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

Glossary of Terms and Abbreviations

Aquaculture	Aquaculture, with respect to this Code of Practice, is the raising of bivalve molluscs from the juvenile state in controlled conditions.
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)
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	Co-ordinated Local Aquaculture Management Systems
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).
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 Seafood Sector.
COP	Code of Practice
DAFM	Department of Agriculture Food and Marine
Dormant Fishery	Fishery has been dormant for at least 12 months, and limited monitoring data is available. Sites that remain dormant are in danger of their Classification becoming lapsed due to a lack of monitoring data. 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 defined as the annual minimum daily mean flow rate with a return period of 50 years. The DWF is a statistical measure of low flow and usually requires

	reliable long-term low flow data or sufficient information that would allow the estimation of the DWF.
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. Traditionally, *E. coli* produce indole from tryptophan at 44°C. Now determined on the basis of the possession of β-glucuronidase activity.
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.
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.
Full classification	A classification based on results from an extensive number of sampling occasions to ensure that potential seasonal and annual variability has been fully covered.
FSAI	Food Safety Authority of Ireland
Geographical Information System (GIS)	A computer-based system that combines mapping and data storage functions in order to manipulate, analyze, 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
Hepatitis A virus HAV	This is a 27nm diameter virus of the Picornaviridae family that contains RNA as its nucleic acid. It is transmitted by the faecal-oral route and although most infections are inapparent or mild feverish episodes, it can cause inflammation of the liver resulting in jaundice.
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.
IMG	Inshore Management Group. A cross agency group chaired by DAFM that considers the management of small-scale fisheries inside 6nm

Implementation Team	The team that reviews the Classifications of Shellfish Production areas whose members are selected from FSAI, SFPA, IFA Aquaculture, BIM and MI chaired by SFPA
IFA Aquaculture	Irish Farmers Association Aquaculture Sector
LA	Local Authority
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.
LBM	Live Bivalve Molluscs
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.
LTA (Rainfall)	Long Term Average rainfall. The percentage of normal rainfall for a fixed reference period of twenty years on a whole year basis.
MC	Management Cell. The Management Cell will comprise representatives from the Food Safety Authority of Ireland, the Sea-Fisheries Protection Authority, the Marine Institute and IFA Aquaculture.
MI	Marine Institute
MPN	Most Probable Number.
NGR	National Grid Reference
NIFF	The national industry representative forum for small scale fisheries inside 6nm
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 full classification
Production area	Any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.
Recommendation	Identifies good practice, which may not be strictly compulsory

	under the legislation.
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
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.
Remote area	An area such as an offshore site that is not subject to impact from any human or animal sources of faecal pollution and where monitoring data is stable.
Representative Monitoring point	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.
RIFF	Regional Inshore Fisheries Forum. The regional industry representative forums for small scale fisheries inside 6nm
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 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 Registration Document	Legally required traceability document to accompany each batch of shellfish from Harvesting to Dispatch centre or processing plant
Shellfish Sample Coordinator	The SFPO with national responsibility for overseeing the operation of the sampling in the Irish Shellfish Monitoring Programme
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.
SOP	Standard Operating Procedure

1. Background and Introduction

1.1 Background

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 (i) the sources and types of faecal contamination (human and animal) in the vicinity of the shellfish production areas and (ii) the results obtained, based on the indicator bacteria *E. coli*, from samples taken in these areas. Areas are classified following a full assessment of this risk 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.

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 draws on best practice in Europe and statutory requirements and outlines procedures for:-

1. Producing sampling plans and conducting sanitary surveys
2. Requirements for sample collection and testing
3. Procedures for making classifications including data interpretation
4. Communication
5. Additional risk management procedures including reacting to high *E. coli* results

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.

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 act as

Shellfish Managers and are responsible for supervising a number of assigned production areas.

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)
- Marine Biotoxins and 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 Sector represents Shellfish Producers whom 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 role in some areas to assist the SFPA with sampling. They also have a role in providing local information to support work on sanitary surveys.

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.

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).

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. 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

All the stakeholders listed above are full members of the Molluscan Shellfish Safety Committee (MSSC). Representatives from the FSAI, SFPA, MI and IFA Aquaculture compose the Management Cell of the MSSC.

1.4.1 ROLE OF THE 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 anyone with a relevant matter to discuss is free to attend and participate.

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 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; and,
- 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 anyone not a member of the MSSC, but co-opted to become a member 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. The meetings are held in the FASI Offices (Dublin), with one meeting each hosted by the SFPA (Clonakilty) and the MI (Galway). Other regional meetings may also be organised from time to time.

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.

1.4.4 The Management Cell.

The MSSC operates a "Management Cell" to proactively assess the risk to public health presented by shellfish from production areas in Ireland. The objective of the Management Cell is to facilitate rapid decision making in non-routine situations

1.5 Legislation

EU & Irish Food Safety Legislation

1. **Regulation (EC) 852/2004** states that primary responsibility for food safety lies with the food business operator.
2. **Regulation (EC) No 853/2004** laying down specific hygiene rules for food of animal origin, gives associated requirements for the industry.
3. **Regulation (EU) 2017/625** lays down rules for the organisation of official controls on products of animal origin intended for human consumption.
4. **Commission Implementing Regulation (EU) 2019/627** Title V. Specific requirements for official controls concerning live bivalve molluscs from classified production and relaying areas.
5. **Regulation (EC) 2073/2005** laying down the microbiological criteria for foodstuffs.
6. **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.
7. **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.
8. **Sea-Fisheries and Maritime Jurisdiction Act 2006.** Transposing of EU Sea Fishery legislation into Irish Law and the establishment of the SFPA.

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.**

The DAFM are responsible for drafting and, transposing fisheries legislation, and food safety legislation for all fishery products.

