Version 8 (December 2018)

Code of Practice for the Irish Shellfish Monitoring Programme (Biotoxins)

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Note on Changes in Version 6:

This version of the COP reflects the changes introduced by the SFPA Notice to Trade on the Harvesting of Scallops, Version 5 (June 2015). It also includes the updated Shellfish Registration Document, Version 3, 2015 in Appendix 5. The previous version of the Shellfish Registration Document will continue to be valid until stocks run out so both versions are included in this version of the COP. For consistency the COP now uses the term Shellfish Registration Document rather than Shellfish Gatherers Document. The section on stakeholders has moved from Chapter 1 to Chapter 2 and some scallop sections have been rearranged.

Note on Changes in Version 7:

This version of the COP reflects the changes to the Marine Institute's HABs Shellfish Monitoring webpage and a short HABS Guide is included in a new Appendix 6. Changes to the biotoxin sample delivery arrangements (Section 4.10) are also included in this version. Some scientific names of shellfish are updated in Appendix 3. Some other small updates to the system are also included.

Note on Changes in Version 8:

This version of the COP includes updates on the HABS database and also additional detail on sampling frequency (Section 4.3) and production period (Section 6.3). There is a new section on the role of the Shellfish Monitoring Co-ordinator (Section 4.1.1) and the changes introduced to the Programme by the SFPA Notice to Trade on the Harvesting of Scallops, version 6 (July 2018) are included in Section 4.15. There is additional detail on phytoplankton and shellfish sampling frequency (Appendices 3 and 5), along with updated samples of the Shellfish Registration Document (Appendix 8). Some other minor updates to the text and links are also included in this version.

Glossary of Terms and 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
INAB	Irish National Accreditation Board

ISO/IEC 17025:2005	The International Standard for testing laboratories which the MI is accredited to.
ISA	Irish Shellfish Association
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/Guidance-Documents
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.
Pseudonitzschia spp.	Phytoplankton species associated with ASP
PSP	Paralytic Shellfish Poisoning
PTX	Pectenotoxins, included in the lipophilic toxin group
Sentinel Sites	Production areas from around the coast that are

	sampled at a higher frequency and analysed for all toxins to give a representative view of toxicity
SFPA	Sea-Fisheries Protection Authority
SFPO	Sea-Fisheries Protection Officer
Shellfish Monitoring Co-ordinator	The SFPO with national responsibility for overseeing the SFPA operation of the Irish Shellfish Monitoring Programme.
Shellfish Manager	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	Senior Port Officer of the SFPA
Spp.	Species (plural)
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 (www.sfpa.ie/Seafood-Safety/Shellfish/Guidance-Documents).

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:-

1. Collection and delivery of shellfish and phytoplankton samples
2. Analysis of shellfish samples
3. Assigning a status to a production area
4. Communication of results
5. 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 also outlines the responsibilities of shellfish samplers and shellfish managers.

2.0 The 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 sub-groups 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). 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 https://www.fsai.ie/about_us/industry_fora/mssc.html.

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 co-ordinating 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 by INAB to ISO/IEC 17025:2005. A key component of the Irish Shellfish Monitoring Programme is the Marine Institute's HABs database (http://webapps.marine.ie/HABs/) 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 also information on predictive forecasted toxin events based on oceanographic and environmental parameters, data and models

The Irish Shellfish Association (ISA) 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 levels 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 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 the ISA. 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 (EC) No 854/2004 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 each production area to correspond with shellfish samples.

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. The equipment and consumables are provided by the MI.

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 5 m 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 using simply the 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 shall be tested for all potentially toxic phytoplankton species on a weekly sampling frequency (see Appendix 3). Every classified shellfish production area should collect weekly phytoplankton samples in order to retain an open status. This requirement applies regardless of the sampling frequency for the shellfish species in the production area.

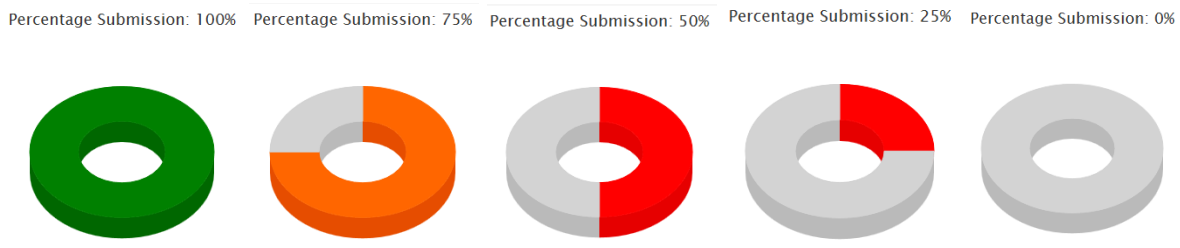
A minimum of three weekly samples will be required in every rolling 4 week period (this includes the preceding 4 week period and not the current week). If the frequency of sampling drops below this level the area will not be assigned an Open status on the next clear shellfish result. **Dormant areas 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, not including the current week) weekly phytoplankton samples will not be assigned an open biotoxin status. 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 Status

Areas that are not in 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.

.4 Phytoplankton Analysis and Reporting

Phytoplankton analysis is carried out by the MI under the Institute's ISO/IEC 17025 scope of accreditation. Results are typically available within two days of receipt of a sample. The results are posted on the MI's HABs database (http://webapps.marine.ie/HABs/)

