through all steps of Protocol for Opening a New Fishery for Bivalve Molluscs before being eligible for consideration for short-term classification. Nothing under this Code of Practice can supersede the rules of this protocol.

[16] Article 62 of EU Regulation 2019/627
[17] As per legal requirements for traceability of food and recall/withdrawal of unsafe food within meaning of Regulation (EC) No. 178/2002 and implementing Regulations as transposed by relevant national food law
[18] FSAI Guidance Note No.10 on Product Recall and Traceability

5.2.5 Dormant Classification

On information supplied by a local SFPO confirming to the SFPA National Shellfish Monitoring Manager that a production area has ceased production for a given classification (i.e. species and production site combination), and that the producer(s) in the area are unlikely to resume production under that classification for at least one year, the National Shellfish Monitoring Manager will update the classification status of the production area to dormant on the published list of classifications on the SFPA website. During dormancy, the microbiological sampling frequency will be reduced to once per quarter to monitor the microbiological contamination of the production area.

A-classified production areas will be reduced to B classification upon being assigned a dormant status. An area that has been downgraded from A classification to B because of dormancy will require a minimum of 12 samples taken not closer together than fortnightly to be eligible for consideration by the implementation team for upgrading to return to A classification at the following annual classification review. Dormant areas which were classified A or B prior to dormancy may return to production at a B classification level following notification to the SFPA and receipt two suitable microbiological sample results (taken not closer than fortnightly and less than 40 days apart) less than the regulatory limit for a B classification (4,600 MPN/100g). Please note that dormant areas must maintain at least quarterly sampling to retain dormant status and should sampling fall below this level areas will be eligible to be considered declassified at the following annual review. In addition, dormant areas will be eligible to be considered for declassification after two years at dormant status. Following two annual reviews where a classification has remained at a dormant status, industry/producers must submit a written request to the SFPA to retain dormant status in the absence of production. Such requests must indicate clear indication of intention to recommence production according to a defined timeline. The requirement for a written request will be notified to producers upon production of the initial draft classification list of production areas for consideration by the Implementation Team under the annual review process.

5.2.6 Classification of Pectinidae

In accordance with legislation[19], data from official monitoring programmes enable the SFPA to classify scallops fished from within existing classified production areas as follows:

- Where the area is specifically classified for scallops, classification is as per the standard rules as outlined above for classification of any bivalve species.
- Where an area is not specifically classified for scallops, scallops harvested within classified production areas are deemed to be B-classified if any other species in that area is classified B.
- Where not specifically classified for scallops, scallops harvested within classified production areas are deemed to be A-classified where all other species classified in the area are A-classified.

5.3 Interpretation of data in a classification area with several monitoring points

Where multiple sampling points RMP are used to represent a single classified area, usually because of the presence of multiple contaminating sources and identification by sanitary survey or local knowledge pollution sources, the results from each point should be assessed on the basis of compliance with the legislative criteria given in **Table 1** and allowing for any anomalous results. The classification for the area should be based on the least sanitary interpretation from all monitoring points (i.e. the most contaminated) as per guidance[20]. All assigned RMPs will be considered in combination when reviewing classification data in order to provide as comprehensive a picture of the classified area as feasible.

[19] Annex III Section VII Chapter IX, Regulation (EC) 853/2004
[20] Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004

5.4 Responding to out-of-range *E. coli* results from the monitoring programme.

When *E. coli* results above the upper limit for the classification of the area are obtained, immediate action should be taken. SFPA FFSU will initiate an SFPA Shellsan Elevated Micro Result Report Form (**Appendix III**). send it to the SFPO who collected the sample in question and to the port office where that SFPO is based. The sampling officer will immediately inform all producers in that classified area of the out-of-range result with a request for them to provide feedback on potential cause within one week of receipt. In addition, this information is to be communicated to BIM representative(s) in order to allow any follow-up investigation on the potential cause they may require. To this end, the local SFPA port office will maintain a mailing list of harvesters in each production area. Note that, outside of this elevated result notification process, sampling data is sent to producers/representatives each month and they are obliged to make themselves aware of results in these data, and any required action resulting from them.

Where such out-of-range results originate from an A-classified production area, the SFPO will advise that out-of-range A classification product cannot be placed directly on the market for human consumption[21]. However, subject to a risk assessment and only on a temporary and non-recurring basis, such product may be placed on the market if subjected to additional treatment consistent with the *E. coli* levels detected i.e. purification in an approved purification centre or heat treatment by an approved process[22]. It should be noted that the accompanying Shellfish Registration Document, as referred to in Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, shall record the requirement of the additional measures required, i.e. purification or heat treatment as per legislation[23].

Where any such out of range results originate from an A-classified production area, and the producers in the area are harvesting or intending to harvest, harvesting operations should cease until a follow up sample taken by the SFPA indicates that the *E. coli* levels are within range for that classification. As noted in **Section 3.4.1** of this CoP (*Follow-up sampling*), follow-up samples after an elevated result are considered a food safety measure to ensure the safety of subsequently harvested product. Data from such samples may only be included for consideration as part of a classified production area's classification monitoring dataset if follow-up sampling is at least two weeks (14 days) following an elevated result to ensure statistical independence from the initial sample (as per guidance[24]). Any such datapoints will be removed from consideration regarding the classification level awarded, while not being removed from the overall dataset.