1.6 Legislative Standards

Table 1 Criteria for the classification of bivalve mollusc harvesting areas under Commission Implementing Regulation (EU) 2019/627 Title V Art 53, Regulation (EC) 853/2004 and Regulation (EC) 2073/2005.

Classification	Standard per 100g of LBM flesh and intravalvular fluid	Treatment required
A	80% of samples ≤ 230 *E. coli*/100g; all samples must be less than 700 E. coli/100g)	None - molluscs can be harvested for direct human consumption
B	LBMs must not exceed the limits of a five-tube, three dilution Most Probable Number (MPN) test of 4,600 *E. coli* per 100 g of flesh and intravalvular liquid.[2]	Purification, relaying in class A area or cooking by an approved method
C	LBMs must not exceed the limits of a five-tube, three dilution MPN test of 46,000 *E. coli* per 100	Relaying for a long period or cooking by

	g of flesh and intravalvular liquid.	an approved method
Prohibited	>46,000 *E. coli* per 100g of flesh and intravalvular fluid[3]	Harvesting not permitted

Notes: [1] Commission Implementing Regulation (EU) 2019/627 Title V Art 53, Regulation (EC) No 853/2004, to Regulation (EC) 2073/2005.
[2] Commission Implementing Regulation (EU) 2019/627 Title V Art 54, the competent authority may continue to classify as being of Class B areas for which the relevant limits of 4,600 E. coli per 100g are not exceeded in 90% of samples.
[3]This level is by default as it is above the highest limit set in legislation.

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 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 results and production area status.

The following legal requirements also apply:

1. Harvesting for placing on the market must only take place from **classified** production areas.
2. Harvesting should only take place from **classified** production areas which are not subject to temporary closures (e.g. due to pollution events)
3. Harvesting should only take place from classified production areas that have an **open status** on the basis of biotoxin results.
4. All harvested live bivalve molluscs must be accompanied by a completed **shellfish registration document** in accordance with Regulation (EC) 853/2004 Annex III Section VII
5. 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). Any product recall or withdrawal must be handled in accordance with these documents.

2. Sampling Plans for Classified Shellfish Production Areas

A Microbiological Sampling plan will be maintained for all classified shellfish production areas and amended as necessary to record bivalve species, sample location code, position of sampling points and frequency of sampling. The sampling plan is the basis of the Microbiological monitoring programme of Classified Shellfish production areas, and the results from such programmes are used in the annual review of Classifications. The sampling plan must ensure that the results of the analysis carried out will be as representative as possible for the area considered.

2.1 Selecting sampling point location

Representative sampling points should reflect the location at highest risk of faecal pollution within a classified production area. To determine this, a sanitary survey of the area should be undertaken. Under Article 56 of Commission Implementing Regulation (EU) 2019/627 Title V a sanitary survey must be undertaken to determine the sampling plan for a new harvesting area prior to classification.

2.1.1 Sanitary surveys

Sanitary surveys involve the identification of potential sources of faecal contamination of bivalve mollusc harvesting areas and an assessment of the likely impact of the sources on the microbiological quality of the fisheries. A sanitary survey is the first step in establishing a classification and a monitoring programme for a bivalve mollusc harvesting area. It provides an overview of pollution influences and thus a scientific basis for subsequent establishment of representative sampling points and a sampling plan.

The SFPA will organise to have sanitary surveys for shellfish harvesting areas undertaken for all newly classified shellfish production areas and establish a programme to conduct Sanitary Surveys of all existing classified shellfish production areas. This may also involve collaborative work with other agencies.

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

1. **A desk-based study to identify pollution sources**
2. **A shoreline survey to confirm initial findings of the desk-based study**
3. **A bacteriological survey**
4. **Data assessment**

2.1.1.1 Desk based study

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

<u>Characterisation of the fishery/production area</u>

Through consultation with industry representatives, IFA Aquaculture, CLAMS and other relevant interested parties, the following characteristics should be identified and recorded for the fishery(ies) in a production area.

1. Location and extent.
2. Bivalve species.
3. Aquaculture or wild stocks.
4. Whether it is a production area or relaying area.
5. Seasonality of harvest.
6. Growth and harvesting techniques.
7. Any conservation controls (e.g. closed season).
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 recorded should include:

1) Continuous sewage discharges
   a) Location.
   b) Size (dry weather flow, maximum flow; population equivalent if other information not available) (cubic metres per day).
   c) Treatment level (e.g. untreated, primary, secondary, tertiary, disinfected, septic tank, soakaway).

2) 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 flow rate (litres per second).

3) Emergency discharges
   a) Location.
   b) Circumstances under which the discharge may operate.
   c) Maximum predicted flow rate (litres per second).

Industrial discharges that have significant sewage content should also be assessed as for a.

4) Land use:
   a) Pasture land.
   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.

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

2.1.1.2 Shoreline survey: Recommendation

A shoreline survey should be undertaken by the SFPA in consultation with the local Sea Fishery Protection Officers and shellfish producers in order to determine whether all significant sources of contamination have been identified by the desk-based study, and whether previously identified sources are still present. The whole shoreline in the vicinity of the bivalve mollusc fishery should be subject to a survey with a view to identifying the pollution sources listed above.
A detailed COP for conducting a shoreline survey is given in Appendix 9.1

2.1.1.3 Bacteriological surveys: Recommendation

If the appropriate location for one or more sampling points for an area is not clear after completing the desk-based study and any shoreline survey, a bacteriological survey may be undertaken by SFPA.

2.1.2 Hydrography / hydrodynamics: Recommendation

The circulation of pollutants should be determined by virtue of current patterns, bathymetry and the tidal cycle in the production area. Available data should be utilised where practically possible and may include:

- Nautical charts (admiralty charts) either within a GIS or hard copy.
- Tidal Atlas', Mariners Handbook, Olsens Nautical Almanac's 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.

