Code of Practice for the Irish Shellfish

Monitoring Programme (Biotoxins)

Version 10 (2024)

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Glossary of Terms & Abbreviations

Alexandrium spp.	Phytoplankton species associated with PSP
ASP	Amnesic Shellfish Poisoning
AZP	Azaspiracid Shellfish Poisoning (part of the Lipophilic Group)
BIM	An Bord Iascaigh Mhara, Ireland's Seafood Development Agency
CA	Competent Authority. An authority which is competent to carry out checks, as defined by EU Legislation
COP	Code of Practice
DSP	Diarrhetic Shellfish Poisoning (part of the lipophilic group)
EHO	Environmental Health Officers of the HSE, who carry out food safety inspections and implement food sampling programmes at the retail, wholesale and catering stages of the food chain
Esters	Esters are naturally occurring derivatives of toxins which are also toxic
FBO	Food Business Operator, the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. This includes dispatch centres and processing premises.
FSAI	Food Safety Authority of Ireland
FSMS	Food Safety Management System, this is the adoption of a HACCP system and other such practices by FBOs to ensure food safety.
HABs	Harmful Algal Blooms
HAB's Shellfish Monitoring webpages	All sample details and associated results from the Irish Shellfish Monitoring Programme for biotoxins and phytoplankton samples are inputted into the MI's Harmful Algal Blooms (HABs) Database. The results are published online at: http://webapps.marine.ie/HABs/

HAB's Bulletins	The MI HAB Bulletins provide information on the potential development of toxic and/or harmful phytoplankton. The bulletins can be accessed via the main MI HABs database webpage.
HPLC	High-performance liquid chromatography, a chemical analytical method
HSE	Health Services Executive
IFA	Irish Farmer's Association
INAB	Irish National Accreditation Board
ISO/IEC 17025:2017	The International Standard for testing laboratories which the MI is accredited to.
ISMP	Irish Shellfish Monitoring Programme. There are two elements to the monitoring programme, namely biotoxin and phytoplankton monitoring (as covered by this COP) and the microbiological monitoring which is covered by a separate COP that is available on the Seafood Safety Section of the SFPA website: www.sfpa.ie/Seafood-Safety/Shellfish/GuidanceDocuments
LC-MS/MS	Liquid chromatography-quadrupole mass spectrometer, a chemical analytical method
Lipophilic Toxins	This grouping is comprised of the following groups of toxins; okadaic acid group, esters of okadaic acid group toxins, pectenotoxins group, yessotoxins group and azaspiracid group.
LBM	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
MI	Marine Institute
MSSC	Molluscan Shellfish Safety Committee
OA	Okadaic Acid, a lipophilic toxin
Official Control	Official Controls are any form of controls taken by the authorities to verify compliance with the relevant legislation

Phytoplankton	Phytoplankton are microscopic plants that live in water
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. Production areas are defined by and classified by the SFPA
Production period	The time period that a valid sample relates to during periods of harvesting. This is set by the sampling frequency and is normally a week, fortnightly or a month. A weekly production period starts on a Sunday. fortnightly starts on every second Sunday and monthly starts on the 1st of the month.
PSP **PTX**	Paralytic Shellfish Poisoning Pectenotoxins, included in the lipophilic toxin group
Sentinel Sites	Production areas from around the coast that are analysed for all toxins (all Lipophilic, Paralytic and Amnesic Shellfish toxins) on a monthly frequency throughout the year (in addition to routine analysis) a representative view of toxicity
SFPA	Sea-Fisheries Protection Authority
SFPO	Sea-Fisheries Protection Officer
Shellfish Monitoring Coordinator **Shellfish Manager**	The SFPO with national responsibility for overseeing the SFPA operation of the Irish Shellfish Monitoring Programme. The SFPO or Loughs Agency Officer with responsibility for a production area
Shellfish Registration Document	This document must be completed for each batch of live bivalve molluscs harvested (both aquaculture and wild caught). It is also known as a Shellfish Gatherers Document.
Shellfish Sampler	The industry representative or Loughs Agency Officer who carries out sampling in a production area
SPO **Spp.**	Senior Port Officer of the SFPA Species (plural)

UPLC	Ultra-performance liquid chromatography, a chemical analytical method
YTX	Yessotoxins, included in the lipophilic toxin group

1.0 Introduction

1.1 Background

Irish shellfish are a wholesome quality product, and it is important that the shellfish industry is supported by a robust monitoring programme. This helps to ensure that consumers, both in Ireland and in other countries, can have confidence that the Irish shellfish they are purchasing is a safe product and that it meets the required legal health standards.

The Irish Shellfish Monitoring Programme includes two monitoring elements that contribute to consumer safety. This Code of Practice has been developed to cover biotoxin and phytoplankton monitoring. A separate Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas is available on the SFPA website.

This Code of Practice has been developed by the Molluscan Shellfish Safety Committee (MSSC) through consultation with all stakeholders. It outlines how Ireland meets its obligations to protect consumers and comply with the requirements laid down in Irish and European legislation. The relevant food safety legislation is set out in Appendix 1.

It is a legal principle of Irish and European Food Law that all food business operators (FBOs) bear the primary responsibility for the safety of any food placed on the market by them. Producers must ensure that harvesting only takes place in a production area when it is safe to do so.

1.2 Aim

The aim of the Irish Shellfish Monitoring Programme is to ensure that Irish live bivalve molluscs placed on the market meet the highest standards of food safety and so maintain the excellent reputation of Irish shellfish.

1.3 Scope

This Code of Practice specifically relates to biotoxins and reflects current best practice and the legal requirements. It outlines the procedures for:

- Collection and delivery of shellfish and phytoplankton samples
- Analysis of shellfish samples
- Assigning a status to a production area
- Communication of results
- Additional management procedures including the Management Cell

The Code of Practice explains the partnership approach of the MSSC to the Irish Shellfish Monitoring Programme and outlines the responsibilities of shellfish samplers and shellfish managers.

2.0 The Molluscan Shellfish Safety Committee (MSSC)

2.1 Role of the MSSC

The MSSC was established in the late 1990s 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. The FSAI took over the organisation of the committee in September 2000 and it now operates as an FSAI Industry Forum. The Industry Forum structure facilitates discussion on the safety of the product from risk management and consumer protection perspectives. The MSSC is an open committee and anyone with a relevant matter to discuss may participate.

The MSSC acts as a consultative body from which the Official Agencies take advice in the context of their statutory roles. The Committee facilitates communication between the Official Agencies, industry representatives and other organisations involved in monitoring or facilitating shellfish production. The application of official controls as they apply to shellfish is the responsibility of the SFPA, who are the competent authority for this activity. 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. It operates under a service contract agreed with the FSAI.

2.2 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
- 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 subgroups or sub-committees. The membership of these sub-groups or sub-committees will be made up of MSSC members but may also include non-members co-opted to become a member of a sub-group or sub-committee.

2.3 Operation of the MSSC

The MSSC meetings are organised and chaired by the FSAI. There are a minimum of four scheduled meetings per year. The meetings are normally held in the FSAI Offices (Dublin), with one meeting each per year hosted by the SFPA (in Clonakilty) and the MI (in Galway). Meetings have also taken place virtually via videoconference. 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.

2.4 Stakeholders

The stakeholders listed below are members of the MSSC and the committee chair is held by the FSAI.

The Food Safety Authority of Ireland (FSAI) has the statutory function of coordinating the enforcement of food safety 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. The FSAI aims to ensure that food complies with legal requirements, or where appropriate with recognised codes of good practice. The Authority carries out its enforcement function through "service contracts" with official agencies. These contracts outline an agreed level and standard of food safety activity that the agencies perform as agents of the Authority. Both the Sea-Fisheries Protection Authority and the Marine Institute have service contracts with the FSAI. The FSAI operates Industry Fora, such as the MSSC, with the aim of fostering high standards of food safety in the Irish food industry.

The Sea-Fisheries Protection Authority (SFPA) is responsible for the implementation and enforcement of National and EU legislation which deals with fisheries control and the health conditions for the production and placing on the market of fish, shellfish, and fisheries products. The SFPA is the Competent Authority (CA) for the enforcement of seafood safety legislation in Ireland and operates under a service contract with the FSAI. The SFPA is responsible for food safety related controls of shellfish growing areas, transport, and seafood establishments. The SFPA implements, manages, and monitors the Irish Shellfish Monitoring Programme. Sea Fisheries Protection Officers of the SFPA act as Shellfish Managers in shellfish production areas and monitor product traceability.

The Marine Institute (MI) is the national agency responsible for marine research, technology development and innovation. It operates under a service contract with the FSAI for its food safety related responsibilities. The Institute provides essential scientific advice and a range of marine environmental monitoring services to help ensure Irish seafood products meet approved safety standards. The Marine Institute is the National Reference Laboratory for the monitoring of marine biotoxins and is responsible for the analysis of both shellfish and water samples. The Institute is accredited to ISO/IEC 17025:2017 by INAB. A key component of the Irish Shellfish Monitoring Programme is the Marine Institute's HABs database which gives easy access to up-to-date monitoring results. The MI also produces a weekly forecasting bulletin which gives an overview on historic and current biotoxin and phytoplankton trends and information on predictive forecasted toxin events based on oceanographic and environmental parameters, data and models.

The Irish Farmer's Association Aquaculture Committee (IFA Aquaculture) is the representative body which supports shellfish producers and works to ensure future sustainability and growth in the sector. The Association represents shellfish producers' interests at local, national, and European level on issues that impact on them such as biotoxins, licensing and food safety regulation. Shellfish producers have primary responsibility for ensuring the safety of the food they produce and as such their active support and co-operation is key to the success of the Irish Shellfish Monitoring Programme.

Producers actively support the programme through their work as phytoplankton and shellfish samplers.

The Health Service Executive (HSE) is responsible for the public health service in Ireland. The Environmental Health Officers (EHOs) of the HSE carry out food safety inspections and implement food sampling programmes at retail, wholesale and catering levels. Checks on shellfish suppliers are carried out routinely by the EHOs during their inspection of food premises. When necessary,

EHOs manage product recalls or withdrawals at retail and wholesale level and investigate food poisoning incidents. The work of the EHOs serves as a secondary check on the efficacy of shellfish production level controls.

An Bord Iascaigh Mhara (BIM) is the Irish State agency responsible for the development of the Irish seafood industry through the provision of technical expertise, business support, funding, training, and the promotion of responsible environmental practices. BIM provides the MSSC with technical advice and information on the sustainable development of the shellfish industry.

The Loughs Agency is a cross-border body that exercises 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.

The Environmental Protection Agency (EPA) is an independent public body established in 1993 under the Environmental Protection Agency Act 1992. The Agency has a wide range of functions to protect the environment as a valuable asset for the people of Ireland and to protect both the environment and people from harmful effects of radiation and pollution.

Irish Water is Ireland's national water utility. Irish Water are responsible for providing water and wastewater services throughout Ireland. Irish Water is committed to improving Ireland’s wastewater quality including where wastewater impacts on shellfish waters.

2.5 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. The

Management Cell of the MSSC is comprised of representatives from the FSAI, SFPA, MI and IFA Aquaculture. The operation of the Management Cell is described in Appendix 2.

3.0 Phytoplankton Monitoring

3.1 Background

Biotoxins are produced by some phytoplankton species found in seawater. If the toxic phytoplankton is ingested by filter feeding shellfish the biotoxins are assimilated into the body of

the shellfish. The shellfish are unaffected by the biotoxins and will clear the biotoxins from their system if they continue to feed.

Regulation (EU) No 2019/627 requires that, in addition to checks for the presence of the toxins in live bivalve molluscs, production areas must be periodically monitored to check for the presence of certain toxin containing phytoplankton. The Marine Institute Website provides additional details on the monitoring of phytoplankton, the species of phytoplankton of significance in Irish waters and their associated toxins.

Phytoplankton cell counts are an essential part of the monitoring programme to support shellfish testing. The supply of phytoplankton samples is an important part of the programme and samples should be supplied from Either individual or amalgamated production areas.

In 2021, for the purposes of the phytoplankton monitoring programme, in several regions, production areas were amalgamated together, particularly those who are in close proximity to each other and were observed to give similar spatial series data of HAB taxa from the NMP over a five-year period (2014-2019). A list and map of amalgamate areas for phytoplankton monitoring are given in Appendix 3.

In conjunction with other indicators, phytoplankton monitoring provides the following benefits:

- an essential early warning of the potential occurrence of toxins in shellfish,
- assistance with the decision-making process on which type of toxin analysis should be carried out
- prompts additional or increased frequency of testing of shellfish samples
- provides scientific evidence to supplement the results of the toxin analysis of the shellfish
- an essential element of risk managing the appropriate shellfish testing requirements.

While these phytoplankton samples cannot replace shellfish samples, they are a very important second line of defence to indicate the potential toxins that may be present in a production area and give a useful early warning to producers. They are essential for the CAs in planning the frequency of shellfish testing, and in deciding what analysis to prioritise in an area.

Rapid increases in toxin producing phytoplankton can indicate the need for additional sampling and/or tests to identify potential harmful toxicity in shellfish. Phytoplankton cell counts are always included in the Management Cell decision process to give a more informed picture upon which to base decisions.

3.2 Phytoplankton sampling points and procedure

Water samples for phytoplankton analysis must be collected according to the MI procedure and at a location approved and agreed by the MI. Phytoplankton sites are located in or adjacent to shellfish production areas taking into account the hydrography of the area. Phytoplankton samplers should ensure that samples are also representative of the water column.

Depending on the sampling site, samples may be taken using a hose sample (Lund Tube) or by a surface bucket. Hose samples are taken where water depth allows a 5m hose to be immersed in the sea and the top is plugged before it is retrieved. The sample of water is then transferred to a bucket where it is gently stirred to ensure it is homogenous. If the sampling site is not suitable for the use of a hose a sample should be obtained a bucket.

A subsample from this bucket is taken into a 50ml Sterilin tube and it is preserved using Lugols Iodine, which both stains and preserves the sample. It is essential to complete the label on the tube giving the date and location of the sample. All equipment and consumables are available from the MI.

Phytoplankton Samples along the coast south of the Shannon Estuary to Youghal should be submitted to:

Marine Institute Phytoplankton Laboratory, c/o Fastnet Mussels,
Gearhies,
Bantry,
Co. Cork.
P75 T971

Phytoplankton samples along the coast from north of the Shannon Estuary to Dungarvan should be submitted to:

Marine Institute,
Rinville, Oranmore,
Co. Galway. H91
R673

3.3 Mandatory phytoplankton sampling

Samples of water from each designated phytoplankton sampling point (see Appendix 3) shall be tested for all potentially toxic phytoplankton species on a weekly sampling frequency (see Appendix 4). Every classified shellfish production area should collect weekly phytoplankton

samples, all year round, in order to retain an open status. This requirement applies regardless of the sampling frequency for the shellfish species in the production area.

A minimum of three weekly samples will be required in every rolling 4-week period (this includes the preceding 4-week period and not the current week). If the frequency of sampling drops below this level the area will not be assigned an Open status on the next clear shellfish result. **Dormant areas that wish to re-open, must send in 2 concurrent weekly samples of phytoplankton (in addition to the shellfish samples) in advance of their expected week of recommencing harvesting and also submit a sample during the week of commencement and every week onwards throughout the harvesting period.**

Please note any samples taken from the current production week must be submitted and received into the MI Phytoplankton laboratories by the end of that same production week. Any samples received after a previous production week or samples which are taken from preceding weeks and not submitted and received by the laboratories during the week the sample was taken will not be analysed and will not be included as a valid sample in the calculation of the percentage submission in the preceding 4-week period.