Additional food safety measures may be required following receipt of elevated *E. coli* not meeting legislative requirements, which may include requirement for increased end product testing. The SFPA will liaise with the harvesters on such additional measures to ensure mitigation of any potential risk to public health. As per legislation[25], where the results of microbiological monitoring show that the health standards for live bivalve molluscs are not met, competent authorities may, on the basis of a risk assessment, and only on a temporary and non-recurring basis, permit continued harvesting without closure or reclassification subject to the following conditions:

(a) the classified production area concerned and all approved establishments receiving live bivalve molluscs from it are under the official control of the same competent authorities;
(b) the live bivalve molluscs concerned are subjected to appropriate restrictive measures such as purification, relaying or processing.

Where a second sample has been submitted as a follow-up sample following an elevated result the results will not be used for the purposes of the classification program unless taken more than 14 days after the initial sample date (see section **3.4.1 Follow-up sampling**). Please see overview of decision tree for responding to out-of-range results provided in **Appendix IV**.

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[21] Article 62(2) EU Regulation 2019/627
[22] Article 62(2) EU Regulation 2019/627
[23] Article 62(2) EU Regulation 2019/627
[24] Section 3.3.1 of: Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004
[25] Article 2(2) of Regulation 2019/627

In addition, where the levels exceed those as indicated in **Table 3** below, an alert status is triggered. In such cases, in addition to the procedures outlined for responding to out-of-range *E. coli* results, specific investigations should focus on establishing whether there is an additional risk to public health. Where significant risks are identified additional controls such as the implementation of closure orders or extended voluntary closures will be considered on a case-by-case basis.

Table 3. Alert Status E. coli result levels

Classification	Alert Status Result
A	> 700 *E. coli* MPN/ 100g
B	> 18,000 *E. coli* MPN/100g
C	> 46,000 *E. coli* MPN/100g

In all cases where alert status results (as per **Table 3**) are received the appropriate SFPO in conjunction with the producer must contact all harvesters in the classified area covered by the sampling point to investigate the likely cause of the elevated micro result.

In order to maximise understanding of circumstances leading to any such result/event, investigations should include (at a minimum) contact being made with the following key organisations:

- Uisce Éireann,
- Local Authorities,
- Environmental Protection Agency,
- BIM and
- IFA.

The nature and extent of the investigation will vary on a case-by-case basis, as will the time required, but the SFPA will endeavour to complete this process as quickly as is possible and the following points should always be considered.

Investigations of Alert Status *E. coli* results should include:

1. Contacting sewage treatment works in the areas to ascertain if any sewage spills may have occurred, in the case of public water treatment Irish Water to be contacted, with private supplies this may be the Environment office of the relevant local County council.
2. Reviewing rainfall in the six-day period preceding the high result for the Met Éireann weather station nearest to the sampling point in order to allow the maximum 24-hour rainfall level to be reviewed in the context of 5-year return rainfall levels (as outlined in the next **Section 5.5**, *Criteria for Discarding Results from the Classification Process*).
3. Changes in agricultural practices (e.g. slurry spreading)
4. Any other exceptional activities (e.g. harbour dredging)
5. Industry view on any causes, ensuring that all producers in a classified area are informed as well as the local BIM representative(s). It should be indicated to industry at this point that they have the option to provide a written submission to the SFPA in relation to their view on the cause of any such result, for consideration under the Annual Review of Classifications process. Such submissions are ideally made within 3 months of the elevated sample result, in order to allow for timely investigation of any proposed cause. This allows the subsequent consideration of findings following the issuance of the draft list of classifications under the annual review of classifications process. Where industry comments on possible causes are made at the time they may trigger further investigation.

5.5 Criteria for Discarding Results from the Classification Process

A result may potentially be identified as anomalous and excluded from the classification dataset (as per legislation[26] and EU best practice guidance[27]) if deemed that it has, or may have, significantly impacted on the microbiological status of the harvesting area and where it demonstrably meets one or more of the below, numbered criteria. Where industry members, or their representative bodies, feel that based on the available evidence a result should be discarded from the classification process they may make a written submission to make a case under one of the numbered criteria below. Results determined to be anomalous by SFPA may be discarded upon determination outside of the annual review process. However, please note that results submitted for scrutiny by industry members may only be discarded as having been determined to be anomalous by agreement within the Annual Review Implementation Meeting (see **Section 5.7**, *Classification Review Procedures*, below):

1. Evidenced failure to comply with agreed sampling or accredited laboratory protocols[28].
2. Evidenced failure of a sewage treatment system resulting in a Category 2 Incident (or worse) under the EPA incident classification scheme, where this incident has been rectified and where the authority responsible for controlling pollution identifies that such a failure is not expected to reoccur.
3. An extreme rainfall event during the six days prior to sampling evidenced as having a return period of 5 years or greater (i.e. documented level of total rainfall in a 24-hour period which is only likely to occur once every five years or longer at the point of sampling). Such a rainfall event must be verified on a case-by-case basis according to the specific sampling location coordinates with reference to Met Eireann's rainfall returns period calculation service at: https://www.met.ie/climate/services. Note that each such 5-year return calculation is arrived at for the coordinates of a given sampling location based on extrapolation from actual rainfall data available on Met Éireann records from existing weather stations.
4. An evidenced, clearly-identified, one-off pollution event that is unlikely to recur and considered to be likely to have impacted the result.

Please note that the Marine Institute will query the accuracy of a laboratory result with the laboratory in question should industry request this. In addition, please note that under their accreditation, laboratories will not report any result if there is a breach in protocols.

