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

Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas

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 (the Irish Sea-Fisheries Board)
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)	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.
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.
Implementation Team	The team that reviews the Classifications of Shellfish Production areas whose members are selected from FSAI, SFPA, ISA, BIM and MI chaired by SFPA
ISA	Irish Shellfish Association
LA	Local Authority
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.

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 the Irish Shellfish Association
MI	Marine Institute
MPN	Most Probable Number.
NGR	National Grid Reference
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 Sampling 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 sampling point should reflect the location at highest risk of faecal pollution within a classified production area

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 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 monitoring the

microbiological and virological contamination of bivalve shellfish. 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 Shellfish Association 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 the ISA 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 particular 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 are 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 (EC) 854/2004** lays down rules for the organisation of official controls on products of animal origin intended for human consumption.
4. **Regulation (EC) 2073/2005** laying down the microbiological criteria for foodstuffs.
5. **The European Communities (Food and Feed Hygiene) Regulations 2009 (SI No 432 of 2009)** transpose the above regulations so far as they relate to Fishery products in Ireland.
6. **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.

7. **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 Appendix II of **Regulation (EC) No 854/2004.**

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 Regulation (EC) No 854/2004, Regulation (EC) 853/2004 and Regulation (EC) 2073/2005.

Classification	Standard per 100g of LBM flesh and intravalvular fluid	Treatment required
A	<230 *E. coli* per100g of flesh and intravalvular liquid[1]	None
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 g of flesh and intravalvular liquid.	Relaying for a long period or cooking by an approved method
Prohibited	>46,000 *E. coli* per 100g of flesh and intravalvular fluid[3]	Harvesting not permitted

Notes: [1] By cross-reference from Regulation (EC) No 854/2004, via Regulation (EC) No 853/2004, to Regulation (EC) 2073/2005.

Samples of live bivalve molluscs from these areas must not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid. The remaining 20 % of samples must not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid, as amended by Regulation (EC) No 2285/2015.

[2] By way of derogation from Regulation (EC) No 854/2004, 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. 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 Regulation 854/2004 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 will be achieved in conjunction with MI, BIM, ISA, LA and the FSAI.

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**:**

Characterisation of the fishery/production area

Through consultation with industry representatives, ISA, 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. Capacity of area.
5. Whether it is a production area or relaying area.
6. Seasonality of harvest.
7. Growth and harvesting techniques.
8. 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.
As much information as possible should be obtained from existing sources in order to minimize the national resources needed. Existing information gathered for the purposes of implementation of the Shellfish Waters Directive is held by the DEHLG and is publically available. The information to be obtained and recorded should, where practically possible, include:

1) Continuous sewage discharges
   a) Location (Latitude/longitude and/or relevant National Grid Reference (NGR)
   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).
   d) Tidal phasing or other periodicity if relevant.
   e) Microbial content (results of any monitoring undertaken on the discharge together with information on the flow conditions pertaining)
   f) Sanitary content (as surrogate if microbial content not available) (measured levels of ammonia, biochemical oxygen demand (BOD), suspended solids together with information on the flow conditions pertaining).
   g) Seasonal variations in any of the above.

2) Rainfall-dependent sewage discharges (combined sewer overflows or storm tank overflow) and other rainfall-dependent discharges (storm water discharges).
   a) Location (latitude/longitude and/or relevant NGR).
   b) Measured or predicted spill frequency (per annum).
   c) Treatment level (if any).
   d) Tidal phasing or other periodicity if relevant.
   e) Maximum flow rate (litres per second).
   f) Microbial content (results of any monitoring undertaken on the discharge together with information on the flow conditions pertaining).
   g) Sanitary content (as surrogate if microbial content not available) (measured levels of ammonia, biochemical oxygen demand (BOD), suspended solids together with information on the flow conditions pertaining).
   h) Seasonal variations in any of the above.

3) Emergency discharges
   a) Location (Latitude/longitude and/or relevant NGR).
   b) Circumstances under which the discharge may operate.
   c) Maximum predicted flow rate (litres per second).
   d) Microbial content of the associated continuous flow (results of any monitoring undertaken on the discharge together with information on the flow conditions pertaining).
   e) Sanitary content of the associated continuous flow (as surrogate if microbial content not available) (measured levels of ammonia, biochemical oxygen demand (BOD), suspended solids together with information on the flow conditions pertaining).
   f) Seasonal variations in any of the above.