Any production area not meeting the minimum of 3 out of 4 (i.e., 75% or greater in the preceding 4-week period for the submission of phytoplankton samples, not including the current week) weekly phytoplankton samples will not be assigned an open biotoxin status for the harvesting of any shellfish species within the affected production area. Except in wholly exceptional circumstances, the management cell will generally not be available to vary any decisions for production areas where phytoplankton sampling is not at the minimum phytoplankton sampling frequency.

The Phytoplankton % submissions are displayed for each production area on the MI's HABs website. Figure 1 shows the HABs phytoplankton web page sampling graphic which displays the latest phytoplankton sample submission for each production area.

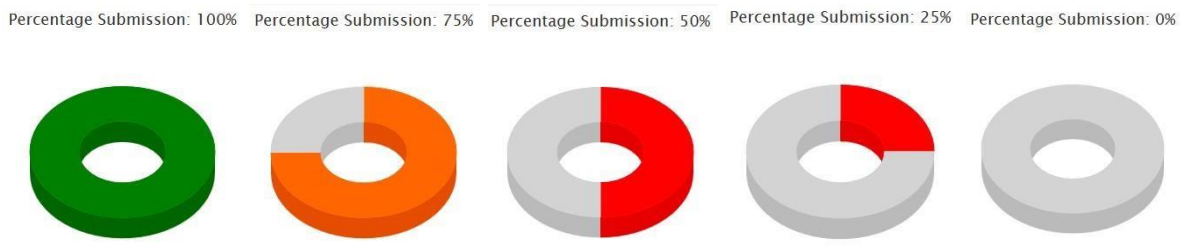


Figure 1 HABs Phytoplankton Sampling Graphic

Where the frequency is calculated at:

- 100% or 75% the production area remains on **Open Status**
- 50%, 25% & 0% the production area is on **Closed Pending Status**

Areas that are not in active production are not required to take weekly phytoplankton samples but if samples are sent to the MI they will be analysed. If an area is sending in shellfish samples then it must send in phytoplankton samples also.

3.4 Phytoplankton analysis and reporting

Phytoplankton analysis is carried out by the MI under the Institute's ISO/IEC 17025 scope of accreditation and in accordance with EU legislation Regulation (EU) 627/2019. Results are typically available within two days of receipt of a sample. The results are posted on the MI's HABs database.

3.5 Additional monitoring when toxic phytoplankton are identified

The presence of toxic species in phytoplankton samples is an important trigger for additional phytoplankton and shellfish monitoring.

PSP Phytoplankton

PSP is caused by toxigenic species of the dinoflagellate genus Alexandrium. This genus contains both toxic and non-toxic species which are difficult to distinguish between, using light microscopy. Furthermore, this species can bloom very quickly and intoxify shellfish within a very short period.

A trigger level of greater than 200 cells per litre of Alexandrium spp. has been set for the commencement of shellfish sampling and testing for PSP see Figure 2.

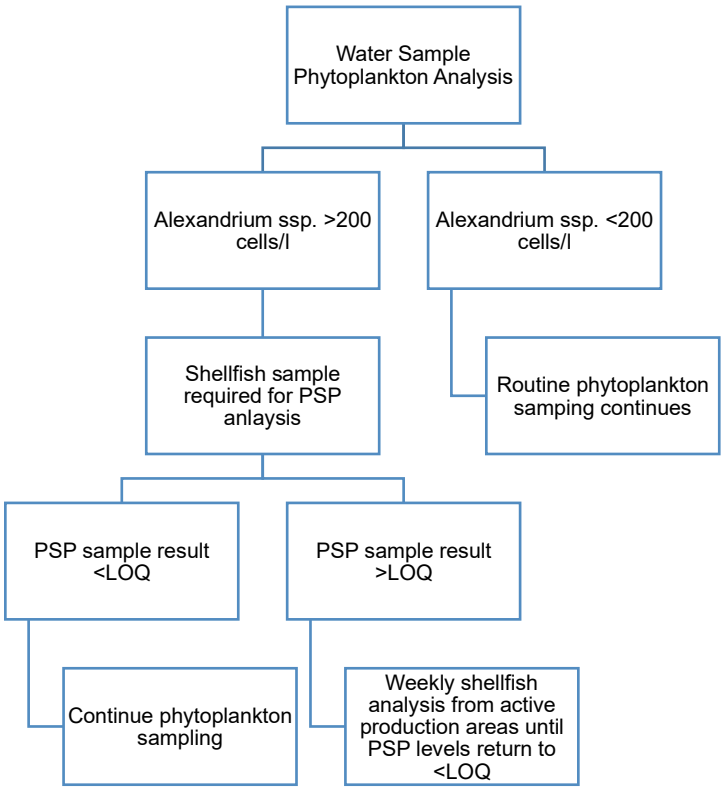


Figure 2 The Decision Tree for the monitoring of Alexandrium spp. and PSP in production areas

However, for samples from areas which usually submit on a monthly frequency, this frequency maybe changed to weekly if:

- Elevated cell numbers are observed of the causative PSP toxin producing organism Alexandrium spp.
- The population numbers, diversity, and composition of other species in the water in comparison to the numbers of Alexandrium spp.
- The time of year, i.e., High Risk period where PSP has occurred historically
- Location – where known PSP events have previously occurred historically

PSP concentrations in shellfish have been detected in other shellfish species within the same area or in adjacent bays.

ASP Phytoplankton

The ASP toxin is produced by the causative diatom species Pseudo-nitzschia spp. This genus contains both toxic and non-toxic species which are difficult to distinguish between, using light microscopy. Furthermore, this species can bloom very quickly and intoxify shellfish within a very short period.

All shellfish samples (except Scallops) submitted from classified production areas are now screened for the presence of Domoic Acid, the ASP toxin, by LC-MS/MS. If any quantifiable ASP concentrations are observed in the sample, the sample is then analysed by UPLC for full quantification.

However, for samples from areas which usually submit on a monthly frequency, this frequency may be changed to weekly if:

- Elevated cell numbers are observed of the causative ASP toxin-producing organism Pseudo-nitzschia spp.
- The population numbers, diversity, and composition of other species in the water in comparison to the numbers of Pseudo-nitzschia spp.
- The time of year, i.e., high risk period where ASP has occurred historically
- Location – where known ASP events have previously occurred historically
- ASP concentrations in shellfish have been detected in other shellfish species within the same area or in adjacent bays.

4.0 Shellfish Sampling, Analysis and Reporting

4.1 Organisation of shellfish sampling

Shellfish production areas are under the Official Control of the SFPA and coordinated by the SFPA Shellfish Monitoring Coordinator. SFPA Senior Port Officers (SPOs) have responsibility for the overall supervision of production areas within their region and for ensuring that Official Control samples are taken at the required frequencies (see Section 4.3). Shellfish Managers and Shellfish Samplers are assigned to each production area.

4.1.1 Responsibilities of the Shellfish Monitoring Coordinator

The Shellfish Monitoring Co-ordinator is the SFPO with national responsibility for overseeing the operation of the Irish Shellfish Monitoring Programme.

Responsibilities of the Shellfish Monitoring Co-ordinator include:

a) Liaising with the MI in setting sampling frequencies and communicating those decisions.
b) Coordinating the SFPA's classification monitoring programme.
c) Organising the annual review of classifications of production areas.
d) Maintaining records of shellfish samplers.

4.1.2 Responsibilities of the Shellfish Managers

Responsibilities of the Shellfish Managers include:

a) Appointing shellfish samplers and back-up samplers for each designated production area.
b) Ensuring that shellfish samplers are trained commensurate with their responsibilities.
c) Supervising shellfish samplers in their area. Managers shall verify that samplers collect samples and that samples have been collected according to the defined sampling procedure.
d) Supplying shellfish samplers with all the equipment required for shellfish/water samples in their production area(s).
e) Ensuring that Official Control samples are taken as required (see Section 4.9).
f) Surveillance of production areas during closed periods to ensure no illegal harvesting of shellfish occurs.
g) Maintaining records of local Shellfish Samplers and all other relevant documents.

4.1.3 Responsibilities of Shellfish Samplers

Shellfish Samplers carry out sampling in a production area as an assistance to the industry. Shellfish Samplers may be an industry representative or other person. Officers of the Loughs Agency act as Shellfish Samplers for the production areas within Carlingford Lough and Lough Foyle.

The responsibilities of the Shellfish Samplers include:

a) The collection of shellfish samples and phytoplankton samples from designated sampling points according to the procedures and schedules set down in this Code of Practice and,
b) The forwarding of the shellfish samples and phytoplankton samples to the specified laboratory in accordance with the sampling frequency specified.

Training and information workshops for samplers will be organised by the MSSC stakeholders on a regional basis as necessary.

4.1.4 Sampling vessel safety guidelines

The activity of conducting shellfish sampling necessitates on occasion for samplers to embark on board a boat. When conducting verification and official control sampling (Section 4.9), SFPA personnel may use the following guidelines to determine the suitability of a vessel for this purpose. This is in accordance with their own obligations under Section 13 of the Safety, Health and Welfare

at Work (SHWW) Act 2005 and is in keeping with the Department of Transport Tourism and Sport (DTTAS) guidelines for the "Code of Practice for the Design, Construction, Equipment and Operation of Small Fishing Vessels of Less than 15m Length Overall" and the Health and Safety Authority's (HSA) document "Managing Health and Safety in Fishing"

Sampling Vessels General Requirements:

In these instances, and in order to adhere to their individual obligation to ensure their own health and safety, SFPOs will use the following checklist to assess the craft prior to embarking:

- The hull must be sound, watertight and free from significant damage and corrosion, and of a size suitable for the safe operation of the vessel in expected sea and weather conditions likely to be met. In this regard, SFPOs could be guided by the obvious visual condition of the boat and by the amount of water (if any) lying in the bilge.
- Propulsion engines and associated stern gear must be of a design, type and rating to suit the design and size of vessel and should provide the required strength and service for the safe operation of the vessel in expected sea and weather conditions likely to be met. It is unlikely that SFPOs will be in a position to substantiate this, however observation of the movement of the boat prior to embarkation, particularly on approach to the embarkation point, will help to guide.
- Small vessels must have alternative means of propulsion, such as oars or a spare outboard engine.
- All vessels must have an efficient means of anchoring.
- All vessels must have an efficient means of bilge pumping. Small vessels must have a 'bailer' on board as a minimum.

4.2 Shellfish species

The Irish Shellfish Monitoring Programme covers all Live Bivalve Molluscs and also live echinoderms and live marine gastropods. The full list of species analysed under the Programme is shown in Appendix 5. The regulatory limits apply to both wild and farmed shellfish. Specific requirements for scallops are outlined in Section 4.15. Gastropods such as periwinkles and abalone are included in the programme. There is no tunicate production in Ireland, but the species would be included if product was planned to be placed on the market.

4.3 Sampling frequency

The frequency of shellfish sampling is based on an assessment of the latest toxicity information available and seasonal trends. Sampling frequencies are generally set at weekly, fortnightly or monthly for each shellfish species in a production area, as shown in Appendix 6. Other frequencies may also be set if conditions necessitate. Sampling should only take place when shellfish harvesting is expected. An explanation of the period of validity is provided for in section 4.3.1 below. Further information on the production period is available in Section 6.2 (Production Period for Harvesting).

4.3.1 Sampling frequency required for samples to be valid

For a sample to be valid it must be taken a **minimum of least 48 hours** after any previous valid sample.

The **maximum gap** allowed between valid samples will depend on the sampling frequency in force:

- When the sampling frequency is **weekly** a sample should be submitted for each production week, with no more than **12 days** between sample dates.

The production period (week) starts on a Sunday and ends the following Saturday.

- When the sampling frequency is **fortnightly** (a two-week production period) a sample should be submitted for each two-week production period, with no more than **19 days** between sample dates. The two-week production period starts on a Sunday and ends the following Saturday week.
- When the sampling frequency is **monthly** (a calendar month production period) a sample should be submitted each calendar month, with no more than **38 days** between sample dates. The production period (month) starts on the first day of the month. Samples should be taken and submitted during the first week of every month.

The maximum gap specified between samples does not include the days of sampling. For example, when the sampling frequency is monthly, if a sample is taken on the 3rd January then the next sample must be taken during the calendar month of February, on or before the 11th.

If the period of validity of a sample has finished and no new valid sample has been taken, then the production area defaults to a closed status.

4.4 Pre-harvest sampling to open an area

When there are no valid samples submitted within the required sample frequency, the default biotoxin status of an area is Closed - Expired. As per section 3.3 on Mandatory Phytoplankton Sampling, **Dormant areas that wish to re-open, must send in 2 concurrent weekly samples of phytoplankton (in addition to shellfish samples) in advance of their expected week of recommencing harvesting.** Before harvesting from any production area may commence, two shellfish samples must have been analysed and have tested below the relevant regulatory limits. Samples to open an area for harvesting must have been taken a **minimum of 48 hours and a maximum of 12 days apart.**

If the first sample tests below the relevant regulatory limits, the area is placed on a Closed Pending status. Then if the second sample tests below the relevant regulatory limits, the area is placed on an Open status with effect from the date of sampling of the second sample. Once the area is assigned an Open status the sampling frequency will revert to the relevant frequency (generally weekly, fortnightly, or monthly) in place for that species and production area.

4.5 Changes to the sampling frequency

The MI continually monitors the results from the analysis of shellfish and phytoplankton. It uses these results along with other information such as seasonal toxicity trends to carry out risk assessments. The MI then identifies when sampling frequency should be increased or decreased for shellfish species in production areas. Where such a risk assessment is carried out and used as the basis for varying an area's sampling frequency it will be kept under review to ensure it reflects the current risk status of the area in question.

When the MI has identified that changes should be made to the sampling frequency it shall inform the Shellfish Monitoring Co-ordinator who will in turn inform all the Shellfish Managers and Shellfish Samplers. Details of the risk assessment will be included in the email to the Shellfish Managers and Shellfish Samplers.

4.6 Sampling for specific toxin groups

Lipophilic Toxin Group

Sampling for lipophilic toxins (DSP, AZP, PTX, YTX) will generally be once per production week for mussels in open production areas. The standard sampling frequency for other species will be

monthly. The sampling frequency is kept under review and will change in response to changes in phytoplankton counts or the toxicity profile of other species.

PSP

Sentinel Sites are tested monthly for PSP or more frequently, depending on the phytoplankton results. When the presence of the Alexandrium spp. is detected over 200 cells per litre in water samples the MI will request additional phytoplankton and shellfish samples from these areas for PSP testing (see Section 3.5, Additional Monitoring When Toxic Phytoplankton Species Identified). Subsequent elevation of these initial counts, or detection (>LOQ) of PSP in the flesh sample will trigger further PSP testing. Samples will be requested through the Shellfish Monitoring Coordinator.

Cork Harbour and Castlemaine Harbour are presently the only areas in Ireland to date where the presence of Alexandrium spp. has been linked to PSP toxicity above the regulatory limit. At a minimum during the months of June, July and August, weekly samples of all species within these two production areas are submitted to the MI in Galway for PSP analysis to be conducted, in addition to the routine Lipophilic Toxin analysis. Two clear results must be obtained prior to harvesting. With the exceptions of mussels within these areas, outside of this period the sampling frequency for all other shellfish species in these areas will revert back to monthly frequency after a risk analysis has been conducted, in accordance with the procedures set out in Section 4.5 (Changes to the Sampling Frequency).