5.6 Closure of areas around outfalls, harbours and marinas

Under the sanitary survey process, where a given area is indicated to be of a higher risk, there may be amendments made to the existing classified production boundaries to exclude active harbours and marinas from the production area (refer to BMPA decision making process under **Section 2.2**, *Sanitary Survey*, of this Code of Practice). Where it is intended to harvest areas from within active harbours and/or marinas and this comes to light following the classification and sanitary survey process an assessment of the likely risk should be undertaken to establish their suitability for use. Where considered necessary an exclusion zone for harvesting may be placed around the point of such inputs. The extent of any such exclusion zone will be decided on a case-by-case basis, giving due consideration to sanitary survey findings, and considering all relevant information including the size of the input and expected extent of the impact of the discharge in the area.

As per guidance where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the harvesting of live bivalve molluscs. The competent authority may re-open a closed production area only if the health standards for molluscs once again comply with Community legislation.

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[26] Article 53, Commission Implementing Regulation (EU) 2019/627
[27] Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004
[28] EN/ISO 16649-3 accredited for detection of *E. coli*.

5.7 Classification review procedures

The status of all classified areas will be reviewed annually. Classifications will normally last for a period of one year and, where the data show clear seasonal or other applicable patterns of *E coli* results, the appropriate classification will be determined as per the classification types outlined in **Sections 5.2**, above.

Proposals for each draft classification will be developed by the SFPA supported by the Marine Institute based on initial interpretation of the classification data available within the previous three-year review period. Draft classifications will be circulated for review along with the applicable, three-year dataset, to a sub-committee of the MSSC comprising the SFPA, FSAI, MI, IFA, BIM and industry representatives. The sub-committee will consider the proposals made and give its recommendations on them to the SFPA. This process includes scope for written submissions made by industry and industry representatives including proposals for amendments to draft classifications as well as for datapoint removal based on the CoP-defined criteria for doing so (see **Section 5.5**). Following closing of the written consultation period, the Implementation Meeting (made up of the described sub-committee of the MSSC as well as interested industry members) will convene to assess all submissions. The meeting will provide a platform for those proposing changes to draft classifications or datapoints. After considering these recommendations, the meeting chair (SFPA) aim to find consensus before assigning a classification category in each instance. Following dissemination of the draft Implementation Meeting minutes to all attendees, and their subsequent acceptance, a revised classification list will be generated. This will go to the SFPA Management Board for approval, and subsequently to the SFPA Authority for their approval. At this point, the SFPA-approved classification list will be published to the SFPA.ie website. Notice of the updated list's publication will be given in the national and marine sector press and on the SFPA website[29].

As part of the annual classification review and sanitary survey processes, maps of production areas and their associated sampling locations will be reviewed and amended as necessary to ensure that the sampling locations are fully representative of the likely pollution sources entering the area. Where maps are newly created or updated this will be communicated to relevant stakeholders and published on the SFPA website[30].

Please see **Figure 2** (below) which summarises all key steps of the classification review processes.

[29] Shellfish Classified Areas | Sea Fisheries Protection Authority
[30] Shellfish Classified Areas | Sea Fisheries Protection Authority

Figure 2. Classification Annual Review Detailed Process Steps

Communication

6.1 Dissemination of Results

The National Shellfish Monitoring Manager will communicate the results of the microbiological monitoring of bivalve mollusc production areas programme on a monthly basis to all MSSC stake holders namely FSAI, MI, IFA Aquaculture, BIM, HSE, Uisce Eireann (UE), EPA LA, other interested stakeholders maybe added from time to time. Results of sampling are considered public record and available to anyone who requests them or signs up for the monthly sampling mailing list by contacting the SFPAfoodandfisheriessupport@sfpa.ie.

6.2 Storage and Validation of Data

Data relating to the monitoring programme is stored in a database form. The following information is held:

1. Sampling plan information
2. Sample information
3. Results
4. Sanitary survey reports/results
5. Information on recorded pollution events
6. Results of investigations of pollution events
7. Anomalous *E. coli* results (as defined in **Section 5.5** *Criteria for discarding results from the classification process* of this CoP)
8. Results of sampling are considered public record and available to anyone who requests them or signs up for the monthly sampling mailing list by contacting the SFPAfoodandfisheriessupport@sfpa.ie.

6.3 Publication of the List of Classified Shellfish Production Areas

The current list of Classified Live Bivalve Mollusc Production Areas in Ireland is available on the SFPA website[31]. This list is updated annually following the Annual Review of Classifications processes, following consultation with required stakeholders through the Annual Review Implementation Meeting, approval by the SFPA Management Board and subsequent approval by the SFPA Authority. Change of classification to dormant status, following industry communication with SFPA personnel, will be updated within three working days on the list of Classified Shellfish Production Areas, and will be carried out independently of the annual review process to ensure that the list is representative of such areas' statuses.

6.4 Monthly Summary of Microbiological Results

The National Shellfish Monitoring Manager will communicate the results of the microbiological monitoring of bivalve mollusc production areas programme on a monthly basis to all MSSC stakeholders FSAI, MI, IFA Aquaculture, BIM, HSE, EPA, Local Authority representatives, LAWPRO Group, industry members and others. Anyone who submits an email request to the National Shellfish Monitoring Manager to be included on the monthly results mailing list will receive such updates as results of sampling are considered public record and available to anyone who requests them or signs up for the monthly sampling mailing list by contacting the SFPAfoodandfisheriessupport@sfpa.ie.