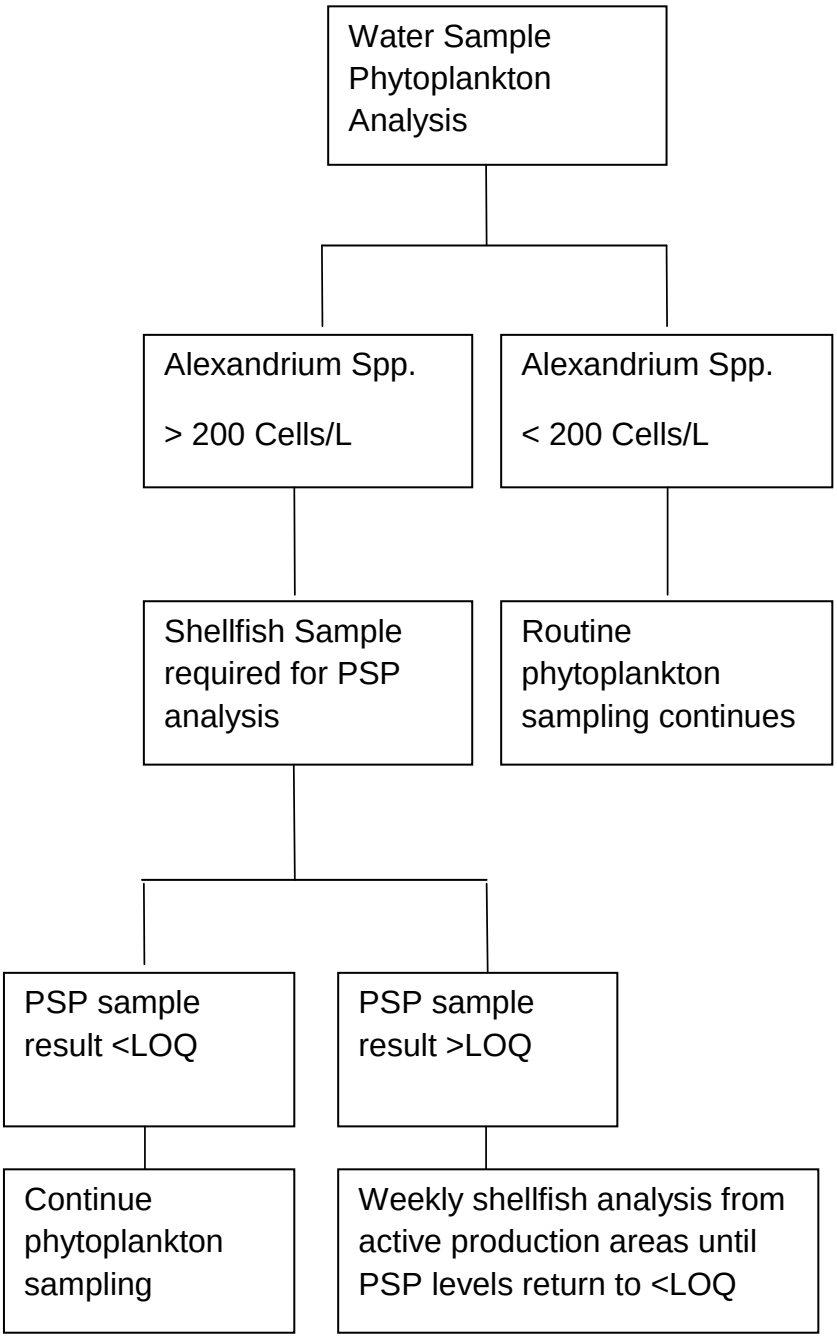
3.5 Additional Monitoring When Toxic Phytoplankton are Identified

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

PSP Phytoplankton -

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 in areas outside of Cork Harbour, see Figure 2.

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



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 HPLC for full quantification.

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 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, ie 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 Co-ordinator

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 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; and,

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”[1] and the Health and Safety Authority’s (HSA) document “Managing Health and Safety in Fishing”[2]

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:

[1] http://www.dttas.ie/maritime/english/code-practice-fishing-vessels-less-15m-length-overall

[2] http://www.hsa.ie/eng/Your_Industry/Fishing/Further_Information/

- 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 regards, 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 4. 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 5. 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 in the information box ‘Sampling frequency required for samples to be valid’. Further information on the production period is available in Section 6.2 (Production Period for Harvesting).

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 of the month.

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 the default biotoxin status of an area is closed. 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 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 Co-ordinator. .

Cork Harbour is the only area in Ireland to date where the presence of *Alexandrium spp.* has been linked to PSP toxicity above the regulatory limit. The SFPA collects weekly shellfish samples in Cork Harbour during the months of June, July and August and these are forwarded to the MI in Galway. Two clear results must be obtained prior to harvesting. Outside of this period the sampling frequency in Cork Harbour may be reduced to monthly sampling, in accordance with the procedures set out in Section 4.5 (Changes to the Sampling Frequency).

ASP -

Sentinel site samples are tested for ASP 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 (http://webapps.marine.ie/HABs/) .

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 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 Quality

Sample size is defined by the number of individual shellfish for each species. Shellfish Samplers should refer to Appendix 4 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 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.

This is an example of a label:

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

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, or for samples which are being hand delivered, the address below may 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. Please note, where samples are being delivered directly to the MI, the sender should notify the MI, at a minimum of 24 hrs prior to sample arrival. In the case of Monday deliveries, the MI should be informed by 12 pm on the Friday before.

Address when samples are delivered directly to the MI:

Marine Institute,

Biotoxin Unit

Rinville,

Oranmore,

Co. Galway,

H91 R673

Shellfish samples should normally be dispatched to arrive no later than Wednesday morning where the result is required that 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:

- insufficient information on the sample identification label
- no sample identification label on the sample
- insufficient 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 Regulation 853/04 sets 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 6). Sample analysis is carried out by the MI under the scope of its INAB accreditation using approved chemical methods.

4.13 Reporting of Biotoxin Results

The Marine Institute publishes the biotoxin results on the MI HABs Shellfish Monitoring webpage: http://webapps.marine.ie/HABs/ (see Appendix 7)

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 8, 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 (http://www.sfpa.ie/Seafood-Safety/Shellfish/Guidance-Documents). 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: www.sfpa.ie/Seafood-Safety/Shellfish/Classified-Areas

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 logsheet number (see Appendix 8, 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' 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 -

Once a 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 fortnightly. This frequency may be increased to weekly during occasions of increased toxicity.

Sample Protocol for scallop from classified areas -

The sample size ishould12 – 15 Scallops, whole in the shell. 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 species:
Date of Sample:
Sample location Code: *
Sample taken by:

* Sample location codes are on the HABs Shellfish Monitoring webpage: http://webapps.marine.ie/HABs/

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

Biotoxin samples of scallops must be sent via An Post postal service directly to the Marine Institute PO BOX 430 Galway Mail Centre, Tuam Road, Galway.

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: http://webapps.marine.ie/HABs/. For further information on results see Section 5.4 (ASP).