ASP

All shellfish samples (except Scallops) submitted from classified production areas are now screened for the presence of Domoic Acid, the ASP toxin by LC-MS/MS, if any quantifiable ASP concentrations are observed in the sample, the sample is then analysed by UPLC for full quantification. Additionally, sentinel site (section 4.8) samples are tested for ASP via UPLC on a monthly basis. This sampling frequency may be increased when low level ASP toxicity is observed and also when any of the scenarios listed in Section 3.5, Additional Monitoring When Toxic Phytoplankton Species are identified ASP Phytoplankton, is observed.

Scallops in classified production areas are sampled for ASP (see Section 4.15.1 Scallops from classified production areas) on a fortnightly frequency in general. This frequency may be increased to weekly during occasions of high toxicity. Scallops from offshore areas are sampled in accordance with Section 4.15.2 (Scallops from offshore areas that are not classified). Each offshore site or ICES Statistical rectangle when fished requires one sample of scallops for biotoxin

analysis per week. Official Control samples of scallops are taken by Officers of the SFPA at FBO premises for verification purposes (see Section 4.9, Official Control Samples).

4.7 Shellfish production areas and sampling points

The SFPA and MI have identified shellfish production areas and designated appropriate sampling points within those areas. Maps showing the locations of the shellfish production areas and the sampling points are available through the MI HABs Shellfish Monitoring webpage.

Each sample point is identified by a code and shellfish samplers must ensure they use the correct code on the sample identification label (see Section 4.10.4, Sample Identification Labels). The codes are in a 6-letter format which is comprised of 2 letters for each of the following, County, production area and sampling point. For example, the code for the sampling point Dunmanus Inner in Dunmanus Bay, Co. Cork is CK-DB-DI.

Any requests for changes to production areas and sampling points should be sent to the Shellfish Monitoring Co-ordinator in the first instance, who will review the request and consult as necessary. The SFPA and MI will agree on any changes to the shellfish production areas or sampling points. The Shellfish Monitoring Co-ordinator will inform the relevant shellfish managers and shellfish samplers of the outcome of the review. All decisions on reviews will be reported to the next meeting of the MSSC.

4.8 Sentinel sites

Sentinel sites are production areas from around the coast that are sampled throughout the year and analysed for all toxins to give a representative view of toxicity. There are fourteen sentinel sites and four shellfish species which are sampled from each site on a monthly basis. Sentinel site samples are analysed for Lipophilic toxins (DSP, AZP, YTX & PTX), and the Hydrophilic toxins PSP and ASP.

4.9 Official control sampling

The SFPA conducts the following Official Control sampling to ensure compliance:

- The Sea Fisheries Protection Authority (SFPA) will take one Official Control shellfish verification sample per month for species/areas on a weekly sampling frequency and quarterly for species/areas on a monthly sampling frequency.

- The SFPA will take an Official Control sample, when a production area is on Closed Pending, to open a production area following a toxic event. If the Official Sample is under the legal limits for toxins, then the area will be assigned an Open status.
- Scallop samples from approved FBOs, in the form that is placed on the market by the FBO, i.e., either whole body or edible parts separately are sampled on a quarterly basis.
- Marine gastropods from approved FBOs are sampled on a quarterly basis when in production.
- Shellfish from Purification and Dispatch Centres are sampled on a quarterly basis.

These Official Controls are carried out by SFPOs in accordance with the SFPA Programme of Official Controls.

4.10 Sampling procedure

4.10.1 Sample collection

All shellfish samples must be collected in accordance with the procedure currently agreed by the MSSC. Samples must be collected from the designated sampling points within production areas. If tides, weather, or a lack of shellfish prevent collection of a sample from the designated sampling point, then samples must be taken from an appropriate point within the specified production area. If the sample is not taken from the designated sampling point, the Sampler should inform the Shellfish Manager and a record kept of where the sample was taken from.

4.10.2 Sample size and quantity

Sample size is defined by the number of individual shellfish for each species. Shellfish Samplers should refer to Appendix 5 for the appropriate number of individual shellfish per sample for each species sampled. Samples must be of an adequate size and the shellfish must be alive when they reach the laboratory, or the sample may be rejected. Samples should be clean and taken from stock with a good meat yield and that represent commercial product that will be sent to market.

Samples containing small meats that take an exceptional length of time to obtain a sufficient sample may be rejected, and further samples will be required.

4.10.3 Wrapping

Every sample should be chilled, placed in a clean plastic bag, which should be tied and placed in another plastic bag. The sample should then be placed in a polystyrene/corrugated plastic box, supplied by the SFPA. The boxes should be securely closed using masking tape.

4.10.4 Sample identification labels

All sample boxes should be marked 'For Biotoxin Analysis'. The sample label must show the following information:

- sample point code (see Section 4.7)
- sample date and time
- shellfish species
- name and address of shellfish sampler.

Failure to use the correct code can delay the publication of results and may lead to samples being rejected.

For Biotoxin Analysis:	
Name of Area Sampled:	Ballinakill, Co Galway
Sample Point Code:	GY-BL-BL
Date of Sampling:	12 – Nov – 2018
Time of Sampling:	13: 15
Species:	Pacific Oysters
Sample taken by:	A. Sampler Ballinakill, Co. Galway

Figure 3 Example of a label

4.10.5 Delivery to the laboratory

Samples should be sent via An Post postal service to:

Marine Institute,
Box No. 430,
Galway Mail Centre,
Tuam Road, Co. Galway.

For samples which are not transported using An Post but use another courier service such as DPD, TNT or DHL, the address below is to be used. Please note that for samples delivered by these means it may not be possible to process them until the following day, depending on the time they arrive at the laboratory.

Address when samples are delivered directly to the MI:

Marine Institute,
Biotoxin Unit,
Rinville,
Oranmore,
Co. Galway,
H91 R673

Hand Delivery of Samples direct to MI

Please note, if samples are required to be delivered directly to the MI it is within strict accordance with the protocols as detailed in Appendix 7. Failure to adhere to these protocols may result in samples not being accepted or rejected for analysis.

Laboratory Receipt Shellfish samples should normally be dispatched by courier to arrive no later than Wednesday morning to the MI Biotoxin laboratory to allow for results to be published during the same week.

The MI operates a three-day turnaround from sample arrival to report. In general, all shellfish delivered by post up to Thursday will be processed on the day of arrival and the result will be issued the following day. Shellfish arriving on a Friday may be held over the weekend depending on laboratory schedule. Additional PSP and ASP analyses when required may take longer to issue results.

4.11 Sample rejection

The sample must arrive to the laboratory with a fully completed legible sample label showing the information indicated in Section 4.10.4 (Sample Identification Labels).

Reasons for possible rejection:

- label on the sample
- insufficient insufficient information on the sample identification label
- no sample identification sample, not enough individual shellfish
- shellfish show signs of decay

Where a sample is rejected, the Marine Institute will inform the SFPA Shellfish Coordinator giving full details of the sample and the reason(s) for the rejection. The SFPA Shellfish Coordinator will follow up the rejection with the Sample Manager and the Sampler. The SFPA Shellfish Coordinator reports to the MSSC on the level of rejections and follow-up.

4.12 Analysis

EU Regulations 853/2004, 627/2019 and 1374/2021 set out the health standards for placing live bivalve molluscs on the market for human consumption. This includes the requirements for marine biotoxin groups, methods of analysis and the toxin limits (see Appendix 8). Sample analysis is carried out by the MI under the scope of its INAB accreditation to ISO 17025 standards using approved chemical methods.

4.13 Reporting of biotoxin results

The Marine Institute publishes the biotoxin results on the MI HABs Shellfish Monitoring webpage (see Appendix 9).

4.14 Biotoxin status on shellfish documentation

All batches of harvested or fished shellfish must be accompanied by a completed Shellfish Registration Document (see Appendix 10, example 1). The current biotoxin status and previous test status must be indicated. This document also records information such as the date of harvesting, quantities harvested, location of harvesting and the Gatherer's details. Shellfish Registration Document Books are issued by the SFPA Port Offices. Instructions on the completion and use of the Shellfish Registration Documents are included at the start of the Books.

4.15 Scallop sampling, analysis, and reporting

The requirements for the monitoring of scallops are detailed in the SFPA Notice to Trade on the harvesting of scallops which is available from SFPA Port Offices and the SFPA website. The requirements for scallops cover both the king scallop (Pecten maximus) and the queen scallop (Aequipecten opercularis). This section explains the protocols for scallops depending on whether they are harvested from within classified production areas or from offshore areas that are not classified.

Scallops harvested from within classified shellfish production areas can only be harvested from production Areas that are on an Open or a Harvest Restricted Biotoxin status for scallops (see Section 4.15.1 Scallops from Classified Production Areas).

> Scallops which are harvested by fishermen from offshore wild fisheries may only be placed on the market by following the protocol in Section 4.15.2 (Scallops from Offshore Areas that are not Classified).

4.15.1 Scallops from classified production areas

Scallops from a classified production area may only be placed on the market for retail sale when the production area has an Open or Harvest Restricted biotoxin status for scallops and the product is placed on the market via an approved dispatch centre.

Unless a production area has been specifically classified for scallops, all scallops harvested within classified production areas 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.

The current list of classified shellfish production areas in Ireland including maps identifying the boundaries of these areas is available on the SFPA's website.

Documentation

Scallops harvested from classified production areas must be accompanied by a completed Shellfish Registration Document recording the classification of the production area harvested, harvest location code, biotoxin status of the production area, date of harvesting, quantities harvested, name of the fishing vessel and EU log sheet number (see Appendix 10, examples 2 and 3).

Biotoxin Testing of Scallops from Classified Shellfish Production Areas The harvesting or fishing of Scallops can only take place from Classified Production Areas that are:

- On an '**Open**' Biotoxin status for scallops when they can be marketed live and whole in the shell, or,
- On a '**Restricted**' Biotoxin status when only shucked product of those parts of the scallop which have tested below regulatory limits for biotoxins can be placed on the market.

No harvesting of scallops is allowed from a classified production area that is on a '**Closed**' or '**Closed Pending**' Biotoxin status for scallops.

In order to commence harvesting, either an 'Open' or 'Restricted' biotoxin status must be obtained for scallops from Classified Production Areas. To achieve this, two samples must be taken **more**

than 48hrs and less than 12 days apart. Both samples should be sent to the Biotoxins Unit, Marine Institute (see sample protocol below). Thereafter, one sample per sample frequency per classified production area is required to maintain the scallop biotoxin status of a production area.

The scallop shellfish samplers are responsible for the collection of scallop samples and phytoplankton samples. Scallop processors and approved dispatch centres handling scallops from classified production areas should agree in advance with fishing vessel operators which vessels will act as scallop shellfish samplers. The identification of scallop shellfish samplers will avoid duplicate sampling where various vessels are fishing in the same classified production area. Duplicate samples will be rejected if they exceed the sampling frequency.

Sampling frequency for scallops harvested from classified production areas

Once a classified production area is on an “open” or a “harvest restricted” biotoxin status for scallops, the sampling must continue at the specified sampling frequency to maintain the biotoxin status for that production area (see Section 4.3, Sampling Frequency).

The biotoxin sampling frequency for scallops from classified production areas is, in general, weekly during active harvesting. This frequency may be decreased to fortnightly during periods of demonstrated decreased toxicity, on the basis of a risk assessment undertaken by a competent authority. However, it should be noted that typical scallop toxin profiles in Ireland are generally unlikely to support deviation from weekly sampling frequency during active harvest periods.

In addition to weekly testing on the shucked product from classified production areas, a “whole animal” sample of scallops (destined for processing) from classified production areas must be submitted at least monthly or more frequently, if required by the competent authority.

Sample Protocol for scallop from classified production areas

The sample size should be 12 – 15 Scallops, whole in the shell. Whole scallop samples should be placed fresh in a sealed clean plastic bag. Scallop sample bags must be labelled with indelible ink with the following information:

For Biotoxin Analysis	
Sample ssp.	
Date of sample	
Sample location code*	
Sample taken by	

* Sample location codes are on the HABs Shellfish Monitoring webpage.

A printout of the sample label should also be included with the sample.

The bagged and labelled sample should then be placed in a polystyrene box securely closed with masking tape to prevent leakage.

Delivery to the Laboratory for analysis is per Section 4.10.5

Phytoplankton monitoring

There is a requirement for phytoplankton samples to be submitted from classified production areas that are fished for scallops in line with the requirements as set out in the section on Mandatory Phytoplankton Sampling see Section 3.3.

Biotoxin Results

The Marine Institute publishes the biotoxin results on the MI HABs Shellfish Monitoring webpage. For further information on results see Section 5.4 (ASP).

4.15.2 Scallops from offshore areas that are not classified

This section applies only to scallops fished from offshore, unclassified areas and landed into ports within the Republic of Ireland.

The results of scallop testing are published online on the HABs Shellfish Monitoring webpage. Fishers are recommended to check if results have been published for the month in which they are fishing. This may help inform decision-making around fishing for scallop and will provide an indication as to whether a sample may need to be submitted on landing (see "Processing/Shucking" below).

This part of the Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins) describes the requirements for the legitimate and lawful placing on the market of the edible part of shucked scallops.

Nothing in this document allows for the placing on the market of whole, unshucked, scallop fished from offshore, unclassified areas.

Scallops harvested from offshore sites can only be placed on the market for human consumption via a processing establishment approved for the shucking of scallops, a fish auction approved for the handling of scallops or a dispatch centre.

Food business operators placing scallops from offshore sites on the market are advised to ensure that biotoxin controls are included in their FSMS. They must be able to demonstrate the clear link between batches of scallop they place on the market and the related biotoxin results issued by the MI.

Documentation

Scallops harvested from offshore areas must be accompanied by a completed Shellfish Registration Document recording the name of the fishing vessel, date of harvesting, quantities harvested, name of the fishing grounds, ICES area, ICES statistical rectangle and EU log sheet number (See Appendix 10, Example 3).

Fishermen landing scallops from offshore sites that are not classified should record 'Not tested' in the Biotoxin Status on the Shellfish Registration Document.

Landing

Landing of scallops fished from offshore, unclassified areas must take place at sites identified as suitable for receiving such landings by the Sea-Fisheries Protection Authority. Once landed, a batch is considered to have been placed on the market for the purposes of EU agri-food law.

Once landed, batches must be directly transported to a processor approved by the Sea-Fisheries Protection Authority to process or shuck scallops.

It is not permitted to place any quantity, however small, on the market locally or to otherwise place whole unshucked scallops on the market for human consumption.

Sample Protocol for scallop from offshore areas that are not classified Scallop samples should be placed fresh in a sealed clean plastic bag. Scallop sample bags must be labelled with indelible ink with the following information:

For Biotoxin Analysis	
Sample ssp.	
Date of sample	
Sample location code*	
Sample taken by	

*Sample location codes are available in the 'Biotoxin and Phytoplankton Production Maps' guide on the HABs Shellfish Monitoring webpage.

A printout of the sample label should also be included with the sample.

Every Sample should be chilled, placed in a sealed clean plastic bag. The sample should then be placed in a polystyrene box securely closed with masking tape to prevent leakage.

Delivery to the Laboratory and Reporting

Biotoxin samples of Scallops must be sent via An Post postal service directly to:

Marine Institute,
PO Box 430,
Galway Mail Centre, Tuam Road
Galway

The MI publishes the biotoxin results on the MI webpage. For further information on results see Section 5.4 (ASP Results).

Processing / Shucking

Prior to processing the approved processor will establish if scallops from the area from which the batch to be shucked has been fished have been analysed by the Marine Institute and if a "whole animal" (WA) result is available. Processing may commence if a sample has been submitted. HOWEVER, should such a sample return a non-compliant result then the batch, whether processed or undergoing processing, must be disposed of as Category 1, Animal Byproducts. Processing while a result is pending is at the processor's risk.