[31] Shellfish Classified Areas | Sea Fisheries Protection Authority

6.5 Publication of maps of Classified Shellfish Production Areas

All maps will be published on the SFPA website linked to the applicable section of the Shellfish Classified Production Areas list[32], and will be subject to periodic review in the context to changes to production areas or sampling points. At a minimum, mapping for a classified production area will be updated following sanitary surveying of that area.

Risk Management

7.1 Risk Management Principles

Section 5.9, *Responding to out-of-range E. coli results from the monitoring programme*, and the documentation provided at **Appendices III** and **IV** provide the details of how situations involving instances of the *E. coli* standard being exceeded will be monitored and managed in the context of the monitoring programme.

In managing any such situation, the overriding concern will be public health/consumer protection. Consideration will also be given to the sustainable, long-term development of the shellfish industry when decisions are made.

7.2 Management Cell

Where elevated *E. coli* results are detected that are sufficient to cause an "alert status" to be declared (see **Section 5.4 Responding to out-of-range *E. coli* results from the monitoring programme**), a Management Cell may be called (generally online) to direct the investigation and any associated follow up.

If convened, the Management Cell (consisting of the SFPA, Marine Institute, FSAI and IFA Aquaculture) will consult on the available information prior to reaching a decision. Decisions will be by consensus. Where it is apparent that consensus cannot be reached, then the view of the SFPA will prevail. The immediate objective of any Management Cell will be to minimise the risk presented to consumers by any shellfish associated with an alert status. To that end, production may be suspended and / or product recalls and withdrawals initiated. The FSAI Guidance[33] should be consulted where product has been harvested. The Management Cell may also request that additional samples are taken in addition to the *E. coli* monitoring scope of this CoP.

[32] Shellfish Classified Areas | Sea Fisheries Protection Authority
[33] Guidance Note 10 Product Recall and Traceability | Food Safety Authority of Ireland

APPENDICES

Appendix I: Sanitary Survey Standardised Report Format

The following sets out the outline requirements for the written harvesting area sanitary survey report; however, the order in which the report is written may vary.

1) Description of the production area
2) Overview of the BMPA or Fishery
3) BMPA or Fishery
4) Location and extent
5) Bivalve species
6) Aquaculture or wild stocks
7) Production area or relay area
8) Seasonality of harvest
9) Harvesting techniques
10) Any conservation controls on fishery
11) Location, size and treatment level of human sources of contamination
12) Location and estimated volume/load of agricultural sources of contamination
13) Significant wild animal/bird populations
14) Land usage
15) Maps, seasonality effects, for these factors
16) Records of shoreline surveys
17) Hydrographic/hydrodynamics of the area
18) Records of bacteriological survey results
19) Assessment of effect of all of the above on contamination of shellfish
20) A recommendation on the extent of the production area (Delineation of BMPA Boundaries)
21) Specific considerations relating to impacting pollutant sources.
22) Species specific sampling plans including RMP location(s)

Appendix II: Guidance Note – Collection and Transport of Shellfish Samples for *E. coli* Testing

Purpose of this document

The purpose of this Guidance Note is to provide guidance to Sea Fisheries Protection Officer's (SFPO) on the collection and transportation of samples to laboratories for E-coli testing.

General

Glossary of Terms

Below is a glossary of terms and acronyms used in this document.

Terms / Acronyms	Description
SFPA	Sea Fisheries Protection Authority
GN	Guidance Note

Relevant Legislation/ Documents

The following legislation is of particular relevance to this Guidance Note:

- EU Regulation 2019/624
- EU Regulation 2019/627

Confidentiality and Data Protection

With regards to information obtained in the performance of their duties, SFPA personnel are subject to confidentiality obligations laid down in section 58 of the Sea-Fisheries and Maritime Jurisdiction Act 2006 and shall have regard to SFPA's Data Protection Policy and to the obligations of SFPA with respect to the processing of personal data as set out in Data Protection Legislation and GDPR.

Guidance

Introduction

All shellfish harvesting areas must be classified according to EU regulations 627/2019. In order to undertake classification, samples of shellfish are required for *E. coli* analysis. Samples should be collected according to individual sampling plans for each harvest area. Sampling officers will normally be Sea Fishery Protection Officers (SFPO) but may include additional sampling officers authorised by the Sea-Fisheries Protection Authority (SFPA). This protocol sets out requirements for collection of samples which must be followed by all authorised samplers.

Responsibility

- It is the responsibility of the SFPA to make arrangements for the collection of samples for *E. coli* testing.
- It is the responsibility of all designated sampling officers to comply with this SOP. Sampling officers must notify the SFPA SPO/Shellfish Sampling Manager and National Shellfish Monitoring Manager immediately where it is not possible to do so or where they experience problems.
  It is the responsibility of the Marine Institute to ensure testing laboratories adhere to appropriate parts of this GN.

Safety

Determine the appropriate health and safety procedures and ensure necessary arrangements are in place in advance of sampling.