2.1.3 Compilation of sanitary survey report: Recommendation

A standardised report format (Appendix 9.3) should be prepared. The Sanitary Survey Report will be held centrally by the sampling co-ordinator and locally by SFPA. It will be made available to all stakeholders.

2.1.4 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 sampling 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.

Recommendation:

If an area is divided into separate sites each capable of being classified at a different category 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:

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.

Any agreed changes to these maxima should be formally acknowledged in the sampling plan. If it is difficult to obtain sufficient shellfish on a number of occasions, a

new point may be identified in consultation with local industry. The old point should then be discontinued. The selection of the sampling points and boundaries will be notified to the MSSC.
Reduced sampling frequency may also be considered on the basis of the sanitary survey findings.

2.1.5 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

It is recommended that a complete re-evaluation of Sanitary Surveys be undertaken by the
SFPA once every six years but may be done less frequently in remote areas. Results from both the annual review or the re-evaluation will be made available to all members of the MSSC.

3. Sampling and Sample Transport.

3.1 Selection of bivalve species to be monitored

In order to provide the highest standards of food safety, the Irish Shellfish monitoring programme samples all harvested shellfish species within each production area. 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.
In wild clam fisheries, where a number of different species of clams exist, a single indicator clam species may be sampled to monitor the microbiological quality of the production area.

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. 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 Sampling frequency

Preliminary Classification.
For preliminary (provisional) classification of an area, at least 12 samples should be taken from each identified sampling point not closer together than fortnightly.

Ongoing Monitoring of Classified Production Areas
The minimum sampling frequency for ongoing monitoring at classified production areas should be at least monthly on a year-round basis.

Stable Areas.
The sampling frequency for areas with greater than three years sampling data, including a minimum of 30 samples, may be reduced to a bimonthly frequency if the site is shown to be stable based on the following criteria:

1. CLASS A – where the site was subject to a sanitary survey which confirmed the location of the representative sampling point and that no result >230MPN *E.coli* /100g was detected in the previous three years

2. CLASS B - where the site was subject to a sanitary survey which confirmed the location of the representative sampling point and that no result >4600 MPN *E.coli*/100g was detected in the previous three years.

This status will be reviewed annually as part of the classification review process.

3.4 Short-Term Classifications

Where there are clear seasonal patterns to commercial activity in class A or B areas, preferably enforced by local fishery regulations, monitoring may be considered for a reduced period of the year. This should start at least 1 month prior to the harvesting season for class A areas and two months prior to the season for class B areas and then continue throughout the season.

3.5 Time of sampling

For the protection of public health, sampling should either be undertaken on as random a basis as 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 should be undertaken under conditions that have been identified as producing the highest levels of contamination. However, it is recognised that samplers are constrained by logistical considerations and it may not be reasonably practical to undertake sampling on this basis.

3.6 Recording of the sampling plan

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

1. Production area name.
2. Unique sampling point identifier.
3. Geographical location of each sampling point (latitude/longitude).
4. Frequency of sampling.
5. Other relevant information.

A record of the sampling plan should 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.

3.7 Sampling and sample transport protocols

All samples will be taken according to the sampling protocol (Appendix 9.2)

- The maximum elapsed time between sampling and arrival at the laboratory must be 48 hours.
- 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
- 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.

All samples must be accompanied by a sample submission form. Complete sample details including the following should be recorded on the sample submission form:

1. Sample point identification number and name.
2. Time and date of collection.
3. Species.
4. Method of collection (hand-picked, dredged, etc).
5. Any other information deemed relevant (e.g. unusual events, adverse weather conditions, Seawater temperature etc.) may also be recorded.

The sampling protocol will be available to all samplers.

3.8 Provision of samples by industry

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. Arrangements for industry sampling should be drawn up on a local basis. In such cases all the arrangements must **comply with all aspects** of the sampling requirements. A level of supervision by official samplers should be maintained during these arrangements. This level of supervision should form part of the sampling plan and be audited to ensure compliance.

3.9 Training of samplers

All samplers should receive formal training before commencing sampling under the monitoring programme. Requirements for training are stipulated in Article 6 of the Official Feed and Food Control Regulation (Regulation (EC) No 882/2004). Samplers should have relevant sampling and safety equipment.

3.10 Audit of sampling and transport procedures

A programme of audits will be drawn up as part of SFPA internal audits and are also included in relevant FSAI audits of the SFPA and the Irish Shellfish Monitoring programme.

3.11 Provision of sample results by the industry

Where, as allowed in Article 65 of Commission Implementing Regulation (EU) 2019/627 Title V it is decided to take into account results obtained by industry, it is necessary to ensure that all available data is taken into account for the purposes of determining the classification status. All results submitted by the industry must come from samples that reflect the contaminating sources and have been sampled, transported, and analysed according to standard protocols. Industry samplers should receive training prior to official samples being taken. Only sample results provided by

accredited laboratories recognised by the Marine Institute for the purpose of the Microbiological Monitoring Programme may be included.

4. Microbiological Testing

The Marine Institute, as the Irish National Reference Laboratory (NRL) for monitoring the viral and bacteriological contamination of bivalve molluscs' is responsible for co-ordinating the activities of official testing laboratories involved in the monitoring programme.

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. Results of analysis are reported to the Marine Institute, the SFPA sampling co-ordinator and local area SFPO on the day they become available.

4.2 Accreditation

All laboratories undertaking testing of bivalve molluscs under a competent authority monitoring programme (including those contributing results of samples taken by, or on behalf of the industry) 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.

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

All samples not complying with sampling criteria will not be included in the classification process. The sampling co-ordinator must be informed on receipt of such samples.

5. Data Handling and Storage

5.1 Storage and validation of data

Data relating to the monitoring programme will be stored in a database form.