4.15.2 Scallops from Offshore Areas that are not Classified

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. Scallops from offshore sites being placed on the market via approved establishments must not contain marine biotoxins in total quantities (measures in the whole body or any part edible separately) that exceed the limits set out in Regulation (EC) 853/2004, Annex III section VII chapter V. If scallop from offshore areas are to be placed whole on the market then additional testing of the whole body will be required in order that FBOs can meet the biotoxin standards laid down in Regulation EC 853/2004 Annex III Section VII Chapter V, as proved by a system of own-checks.'

Food business operators placing scallops from off-shore 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 logsheet number (See Appendix 8, 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.

Sampling frequency: The biotoxin sampling frequency for wild scallops fished from offshore scallop grounds is weekly. Each offshore site or ICES Statistical rectangle when fished requires one sample of scallops for biotoxin analysis per week.

Scallop producers are required to check the Marine Institute's 'Submitted Shellfish Harvesting Notifications' on http://webapps.marine.ie/HABs/ in order to coordinate their samples to the Marine Institute and avoid needless sample rejections. If the area fished is not on the current week of harvesting notifications, then a 'New Notification' must be completed online.

NB Offshore sites are NOT classified grounds and therefore do not require two samples taken more than 48hrs and less than 12 days apart.

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 Species:
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: : http://webapps.marine.ie/HABs/

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

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 http://webapps.marine.ie/HABs/. For further information on results see Section 5.4 (ASP Results).

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 6 (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 production period
Closed	The most recent valid sample has exceeded the regulatory limit or the open status has lapsed. 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 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 limit but there is no previous valid sample. The production area is closed for harvesting for that shellfish species until a second result below the limit is obtained

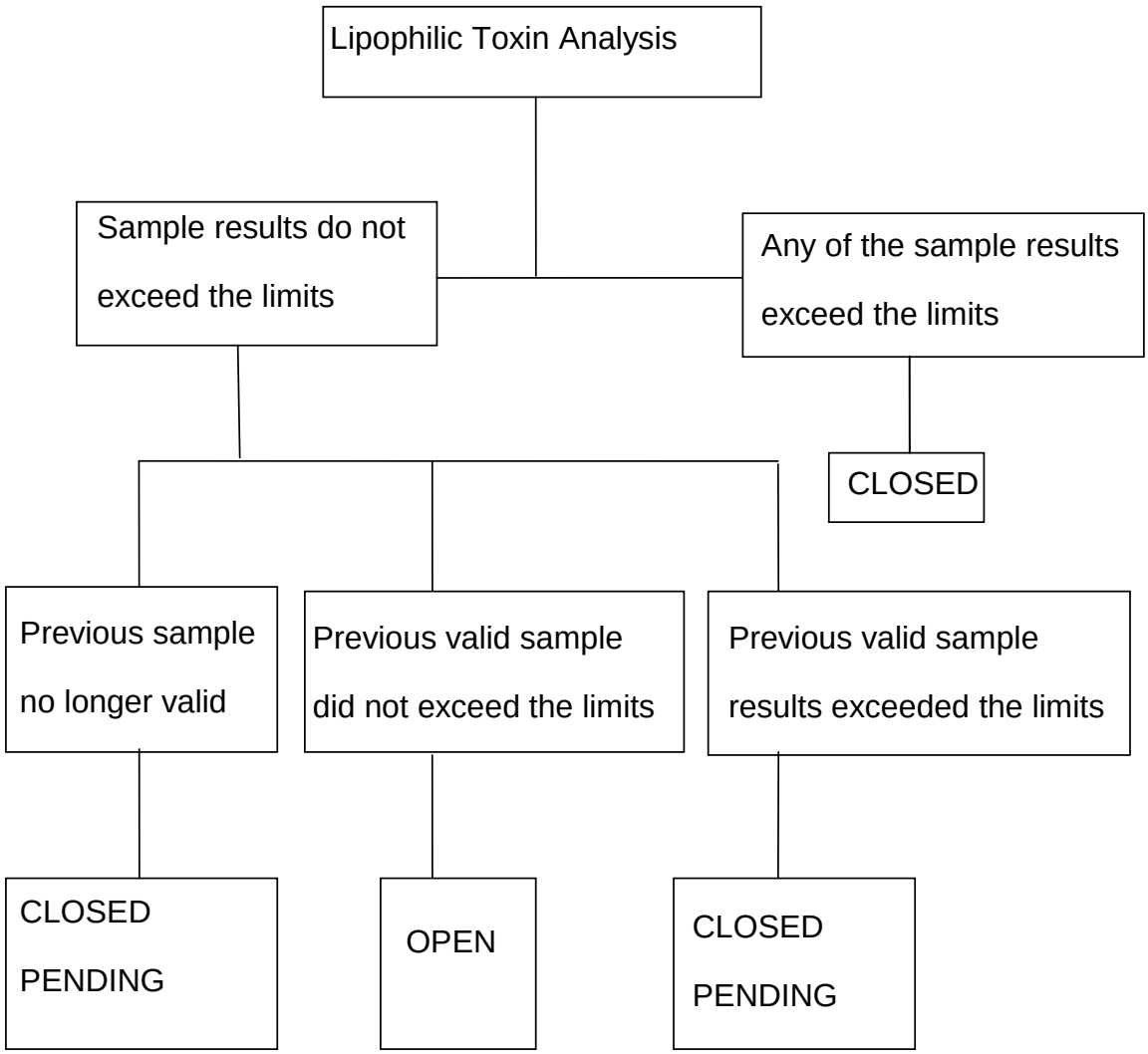
Samples must normally be taken in the same or successive production period for an Open status to be maintained, although variations to this may be agreed by the Management Cell (see Appendix 2, The Management Cell).

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 3, 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).