Procedure

The following Equipment will be supplied to all sampling officers

- Shellfish sampling plan
- Suitable protective clothing / equipment
- Thermometer
- Handheld GPS (or mobile phone location app)
- Sample advice notes
- Gloves
- Cool boxes and chill packs
- Heavy duty plastic sample bags and ties
- Clippers for opening oyster bags
- Waterproof marker pen
- Spade, trowel or rake where appropriate

Sampling Points

- All sampling points are at fixed geographical locations and are listed in the shellfish sampling plans established for individual harvesting areas.
- Samples must be collected within 100 metres of the fixed location for hand-picked or raked samples.
- Samples must be collected within 250 metres of the fixed location for dredged samples.
- Where it is not possible to collect samples within these limits the local SFPA the Senior Port Officer/Shellfish Sampling Manager (or SFPO with responsibility as Shellfish Sampling Manager in the area), Food and Fisheries Support Unit (FFSU) and local industry must be informed and alternative sampling locations agreed.
- When a sample is taken outside of these limits the co-ordinates of the actual sampling point shall be taken and notified to the local SFPA SPO/Shellfish Sampling Manager and National Shellfish Monitoring Manager (see Contact details section below).
- Where amendments to sampling points are required on local SFPA knowledge of the production area and specific sampling requirements (e.g. health and safety, changes to the layout of the local production site etc.), a review of the designated sampling points and the associated classified production area mapping may be necessary.
- In all such cases, the local SFPA SPO, relevant industry representatives and the Food and Fisheries Support Unit (FFSU) must be provided with the new location coordinates along with a clear rationale for the proposed change(s) to the sampling point(s).
- If the justification is not deemed sufficient by either the local SFPA SPO/Shellfish Sampling Manager or the National Shellfish Monitoring Manager further review of the proposed sampling point(s) may be required.
- All sampling points have been given a unique reference code. The reference code is identified in the sampling plan for the shellfish area. This reference code should be used at all times to identify the sampling location.
- Changes to sampling locations must be agreed with the SFPA National Shellfish Monitoring Manager in order for the sampling plan to be updated.
- Where sampling points are only accessed by boat, and health and safety prevent SFPOs from being on board to verify the exact sampling location, alternative verifications methods may be employed. In such cases, SFPOs may use a GPS device (including the use of GPS enabled mobile phones) to confirm the sampling location. A GPS device can be provided to operational staff to place on the vessel during sampling, allowing verification that the correct coordinates have been reached.
- A visual inspection of the vessel may be carried out prior to sampling to confirm that no other live bivalve mollusc (LBM) samples are present. This verification should be conducted in addition to any shore-based monitoring activities by SFPOs, such as observing using binoculars.

Sample Size

The following minimum quantities of shellfish must be taken from each sampling location to constitute an individual sample.

Shellfish Species		Minimum Number	Minimum Shellfish Size
Native Oysters	*Ostrea edulis*	10	7.5 cms
Pacific Oysters	*Magallana gigas*	10	8 cms

Mussels	*Mytilus edulis*	15	4 cms
Cockles	*Cerastoderma* spp.	30	3 cms
King Scallops	*Pecten maximus*	15	10 cms
Manila Clams	*Tapes semidecussatus*	30	4 cms
Pallourdes	*Tapes decussatus*	30	4 cms
Razor Clams	*Ensis* spp.	10	10 ms

- For other species contact the local SFPA SFPO or SPO and National Shellfish Monitoring Manager to discuss requirements for sample size.
- If problems are encountered in obtaining the minimum shellfish numbers from a particular sampling location contact the local SFPA SFPO or SPO and National Shellfish Monitoring Manager to consider moving the sampling location.

Sampling Frequency

- The sampling frequency for each sample location is recorded in the sampling plan for the shellfish area.
- If planned samples are missed the SFPA sample manager should be informed and alternative arrangements for sampling considered.
- Additional samples may be required following high *E. coli* results. The National Shellfish Monitoring Manager will advise of such occasions.

Sample Collection

- Shellfish samples should be collected by dredging, hand-picking raking or other suitable means which is representative of the usual harvest process wherever possible.
- Once the minimum numbers of shellfish have been collected, as much mud and debris as easily possible should be removed by rinsing with seawater. Shellfish must not be completely re-immersed in water at any time between sampling and testing.
- Shellfish should be placed into heavy duty sample bags which prevent leakage.
- The samples must be clearly marked with the sample location name, sampler name, sample point reference code, sampling date, air temperature and sampling time using waterproof markers. This information must be recorded on the samples at the time of sampling.
- The bag should be securely sealed using a tie to prevent possible cross –contamination with other samples.

- Samplers must fully complete an SFPA Shellfish Sample Advice Note and place in a waterproof document wallet accompanying the sample.
- Samplers must place samples in a suitable chilled/refrigerated container or cooler box containing chill packs irrespective of the expected time to delivery at the laboratory destination. Shellfish samples must not be frozen and should not come into direct contact with the chill packs.

Sampling from Wild Fisheries

In general, it is desirable for official samples to be taken by SFPOs. This may not always be practical in the case of wild fisheries conducted by vessels at sea, with particular regard to health and safety issues. It is therefore not specifically required in those instances that official sampling personnel go to sea in order to perform the actual sampling. In such circumstances, samples may be taken by arrangement from the fishing vessel on landing. When collecting the sample from the vessel, coordinates of the actual point from where the sample were fished should be obtained. Sampling officers should take any additional steps available to confirm that vessels are fishing in the areas indicated. Vessels collecting razor samples should be instructed not to de-grit samples while they are held aboard the vessel.

Sample Storage and Transport

- Shellfish samples must be transported to the testing laboratory within 48 hours of sampling. Samples received after this time may not be tested or if tested the results may not be used in the classification programme.
- During transport samples must be maintained below 15ºC. Testing laboratories will record the temperature of the sample on receipt. Samples received above 15ºC may not be tested or the results may not be used in the classification programme. If samples are transported to the laboratory within 4 hours the temperature on receipt in the laboratory does not have to be below 15ºC, however please note that best practice is to store all samples in appropriately insulated containers with cool packs irrespective of expected transport duration.
- On receipt in the laboratory samples must be accompanied with a fully completed sample advice note. This sample advice note should be checked against sample labelling requirements outlined in Section 2.8 (above).
- Only test laboratories contracted by the Marine Institute may be used for analysing samples for classification monitoring. Contact details can be obtained from the Marine Institute.