The following information will be held.
1. Sampling plan information
2. Sample information
3. Results
4. Results from sanitary survey
5. Information on pollution events
6. Results of investigations of pollution events
7. Anomalous *E.coli* results

5.2 Dissemination of Results

The Shellfish Sample coordinator 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, and LA

6. Classification

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. It 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.

Data gathered from the sanitary survey, sampling programme and local information from industry will be used to decide on the boundaries of the classified area. The boundaries will be decided by the SFPA and MI in conjunction with local SFPO's and industry. Interpretation of monitoring programme data

6.1.1 Preliminary classification

The results of 12 samples taken not closer together than fortnightly should be assessed against the criteria given in the legislation (see Table1) and allowing for any anomalous results.

After three years, a full classification may be determined on the basis of the criteria given in the legislation (see Table1) taking into account a minimum of 1 sample per month over a period of at least three years and allowing for any anomalous results.

6.1.2 Full classifications

Results from each monitoring point should be reviewed on an annual basis, taking into account the last 3 years' data, or all data if there is less than 3 years' worth is available. The classification should be determined on the basis of demonstrating compliance with the criteria given in the legislation (see Table1) and allowing for any anomalous results. 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. A full classification established on the basis of this, will normally last at least one year. A 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 case, consideration should be given to suspension or downgrading of the classification until sufficient additional samples have been taken at the prescribed intervals.

6.1.3 Short Term Classifications

Where there are clear Seasonal Patterns to commercial activity in Class A or B areas, classification may be considered for a reduced period of the year. In

such cases sampling must start at least one month prior to harvesting for Class A areas and two months prior to the season for Class B areas.

6.1.4 Seasonal Classifications

At least 3 years' worth of data showing a clear seasonal trend of *E coli* results is necessary to establish a seasonal classification. The minimum number of samples required will be 30 samples with monitoring samples taken during all seasons.
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 when changing from class C to B and 1 month 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 % 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

6.1.5 Dormant Production areas.

On information supplied by the local Sea Fishery Protection Officer confirming that a production area has ceased production, and that the producer(s) in the area are unlikely to resume production for at least one year, the microbiological sampling programme will be reduced to once per quarter to monitor the microbiological contamination of the production area, and in the case of an A classified production area, it's classification will be reduced to B classification at the next review of Classifications. A Dormant production area that has been downgraded from A classification to B will require a minimum of 12 samples taken not closer together than fortnightly to be eligible for consideration by the implementation team for upgrading at the annual review of classifications.

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

Where multiple sampling points are used to represent a single classified area, usually because of the presence of multiple contaminating 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 zone should be based on the worst-case scenario obtained from all of the monitoring points (i.e. the most contaminated).

6.3 Effect of environmental factors

In production areas where the trend of results has been shown to be markedly affected by either individual rainfall events or the total annual rainfall, and the most recent two years' have had lower annual rainfall than average, the number of years to be included in the analysis should be extended by two.

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

When *E. coli* results are obtained during the routine monitoring programmes that are above the upper limit for the classification of the area, immediate action should be undertaken. The Shellfish Sample Coordinator will initiate an SFPA Shellsan Elevated Micro Result Report Form (appendix 9.5) and 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 the producer of the out of range result.

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.

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 and 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, ie purification or heat treatment.

Additionally where 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.

Further details are given in the decision tree in appendix 9.6.

In addition, where the levels exceed those in Table 2 below an alert state 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 2. Alert Status.

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

In all cases**,** where doubt exists over the validity of result the MI will immediately check with the testing laboratory whether the results comply with the quality criteria and are valid.

In all cases the appropriate SFPO in conjunction with the producer will conduct an investigation into the likely cause of the elevated micro result. The nature and extent of the investigation will vary on a local basis but the following should be considered.

1. Contacting sewage treatment works in the areas to ascertain if any sewage spills may have occurred
2. Rainfall in the period preceding the high result.
3. Changes in agricultural practices (e.g. slurry spreading)
4. Any other exceptional activities (e.g. dredging)

5. Industry view on any causes

6.4.1 Dissemination of Out of Range Results

In addition to the procedures outlined for responding to out of range *E.coli* results and alert status results, the Shellfish Sample Coordinator will compile and submit a report on all out of range *E.coli* results for each MSSC meeting.

6.4.2 Criteria for discarding results from the classification process

Results due to the following events may be identified as anomalous and excluded from the dataset used for determining classification status:

- Failure of a sewage treatment system, of at least a Category 2 Incident under the EPA Classification Scheme for incidents, that has been rectified, and where the authority responsible for controlling pollution identifies that such a failure is not expected to reoccur.

- An extreme rainfall event during the days prior to sampling with a return period of 5 years or greater (i.e. total rainfall in a 24 hour period up to six days prior to sampling which is only likely to occur once every five years or longer – this varies from location to location). Such a rainfall event must be verified on a case by case basis with reference to Met Eireann's rainfall returns period at: https://www.met.ie/climate/services and where the authority responsible for the monitoring programme deems that this has, or may have, significantly impacted on the microbiological status of the harvesting area.

- Clearly identified one-off pollution event that is unlikely to recur.

6.5 Closure of areas around outfalls, harbours and marinas

Where it is intended to harvest areas from within active harbours and marinas 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 considering all relevant information including the size of the input and expected extent of the impact of the discharge in the area.