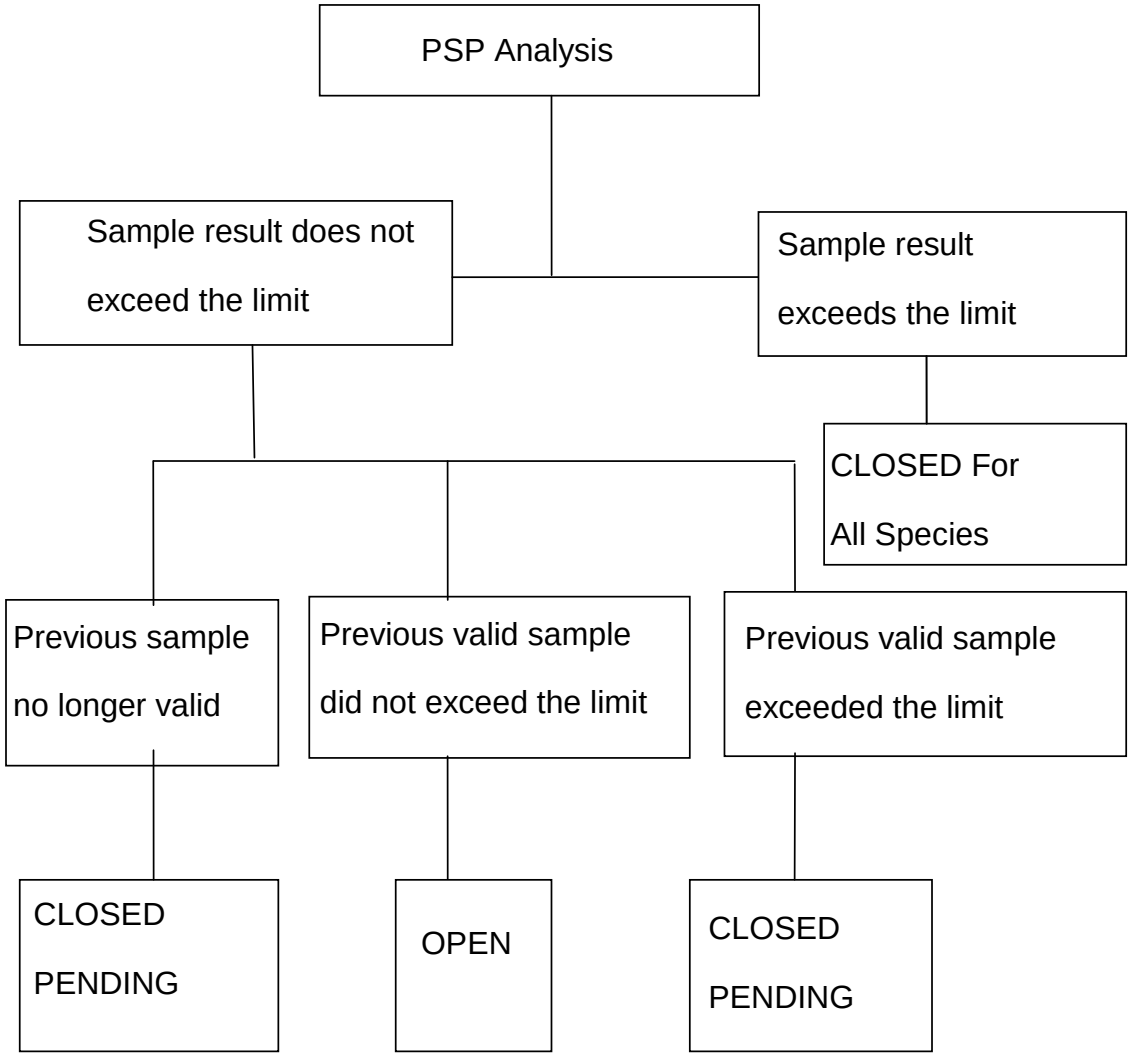
Figure 3. Lipophilic Toxin Decision Tree



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. This ban on the harvesting of all species from a production area does not apply if limits for lipophilic toxins, or ASP are exceeded. The PSP decision tree for assigning the status of a shellfish production area is shown in Figure 4. The phytoplankton monitoring decision tree for *Alexandrium spp.* and PSP in production areas outside of Cork Harbour is shown in Figure 2 (see Section 3.5, Additional Monitoring when Toxic Phytoplankton are Identified).

Figure 4. 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 HPLC for full quantification. In addition shellfish from sentinel sites are tested for ASP via HPLC.

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).

5.4.2 ASP – Scallops from Classified Production Areas

The following scallop tissues are analysed for ASP (see Figure 3, 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 3, 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 3 & 5). 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 5. ASP Decision Tree for scallops from classified production areas

(See also the requirements for Lipophilic Toxins, Figure 3)