Contact details

SFPA Headquarters	**Marine Institute**	**FSAI**
Food and Fisheries Support Unit,	Bill Doré	David Lyons,

Sea Fisheries Protection Authority, National Seafood Centre Block B, Clogheen Clonakilty Co. Cork Tel: 023 8859300 Email: sfpafood&fisheriessupport@sfpa.ie	Microbiology Marine Institute Rinville Oranmore Co. Galway Tel. 091 387224 Email: bill.dore@marine.ie	Contracts Manager Food Safety Authority of Ireland Abbey Court Abbey Street Dublin 1 Tel: 01 8171300 Fax: 01 81713 Email: dlyons@fsai.ie

Appendix III: Shellsan Elevated Micro Result Report Form

Date:

Part I (Initial Investigation)

Production Area: _____ Bed Name: _____ Micro Code: _____

Classification: _____ Micro result: _____ Result Date: _____

*Alert Status? Y/N

Immediate Action

Name(s) of Producer(s) informed?

_____

Date informed: _____Method of communication: _____

Harvesting? Y/N _____

Risk to public health? Y/N_____

(If risk to public health detail action taken by FBO and local SFPO)

_____

_____

Follow Up action required?

_____

AN t-ÚDARÁS UM CHOSAINT IASCAIGH MHARA | SEA-FISHERIES PROTECTION AUTHORITY

Investigation of Routine Elevated Results

Heavy Rainfall >24 Hrs Prior to sampling? _____Extreme Met event > than 5 yr return period ? Y/N _____

Industry View on cause? _____ (Additional notes in comment box below)

Recent Changes in Agricultural Practice e.g. Slurry Spreading? _____

Exceptional Activities identified in the area prior to Sampling? e.g. Dredging, Construction, Road works, Drainage works, Renovation of Quay Walls?

_____

Part II (Additional Investigation of Alert Status Results)

* **Alert Status Results**

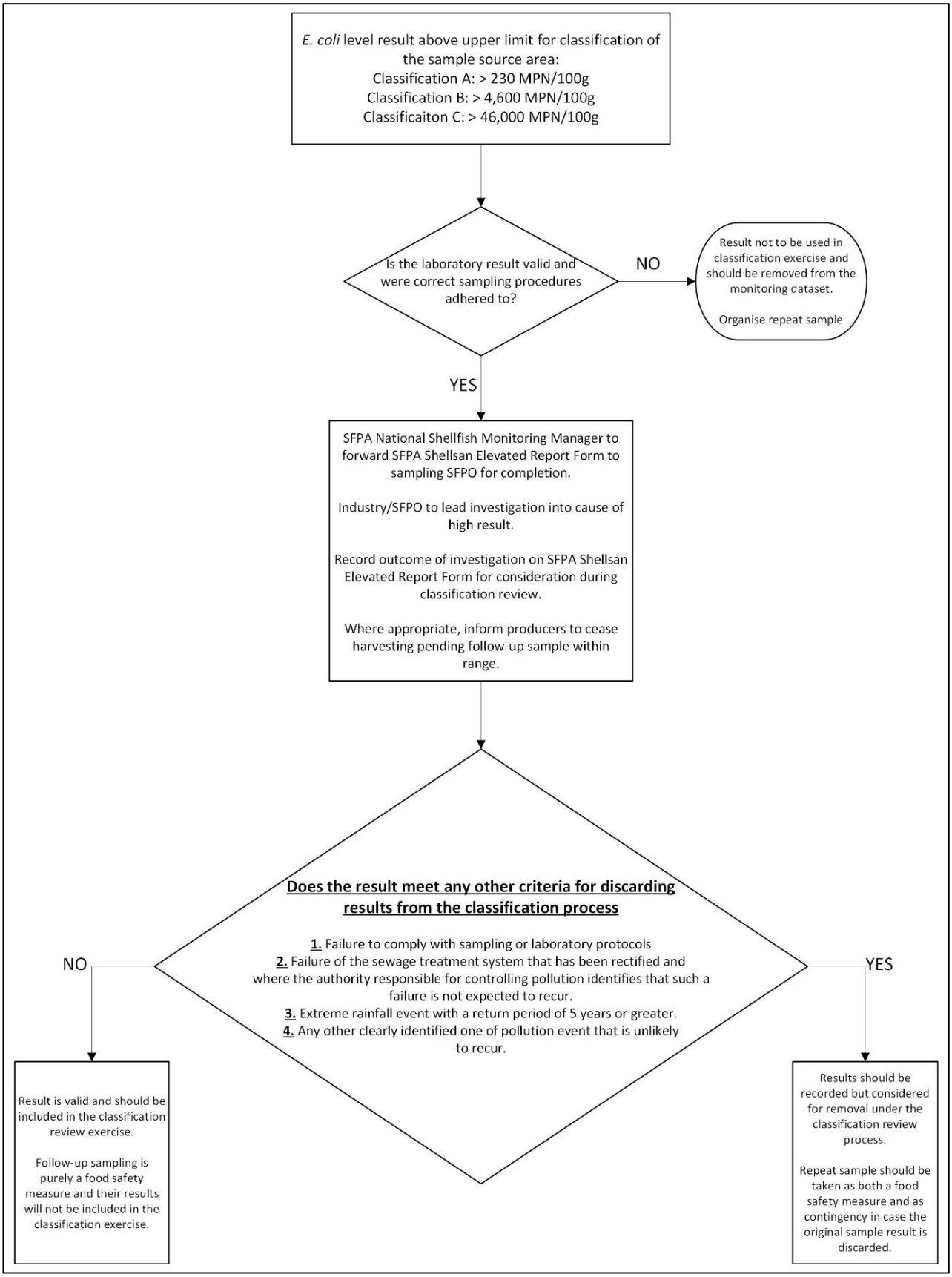
Class A ≤ 700 *E. coli*/100g Class B > 18000 *E. coli*/100g Class C > 46,000 *E. coli* /100g