6.6 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 shows clear seasonal trends of *E coli* results, the appropriate classification for each season will be considered as described in 6.1.4. The SFPA sampling coordinator will make an initial assessment of the data to hand and make proposals for each area to a sub-committee of the MSSC comprising the SFPA, FSAI, MI, ISA and BIM (Implementation Team). The sub-committee will consider the proposals made and give its recommendations on them to the SFPA. After considering these recommendations, the SFPA will assign a classification category (or categories) to

each area. Notice of these will be given in the national and marine sector press and on the SFPA website at www.sfpa.ie
As part of the annual classification review, maps of production areas and their associated sampling locations will be reviewed and amended as necessary to ensure that the sampling locations are as representative as possible of the likely pollution sources entering the area.
Following the classification review, maps of the classified areas will be produced (example Appendix 9.4). These will be communicated to relevant stakeholders and published on the SFPA websites

6.7 Additional Classifications of Pectinidae

In accordance with Regulation (EC) 853/2004 Annex III Section VII Chapt IX. Where data from official monitoring programmes enable the SFPA to classify scallops fished from within existing classified production areas as follows:

Unless a production area has been specifically classified for scallops, all scallops harvested within classified production areas in Ireland are classified as B unless harvested within classified production areas where all other mollusc shellfish are classified of being class A, then such scallops may be classified as A.

7. Communication

7.1 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.

7.2 Monthly Summary of Microbiological Results

The Shellfish Sample Coordinator 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 and LA.

7.3 Publication of maps of Classified Shellfish Production Areas

All maps will be published on the SFPA website.

8. Risk management

8.1 Risk Management Principles

Section 6.4 and the decision trees at Appendices 9.5 and 9.6 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 consumer protection. Consideration will also be given to the sustainable long-term development of the shellfish industry when decisions are made.

8.3 Management Cell

Where excesses of the *E. coli* standard are detected that are sufficient to cause an "alert state" (see Section 6.4) to be declared, a Management Cell may be called to direct the investigation and any associated follow up.

If convened, the Management Cell 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 state. To that end, production may be suspended and / or product recalls and withdrawals initiated. The FSAI Guidance Note No 10 Product Recall and Traceability should be consulted where product has been harvested. The Management Cell may also direct that additional samples are taken for virus testing.

9 Appendices

9.1 COP SH02 Shoreline Survey

9.2 GN SH05 Sampling and Sampling Transport Protocol

9.3 Sanitary Survey Report ---- Standardised Report Format.

9.4 Sampling Plan Record ----- Standardised template/form

9.5 SFPA Elevated Shellsan Micro Report Form

9.6 Decision Tree: High Results

Appendix 9.1
Shoreline Survey COP

Document:	**Code of Practice**		Version 2
Title:	**COP SH02** **Conducting a Shoreline Survey.**		
Section:	**Sea Fisheries Protection Authority**		
Approved:	**14 August 2020**		
1.0	**PURPOSE** To define the procedure for carrying out a shoreline survey of bivalve mollusc production areas.		

A shoreline survey forms a component part of the full sanitary survey of a shellfish harvesting area typically being carried out after an initial desktop-study. The shoreline survey itself is the physical inspection of the shoreline in the vicinity of the shellfish harvesting area in order to confirm the location of sources of contamination and to also identify any sources of contamination previously unidentified. It is also a survey to confirm information on the location and extent of the bivalve shellfish fishery/farm.
It involves recording the location of all observations made, photographing each and making a description of same. Upon completion this information is then used to populate the sanitary survey for the harvesting area.

Pre Survey

Site selection for a shoreline survey will be agreed with the Food Safety Unit and the Sanitary Survey Co-ordinator prior to commencement. A desktop study survey of the harvesting area will be completed prior to the shoreline survey and will provided details of the existing shellfish areas and licences in conjunction with details of any known sources of human or animal contamination to the area. This information will be provided to surveyors in a mapped format to assist in confirming the location of each particular shellfish area and discharges. Surveyors should familiarise themselves with these maps before commencing the survey.
It is recommended that surveyors should also consult the relevant Ordnance Survey Ireland Discovery Series maps and other online mapping sources (google earth) prior to entering the harvesting area in order to identify other potential points of interest including access routes to and from the shore.
It is recommended that surveyors consult with local shellfish harvesters also prior to commencing the survey. Harvesters will have direct knowledge of shellfish beds and may also be aware of previously unidentified discharges. This information may be beneficial terms of efficiency and accurate recording.
Surveyors should always consult the weather forecast prior to commencing any shoreline survey work. Surveying in adverse weather conditions should be avoided both in terms of access to the shore and from surveyor safety. Similarly, prior to entering on to the shore surveyors should consult the tide tables relevant to the harvesting area.

Survey Equipment

It is strongly recommended that each of these items would be carried by all fieldworkers at all times:

- Desk top generated maps of shellfish beds and discharges -
- Survey record sheets – observation record
- Handheld SATMAP GPS unit – navigation and location record
- Phone/camera – communications and photographic record
- Tetra Radio – secure communications/man down alarm
- Personal Protective Equipment – As required. Consult SFPA COP's
- Identification – SFPA identification

It is also suggested that the following may be usefully carried by field workers when conducting shoreline surveys:

- A4 Weather-writer clipboard
- Ordnance Survey Ireland Discovery Maps
- Binoculars
- Backpack
- Notebook

Please note that it is essential that all electronic equipment (mobile phones, cameras, GPS and Tetra Radio Units) is fully charged each morning prior to field work.

Health and Safety

By its very nature the shoreline survey takes place in exposed areas, adjacent water and in places subject to dynamic tidal fluctuations. For this reason field surveyor health and safety is paramount. It is important then that all field workers carrying out shoreline surveys carry and use the Tetra Radio System at all times.

All other SFPA health and safety code of practices should also be consulted and adhered to.

Shoreline Survey

The shoreline survey will be carried out by walking the actual shore of the area subject to the sanitary survey. In certain circumstances surveying by boat may also be considered. Dangerously steep areas should be avoided and can be surveyed using binoculars in combination with aerial photographs. Urban areas where access is not possible may also be similarly surveyed.

Where access to a particular section of the harvesting area is denied or where surveyors deem it unsafe to proceed then this should be recorded in the field notes as not having been surveyed. There will be areas where a combination of these issues will arise and where it will not be possible to survey.