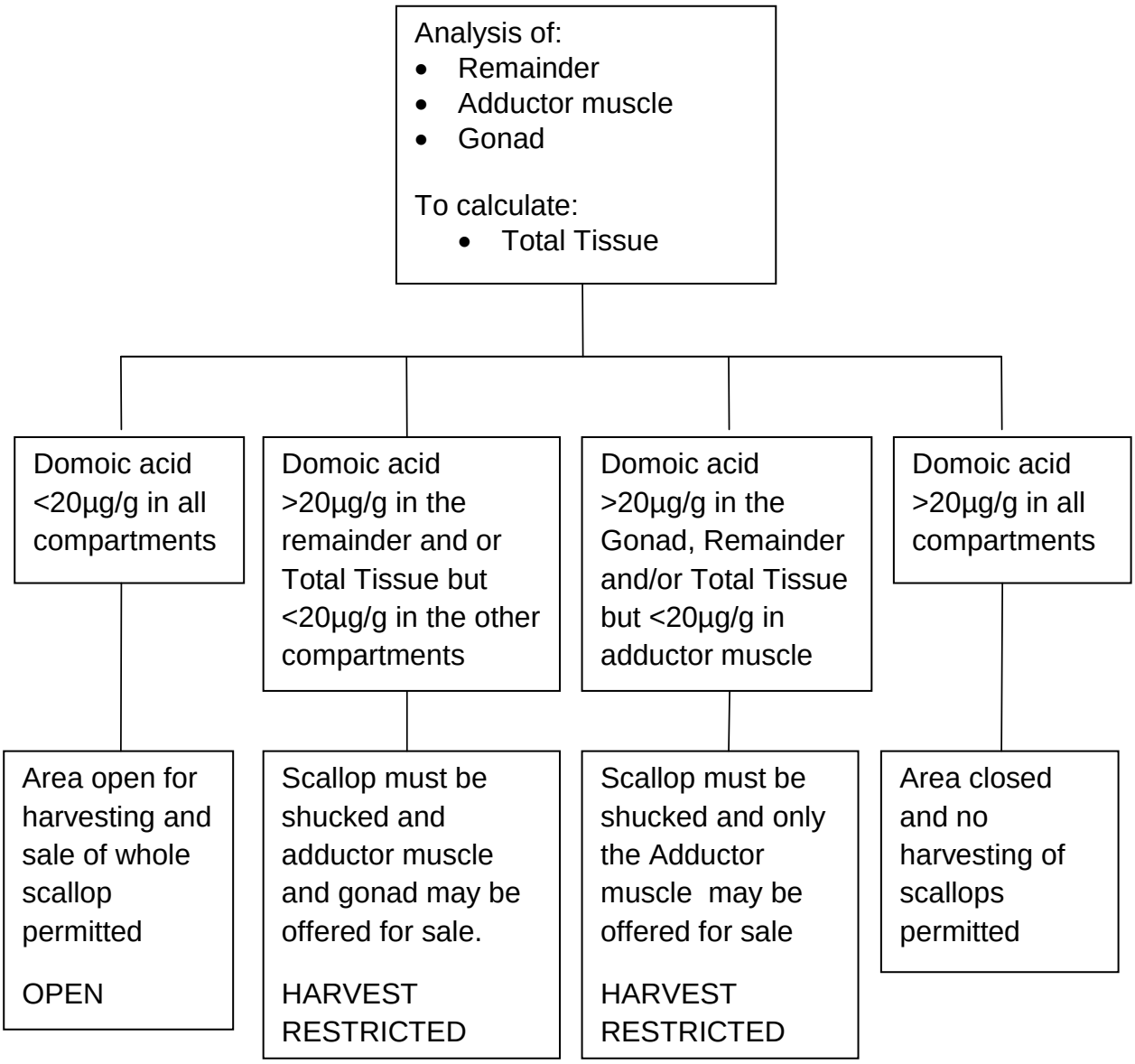


Table 2. Production Area Status for Scallops from Classified Areas

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.
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.

The standard paragraphs used in the reporting of ASP results from classified production areas are shown in Table 3.

Table 3.. Standard paragraphs for MI results for scallops from classified production areas

Biotoxin Analysis Result	**MI Result Standard Paragraph**
Scallops from a production area where all compartments <20 µg/g Domoic Acid and < associated Lipophilic Toxin limits in the remainder or in all compartments and where the previous valid sample status assigned is Open or Closed Pending	"(Insert applicable Location code) is open and scallops may be marketed in the shell."
Scallops from a production area where all compartments <20 µg/g Domoic Acid and < associated Lipophilic Toxin limits in the remainder and where the previous valid sample status assigned is Closed	"(Insert applicable Location code) is Closed Pending. Scallops from this area must not be harvested"
Scallops from a production area >20 µg/g Domoic Acid in all compartments and < associated Lipophilic Toxin limits in the remainder	"(Insert applicable Location code) is closed. Scallops from this area must not be harvested"
Scallops from a production area >20 µg/g Domoic Acid in all compartments and > associated Lipophilic Toxin limits in the remainder	"(Insert applicable Location code) is closed. Scallops from this area must not be harvested"
Scallops from a production area <20 µg/g Domoic Acid in all compartments and > associated Lipophilic Toxin limits in all compartments	"(Insert applicable Location code) is Closed. Scallops from this area must not be harvested"
Scallops from a production area where the Gonad, Remainder and or Total Tissue is >20 µg /g Domoic Acid but <20 µg/g Domoic Acid in the Adductor Muscle and < associated Lipophilic Toxin limits in the Remainder Tissue	"(Insert applicable Location code) is under a restricted harvesting regime and scallops from it must be processed before only the Adductor Muscle maybe marketed"
Scallops from a production area where the Remainder and or Total Tissue is >20 µg/g Domoic Acid but <20 µg/g Domoic Acid in the adductor muscle and gonad tissues and < associated Lipophilic Toxin	"(Insert applicable Location code) is under a restricted harvesting regime and scallops from it must be processed before only the Adductor Muscle and Gonad are marketed"

limits in the remainder tissue	
Scallops from a production area <20 µg/g Domoic Acid in all compartments and > associated Lipophilic Toxin limits in the Remainder Tissue but < associated Lipophilic Toxin limits in the Adductor Muscle and Gonad tissues	"(Insert applicable Location code) is under a restricted harvesting regime and scallops from it must be processed before only the Adductor Muscle and Gonad are marketed"
Scallops from a production area <20 µg/g Domoic Acid in all compartments and > associated Lipophilic Toxin limits in the Remainder and Gonad tissue < associated Lipophilic Toxin limits in the Adductor Muscle tissues	"(Insert applicable Location code) is under a restricted harvesting regime and scallops from it must be processed before only the Adductor Muscle maybe marketed"
Scallops from a production area where a Management Cell Decision has been taken.	The following Management Cell Decision has been taken according to the procedure detailed in the ISMP Code of Practice:- "

5.4.3 ASP – Scallops from offshore fisheries

The adductor muscle and gonad are analysed separately from wild fished processed scallop. If the amount of Domoic Acid is found to be <20µg/g in both of these compartments then both the adductor muscle and gonad from that batch may be placed on the market for human consumption (see Figure 6). The batch from which these scallops come from is said to have a **Harvest Restricted** status i.e. the shellfish can only be sold after they have been shucked and the separate compartments analysed.

If the amount of Domoic Acid is found to be <20µg/g in the adductor muscle but >20µg/g in the gonad then only the adductor muscle from that batch may be placed on the market for human consumption.