5.0 Production Area Status

5.1 Assigning a production area status

Production area status is assigned based on the results of the analysis of samples taken under the Irish Shellfish Monitoring Programme. Samples which have been analysed privately are not valid samples for the purposes of assigning a status to a production area.

The following is a guide to the assignment of production area status. The decision trees shown here have been developed to assist in the assignment of status but they are for guidance only. Table 1 outlines the terms used to assign production area status for the lipophilic toxin group and PSP. Terms used in relation to the ASP status of shellfish are explained in Section 5.4 (ASP). EU regulatory limits are shown in Appendix 8 (Biotoxin Methods of Analysis and EU Regulatory Limits).

Table 1 Production Area Status

Status	Explanation

Open	The most recent valid sample is below the regulatory limit. The production area is open for harvesting for that species until the end of the current production frequency period.
Closed	The most recent valid sample has exceeded the regulatory limit. The production area is closed for the harvesting or lifting of shellfish unless the express permission of the SFPA has been obtained for the movement of shellfish. Date of closure is backdated to the start of the current production period as per section 6.2.
Closed Pending	The most recent valid sample is below the regulatory limit but there is no previous valid sample within the required current sample frequency for the species. The production area is closed for harvesting for that shellfish species until a second sample is submitted within the required timeframe and the result obtained is below regulatory limits.
Closed Expired	The sample frequency for the species listed has expired, where no sample for that species has been submitted within the specified sample frequency period, and the area is now Closed for the listed species.
Harvest Restricted	Refer to Table 2. Applied to scallop (*P. maximus)* samples from classified production areas, submitted whole in the
	shell where at least one of the tissues analysed is > regulatory levels.

Samples must normally be taken in the same or successive production period for an Open status to be maintained, although variations to this may be agreed by the Management Cell (see Appendix 2, The Management Cell).

On the detection of toxins over the regulatory limit, any product harvested during the production period may need to be recalled. For an explanation of production period see Section 6.2 (Production Period for Harvesting).

5.2 Lipophilic toxin group results

On the initial detection of Lipophilic toxins over the regulatory limit, in any bivalve species from any production area, a ban on harvesting of that bivalve species from that production area will be immediately in force (see Figure 4, Lipophilic Toxin Decision Tree). Harvesting may not resume until two valid samples have been tested and shown to be below the regulatory limit. The Management Cell of the MSSC may, however, authorise harvesting in certain circumstances (see Appendix 2).

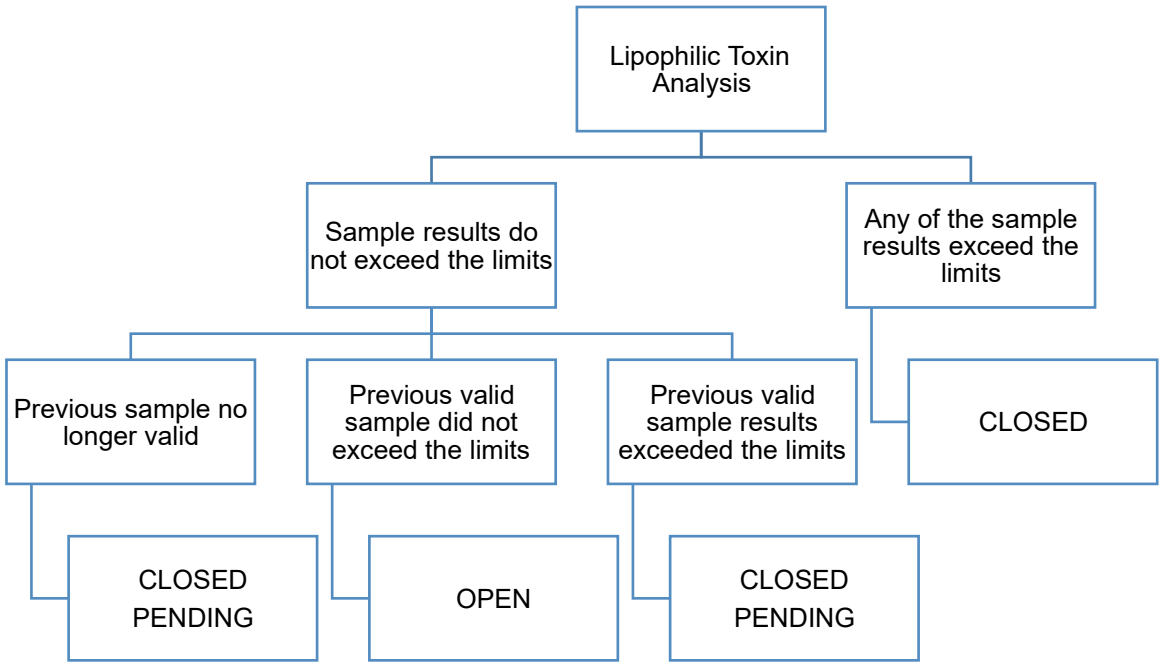


Figure 4 Lipophilic Toxin Decision Tree

5.3 PSP results

On the initial detection of PSP toxins over the regulatory limit, in any bivalve species from any production area, **a ban on harvesting of all bivalve species from that production area will be immediately implemented**. No harvesting of a species will be permitted from the production area until results are available that show that the species is below the regulatory limit.

When PSP results are increasing towards, or have reached/exceeded half the regulatory limit, i.e., ≥400µg/kg, but still remain below the regulatory limit (800 µg/kg) a meeting of the Management Cell will be called to determine the most appropriate course of action to be taken. This may include recommending voluntary closures of production sites.

The PSP decision tree for assigning the status of a shellfish production area is shown in Figure 5. The phytoplankton monitoring decision tree for *Alexandrium spp*. and PSP in production areas is shown in Figure 2 (see Section 3.5, Additional Monitoring when Toxic Phytoplankton are Identified).

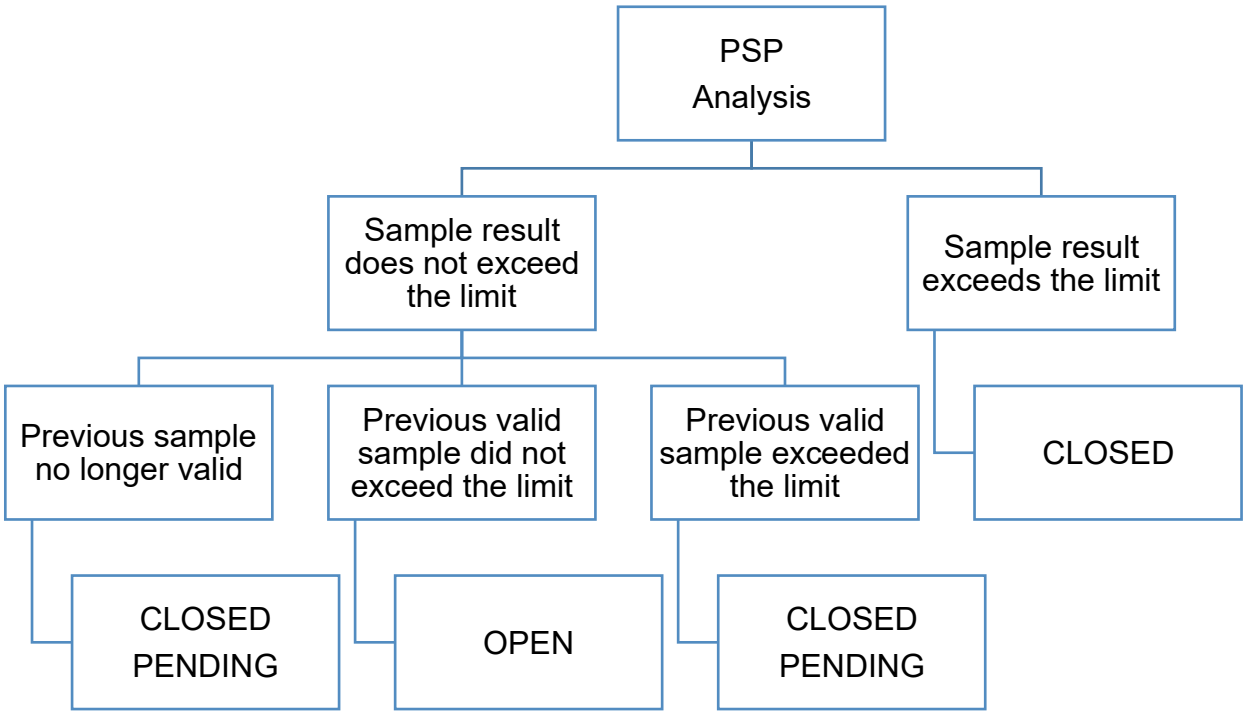


Figure 5 PSP Decision Tree

5.4 ASP results

5.4.1 Live bivalves – excluding scallops

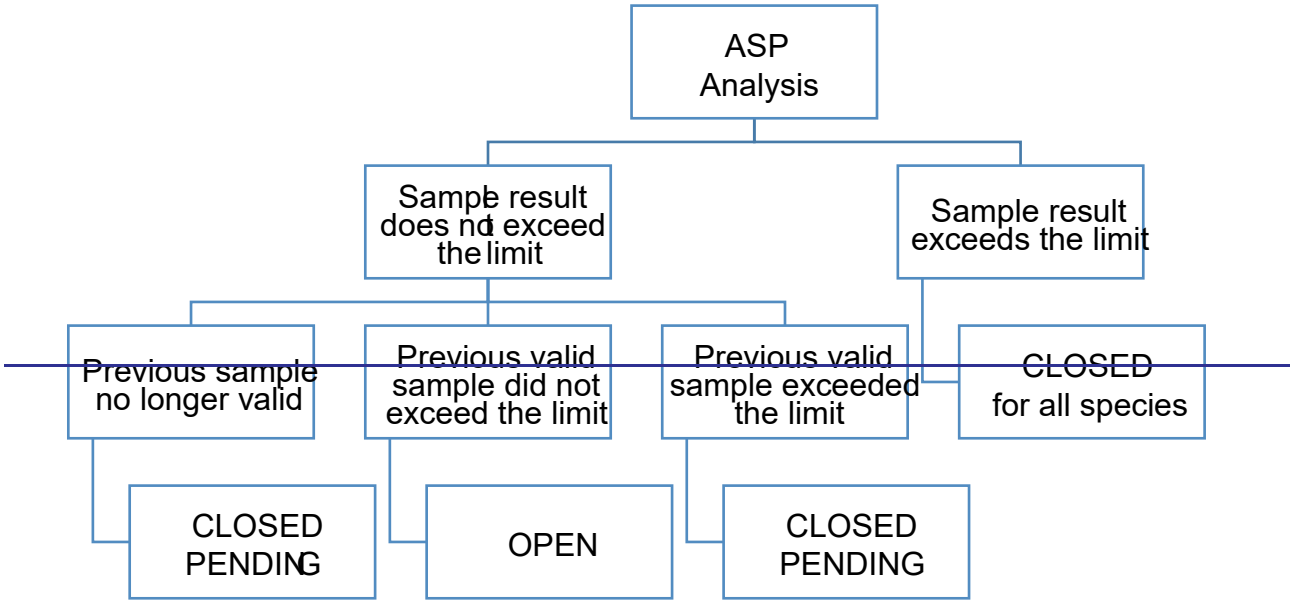
All shellfish samples (except Scallops) submitted from classified production areas are now screened for the presence of Domoic Acid, the ASP toxin by LC-MS/MS, if any quantifiable ASP concentrations are observed in the sample, the sample is then analysed by UPLC for full quantification. In addition, shellfish from sentinel sites are tested for ASP via UPLC. The ASP decision tree for assigning the status of a shellfish production area is shown in Figure 6.

On initial detection of ASP toxins over the regulatory limit, in any bivalve species with the exception of scallops, the area will have a closed status for all species from that production area. The ban on harvesting for other species will continue until they are tested and found to be below the regulatory limit. The Management Cell may however decide to open an area in certain circumstances (see Appendix 2, The Management Cell).

Figure 6 ASP Decision Tree

5.4.2 ASP – Scallops from classified production areas

The following scallop tissues are analysed for ASP (see Figure 7, ASP Decision Tree for scallops



from classified production areas):

- Gonad
- Adductor Muscle
- Remainder

Total Tissue – this is a calculated result based on the sum of the amounts (tissue weight × ASP concentration observed) for each of the above tissues (corrected for recovery).

The following scallop tissue is analysed for Lipophilic Toxins (see Figure 4, Lipophilic Toxin Decision Tree)

Remainder – this tissue is deemed to have (if present) the highest concentration of lipophilic toxins of the three tissue types.

If quantifiable lipophilic toxin concentrations are observed in the Remainder tissue, the Gonad and Adductor Muscle maybe analysed for Lipophilic Toxins.

If all compartments analysed are found to contain <20µg/g (<20mg/kg) of Domoic Acid and < the associated regulatory levels for Lipophilic toxins the area is determined to have a status of Open and scallops can be harvested from that area (see Figures 4 & 6). If all compartments analysed have >20µg/g of Domoic Acid and or > the associated regulatory levels for Lipophilic toxins the area is assigned a Closed status for scallop harvesting.

If the separate compartments of the adductor muscle and gonad are analysed separately and if the amount of Domoic acid is found to be <20µg/g in either or both of these compartments and < the associated regulatory levels for Lipophilic toxins in either or both of these compartments or the remainder tissue they can be placed on the market for human consumption. The area from which these scallops come from is said to have a Harvest Restricted status i.e., they can only be sold after they have been shucked and the separate compartments analysed. See Table 2 for a summary of production area status for scallops from classified areas.

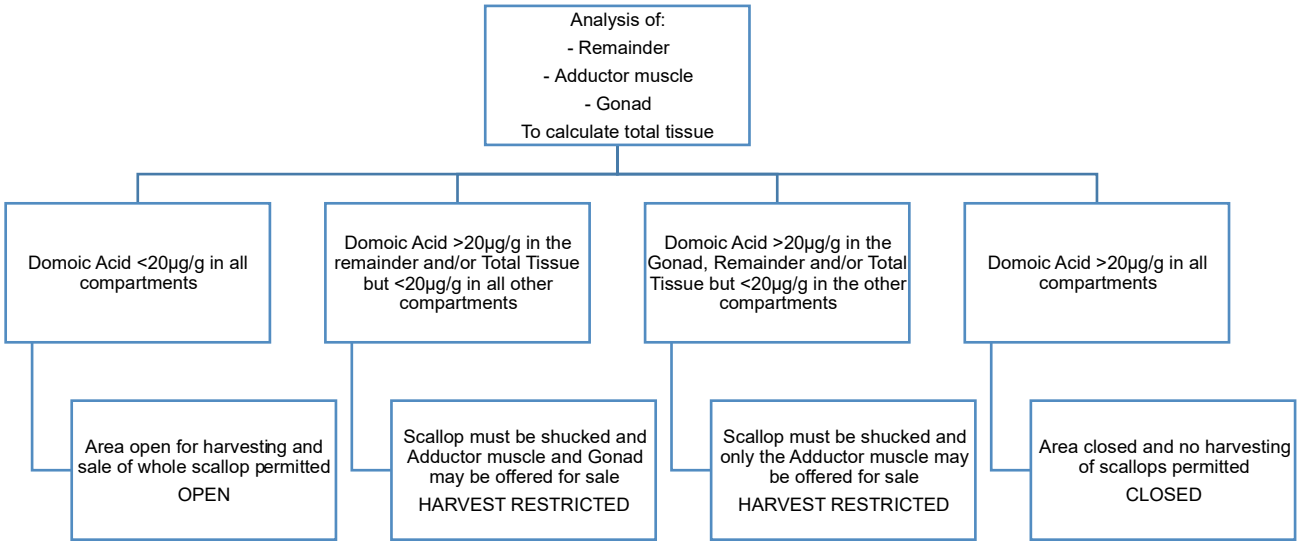


Figure 7 ASP Decision Tree for scallops from classified production areas

Status	Explanation
Open	The most recent valid sample is below the regulatory limit for Domoic Acid in all compartments and below the regulatory limit for Lipophilic Toxins in the Remainder Tissue. The production area is open for harvesting for that species until the end of the production period.
Closed	The most recent valid sample has exceeded the regulatory limit for Domoic Acid in all compartments and or Lipophilic Toxins in all compartments. The production area is closed for harvesting or lifting of shellfish Date of closure is back to the start of the current production period as per section 6.2
Closed Pending	The most recent valid sample is below the regulatory limits in all compartments for Domoic Acid and in the remainder tissue for Lipophilic Toxins but there is no previous valid sample (i.e., sample frequency was not maintained). The production area is closed pending for harvesting of scallops until a second result below the limit is obtained within the required.
Closed Expired	The sample frequency for the scallop species listed has expired, where no sample for that species has been submitted within the specified sample frequency period, and the area is now Closed for the listed scallop species.
Harvest Restricted	Any of the following scenarios will result in the production area having a Harvest Restricted status assigned for scallops allowing for the placing on the market of either or both adductor muscle and gonad tissues: • If the Domoic Acid regulatory limit is exceeded in the remainder and or Total Tissue and < regulatory limit in both or either of the Gonad and Adductor Muscle AND/OR • if the associated Lipophilic toxin limits are exceeded in the remainder and < regulatory limit in both or either of the Gonad and Adductor Muscle.