All areas in the vicinity of the shellfish beds should be surveyed and in the case of an existing harvesting area the whole area should be surveyed. The desktop study element of the sanitary survey will make recommendations to the extent that any surveying should extend beyond the harvesting area boundaries.

It is recommended, when possible, that shoreline surveys should take place around the low water tidal period. Surveyors should consult local tide tables in planning their shoreline survey. Inter-tidal shellfish sites will not be visible at high water. Similarly, some discharge pipes and other potential sources of contamination may be covered at

high water or half tide and may be missed if surveying is carried out during those periods.

Field Recording Methodology

At the commencement of each days surveying the following should be recorded by surveyors in their survey record sheet:

- Name(s) of surveyor(s)
- Date of survey
- Production Area being surveyed
- Starting time of survey
- Extent of area surveyed (from…..to…)
- Tidal state on the day of the survey
- Weather (rain the previous 48 hours and weather during the survey including wind speed, direction, cloud cover and precipitation)

During the shoreline survey the surveyor will record the location, make a description off and take a photograph of each relevant observation. These three steps are to be carried out for all observations.

1. **Location** – All observations made by the surveyor should have the exact location recorded. The location will be recorded on the handheld GPS Unit and also manually entered into the survey record sheet. In order to standardise an approach all locations will be recorded in the decimal degrees (DDD.DDDDDD) format. Surveyors should insure that the correct format is selected in their GPS units before recording an observation.
2. **Description** - All observations recorded should be described in the survey record sheet. A brief description of the actual observation e.g. discharge pipe, stream, drainage ditch, wastewater treatment works etc. and any other supplementary information that may inform the sanitary survey should be entered.
3. **Photograph** - A photograph should be taken of the observation. Photographs should be clear, focused and readily identify the observation being described.

Observations

The following is a guide to the types of observations each surveyor will likely encounter and which they should record.

Shellfish Licences & Beds

Surveyors should make a note of the location and extent of any area of shellfish farming or wild shellfish beds encountered during the survey whilst confirming the location of the beds/licences identified from the desktop study maps. For sub-tidal beds not visible during the survey it may be useful to make a note of any shellfish vessels harvesting in the area.

Surveyors should record the species being farmed and the farming method such as bag/trestles, long-lines, bouchot poles etc.

Sewage Discharges

Surveyors should record all sewage discharges encountered including those discharges not actively flowing at the time of the survey. Rainfall dependent discharges should also be recorded and photographed, these will include stormwater overflows, combined sewer overflows and emergency discharges. Associated infrastructure such as pumping stations and wastewater treatment plants should also be recorded. Septic tanks if

encountered should be recorded. Surveyors should record a basic description of the infrastructure, any flows emanating, odours, discolouration etc.

Other Discharges
All other discharges both known and unknown should be recorded where encountered. These will include any pipes, whether flowing or not, discharging directly into the production area or into those water courses nearby. A record of any signs of enrichment, discolouration or odour emanating from the pipes should also be made as should the strength of flow emanating.

Waterways
Record all rivers, streams and drains encountered during the survey. Record any supplementary information relating to the water course also such as size, flow and land type through which it is flowing.

Farm Animals
Make a record of any farm animals on both lands adjacent the shore and those upon the shore itself. This can include cows, sheep, horses or pigs. Record the species and an approximate number of the individuals. Similarly where large amounts of animal manure is encountered, on the shore or immediately adjacent, a record should also be made.

Land Usage
Record the land type adjacent the production area and where the surveyor believes it may be influencing contamination to the production area. This might include pasture for cattle, sheep, horses etc. Similarly record any incidences of manure or slurry spreading or where animal sheds and slatted houses are located near the shore.

Wild Animals
Make a record of any wild animals encountered during the survey on both the shore and the land adjacent. Make note of large numbers in the general vicinity but record smaller numbers when close to the shellfish fishery/beds. This can include birds, seals, otters, dolphins, deer etc. Also record the approximate numbers sighted.

Piers/Marinas
Make a record of any piers, slipways, marinas and moorings encountered during the survey. Make a note of the number and types of vessels at these facilities and or any associated wastewater facilities. Areas where relatively large numbers of boats pass through should also be noted.

Miscellaneous
A record should be made of any additional observations made by surveyors where it is felt that they may have an influence on amounts of human or animal pollution of the production area or inflowing waters thereof. Such examples could include tourist facilities such as caravan parks, industrial activity such as dredging or building works or natural phenomena such as algal blooms.
This list is not exhaustive and where surveyors encounter scenarios that they feel may contribute to organic pollution of the shellfish fishery they should record these in the survey record sheets also.

Sampling

Where possible, water samples should be taken from discharges or watercourses discharging near the shellfish harvesting areas. Where deemed appropriate seawater samples from within the production area may also be taken. Sample locations can be determined at the time of the survey in conjunction with the sanitary survey co-ordinator. All water samples should be analysed for E.coli.

It is recommended that any water sampling in the production area should be carried out on the same day in order to allow spatial comparison of the results. It is also recommended that this sampling should be carried out on a day where environmental conditions (e.g. after heavy rain) are likely to lead to a higher risk of contamination.

All water samples should be submitted to the accepting laboratory using the Official Sample Advice Note book and should be clearly identified as having been taken as part of the sanitary survey process.

In addition to water sampling it may be appropriate to conduct shellfish sampling also. In particular this may be undertaken if the most suitable representative monitoring point is unclear after the desk top study and shoreline survey. This can be determined at the time of the survey in conjunction with the sanitary survey co-ordinator.