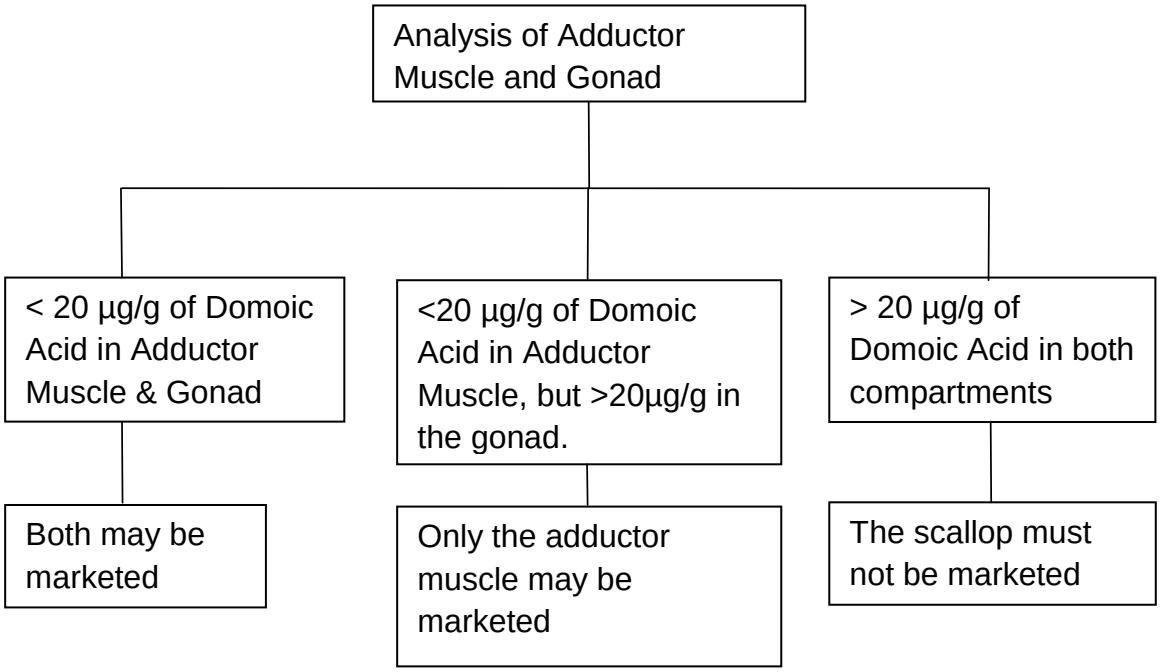
If the amount of Domoic Acid is found to be >20µg/g in both compartments then the batch must be rejected and must not be placed on the market for human consumption.

The Production Area status assigned to scallops submitted from offshore sites will be assigned and reported as 'Not Classified'. The standard paragraphs used in the reporting of ASP results from offshore areas are shown in Table 4.

Table 4. Standard Paragraphs for MI results for scallops from offshore areas

Analysis Result	MI Result Standard Paragraph
Offshore Fisheries, where both the Adductor Muscle and Gonad are < 20 µg /g,	“The scallops from (insert applicable Location code) landing must be processed. Only the Adductor Muscle and Gonad may be marketed.”
Offshore Fisheries, where the Adductor Muscle is <20 µg /g. This applies when either the adductor muscle tissue is submitted by itself or when the accompanying Gonad tissue is >20 µg /g	“The scallops from (insert applicable Location code) landing must be processed. Only Adductor Muscles may be marketed.”
Offshore Fisheries where both the Adductor Muscle and Gonad are >20 µg /g	“The scallops from (insert applicable Location code) landing must not be marketed.”
Offshore Fisheries, where a Management Cell Decision has been taken.	“The following Management Cell Decision has been taken according to the procedure detailed in the ISMP Code of Practice for Biotoxins:“

Figure 6. ASP Decision Tree for Scallops from Offshore Fisheries (Non Classified areas)



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 (EC) No 854/2004 and the SFPA enforce the legislation using results published on the http://webapps.marine.ie/HABs/. 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 432/2009 - The European Communities (Food and Feed Hygiene) Regulations, 2009.

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' on http://webapps.marine.ie/HABs/ 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, which is available at: www.fsai.ie/publications_guidancenote10_recall/). 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 production period in question;
- shellfish should only be placed on the market when the result of the sample taken in the **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 (see FSAI link above).

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 and if necessary ordering the recall, withdrawal and/or destruction of scallops and scallop products; and any other measure the SFPA may deem appropriate.

7.0 Communication

7.1 Data Management and the Publication of Results

In the interests of consumer safety and protection, the widest practical dissemination is given to biotoxin 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 data and it publishes the results on the MI HABs Shellfish Monitoring webpage: http://webapps.marine.ie/HABs/.

7.2 Minutes of the MSSC Meetings

The minutes of meetings of the MSSC will be published online (at www.fsai.ie) once they have been agreed by the Committee.

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 at: www.fsai.ie/publications_guidancenote10_recall/

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 (http://www.fsai.ie/legislation) 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.

Guide to the requirements for Bivalve Molluscs in EU Food Legislation –

Area	**Legislation**
General Principles of Food Law Traceability Responsibilities for FBOs	178/02 - Article 18 - Article 17 & 19, 852/2004 Article 1
All FBOs Primary Producers All other food operators, including transport HACCP	852/04 Article 4 - Annex I - Annex II - Article 5
Registration & approval of establishments General requirements Registration and where approval is required Approval of establishments	 852/04 Article 6 853/04 Article 4 854/04 Article 3***
Identification Marking General requirements Identification and labelling of live bi-valve molluscs	 853/04 Article 5 & Annex II, Sectn I 853/04 Annex III, Section VII, Chpt VII
Live Bivalve Molluscs Specific Hygiene Rules - General requirements, wrapping, transport - Production & harvesting requirements - Purification & dispatch centres - Health standards - Requirements for wild scallops	 853/04 Annex III, Section VII - Chapters I, VI & VIII - Chapter II - Chapters III & IV - Chapter V - Chapter IX 854/04 Annex II***

Official Controls - Classification & monitoring of areas* - Controls on wild scallops and gastropods	 - Chapter II - Chapter III
Biotoxin Methods	2074/05 Article 3, Annex III**
Microbiological Criteria*	2073/05 Annex I, Chpt I (1.17,1.24)
Fishery Products	
Specific Hygiene Rules	853/04 Annex III, Section VIII
- Requirements for vessels	- Chapter I
- Landing and first sale	- Chapter II
- Establishments and vessels	- Chapter III
- Cooked crustaceans and molluscs	- Chapter IV
- Health standards including biotoxins	- Chapter V
- Wrapping, storage & transport	- Chapters VI, VII & VIII
Official Controls	854/04 Annex III***
Microbiological Criteria	2073/05 Annex I (1.2, 1.16, 1.25, 1.26, 2.4)
Animal Health Rules	
Aquaculture Diseases	2006/88 (Directive)
Water Quality	
Water Framework Directive	2000/60
Marine Strategy Framework Directive	2008/56
Official Controls	
Verification of compliance	882/04***

*As amended by Commission Regulation 2015/2285 on live bivalve mollusc classification and microbiological testing criteria

** As amended by Commission Regulation 15/2011, on the recognised testing methods for detecting marine biotoxins. This amendment is included in the consolidated version of 2074/05.