Industrial discharges that have significant sewage content should be assessed as for a continuous sewage discharge but the proportion of sewage, and the effects of any antibacterial action of the chemical constituents should be estimated.

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. As part of the desk study, an assessment needs to be made as to the extent that the survey needs to extend beyond the immediate vicinity of the fishery (e.g . how far upstream)
A detailed SOP 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 in consultation and with the assistance of the MI to obtain a more accurate assessment of the location and extent of contamination.

2.1.2 Hydrography / hydrodynamics: Recommendation

It may assist in deciding on sampling points to have information on the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area should be determined where practically possible using the available information. These 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) which includes the following details should be prepared.

1. Overview of the fishery/production area.
2. Hydrography / hydrodynamics.
3. Human sources of contamination.
4. Agricultural sources of contamination.
5. Significant wild animal/bird populations.
6. Records of shoreline surveys.
7. Records of baseline bacteriological monitoring results.
8. Assessment of effect on contamination of shellfish.

The report should contain maps indicating the location of inputs into the production area, fisheries and other relevant information to aid interpretation and include details of any seasonal effects on contamination. 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. If impact is considered to be likely, a subsequent hydrodynamic assessment may be made to see whether there is still an impact when currents are taken into account.

Particular attention to the number and location of sampling points should be given to circumstances where intermittent sources of contamination may not be covered by the regular monitoring program or where the monitoring programme based on *E. coli* may not adequately reflect the pathogen risk (e.g. a major discharge disinfected by UV).

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

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. This process includes:

1. File review on the status of all bivalve mollusc growing areas.
2. Performance records for all sewage treatment works and industrial discharges.
3. A status report on abatement of pollution from sources identified during past sanitary surveys.
4. Evaluation of new pollution sources.
5. Licence.

It is recommended that a complete re-evaluation of Sanitary Surveys be undertaken by the SFPA once every six years. 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

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 Regulation (EC) No 854/2004 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, ISA, 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 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 or elevated *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 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. 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

Failure of a sewage treatment system 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 determined on a case by case basis and with reference to Met Eireann annual weather reports. Where the Long Term Average has been exceeded by a minimum of 5 years or more, 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.

6.4 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 sewage or animal slurry inputs discharge directly into a classified area a risk assessment should be undertaken to establish the impact on the shellfishery. 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.

6.5 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

6.6 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

7.1.1 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, ISA, 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.

8.2 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

Document:	**Code of Practice**		Version 1
Title:	**COP SH02** **Conducting a Shoreline Survey.**		
Section:	**Sea Fisheries Protection Authority**		
Approved:	**14 August 2013**		

1.0	**PURPOSE** To define the procedure for carrying out a shoreline survey of bivalve mollusc production areas.
2.0	**SCOPE** Planning, carrying out and reporting on a shoreline survey of bivalve mollusc production areas as part of a sanitary survey required by the Sea Fisheries Protection Authority
3.0	**RESPONSIBILITY** It shall be the responsibility of the Sea Fisheries Protection Authority to organise to have shoreline surveys undertaken as part of a Sanitary Survey when deemed necessary.
4.0	**DEFINITIONS** **Shoreline Survey:** A shoreline survey is an investigation of a defined coastal region to identify actual or potential sources of pollution in that area. It will identify all properties/significant structures of the shoreline, and quantify, in so far as is reasonably practicable all potential or actual sources of pollution in the region. **Actual Pollution Source**: A known source of pollution, which is, or is capable of, causing the microbiological standards for classified shellfish areas to be exceeded. A source can only be described as actual if: It has been found to have consistently high microbiological levels, or It is determined, beyond a reasonable doubt, that the source is polluting, or capable of polluting the surrounding area, e.g. a WWTP outfall or failing septic system. Actual pollution sources should be re-evaluated a minimum of every six years.