Contact local sewage works/local authorities, details of any sewage spills or storm releases? Was the event Category 2 or more? Category 2 incident under EPA classification scheme for incidents.

Additional Comments or Follow up Actions.

Signed: _____**SFPO** **Date returned:** _____

Appendix IV: Decision Tree for Elevated *E. coli* Results



Appendix V: Sampling Plan Record Standardised template/form

Species	
Production Area / Site name	
Sample point identifier (format XX-XX-XX)	
Geographical location of sample point (X & Y decimal degrees)	
Sampling frequency	
Sampling depth (where appropriate)	
Max. allowable distance from designated sampling point (metres)	
Sampling method	
Sample size (if species other than identified in CoP sample size guidance)	
Authorised samplers (if other than SFPOs)	

Glossary of Terms

Below is a glossary of terms and acronyms used in this document.

Term / Acronyms	Description
Aquaculture	Aquaculture, with respect to this Code of Practice, is the raising of bivalve molluscs from the juvenile state in controlled conditions.
Bacteriological Survey	Short-term monitoring undertaken in order to help identify the position(s) for representative sampling point(s) for the classification monitoring programme. This is usually undertaken at a larger number of points than will be used in the ongoing programme.
Bivalve Mollusc	Any marine or freshwater mollusc of the class *Pelecypoda* (formerly *Bivalvia* or *Lamellibranchia)*, having a laterally compressed body, a shell consisting of two hinged valves, and gills for respiration. The group includes clams, cockles, oysters and mussels. In the context of the requirements of European food hygiene legislation, the term also covers echinoderms, tunicates and marine gastropods.
BIM	Bord Iascaigh Mhara (Ireland's Seafood Development Agency)
BMPA	Bivalve Mollusc Production Area – also known as classified production area.
BWG	Bivalve Working Group. The BWG was established in 2017 to co-ordinate the identification and prioritisation of areas where new fisheries for bivalve molluscan shellfish, such as cockles, clams, razor clams, etc. could be developed.
CLAMS	The Co-ordinated Local Aquaculture Management Systems (CLAMS) process is a nationwide initiative to manage the development of aquaculture in bays and inshore waters throughout Ireland at a local level.
Classification of Bivalve Mollusc Harvesting Areas	A system for grading harvesting areas based on levels of bacterial indicator organisms (*E. coli* in shellfish within the EU).
Clean Seawater	Clean seawater' means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food.
Combined Sewer Overflow	A system for allowing the discharge of sewage (usually dilute crude) from a sewer system following heavy rainfall. This diverts high flows away from the sewers or treatment works further down the sewerage system and thus avoids overloading of works and flooding of properties, etc.
Competent Authority (CA)	Means the central Authority for the organisation of official controls. The Sea-Fisheries Protection Authority is the Competent Authority for the purposes of Food Safety Legislation in the Irish Seafood Sector.
Conditioning	Conditioning means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.
COP	Code of Practice

DAFM	Department of Agriculture Food and Marine
Dispatch Centre	'Dispatch centre' means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.
Dormant Classified Production Area	Classified production area has been dormant, i.e. not expected to be harvested from or subject to active aquaculture for at least 12 months, and limited monitoring data are available. Dormant sites are monitored at reduced frequency of quarterly sampling. Sites that are dormant, but do not submit the minimum 12 samples in a 3-year classification review period may have their classification lapse, subject to SFPA consideration of the most recent five-year monitoring dataset. Producers should contact their local SFPA office if Re-activating in order that monthly classification monitoring sampling may resume.
Dry Weather Flow (DWF)	The Dry Weather Flow (DWF) is the average daily flow to a wastewater treatment works (WWTW) during a period without rain[34].
Enteric Viruses	A group of unrelated viruses that have the common characteristic of being transmitted via the faecal-oral route. The group included norovirus and hepatitis A virus.
Escherichia coli (E. coli)	A species of bacteria that is a member of the faecal coliform group. It is more specifically associated with the intestines of warm-blooded animals and birds than other members of the faecal coliform group and is used as an indicator of faecal contamination.
FFSU	SFPA's Food and Fisheries Support Unit
Flesh and Intervalvular Fluid	The muscles and organs of a bivalve mollusc, together with the liquid contained within the shells when the animal is tightly closed out of the water.
FSAI	Food Safety Authority of Ireland
Full Classification	Microbiological classification of a classified live bivalve production area based on results from an extensive number of sampling occasions to ensure that potential seasonal and annual variability has been fully covered.
Geographical Information System (GIS)	A computer-based system that combines mapping and data storage functions in order to manipulate, analyse, display and interpret spatially-referenced data.
GN	Guidance Note
Harvesting area	The term harvesting area is used in this Code of Practice to cover both Production and Relay Areas.
Hydrodynamic Models	In the context of this Code of Practice, numerical models that approximate flow of seawater, i.e. velocities and water depths as functions of time and space. Output from these models can then be used together with a representation of diffusion processes in the water column to represent the fate and dispersion of bacteria.
IFA Aquaculture	Irish Farmers Association Aquaculture Sector
IMG	Inshore Management Group. A cross-agency group chaired by DAFM that considers the management of small-scale fisheries inside 6nm