Any shellfish sampling should follow the SFPA 'Guidance Note' 'Collection and Transport of shellfish samples for E. coli testing'. Samples should be submitted to accepting laboratories using the SFPA Shellfish Sample Advice Notes book. Each sample submitted as part of the sanitary survey programme should be clearly identified in the advice book as such. The location code should use the identifying acronym SS1, SS2 etc. to identify it as a sanitary survey shellfish sample. For example a sanitary survey shellfish sample from Sligo Harbour should be identified as SO-SH-SH-SS1.

Post Survey

As soon as is possible after surveying the survey notes and records should be uploaded into an excel format database and saved. Each observation made during the survey should be numbered sequentially and the associated photograph associated with that number should also be uploaded and saved with an identical number.

The results of any sampling carried out should also be saved and stored in an excel format with the longitude and latitude of the sample location also recorded.

The data generated by the shoreline surveys will be incorporated into the final sanitary survey document and will guide the final outcomes of the same document.

Appendix 9.2

Document:	**GUIDANCE NOTE**	Version 1
Title:	**GN SH 05** **Collection and Transport of shellfish samples for E. coli testing.**	
Section:	**Sea Fisheries Protection Authority: FOOD SAFETY**	Page 36 of 45
Approved:	14 Aug 2013	

1. Purpose and Scope

1.1 All shellfish harvesting areas must be classified according EU regulations 854/2004. 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.

2. Responsibility

2.1 It is the responsibility of the SFPA to make arrangements for the collection of samples for *E. coli* testing. The SFPA will arrange training for sampling officers.

2.2 It is the responsibility of all designated sampling officers to comply with this SOP. Sampling officers must notify the SFPA shellfish sample co-ordinator immediately where it is not possible to do so or where they experience problems.

2.3 It is the responsibility of the Marine Institute to ensure testing laboratories adhere to appropriate parts of this GN.

2.4 It is the responsibility of the SFPA and the Food Safety Authority of Ireland to monitor compliance with this GN

3. Safety

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

4. Procedure

4.1 The following Equipment will be supplied to all sampling officers

4.1.1 Shellfish harvesting sampling plan.

4.1.2 Suitable protective clothing / equipment.

4.1.3 Thermometer

4.1.4 Handheld GPS

4.1.5 Sample advice notes

4.1.6 Gloves

4.1.7 Cool boxes and chill packs

4.1.8 Heavy duty plastic sample bags and ties

4.1.9 Clippers for opening oyster bags

4.1.10 Waterproof marker pen

4.1.11 Spade, trowel or rake where appropriate.

4.2 Sampling points

4.2.1 All sampling points are at fixed geographical locations and are listed in the shellfish sampling plans established for individual harvesting areas.

4.2.2 Samples must be collected within 100 metres of the fixed location for hand-picked or raked samples.

4.2.3 Samples must be collected within 250 metres of the fixed location for dredged samples.

4.2.4 Where it is not possible to collect samples within these limits the SFPA shellfish sample co-ordinator and local industry must be informed and alternative sampling locations agreed

4.2.5 When a sample is taken outside of these limits the co-ordinates of the actual sampling point shall be taken and notified to the shellfish sample co-ordinator.

4.2.6 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.

4.2.7 Changes to sampling locations must be agreed with the SFPA shellfish sampling co-ordinator in order for the sampling plan to be updated.

4.3 Sample Size

4.3.1 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 cm
Pacific Oysters	*Crassostrea gigas*	10	8 cm
Mussels	*Mytilus edulis*	15	4 cm
Cockles	*Cerastoderma* spp.	30	3 cm
King Scallops	*Pecten maximus*	15	10 cm
Manila Clams	*Tapes semidcussatus*	30	4 cm
Pallourdes	*Tapes decussatus*	30	4 cm
Razor Clams	*Ensis* spp.	10	10 cm

4.3.2 For other species contact the SFPA sample co-ordinator to discuss requirements for sample size.

4.3.3 If problems are encountered in obtaining the minimum shellfish numbers from a particular sampling location contact the shellfish sample co-ordinator to consider moving the sampling location.

4.4 Sampling Frequency

4.4.1 The sampling frequency for each sample location is recorded in the sampling plan for the shellfish area.

4.4.2 If planned samples are missed the SFPA sample manager should be informed and alternative arrangements for sampling considered.

4.4.3 Additional samples may be required following high *E. coli* results. The shellfish sample co-ordinator will advise of such occasions.

4.5 Sample Collection

4.5.1 Shellfish samples should be collected by dredging, hand-picking raking or other suitable means.

4.5.2 Once the minimum numbers of shellfish have been collected, as much mud and debris as easily possible should be removed by rinsing with water. Shellfish must not be completely re-immersed in water at any time between sampling and testing.

4.5.3 Shellfish should be placed into heavy duty sample bags which prevent leakage. The samples should be clearly marked with the sample point reference code and date & time of sampling using waterproof markers.

4.5.4 The bag should be sealed using a tie to prevent possible cross – contamination with other samples.

4.5.5 Fully complete an SFPA Shellfish Sample Advice Note note and place in a waterproof document wallet.

4.5.6 Place samples in a suitable chilled/refrigerated container containing chill packs. Shellfish samples must not be frozen and should not come into direct contact with the chill packs.

4.6 Sampling from Wild Fisheries.

4.6.1 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.

4.7 Sample Storage and Transport

4.7.1 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.

4.7.2 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

4.7.3 On receipt in the laboratory samples must be accompanied with a fully completed sample advice note.

4.7.4 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.

5. CONTACT DETAILS

SFPA Headquarters

Food Safety Unit,
Sea Fisheries Protection Authority,
National Seafood Centre
Block B,
Clogheen,
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Appendix 9.3 Format for Sanitary Survey Report.

The following contains the outline requirements for the written harvesting area sanitary survey report.