*** Regulation (EC) 2017/625 replaces Regulation (EC) No 882/2004 with effect from the 14th December 2019. Regulation (EC) No 854/2004 will also be repealed and replaced at this time.

Links to legislation include the latest consolidated versions

Irish Legislation

- Irish Acts

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

- Transposition of EU Legislation into Irish Law

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:

European Legislation	**National Statutory Instrument**
Regulations 178/02, 852/04, 853/04, 854/04, 882/04	SI 432 of 2009 Food and Feed Hygiene Regulations, 2009, as amended (transposes the legislation for fishery products and live bivalve molluscs)
Animal Health Rules, Aquaculture Diseases Directive 2002/99	SI 820 of 2004 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 from each of the following:-

1. The FSAI (The Director of Enforcement Policy or alternate): The FSAI is the CA responsible for the enforcement of all food legislation in Ireland. The FSAI acts as chair the Management Cell
2. The SFPA (Director or alternate): With respect to seafood and live bivalve molluscs, the SFPA is the CA under Regulation EC 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
3. The Marine Institute (Section Manager/Team Leader, Biotoxin Unit, or alternate): The MI, will provide the necessary chemistry and phytoplankton results, as well as relevant scientific analysis and commentary.
4. The Irish Shellfish Association (ISA) (the Executive Secretary or nominated alternate): The role of the ISA 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 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.

A member of the Management Cell will convene the Cell by contacting the SFPA representative or their alternate. The FSAI will co-ordinate communications 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 the ISA, 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);
- 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 to hand are being analysed. In reaching a decision the Management Cell may attach different weights or priorities to information provided.

All decisions taken by the Management Cell will be consistent with Regulation (EC) No 854/2004 and Commission Regulation (EC) No 2074/2005. 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.

Status of Management Cell Decisions -

A decision of the Management Cell is a collective view expressed by its combined membership and directed to the relevant CA 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.

Record Keeping -

The FSAI and SFPA 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.

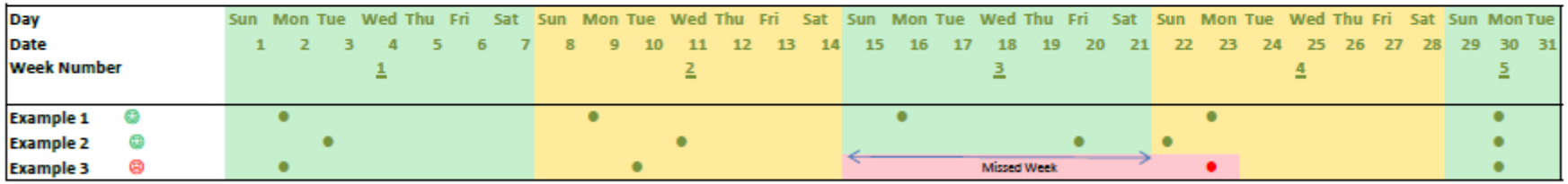
All records relating to decisions will be retained. Where the MI is prevented by exceptional circumstances from participating in a Management Cell, the FSAI will record the final decision and arrange any necessary follow up action.

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.

Appendix 3 – Phytoplankton Sampling Frequency

Phytoplankton Frequency

Phytoplankton 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 area per week, any more that this will be discarded. 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 that harvesting is taking place.
Failure to provide a weekly sample will result in the production are going to Closed status for the missed period.



Appendix 4 – 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	Carpet Shell or Corrugated Venus	50 – 150

senegalensis)		
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 5 – Shellfish Sampling Frequency and Area Closure

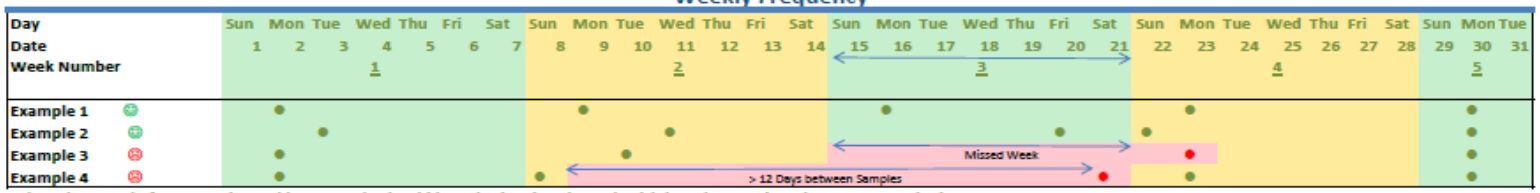
The following three diagrams show the frequency required for acceptable sampling of LBM to maintain status in a production area. In these diagrams it is taken that all samples are testing below the toxin threshold and is to explain the frequency rather than status closures due to exceeding the toxin 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 per sampling period will be tested by the National Reference Laboratory. Any extra samples will be only tested if 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 ● samples will result in the area going on a closed pending status. There are two main conditions necessary to be met.

(1) Weekly sample should be submitted during each calendar week Sunday to Saturday, Fortnightly samples during the Sunday to Saturday +1 week and Monthly Frequency must be submitted each Calendar Month

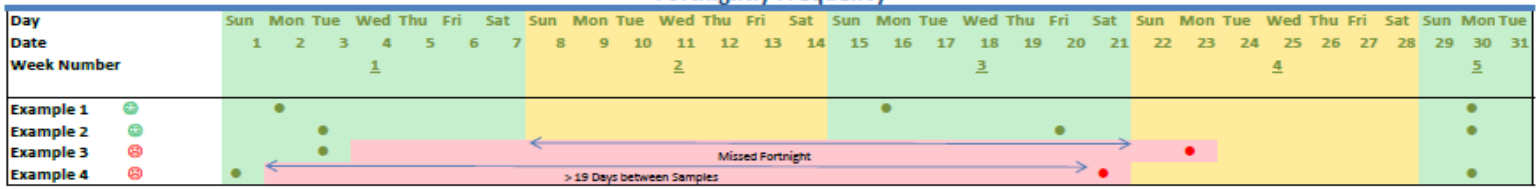
(2) Weekly Samples must be less than 12 days apart (eg sample taken on Sunday must be sampled before the Wednesday on the next week), Similarly fortnightly samples must be less than 19 days and Monthly less than 38 days apart between sampling dates.