	Potential Pollution Source: Any source found which has the potential to infrequently and/or unpredictably release contaminants to the surrounding shellfish growing waters, at levels, which may cause the microbiological standards for classified shellfish production areas to be exceeded. Examples include storm water overflows, agricultural runoff, marinas etc. During an initial shoreline survey all sources found may be classified as potential until further bacterial or other investigations can be conducted. Potential pollution sources should be re-evaluated, through sampling or other means, at least every six years. **Point Sources:** Identifiable single sources of effluent which is discharged via pipes or drains or similar, e.g. discharges from industrial facilities and waste water treatments plants. **Non point source**: diffuse source(s) of effluent which cannot be traced back to a single source, e.g.: land runoff, precipitation, atmospheric deposition, drainage, seepage, etc **Live Bivalve Molluscs:** Filter-feeding shellfish with two shells. The legal requirements for LBM also relate to live echinoderms, live tunicates and live marine gastropods .
5.0	**RELEVANT LEGISLATION** Regulation (EC) No 178/2002 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 Regulation (EC) No 852/2004 on the hygiene of foodstuffs Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. EC (Hygiene of Fishery Products and Fish Feed) Regulations 2009 (SI 432/2009) Commission Regulation (EC) No. 2073/2005 of 15 November 2005 on Microbiological Criteria for Foodstuffs
6.0	**RELATED DOCUMENTS** Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas. Sanitary Survey Report. Map of bivalve mollusc production area.

7.0 **MATERIALS AND EQUIPMENT.**

Map of the area to be surveyed.
GPS.
Notebooks and writing materials.
Digital Camera.
Personal Protective equipment as required.

8.0 **PROCEDURE**

For practical and logistical reasons the survey area must be clearly defined and identified on a map of the production area. This defined area will be given a particular designation which must be detailed on all reports and data associated with the survey. Information and assistance should be sought from ISA/local CLAMS group/ local advisory committees for wild fisheries and other relevant parties.

Assemble and assess existing background information, including historical survey findings where available.

Determine whether the area is to be surveyed on foot or by boat or both.

Determine the appropriate health and safety procedures and ensure necessary arrangements are in place in advance of the on-site visit.

On-site survey:

Identify the location of each WWTP, industrial or agricultural pollution source.

Describe in as far as is practicable the nature and extent of the discharge.

Identify sources of effluent which require sampling for analysis.

Describe weather conditions pertaining during the survey period.

Evaluate the numbers and types of farm animals, in so far as is reasonably practicable.

Identify the location of marinas and evaluate in so far as is reasonably practicable associated discharges.

Note any flocks of wild fowl/populations of wild animals evident and where possible include an estimation of their numbers.

Identify and evaluate drainage ditches.

Identify and evaluate any other significant sources of pollution observed.

A report shall be compiled describing each pollution source identified.

A map of the area shall be produced clearly identifying each of the pollution sources found.

Recommendations for further investigations, including sampling of discharges shall be included in the Shoreline Survey report, where

	deemed necessary.

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 32 of 42
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,
Clonakilty,
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Appendix 9.3 Format for Sanitary Survey Report.

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

1. *Executive Summary.*

2. *Overview of the Fishery/Production area:*

2.1. Location Map or chart showing the location/extent of growing/harvesting area.
2.2. Description of the area and its functions (e.g. production/relaying) and boundaries: including the capacity of the area.
2.3. Description of the species concerned, growth and harvesting techniques, whether aquaculture or wild stocks, and any conservation measures in place.
2.4. Current Classification of the Production Area if already an existing classification

3. *Hydrography/Hydrodynamics.*

3.1. Tides (type and amplitude), and currents (velocity and direction)
3.2. Rainfall data:
3.2.1. Amount
3.2.2. When (e.g. time of year)
3.2.3. Frequency of significant rainfalls
3.3. Winds (Seasonality and effects on pollution dispersion).
3.4. River discharges (volume and seasonality)
3.5. Discussion concerning effects of pollution distribution and hydrographic factors (dilution, dispersion, and time of travel) on water quality throughout the growing area
3.6. Salinity, depth, and stratification characteristics
3.7. Simple/Complex models if available.

4. *Identification of Pollution Sources.*

4.1. Summary of sources and location.
4.1.1. Information gathered under the desktop survey procedures outlined in Section 2.1.1.1, including sewage discharges, industrial discharges, land use and so forth.
4.1.2. Map or chart showing the location of major sources of actual or potential pollution in the area (all categories identified). This information may be incorporated in the Location Map as described at 2.1 above.
4.1.3. Table of sources of pollution cross referenced to the area map.
4.1.4. Shoreline survey report where a shoreline survey has been carried out.

5. *Sampling Information.*

5.1. Location of sampling points and reasons for selection, including map/chart showing sample point locations.
5.2. Results of any microbiological analysis/ bacteriological survey undertaken (if any).