Table 2 Production Area Status for Scallops from Classified Areas

5.4.3 ASP – Scallops from offshore fisheries

Prior to processing the approved processor handling the batch will establish if scallops from the area from which the batch to be shucked has been fished have been analysed by the Marine Institute and if a "whole animal" (WA) result is available (see Section 4.15.2 above).

The procedure to be followed is summarised in Figure 8 (ASP Decision Tree for Scallops from Offshore Fisheries (Non-Classified Areas)) below.

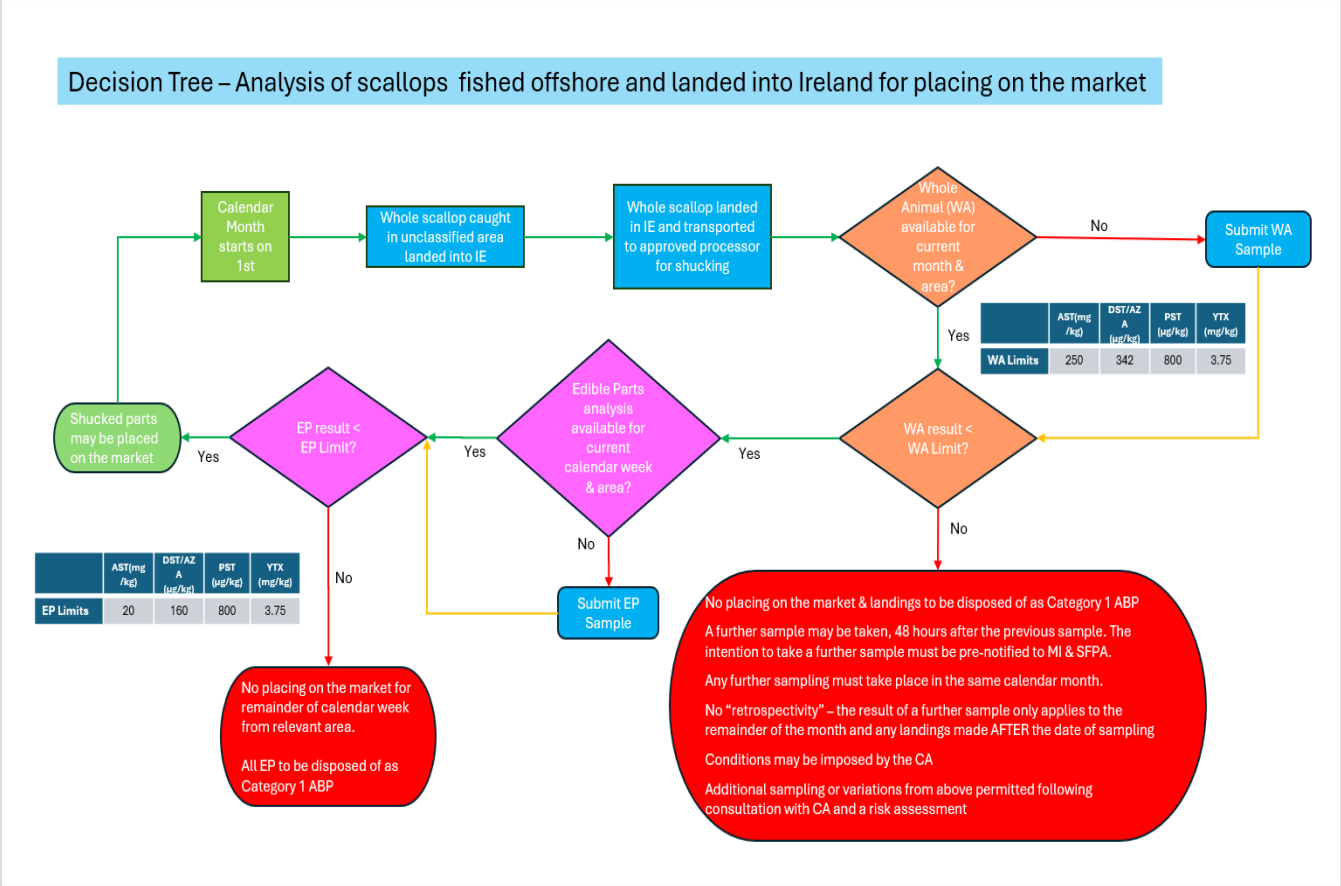


Figure 8 ASP Decision Tree for Scallops from Offshore Fisheries (Non-Classified Areas)

Whole Animal (WA) Analysis

The WA result must derive from a sample taken from a batch fished from the same area as the batch to be processed. Furthermore, the sample must have been taken in the same calendar month as the batch to be processed was fished and on an earlier date than the catch date for the batch to be processed.

Samples taken in one month have no relevance to succeeding months even if they were taken from a batch fished close in time to the batch to be shucked. In effect, each calendar month must be treated as a discrete time period.

If a WA result **is not available**, or there is no indication that a sample has been previously submitted, then the approved processor must arrange for a sample to be submitted.

Processing may commence if a sample has been submitted. HOWEVER, should such a sample return a non-compliant result then the batch, whether processed or undergoing processing, must be disposed of as Category 1, Animal Byproducts. Processing while a result is pending is at the processor's risk. (see Section 4.15.2 above).

If a WA result is available, then it must be assessed against the following "WA Limits":

	AST(mg/kg)	DST/AZA (µg/kg)	PST (µg/kg)	YTX (mg/kg)
WA Limits	250	342	800	3.75

If the result of the Whole Animal analysis taken in the month in which the batch for shucking has been fished is below the WA Limits then consideration may be given to the analysis of the Edible Parts (EP) – see below.

If the result of the Whole Animal analysis taken in the month in which the batch for shucking has been fished is above the WA Limits then the batch shall not be processed and must be disposed of as Category 1, Animal By-products (see Section 4.15.2 above). Such batches must not be retained or otherwise held pending the outcome of any future sampling.

In the situation where the Whole Animal analysis returns a result that is above the WA Limits, a further sample may be submitted for analysis by the Marine Institute. Such further sampling is subject to the following conditions:

1. The intention to submit a further sample must be communicated to the Sea-Fisheries Protection Authority and the Marine Institute.
2. The Sea-Fisheries Protection Authority and the Marine Institute may set such conditions as they deem appropriate regarding the submission of a further sample.

3. The sample must come from a different batch to the original sample. Such different batch shall have been fished at least 48 hours later in the same month as the originally sampled batch. A further sample cannot be taken from the same batch originally sampled.
4. Both the original and the further sample must come from batches fished in the same calendar month.
5. The result from a sample taken as a further sample is only valid for the calendar month in which it is taken.

The result of any further sample will be assessed against the WA limits (above).

If the result of the further sample, is below the WA Limits then consideration may be given to the analysis of the Edible Parts (EP) – see below.

The result of a further sample only applies to batches caught after the batch from which the further sample was taken, was landed. A further sample cannot be used retrospectively to assess the suitability of batch, fished before the date of sampling.

Where a batch has returned a result from a further sample exceeding the WA limits for the month in question, then the approved processor must dispose of the batch as Category 1, Animal By-products. Batches shall not be retained pending the outcome of future samples.

If the further sample, subject to Whole Animal analysis returns a result that is above the WA Limits then any additional sampling must only be carried out with the express permission of the Sea-Fisheries Protection Authority.

Any request for additional sampling must be submitted in writing to the Sea-Fisheries Protection Authority and include a rationale. Before permitting additional sampling, the Sea-Fisheries Protection Authority will carry out a risk assessment with the assistance of the Marine Institute and Food Safety Authority of Ireland to determine if additional sampling is justified.

The Sea-Fisheries Protection Authority may impose such conditions as it sees fit on any additional sampling including conditions relating to, the specific location of additional sampling, the manner in which the sample is to be handled and/or the arrangements for any associated batches.

Edible Parts (EP) Analysis

Where a sample relating to a batch has been determined to meet the WA limits, then the approved processor may consider the batch for processing and shucking.

Before processing or shucking takes place, the approved processor will establish if scallops from the area from which the batch to be shucked has been fished have been analysed by the Marine Institute and if an “edible parts” (EP) result is available.

The EP result must come from a sample from a batch fished from the same area as the batch to be processed or shucked. Furthermore, the sample must have been taken in the same calendar week as the batch to be processed was fished.

Samples taken in one calendar week have no relevance to a succeeding calendar week even if they were taken from a batch fished close in time to the batch to be shucked. In effect, each calendar week must be treated as a discrete time period.

If an EP result is not available, then the approved processor must arrange for a sample to be submitted.

When an EP result is available, then it must be assessed against the following “EP Limits”

	AST(mg/kg)	DST/AZA (µg/kg)	PST (µg/kg)	YTX (mg/kg)
EP Limits	20	160	800	3.75

If the result of the EP analysis taken in the calendar week in which the batch for shucking has been fished is below the EP Limits then the batch may be processed/shucked and sold for human consumption.

If the result of the EP analysis taken in the week in which the batch for shucking has been fished is above the EP Limits then the batch shall not be processed and must be disposed of as Category 1, Animal By-products.

No further or additional sampling of edible parts is permitted for that calendar week.

Enforcement

Batches found not to be compliant with this Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins) shall be dealt with according to the Enforcement Policies of the Sea-Fisheries Protection Authority and the Food Safety Authority of Ireland.

Batches not compliant with this Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins) and placed on the market shall be withdrawn or recalled as necessary. The Food Safety Authority of Ireland shall implement the measures necessary to protect consumer health and comply with food law.

The relevant competent authorities will decide which statutory measures are appropriate in the event a non-compliance with this Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins) is detected. This may include the application of statutory measures available under the Food Safety Authority of Ireland Act 1999; and the Sea Fisheries and Maritime Jurisdiction Act 2006.

6.0 Harvesting and Processing

6.1 Responsibilities of harvesters and processors

It is a requirement of Irish and European Food Law that 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. Anyone involved in the placing of food on the market is required to take all reasonable steps, insofar as they are concerned, to ensure the safety and hygienic standard of that food.

Controls in this area are derived from Regulation (EU) 2017/625 and the SFPA enforce the legislation using results published on the MI's HABs webpage. The relevant pieces of Irish legislation are as follows:

- The Food Safety Authority of Ireland Act,1998.
- The Sea-Fisheries and Maritime Jurisdiction Act 2006. and
- SI 22 of 2020 European Union (Food and Feed Hygiene) Regulations, 2020.

EU legislation states that, in each Member State, the CA must provide for periodic checking of production areas. The results of these checks are published by the MI. Primary producers and processors must ensure they are aware of the current status of a production area and relevant results. As an assistance to industry the MI publishes a 'Weekly HAB Bulletin' online which provides information on the potential development of toxic and/or harmful phytoplankton. These bulletins provide an overview on historic and current biotoxin and phytoplankton trends and also information on predictive forecasted toxin events based on oceanographic and environmental parameters, data and models.

6.2 Production period for harvesting

Shellfish gatherers/harvesters are responsible for ensuring that classified production areas are open for harvesting in the current production period before any shellfish are lifted from the water.

The production period is the period of time for harvesting that a valid sample relates to. The production period changes to match the current sampling frequency assigned to the individual shellfish species in the production area. For example, when the sampling frequency is weekly for mussels in a production area then the production period will be weekly for mussels in that production area. As explained in Section 4.3 (Sampling Frequency) the sampling frequency is set to weekly, fortnightly or monthly but other frequencies may also be set if conditions necessitate.

For a production area to remain open, and to allow harvesting to take place, a sample must be taken, submitted and the result published for each production period. There is some flexibility available within production periods to allow samples to be taken at different times, but if an entire production period elapses, and no sample is taken, then the production area reverts to being closed.

In order to re-open an area for harvesting samples must then be taken a **minimum of 48 hours and a maximum of 12 days apart**. The results of both samples must be less than the regulatory limit. See further information on opening an area in section 4.4 (Pre-Harvest Sampling to Open an Area). This requirement may be varied by a decision of the Management Cell.

When Sampling Frequency Is Weekly:

When sampling frequency is weekly then the production period is a period of seven days starting from Sunday to the following Saturday. The status of a production area for a given week is defined by the results from the sample or samples taken in that production period.

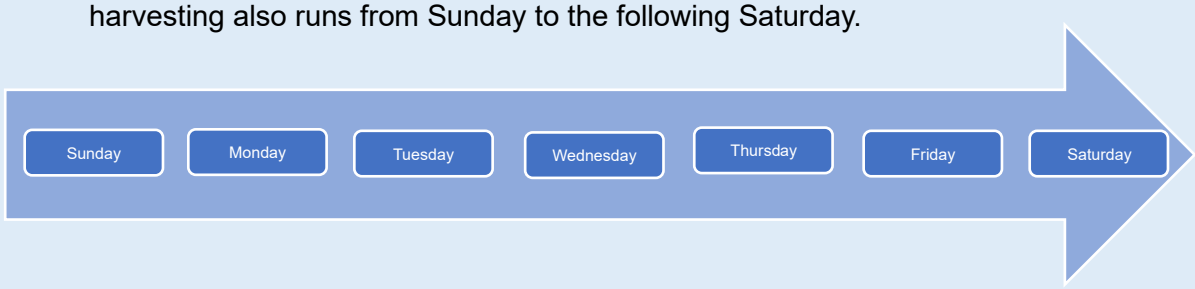
When Sampling Frequency Is Fortnightly:

When sampling frequency is fortnightly then the production period is a period of fourteen days starting from Sunday to the following Saturday week. The status of a production area for a given fortnight is defined by the results from the sample or samples taken in that production period.

When Sampling Frequency is Monthly:

When sampling frequency is monthly then the production period is a calendar month. The status of a production area for a given month is defined by the results from the sample or samples taken in that production period.

The production period is dependent on the sampling frequency. For example, when the sampling frequency is set to weekly then the production period for harvesting also runs from Sunday to the following Saturday.



If the sampling frequency is fortnightly, then the production period for harvesting runs from Sunday to the following Saturday week.

If the sampling frequency is monthly, then the production period for harvesting runs from the beginning to the end of each calendar month.