1) Description of the production area
2) Overview of the bivalve fishery
3) Fishery
    a. Location and extent
    b. Bivalve species
    c. Aquaculture or wild stocks
    d. Production area or relay area
    e. Seasonality of harvest
    f. Harvesting techniques
    g. Any conservation controls on fishery
4) Location, size and treatment level of human sources of contamination
5) Location and estimated volume/load of agricultural sources of contamination
6) Significant wild animal/bird populations
7) Land usage
8) Maps, seasonality effects, for these factors
9) Records of shoreline surveys
10) Hydrographic/hydrodynamics of the area
11) Records of bacteriological survey results
12) Assessment of effect of all of the above on contamination of shellfish
13) A recommendation on the extent of the production area (geographic delineation)
14) Specific considerations relating to impacting pollutant sources
15) Species specific sampling plans

Appendix 9.4 Sampling Plan Format

Species	
Site name	
Sample point identifier	
Geographical location of sample point	
Sampling frequency	
Sampling depth (where appropriate)	
Maximum allowed distance from sampling point	
Sampling method	
Sample size	
Authorised samplers	

9.5 Appendix 9.5 Shellsan Elevated Micro Result Report

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?

_____

Investigation of Routine Elevated Results

Heavy Rainfall >24 Hrs Prior to sampling? _____Extreme Met event? 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 > 7000 *E. coli*/100g Class B > 18000 *E. coli*/100g Class C > 46,000 *E. coli* /100g

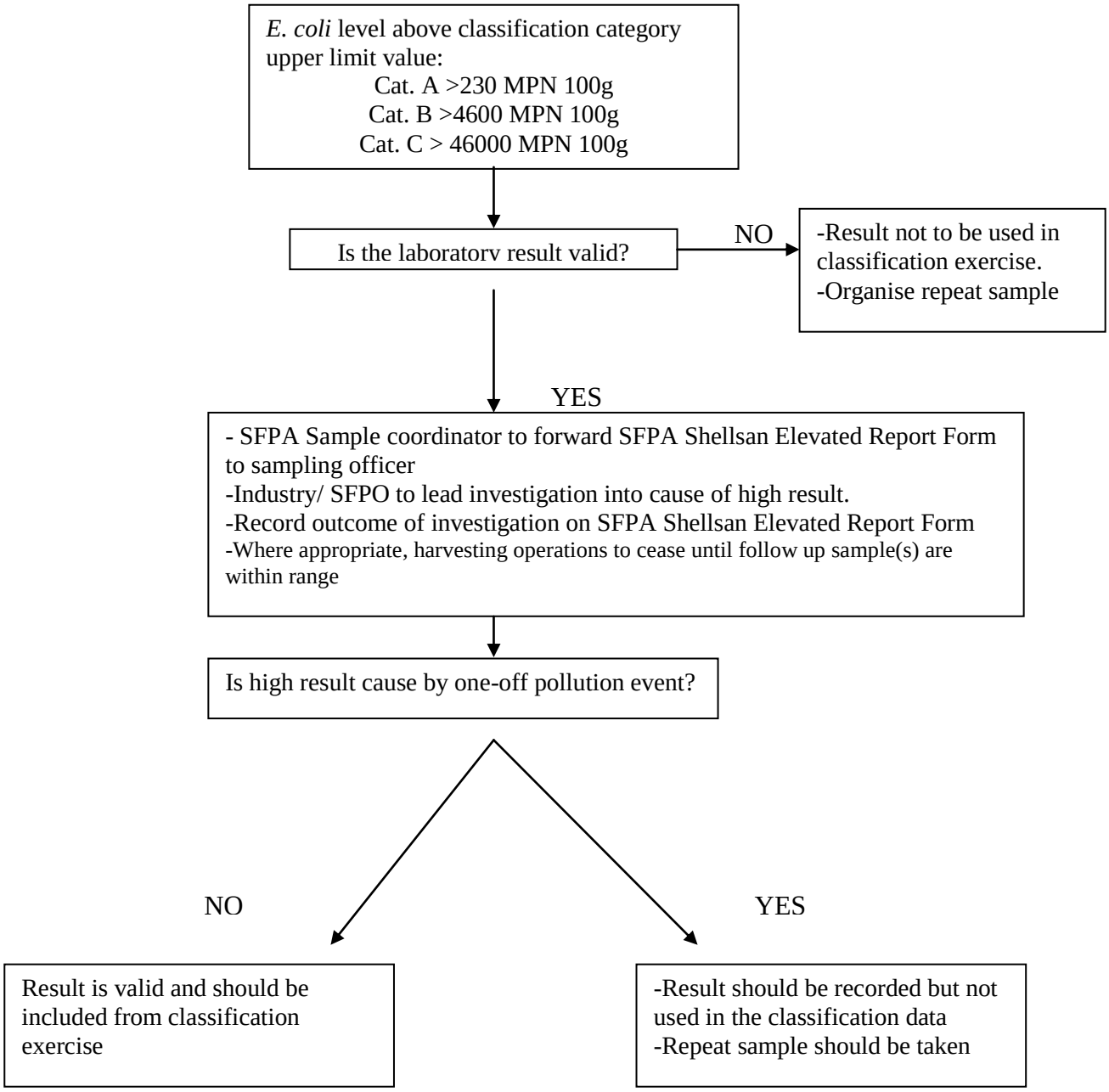
Contact local sewage works/local authorities, details of any sewage spills or storm releases?
_____
_____

Additional Comments or Follow up Actions

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

9.6 Appendix 9.6 - Decision trees: High Results

Shellfish Classification monitoring high results: Procedures for results above the upper limit for a classification category



Criteria for Discarding Results from the Classification Process

- Failure to comply with sampling or laboratory protocols.
- Failure of the sewage treatment system that has been rectified and where the authority responsible for controlling pollution identifies that such a failure is not expected to recur.
- Extreme rainfall event with a return period of 5 years or greater.
- Any other clearly identified one of pollution event that is unlikely to recur.