Appendix 9.4 Sampling Plan Format

Production Area Name	
Sampling Point Name (s)	
Sample point(s) Identifier(s)	
Geographical location of each sample point	
Allowed buffer zone.	
Depth of Sampling (where defined).	
Annual Target Number of samples	
Sampling Frequency	
Sampling Method	
Authorised Sampler(s): Name and contact details	
Additional Information:	

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

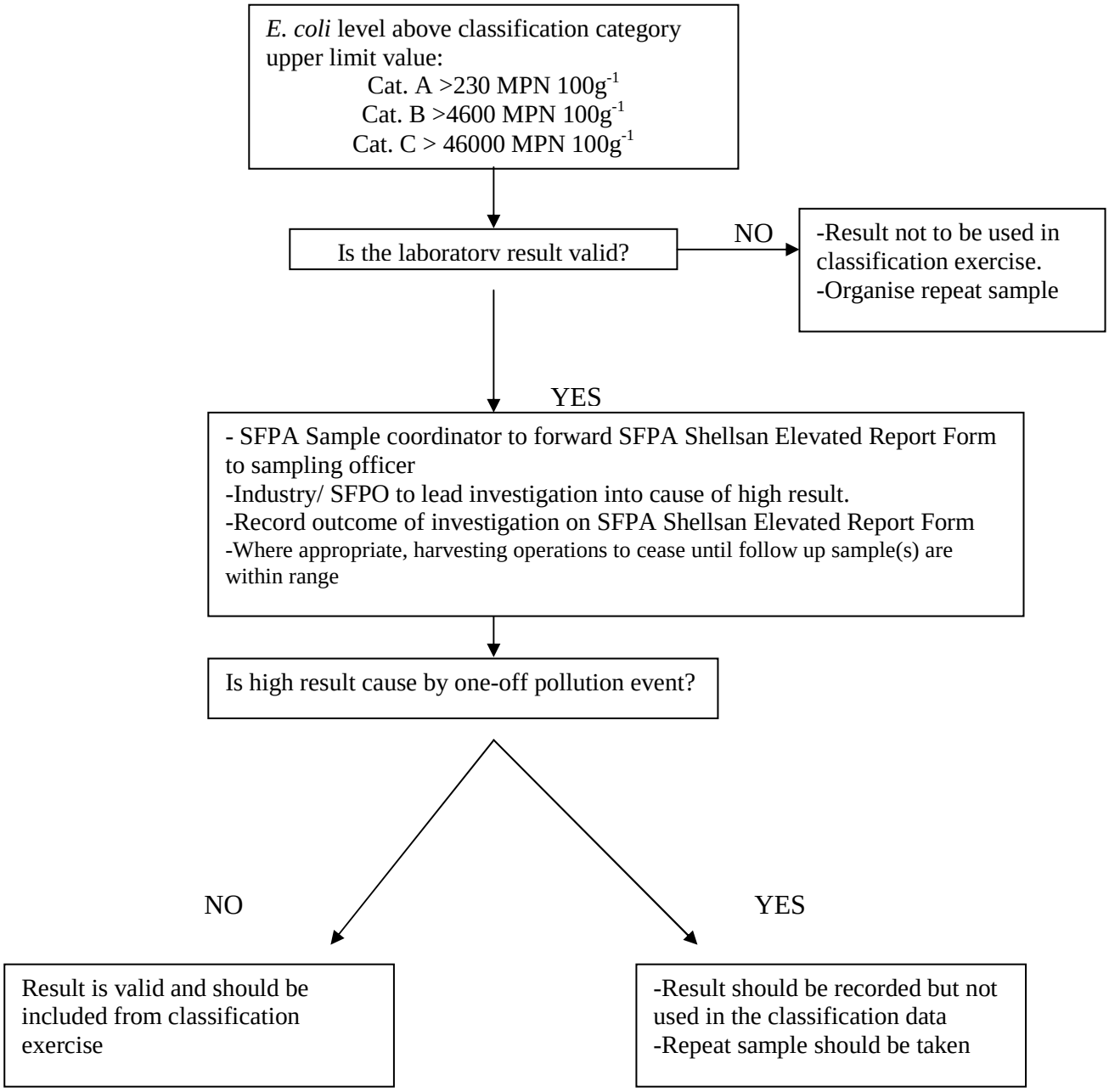
Contact local sewage works/local authorities, details of any sewage spills or storm releases?
_____
_____

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.