[34] Calculating dry weather flow (DWF) at wastewater treatment works - GOV.UK

Implementation Team	The team that reviews the classifications of shellfish classified production areas whose members are selected from FSAI, SFPA, IFA Aquaculture, BIM and MI chaired by SFPA
LA	Local Authority
LBM	Live Bivalve Mollusc
Log-Normal Distribution	A log-normal distribution is one in which the logarithms of the values have a normal (bell-shaped) distribution. Environmental monitoring data for many bacteria follow a log-normal distribution.
Loughs Agency	The Loughs Agency is a cross-border body, exercising a statutory remit for conservation, protection and development across the catchment areas of Lough Foyle and Carlingford Lough.
LTA (Rainfall)	Long Term Average rainfall. The percentage of normal rainfall for a fixed reference period of twenty years on a whole year basis.
MI	Marine Institute
MPN	Most Probable Number.
NGR	National Grid Reference – mapping term meaning location coordinate according to a national scheme of coding (e.g. Irish NGR).
NIFF	The National Industry Fisheries Forum - national industry representative forum for small scale fisheries inside 6 nautical miles.
Norovirus	Noroviruses are small, 27 to 32nm, structured RNA viruses, which have been implicated as the most common cause of nonbacterial gastroenteritis outbreaks. (They were formerly called Small Round Structured Viruses (SRSVs) and Norwalk-like viruses (NLVs)). It is transmitted via the faecal-oral route.
Preliminary Classification	A provisional classification based on results from a limited number of sampling occasions. This is a temporary classification and areas would expect to move to a non-preliminary classification under the first annual review of classifications after preliminary classification is obtained.
Production area	Any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for their cultivation, from which live bivalve molluscs are harvested (collected or fished).
Recommendation	Documented statement identifying good practice, which may not be compulsory under the legislation but may form part of mandatory national policy.
Relay area	Any classified sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs. Note, there are no relaying areas currently allowed to operate in Ireland's jurisdiction.
Relaying	'Relaying' means the transfer of shellfish from restricted areas to areas approved for natural biological cleansing using the marine environment as a treatment system. Note relaying is not currently authorised at any location in the Republic of Ireland.
Remote area	An area such as an offshore site that is not normally subject to impact from any human or animal sources of faecal pollution and where monitoring data is stable.

Representative Monitoring point (RMP)	A specified geographical location from which samples are taken to represent either a single or several, wild bivalve mollusc beds or aquaculture sites. The representative monitoring point should reflect the location at highest risk of faecal pollution within a classified production area.
RIFFs	Regional Inshore Fisheries Forums. The regional industry representative forums for small scale fisheries inside 6 nautical miles, representatives from which make up the NIFF (see above).
Sanitary survey	An evaluation of the sources of faecal contamination in or near a harvesting area together with an assessment of the potential impact of these sources on the microbial status of the harvesting area
Seasonal Classification	The classification of a production / harvesting area which allows for variation in the classification status of that area over a twelve-month calendar-year period.
Sewage	A liquid that is or has been in a sewer. It consists of waterborne waste from domestic, trade and industrial sources together with rainfall from subsoil and surface water.
Sewage Treatment Works (STW)	Facility for treating the wastewater from domestic and trade premises.
Sewer	A pipe for the transport of sewage.
Shellfish Monitoring Manager	The SFPA representative with national responsibility for overseeing the operation of the sampling in the Irish Shellfish Monitoring Programmes (Microbiological and Biotoxin).
Shellfish Registration Document (SRD)	Legally required traceability document to accompany each batch of shellfish from Harvesting to Dispatch centre or processing plant (also referred to sometimes as “Shellfish Gatherers Documents”.
Short-term Classification	Short-term classification is a non-standard approach to classification of fished shellfish production areas for wild bivalves where sampling opportunities are limited at certain times of year (due to weather, health and safety etc.) and which, as a result, may have certain patterns of commercial exploitation.
SFPA	Sea-Fisheries Protection Authority
SFPO	Sea-Fisheries Protection Officer
Shoreline Survey	A physical survey of the shoreline and area adjacent to the shore to confirm the presence of potentially contaminating sources identified through a desk-based study and to identify additional potential sources of contamination. A component of a sanitary survey for a shellfish production area.
SOP	Standard Operating Procedure
Stable Classification	An area is considered to have a stable classification status when no results for 100g of shellfish flesh and intravalvular fluid exceed the applicable classification limits in the previous three years (i.e., for Class A no result exceeding 230 MPN/100g and for Class B no result over 700 MPN/100g). In addition, in order to qualify as a stable classification the site must have been subject to a sanitary survey confirming the location of the representative monitoring point(s).

Further Information Sources

- Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins)
- Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Implementing Regulation 2019/627
- FSAI Guidance Note No.10 on Product Recall and Traceability
- Marine Institute HABs Website (source of information for biotoxin and harmful algal bloom information)
- Protocol for Opening a New Fishery for Bivalve Molluscs
- Seafish Publication: Review of the application of the Official Control Regulations for shellfish production as they relate to microbial contamination
- Shellfish Classified Areas | Sea Fisheries Protection Authority