6.3 Harvesting

Producers and Processors must be familiar with the relevant results and status of a production area. The following legal requirements apply:

1. Harvesting for placing on the market must only take place from a **classified production area**, except for the offshore scallop fishery.
2. Harvesting must only take place when a classified production area is **not subject to a temporary closure** (e.g., due to pollution or other events)
3. Harvesting should only take place from a production area that has a **current open status on the basis of biotoxin results** and also has a **100% or 75% phytoplankton submission rate**.
4. Before any 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 this document.

It is important to note that:

- Harvesting can only take place from production areas during production periods where the most recent result indicates the area to be open for the current production period in question.
- Shellfish should only be placed on the market when the result of the sample taken in the current production period (see Section 6.2, Production Period for Harvesting) demonstrates that the production area is open, and,
- Before any shellfish are placed on the market, robust product recall and traceability procedures must be in place.

Where an area is “open,” and a sample is taken for analysis, producers are strongly advised not to harvest from an area until the full result of the analysis is known. This is to prevent a situation arising where a batch of product is harvested and made ready to be placed on the market only for a failed sample result to require the product’s recall or disposal.

6.4 Processing

FBOs processing live bivalve molluscs and/or manufacturing products incorporating such shellfish are required to have a robust Food Safety Management System in place that incorporates Hazard Analysis and Critical Control Point (HACCP) principles and that is operating effectively.

The Food Safety Management System must include clear specifications for incoming raw material and finished product, along with procedures and instructions to be followed in the event of a batch of raw material or processed product failing to meet the requirements of these specifications.

Where shellfish do not meet the legal requirements or the specifications of the processor’s Food Safety Management System, they should be disposed of in accordance with the relevant animal by-products regulations.

FBOs handling scallop should **only place product on the market when the sample results for that batch are available**. If shellfish have left the control of the FBO and are found to not meet the legal requirements or product specification, they should be recalled and withdrawn from the market and the SFPA should be notified.

The extent of any recall or withdrawal will largely depend on the traceability system in use by the FBO. Further information is available in Guidance Note No. 10 (Product Recall and Traceability) published by the Food Safety Authority of Ireland.

6.5 Controls in the event of non-compliant scallops

Where biotoxin levels are over the legal limits the SFPA will take appropriate action in the relevant production area(s). Such action may include, where appropriate, the following measures:

- Restriction or prohibition on fishing or placing on the market
- Monitoring
- Ordering the recall, withdrawal and/or destruction of scallops and scallop products, if necessary, and,
- Any other measure the SFPA may deem appropriate.

7.0 Communications

7.1 Data management and publication of results

In the interests of consumer safety and protection, the widest practical dissemination is given to biotoxin and phytoplankton data from the Irish Shellfish Monitoring Programme. In order to promote confidence in the programme, stakeholders and particularly producers are given the widest possible access to results and the other associated information, such as calibration records. The MI is responsible for the management of all biotoxin, and phytoplankton data and it publishes the results on the MI HABs Shellfish Monitoring webpage.

7.2 Minutes of the MSSC meetings

The minutes of meetings of the MSSC are agreed by the Committee at the following meeting (e.g., Q1 minutes are reviewed and agreed during the Q2 meeting). The minutes will be published online 7 days after they have been agreed by the Committee. Further comments can be submitted during this 7-day period.

7.3 Product recall - retail and catering

The FBO has the primary responsibility to remove unsafe food from the market if it has left their immediate control. Where food has reached the consumer, FBOs must inform consumers of the reason for the removal of the food from the market and if necessary, recall the food from consumers when other measures are not sufficient to achieve a high level of health protection.

FBOs are legally required to notify and cooperate with the CAs regarding recall/withdrawal of unsafe food. FBOs must also notify other FBOs and cooperate to facilitate effective and efficient

food recall/withdrawal. The FBO should prioritise the use of available resources to the efficient and effective removal of affected food from the market.

Notwithstanding the obligations on FBOs to remove unsafe food from the market and communicate the food recall/withdrawal appropriately with customers and consumers, the CAs have a role to make sure that the process is being managed effectively. Recalls of live bivalve molluscs in retail and catering establishments shall be coordinated by the Environmental Health Service of the HSE in accordance with procedures laid down under the FSAI Guidance Note 10 Product Recall and Traceability.

Appendix 1 – Live Bivalve Mollusc Legislation

The production and the placing on the market of live bivalve molluscs is regulated under EU and Irish Legislation. The FSAI website includes a legislation section which is kept up to date with the latest legislation including consolidated versions. An overview of the specific legislation relevant to aquaculture and aquaculture products is included.

EU Legislation

The EU Food Legislation relevant to this COP is shown below in the 'Guide to the requirements for Bivalve Molluscs in EU Food Legislation'. All the legislation in the table are Regulations, apart from the Water Framework and Animal Health Rules which are both Directives. The EU produces consolidated versions of legislation which are updated to include amendments.

Area	Legislation
General Principles of Food Law	Regulation (EC) No 178/2002
Traceability	Article 18
Responsibilities for FBOs	Articles 17 and 19
Hygiene of Foodstuffs	Regulation (EC) No 852/2004
Scope	Article 1
Hygiene requirements	Article 4
HACCP	Article 5
Primary producers	Annex I
All other FBOs	Annex II
Registration and Approval of Establishments	
General Requirements	Regulation (EC) No 852/2004Article 6
Requirements for products of animal origin	Regulation (EC) No 853/2004Article 4
Procedure for approval of establishments	Regulation (EU) No 2017/625Article 148
Official Controls	
Classification & monitoring of areas	Regulation (EU) No 2017/625
Controls on wild scallops and gastropods Verification of compliance	Article 18
Specific Requirements for Products of Animal Origin	
	Regulation (EC) No 853/2004
General requirements for identification marking	Article 5 and Annex II Sect. I
Live Bivalve Molluscs	
Specific hygiene rules for LBMs	Annex III, Section VII
Identification and labelling of LBMs	Annex III, Sect. VII, Chpt. VII
General requirements, wrapping, transport of LBMs	Annex III, Section VII, Chpts. I, VI & VIII
Production & harvesting requirements for LBMs	Annex III, Section VII, Chpt. II
Purification and dispatch centres for LBMs	Annex III, Section VII, Chpts. III & IV
Health standards for LBMs	Annex III, Section VII, Chpt. V
Requirements for wild scallops	Annex III, Section VII, Chpt. IX
Fishery Products	
Specific hygiene rules for fishery products	Annex III, Section VIII
Requirements for vessels	Annex III, Section VIII, Chpt. I
Landing and first sale	Annex III, Section VIII, Chpt. II
Establishments and vessels	Annex III, Section VIII, Chpt. III
Cooked crustaceans and molluscs	Annex III, Section VIII, Chpt. IV
Health standards including biotoxins	Annex III, Section VIII, Chpt. V
Wrapping, storage and transport	Annex III, Section VIII, Chpts. VI, VII, VIII
Microbiological Criteria & Testing Methods	
Microbiological criteria for fishery products & LBMS	Regulation (EC) No 2073/2005 Annex I (1.2, 1.16, 1.17, 1.25, 1.26, 1.27 2.4) Regulation (EC) No 2074/2005Article 3
Biotoxin Methods	Regulation (EU) No 2019/627 -Annex V
Animal Health rules	
Aquaculture diseases	Regulation (EU) No 2016/429
Water Quality	
Water Framework Directive	Directive 2000/60/EC
Marine Strategy Framework Directive	Directive 2008/56/EC

Table 3 Guide to the requirements for Bivalve Molluscs in EU Food Legislation

Irish Legislation

The two main pieces of Irish legislation that govern the monitoring and control of bivalve molluscs are as follows:

- The Food Safety Authority of Ireland Act, 1998
- The Sea-Fisheries and Maritime Jurisdiction Act, 2006

Some EU legislation requires the introduction of a Statutory Instrument (SI) for it to become fully enforceable in Ireland. EU Regulations are directly applicable and binding in Ireland, but an SI must be introduced to set out measures for the Regulation's enforcement, such as penalties for infringement and to clearly identify which national agency will be responsible for enforcement. EU Directives have no legal force until they are transposed into national law through an SI. The main relevant SIs are shown in the table below:

Table 4 Guide to National Legislation

European Legislation	National Statutory Instrument
Regulation (EC) No 178/2002 Regulation (EC) No 852/2004 Regulation (EC) No 853/2004 Regulation (EU) No 2017/625	SI 22 of 2020 European Union (Food and Feed Hygiene) Regulations, 2020.
Animal Health Rules, Aquaculture Diseases Regulation (EU) 2016/429	SI 820 of 2004 European Communities (Trade in the Production, Processing, Distribution and Introduction of Products of Animal Origin for Human Consumption) Regulations, 2004, as amended
Water Framework Directive Directive 2000/60	SI 722 of 2003 Water Policy Regulations, 2003, as amended

Appendix 2 – 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.

Scope

The Management Cell focuses primarily, but not exclusively, on rope mussels in view of their risk profile. It will consider borderline, or out of character test results. It determines the appropriate action to be taken in the event of prolonged closures affecting a particular site. The Management Cell may also deal with other work, projects or functions delegated to it by the MSSC.

Membership and Roles

The Management Cell consists of a nominee and an alternate from each of the following:

1. **The FSAI** *(Enforcement Policy Manager for the Marine Contracts and alternate)*: The FSAI is the Competent Authority (CA) responsible for the enforcement of all food legislation in Ireland. The FSAI acts as chair the Management Cell.
2. **The SFPA** *(Director of Food and Fisheries Support Unit and alternate)*: With respect to seafood and live bivalve molluscs, the SFPA is the CA under Regulation (EU) No. 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The SFPA will communicate the final decision of the Management Cell to the Cell.
3. **The Marine Institute** *(Shellfish Safety Manager, and alternate)*: The MI, will provide the necessary chemistry and phytoplankton results, as well as relevant scientific analysis and commentary.
4. **IFA Aquaculture** *(Aquaculture Executive and alternate)*: The role of the IFA will be to provide local information as a key input into the decision-making process and ensure that the Management Cell maintains a commercial as well as a consumer protection focus aimed at developing markets and protecting consumer health.

Convening the Management Cell

The Management Cell will be convened, at the request of any of its members and in the following situations, where:

- the results from test analyses are inconsistent with trends
- sampling continuity has been interrupted*
- a production area has been assigned an incorrect status, or

- results from sampling indicate that the sampling frequency for an area or species can be modified.

* The Management Cell is not a substitute for missed samples or incorrect sampling frequency periods

A member of the Management Cell will convene the Cell by sending an email outlining the situation to be resolved to all members of the management cell and their alternates. The members of the Management Cell may decide to hold a teleconference/videoconference to discuss the situation, however decisions can also be made via email communication. Where a teleconference of videoconference is requested, the FSAI will organise same and coordinate participation between all members of the cell.

In exceptional circumstances, where a representative or their alternate cannot be contacted, the SFPA, and any two of the MI, the FSAI, or IFA Aquaculture may act to convene the Management Cell.

Risk Management

The Management Cell will take an informed risk management decision, which may result in the following:

- changing of a production area's status to open, closed or closed pending
- recommending a voluntary closure to producers
- where results in one production area give cause for concern, closing adjacent areas within the same bay, or a neighbouring bay, in the increasing toxicity (Spring) and elevated toxicity (Summer) periods
- increasing sampling frequency and seek an intensive series of chemical tests, for example during elevated toxicity (Summer) periods
- decreasing sampling frequency during the declining and low toxicity seasons (Autumn and Winter respectively)
- specific management plans for an area/bay during toxin events and episodes
- other action as appropriate.

The Management Cell may also recommend that precautionary action is taken by producers such as voluntary suspensions in harvesting. This may be recommended where data, including phytoplankton data, indicate that the risk profile in an area could change rapidly and without warning between samples or while samples are in transit or undergoing analysis. In reaching a decision the Management Cell may attach different weights or priorities to information provided.

Decision Making

When 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.

In reaching a decision, the Management Cell may consider the following factors:

- the species of bivalve mollusc
- chemistry results
- phytoplankton results
- time of year/toxicity profile
- adjacent areas status
- relevant historical data and data analysis reports as provided by the MI
- any other relevant data.

All decisions taken by the Management Cell will be consistent with Regulation (EU) No 2017/625 and Commission Implementing Regulation (EU) 2019/627.

Status of the Management Cell Decision

A decision of the Management Cell is a collective view expressed by its combined membership and directed to the relevant CAs as to what action should be taken. Decisions are not instructions that must be implemented.

CAs are not bound to follow the decisions of the Management Cell where they feel to do so would conflict with their statutory or other obligations. However, where a CA opts not to implement a decision of the Management Cell, a reason will be provided and recorded.

Record Keeping

The SFPA, or by agreement the FSAI, will provide written confirmation (generally by email) of all decisions. If a Management Cell decision results in a change of status of a production area, the MI will re-issue any relevant results.

All records relating to decisions will be retained by the SFPA.

A review of Management Cell will be a standing item at the MSSC meetings, and the MI will provide a report on all Management Cells decisions that were requested since the previous MSSC meeting. Changes to the way in which the management cell operates may be proposed under this agenda item.

Members of the Management Cell and their Alternates					Contact details to be used if both nominee and alternate are unavailable
Competent Authority	**Nominee**	**Alternate**	**Email addresses**	**Contact number**	**Out of hours contact**
FSAI	David Lyons *Enforcement Policy Manager*	Christine King *Enforcement Policy Executive*	dlyons@fsai.ie cking@fsai.ie	David Lyons (087 4158400) Christine King (01 817 1308)	FSAI Out of Office/Emergency Contact details 01 685 6555
SFPA	Sarah Buckley *Director of the Food and Fisheries Support Unit*	Gary McCoy *National Shellfish Monitoring Manager*	sarah.buckley@sfpa.ie gary.mccoy@sfpa.ie	Sarah Buckley (085 253 9778) Gary McCoy (085 885 6908)	sfpafoodsafety@sfpa.ie
MI	Dave Clarke *Shellfish Safety Manager*	Patrick Costello *Senior Laboratory Analyst*	dave.clarke@marine.ie patrick.costello@marine.ie	Dave Clarke (087 969 2612) Patrick Costello (087 995 9744)	habs@marine.ie
IFA Aquaculture	Teresa Morrissey *Aquaculture Executive*	Finian O'Sullivan *Mussel Producer & IFA Committee Member*	teresamorrissey@ifa.ie finianos@eircom.net	Teresa Morrissey (087 795 4728) Finian O'Sullivan (085 172 9177)	info@ifa.ie

Appendix 3 - Phytoplankton Production Area Amalgamation

Table 5 Phytoplankton Amalgamated Classified Production Areas Table

Coast	Production Area	Site Name	Site Codes	Species Harvested	Phyto Site to be monitored
East	Skerries	Skerries	DN-SS-SS*	*E.siliqua*	**DN-SS-SS**
	Malahide	Malahide	DN-ME-ME		
SouthEast	Rosslare	Rosslare	WX-RE-RE	*E.siliqua/L.lutraria*	**WX-WB-CE**
	Wexford Bay	Curracloe	WX-WB-CE		
SouthWest	Sherkin North	Sherkin North	CK-SN-SN*	*C.gigas*	**CK-SW-KH**
		Turk Head	CK-SN-TH		
	Sherkin West	Kinish	CK-SW-KH		
		Frolic Point	CK-SW-FP		
SouthWest	Bantry North	Snave	CK-BN-SE	*M.edulis*	**CK-BN-SE** North Chapel
	Bantry Middle	Whiddy Point	CK-BM-WP		
		CK-BM-NC*			
SouthWest	Newtown	Newtown	CK-NN-NN	*M.edulis*	**CK-BS-SC**
	Bantry South	South Chapel	CK-BS-SC		
SouthWest	Gouleencoush	Gouleencoush	CK-GH-GH	*M.edulis*	**CK-CA-CA**
	Cleandra	Cleandra	CK-CA-CA		
West SouthWest	Carrigaholt	Carigaholt	CE-CT-CT	*C.gigas*	**CE-PY-PY**
	Poulnasherry	Poulnasherry	CE-PY-PY*		

West	Mannin	Mannin	GY-MN-MN	*C.gigas*	**GY-CN-CO**
	Clifden	Clifden Outer	GY-CN-CO	E.magnus/S.solida	
		Ardbear	GY-CN-AR	*E.magnus/ S.solida/ M.edulis/ L. lutraria*	
West	Killary Approaches	Killary Approaches	GY-KY-KY	*E.magnus/E.siliqua*	**GY-KO-KO**
	Killary Outer	Killary Outer	GY-KO-KO*	*M.edulis*	
	Killary Middle	Killary Middle	GY-KM-KM		
	Killary Inner	Killary Inner	GY-KI-KI		
West NorthWest	Drumcliff	Drumcliff	SO-DB-DB*	*C.edule/M.edulis/ R.philipinarum/C.gigas*	**SO-DB-DB**
		Rosses Point	SO-DB-RP		
	Sligo Harbour	Sligo Harbour	SO-SH-SH	*R.philipinarum/C.gigas*	

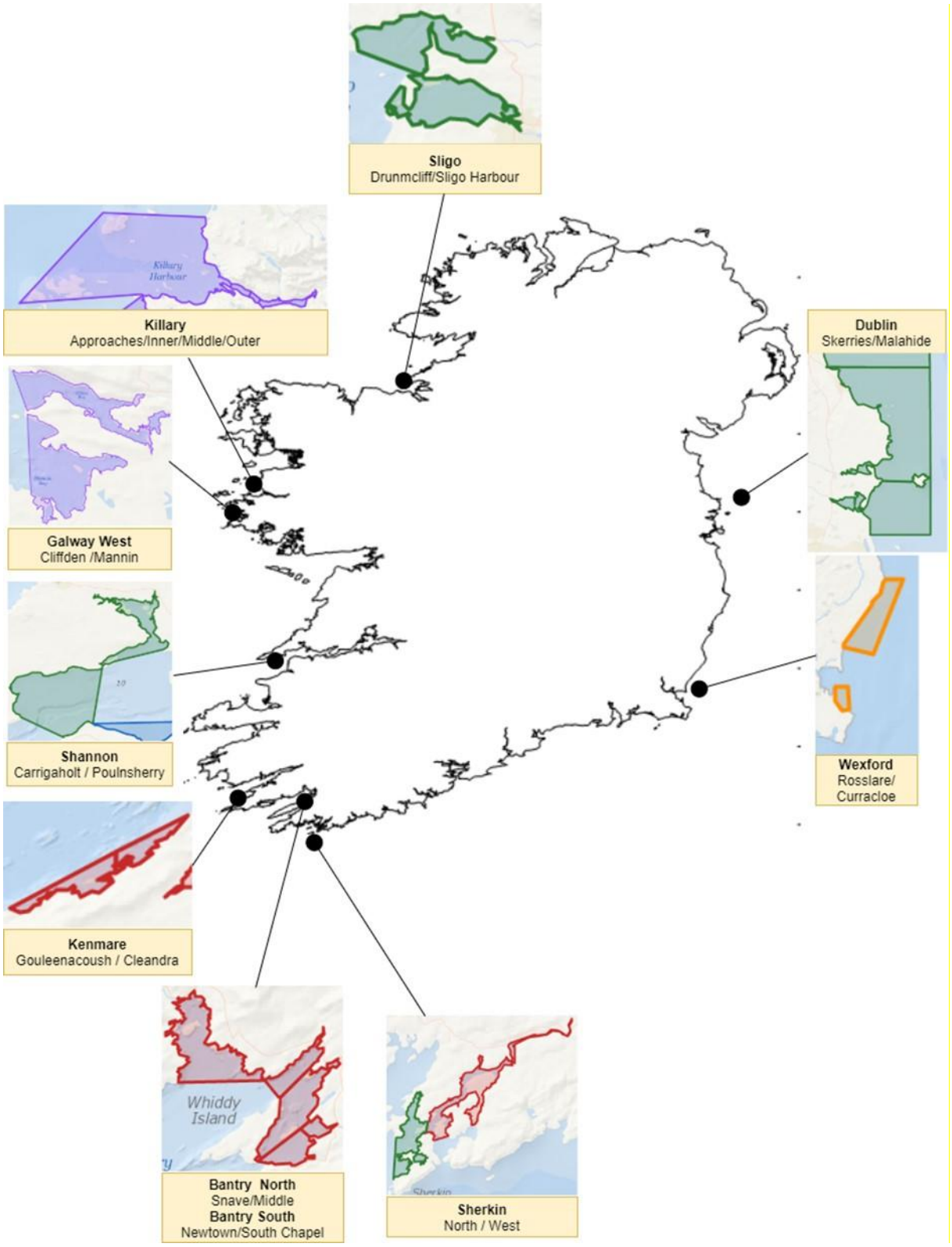


Figure 9 Phytoplankton Amalgamated Classified Production Area Map

Appendix 4 – Phytoplankton Sampling Frequency

Phytoplakton samples are required on a weekly frequency from all areas that are actively harvesting, regardless of shellfish frequency. One sample will be accepted per production week, any more than this will be discarded. A minimum of three weekly samples will be required in every rolling 4-week period (this includes the preceding 4-week period and not the current week). If the frequency of sampling drops below this level the area will not be assigned an Open status on the next clear shellfish result. If an area is not harvesting, phytoplankton samples are not required, but prior to resuming harvesting, two weekly samples must be submitted for each of the two weeks prior to the week and including the week of harvesting taking place. Continual weekly phytoplankton samples are required to maintain an Open shellfish status.

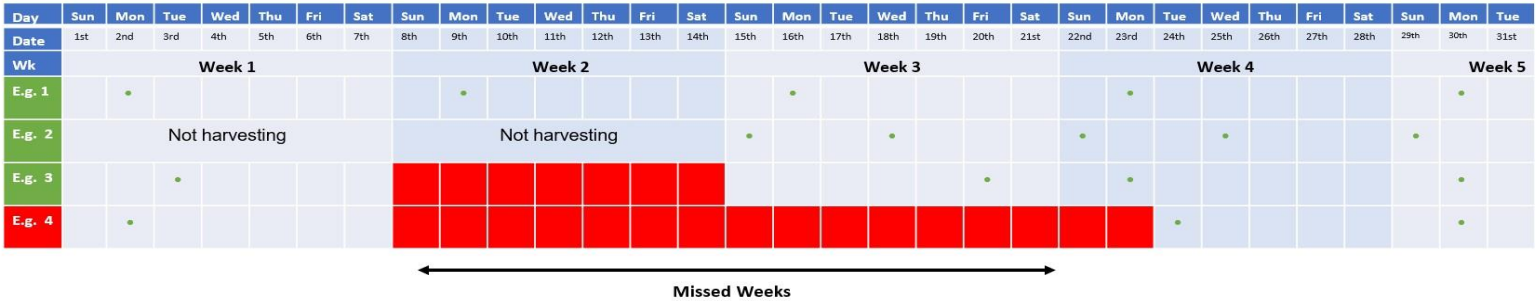


Figure 10 Phytoplankton Sampling Frequency Examples – Green dot indicates day sample was taken

In the example above, if we consider the status for week 5 – Example 1 has submitted samples each week for weeks 1-4, therefore assigned an Open status (100% sample submission). Example 2 was not harvesting for weeks 1&2 but has submitted 2x weekly samples for weeks 3 & 4, and during week 5 therefore assigned an Open status can be assigned from week 5. Example 3 has missed a sample from week 2, 75% sampling frequency for weeks 1-4, therefore assigned an Open status. Example 4 has missed samples in weeks 2 & 3, 50% sampling frequency, therefore assigned a Closed-Pending status.

Appendix 5 – Minimum Sample Size of LBMs for Biotoxin Testing

Table 6 Minimum Sample Size of LBMs for Biotoxin Testing

Scientific name	Common name	No. of shellfish per sample
Mytilus edulis	Blue Mussel	50 – 150
Crassostrea gigas (also known as *Magallana gigas*)	Pacific Oyster	15 -30
Ensis magnus (previously known as *Ensis arcuatus*)	Arched Razor Shell	20 – 40
Ensis ensis	Pod Razor Shell	20 – 40
Ensis siliqua	Sword Razor Shell	15 – 20
Pecten maximus	King Scallop	12 – 15
Ostrea edulis	Flat Oyster or Native Oyster	20 – 40
Ruditapes philippinarum (previously known as *Tapes philipinarum, Tapes semidecussata*)	Manila Clam or Japanese Carpet Shell	50 – 150
Paracentrotus lividus	Purple Sea Urchin	20 – 60
Echinus esculentus	Edible Sea Urchin	20 – 60
Aequipecten opercularis	Queen Scallop	20 – 40
Cerastoderma edule	Cockle	50 – 150
Spisula solida	Thick Trough Shell or Surf Clam	50 – 150

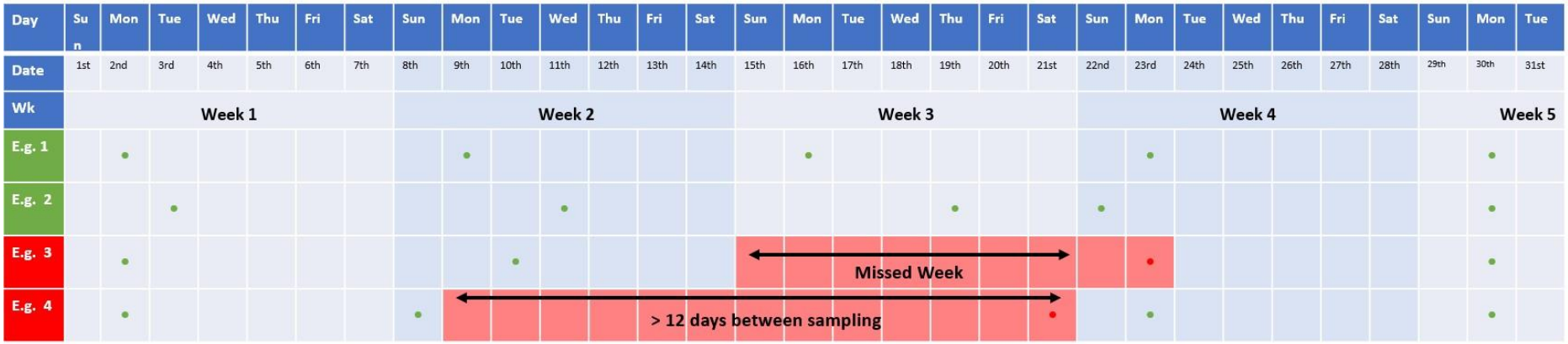
Dosinia exoleta	Rayed Artemis	50 – 150
Glycymeris glycymeris	Dog Cockle	50 – 150
Haliotis discus hannai	Japanese Green Abalone	10 - 30
Venerupis corrugata (previously known as *Venerupis senegalensis*)	Carpet Shell or Corrugated Venus	50 – 150
Venus verrucosa	Warty Venus	50 – 150
Patella vulgata	Common limpet	20 - 40
Littorina littorea	Periwinkle	20
Buccinum undatum	Whelk	10-15
Lutraria lutraria	Otter Shell	15 - 20

Appendix 6 – Shellfish Sampling Frequency and Area Closure

The following three diagrams show the frequency required for acceptable sampling of LBMs to maintain open status in a production area. In these diagrams it is taken that all samples are testing below the toxin threshold and is to explain the frequency rather than the status closures due to exceeding the toxin threshold. Status can only be assigned once the sample has been submitted in accordance with the rules set out regarding frequency in place for the particular shellfish species and location and this frequency may change from time to time to account for changing risk. A maximum of one sample [er sampling period will be tested by the National Reference Laboratory. Any extra samples will be only tested in requested by the competent authority or NRL. Additional samples if submitted will be discarded.

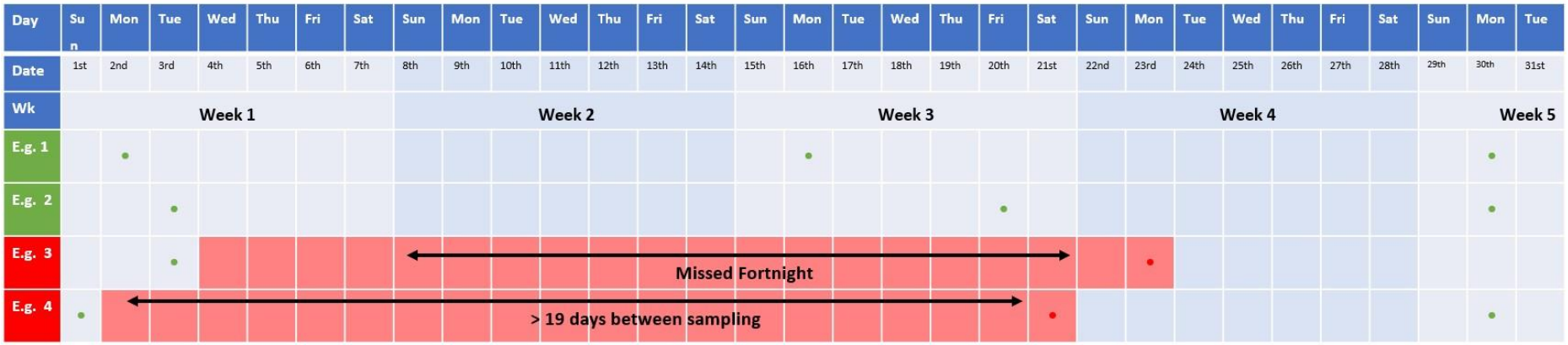
The diagrams below indicate sample submitted at a correct frequency by the • symbol and samples that are not at the correct frequency by the • symbol. These • symbols will result in the area going on a **Closed-Pending** status. There are two main conditions to be met:

1) Weekly samples should be submitted during each calendar week Sunday – Saturday, fortnightly samples during the Sunday – Saturday +1 week and monthly samples should be submitted each calendar month.
2) Weekly sample must be taken <12 days apart, fortnightly samples must be taken <19 days apart and monthlysamples must be taken <38 days apart.



When the sample frequency is **weekly** a sample should be submitted each week with **less than 12 days between sampling dates**

Figure 11 Weekly Sampling Frequently



When the sample frequency is **fortnightly** a sample should be submitted every second week with **less than 19 days between sampling dates**

Figure 12 Fortnightly Sampling Frequency

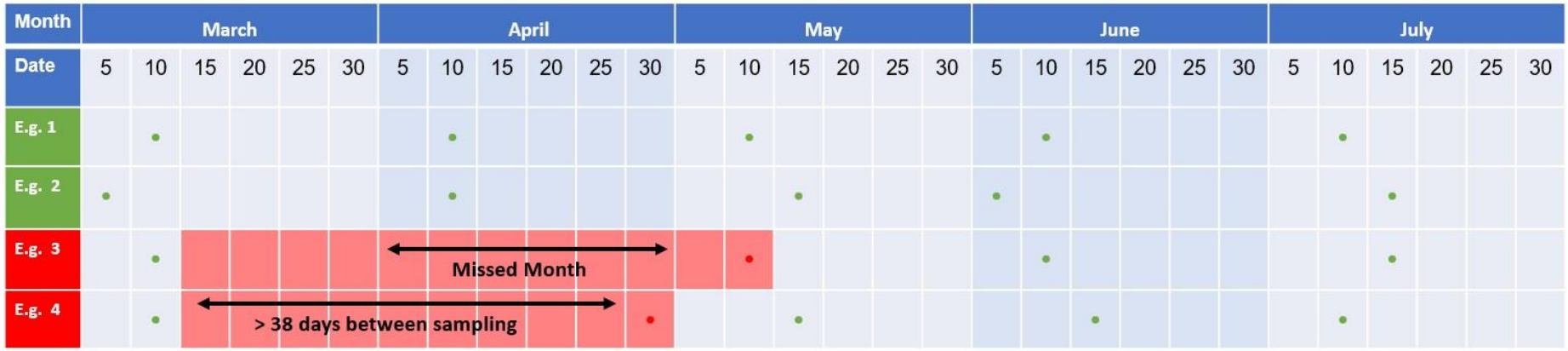


Figure 13 Monthly Sampling Frequency

Appendix 7 - Delivery of Sample to the Marine Institute

Procedure for the submission of shellfish samples for Biotoxin Analysis April 2021

1) **An Post network**

Shellfish Samples should continue to be submitted through the An Post regional and local network through An Post offices. Samples are to be addressed to PO Box 430, An Post Galway Mail Centre, Tuam Road, Galway.

2) **Hand Deliveries to An Post Delivery Depot, Tuam Road, Galway (091 778700)** If a sample is required for analysis in a shorter timeframe, samples can be delivered to the main delivery depot in Galway. Samples are to be delivered to the front reception area only, between **08:00am to 19:00pm daily** (weekdays only, excludes Public Holidays)) for collection next day, boxes to be fully labelled with consignment ID and documentation, a receipt will be generated. Please ask An Post personnel to place boxes in the Marine Institute cage PO Box 430. Any samples delivered through this mechanism will be collected by Marine Institute contractors the following working day.

3) **Hand deliveries to MI**

Samples should only be hand delivered when absolutely necessary or critically important (i.e., on the onset, during and the outgoing periods of a toxic event) and should not be used as a substitute or a replacement for using the available options 1) & 2) above. The An Post network is the primary mechanism for the submission of shellfish samples for biotoxin analysis.

Samples can only be accepted between **09:00 – 10:00am Mon – Thurs** (excludes Public Holidays) in the **MI stores department only**. Samples dropped of anywhere else inside or outside of the building will not be accepted and will be disposed of. Under no circumstances will anyone delivering samples will be permitted past the MI stores. Please note it is not possible under any circumstances to accept samples after 10:00am, any samples arriving after this time will be refused and not accepted.

All samples will have to be booked in advance at a minimum of the day before expected due delivery day before 12:00pm the previous day (for delivery on a Monday, MI personnel require notification by 12:00pm the Friday preceding the Monday of expected delivery). If samples are delivered where prior notification and acceptance has not been received or confirmed, samples will not be accepted and will be refused.

Booking notification is via email only to all 3 email recipients below:

Pat Costello patrick.costello@marine.ie

Conor Duffy conor.duffy@marine.ie

Dave Clarke dave.clarke@marine.ie

The email should clearly identify, the name of the person and contact number details of the person delivering the sample. Sample details including location, samples date and species should also be included in the email notification. A written confirmation email will be sent to the original requestor from MI personnel confirming acceptance and approval for the delivery of samples. Please note, samples can only be delivered once confirmation has been sent to the requestor. Samples cannot be accepted if no confirmation of approval is sent.

All sample boxes must be clearly labelled on the outside for ‘Biotoxin Analysis’, where samples must be packaged and labelled in accordance with the Code of Practice.

Samples are to be delivered to the MI Stores department only, samples are to be placed on the designated shelving unit labelled ‘Shellfish Samples’ only, just on the right-hand side inside the entrance door.

Appendix 8 – Biotoxin Methods of Analysis and EU Regulatory Limits

Table 7 Biotoxin Methods of Analysis and EU Regulatory Limits

Toxin Group	Toxins	Method of Analysis	Regulatory Limit	Reported As
Okadaic acid group*	OA, DTX1, DTX2, including their esters	LC-MS/MS EURLLCMSMS	0.16 µg/g (160µg/kg)	OA equivalents
Azaspiracids group*	AZA1, AZA2 and AZA3	LC-MS/MS EURLLCMSMS	0.16 µg/g (160µg/kg)	AZA-1 equivalents
Pectenotoxins group*	PTX1 and PTX2	EURL-LCMSMS	0.16 µg/g (160µg/kg)	PTX Equivalents
Yessotoxins group*	YTX, 45 OH YTX, homo YTX and 45 OH homo YTX	LC-MS/MS EURLLCMSMS	3.75 µg/g (3.75 mg/kg)	YTX equivalents
Paralytic Shellfish Poison	dcGTX23, dcSTX, GTX2,3, GTX5, STX, C1,2, GTX1,4, NEO, dcNEO	HPLC FD Lawrence Method AOAC 2005/06	800 µg/kg (800 µg/kg)	STX diHCl equivalents
Amnesic Shellfish Poison	DA and epi-DA	AOAC 2006/02 HPLC UV	20mg/kg (20 mg/kg)	Sum of Domoic Acid & epi Domoic acid.

The limits shown are those used in the MI's HABs2 website and the limits in brackets are as laid down in EU Legislation.

*Lipophilic Toxin Group

Appendix 9 – The HABS2 Quick Reference Guide

This guide explains how to obtain the latest biotoxin information on the MI HABs Shellfish Monitoring webpage.

HABs² – Quick Reference Guide

If you have any problems using the website or have a comment, contact us – habs@marine.ie

The HABs² website landing page www.marine.ie/Habs gives the user a choice between searching for the latest shellfish safety information for Inshore or Offshore areas.

The user can select the area of interest by either selecting from the list or by typing a few letters of the area into the search production area field. The page displayed for the area selected is split into 2 parts, Biotoxin Data and Phytoplankton Data.

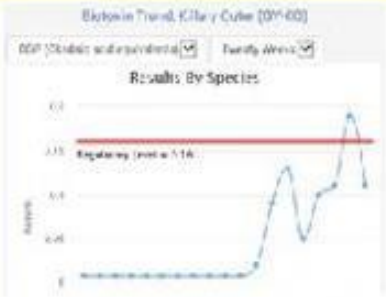
BIOTOXIN DATA

This page contains the biotoxin information and results for the selected area and includes a host of new features including Latest Summary table, Production area map, Sample Progress Tracker, Biotoxin Trend graph and a searchable table of results.

Latest status summary – table showing the latest status per species, date of last sample and the date the next sample is due by

Production Area Map – Map showing the selected area and sites, user can pan and navigate to other areas, and minimise/maximise the map.

The Sample Progress Tracker table shows any samples which have been received in the lab, at which % stage of analysis the sample is at and when the result is estimated to be available, samples which have been reported are at 100% with a green tick in the completed column

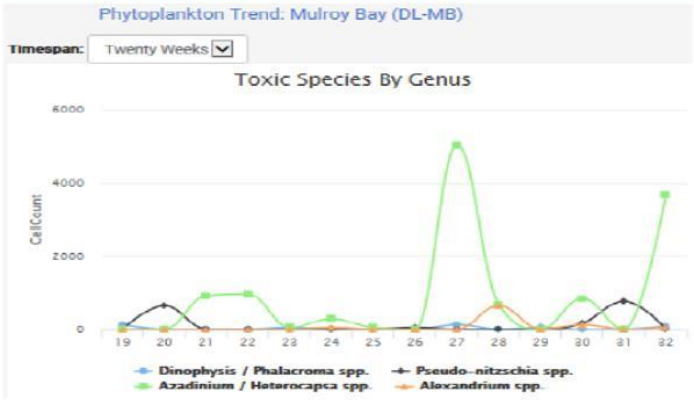


The Biotoxin Trend graph shows the levels of the different biotoxin groups (AZP, DSP etc.) and if they are increasing / decreasing over the last 20 weeks

PHYTOPLANKTON DATA

This page contains the phytoplankton information and results for the selected area and includes a host of new features including Sample % Submission doughnut, Toxic Species summary table, Toxic Phytoplankton Species Trend graph and a searchable table of results.

The doughnut illustrates the current **% Sample Submission** over the preceeding 4 weeks (the % of weekly phytoplankton samples received



The **Toxic Phytoplankton Species Trend** graph illustrates the cell no.'s / litre of different Toxic Phytoplankton species groups observed in samples over the last 20 weeks for the selected area. Clicking on the species group in the legend turns the data set on/off.

Toxic Samples

Week 35 - Week Beginning: 27/08/2017

No Sample Received during this week for analysis

Week 34 - Week Beginning: 20/08/2017

Sample(s) Analysed - No Toxic Species Observed to be present

Week 33 - Week Beginning: 13/08/2017

Sample(s) Analysed - No Toxic Species Observed to be present

Week 32 - Week Beginning: 06/08/2017

Toxin	Species	Cells/Litre (Cells/L)
AZP	Azadinium/heterocapsa spp.	240

Week 31 - Week Beginning: 30/07/2017

Toxin	Species	Cells/Litre (Cells/L)
AZP	Azadinium/heterocapsa spp.	160
DSP/PTX	Phalacroma rotundatum	40
DSP/PTX	Prorocentrum lima	40
PSP	Alexandrium spp.	320

The **Toxic Species in Samples Observed** summary table displays the current and preceding 4 weeks of toxic phytoplankton species expressed in cell no.'s/litre observed.

Comments are assigned in the table where there are no toxic species observed, or if no samples have been received for a particular week, or if the sample has been received for a particular week and is in analysis.

Appendix 10 – The Shellfish Registration Document

Example 1. A sample Shellfish Registration Document for pacific oysters harvested from a classified production area

Serial No. IE 20001(6 digit)

SHELLFISH REGISTRATION DOCUMENT

DATE OF HARVEST: (a) 03 MARCH 2018	PRODUCTION AREA HARVESTED: (b) CASTLETOWNBERE	HARVEST LOCATION CODE (c) CK-CE-CE
BIOTOXIN STATUS: (d) OPEN	WEEK NUMBER: (e) 14	PREVIOUS TEST STATUS: (f) OPEN
CLASSIFICATION OF PRODUCTION AREA: (g)	A	B ✓ C
NAME AND REGISTRATION OF VESSEL (if applicable): (h)		
EU LOGSHEET NUMBER (if applicable, vessels>10m):	ICES AREA: (i)	ICES Statistical Rectangle (j)
FISHING START TIME	END OF FISHING TIME	LANDING PORT
DREDGE TYPE (r)	NO. OF DREDGES	DREDGE WIDTH (cm)

SHELLFISH SPECIES HARVESTED: (l)

COMMON NAME	SCIENTIFIC NAME	QUANTITIES HARVESTED (Kg)
PACIFIC OYSTERS	CLASS OSTREA	
	GIGAS	500 kg

DESTINATION OF SHELLFISH HARVESTED: (k) (Name, Address in Block Capitals)	Destination 1: Pure Irish Oysters CASTLEBAR Co Mayo	Destination 2: (If applicable)
Market Category (s)		

GATHERER'S NAME: (n) (Block Capitals)	JOE SMITH
GATHERER'S ADDRESS: (o) (Block Capitals)	Main Street Adrigole Co. Cork
TELEPHONE NUMBER: (p)	027 70439
Signature: (q)	
Date: (r)	4/3/2018

Company Date Stamp: (s)

To be stamped on receipt by the dispatch or purification

This sheet **must accompany each batch** of shellfish harvested and a copy be retained for inspection in the document book for a minimum of **three years** from the date of harvest.

Example 2. A sample Shellfish Registration Document for scallop harvested from a classified production area

Serial No. IE 200001(6 digit)

SHELLFISH REGISTRATION DOCUMENT

DATE OF HARVEST: (a) 17 Oct 2018	PRODUCTION AREA HARVESTED: (b) Dunmanus Bay	HARVEST LOCATION CODE (c) Ck-DB-DO
BIOTOXIN STATUS: (d) HARVEST RESTRICTED	WEEK NUMBER: (e) 42	PREVIOUS TEST STATUS: (f) HARVEST RESTRICTED
CLASSIFICATION OF PRODUCTION AREA: (g)	A	B ✓ C
NAME AND REGISTRATION OF VESSEL (if applicable): (h) Dunmanus Lady		
EU LOGSHEET NUMBER (if applicable, vessels>10m): IRL 1234567	ICES AREA: (j)	ICES Statistical Rectangle (i)
FISHING START TIME	END OF FISHING TIME	LANDING PORT
DREDGE TYPE (r): SPRING	NO. OF DREDGES: 4	DREDGE WIDTH (cm)

SHELLFISH SPECIES HARVESTED: (j)

COMMON NAME	SCIENTIFIC NAME	QUANTITIES HARVESTED (Kg)
King Scallops	Pecten Maximus	150 kg

DESTINATION OF SHELLFISH HARVESTED: (k) (Name, Address in Block Capitals)	Destination 1: Shellfish Heuen Durrus Co. Cork	Destination 2: (If applicable)
Market Category (s)		

GATHERER'S NAME: (l) (Block Capitals)	Michael O'Shea
GATHERER'S ADDRESS: (m) (Block Capitals)	Main Street Bantry Co. Cork
TELEPHONE NUMBER: (n)	027 429851
Signature: (o)	Michael O'Shea
Date: (p)	17 Oct 2018

Company Date Stamp: (q)

To be stamped on receipt by the dispatch or purification centre / processing plant

This sheet **must accompany each batch** of shellfish harvested and a copy be retained for inspection in the document book for a minimum of **three years** from the date of harvest.

Example 3: A sample Shellfish Registration Document for scallop harvested from an offshore area

Serial No. IE 200001(6 digit)

SHELLFISH REGISTRATION DOCUMENT

DATE OF HARVEST: (a) 10 Oct 2018	PRODUCTION AREA HARVESTED: (b) WEXFORD GROUND		HARVEST LOCATION CODE (c) OS-WD-WD
BIOTOXIN STATUS: (d) NOT Tested	WEEK NUMBER: (e)		PREVIOUS TEST STATUS: (f)
CLASSIFICATION OF PRODUCTION AREA: (g)	A	B	C
NAME AND REGISTRATION OF VESSEL (if applicable): (h)	FULMAR D112		
EU LOGSHEET NUMBER (if applicable, vessels>10m): 2018025	ICES AREA: (i) VIIa		ICES Statistical Rectangle (i) 33E3
FISHING START TIME	END OF FISHING TIME		LANDING PORT
DREDGE TYPE (r) SPRING	NO. OF DREDGES 8		DREDGE WIDTH (cm)

SHELLFISH SPECIES HARVESTED: (j)		
COMMON NAME	SCIENTIFIC NAME	QUANTITIES HARVESTED (Kg)
King Scallops	Pecten Maximus	250 kg

DESTINATION OF SHELLFISH HARVESTED: (k) (Name, Address in Block Capitals)	Destination 1: Scallop Producers Ltd Dungarvan Co Waterford	Destination 2: (If applicable)
Market Category (s)		

GATHERER'S NAME: (l) (Block Capitals)	BRENDAN O SHEA
GATHERER'S ADDRESS: (m) (Block Capitals)	The Rise, Dunmore East
TELEPHONE NUMBER: (n)	051 851429
Signature: (o)	Brendan O Shea
Date: (p)	12 Oct 2018

Company Date Stamp: (q)

To be stamped on receipt by the dispatch or purification centre / processing plant

This sheet **must accompany each batch** of shellfish harvested and a copy be retained for inspection in the document book for a minimum of **three years** from the date of harvest.