Weekly Frequency



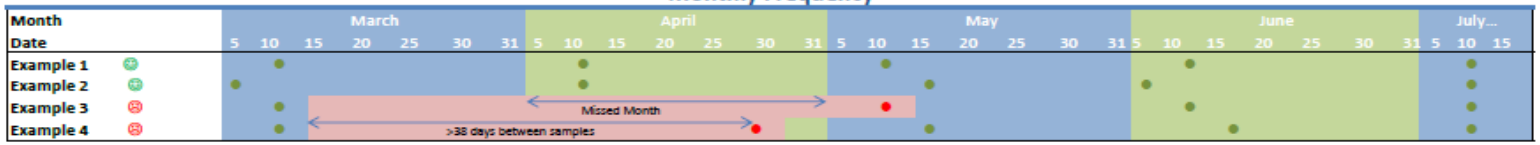
When the sample frequency is weekly a sample should be submitted each week with less than 12 days between sample dates

Fortnightly Frequency



When the sample frequency is Fortnightly a sample should be submitted each week with less than 19 days between sample dates

Monthly Frequency

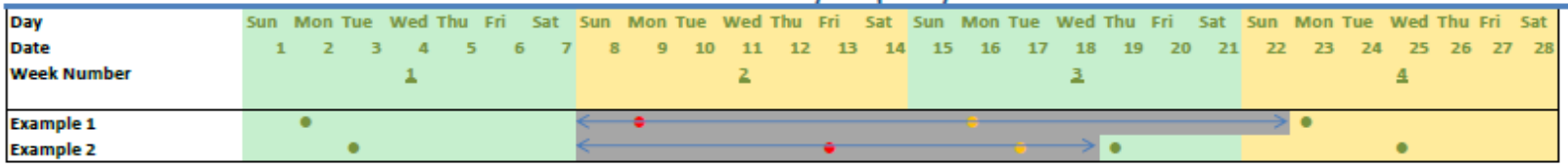


When the sample frequency is Monthly a sample should be submitted each calendar month with less than 38 days between sample dates

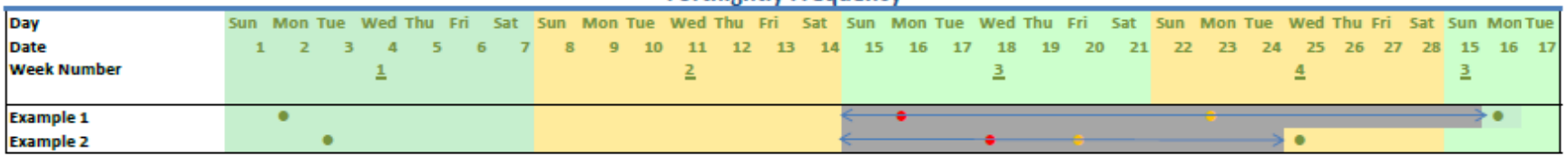
Closure / Recall if Sample is Positive and Reopening Situation

If an area goes from Open Status to a Closed Status following a positive result, the area is closed back to the start of the current production period (Week, Fortnight or Month). In most cases this will be no more than a week because the risk will have been assessed and an area going to closed status should be already sampling at a weekly frequency. The current reports on HABs database only indicate the status as from the Sample Date, however the closure extends back to the start of the production period, and any product on the market will be recalled by Competent authority. Reopening is on the basis of two clear tests no less than 48 hours apart.

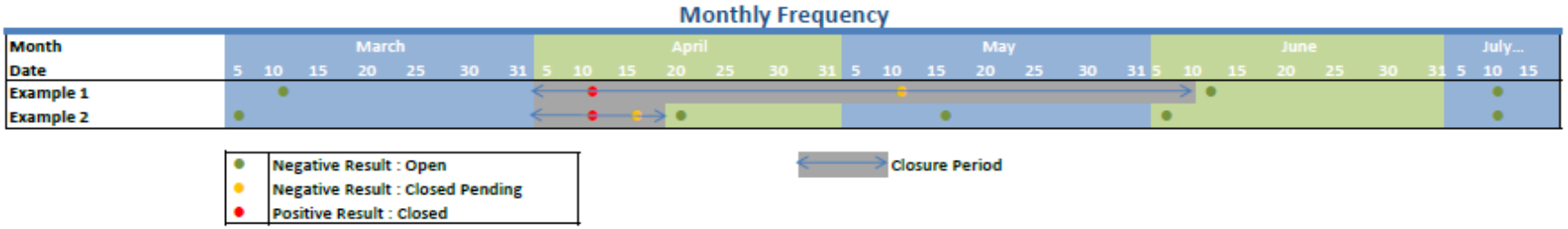
Weekly Frequency



Fortnightly Frequency



Monthly Frequency



Appendix 6 – Biotoxin Methods of Analysis and EU Regulatory Limits

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 EURL-LCMSMS	0.16 µg/g (160µg/kg)	OA equivalents
Azaspiracids group*	AZA1, AZA2 and AZA3	LC-MS/MS EURL-LCMSMS	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 EURL-LCMSMS	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 HABs[2] website and the limits in brackets are as laid down in EU Legislation.

*Lipophilic Toxin Group

Appendix 7 – The HABs^2 Quick Reference Guide

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

HABs^2 – Quick Reference Guide

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

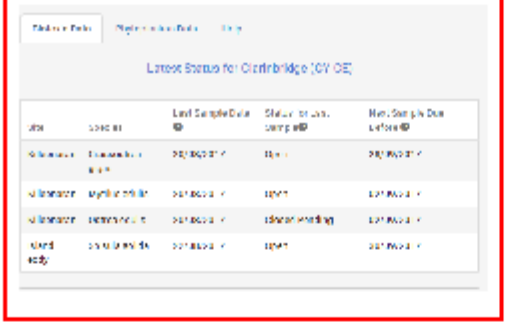
The HABs^2 website landing page www.marine.ie/Habs gives the user a choice between searching for the latest shellfish safety information for Inshore or Offshore areas.

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.

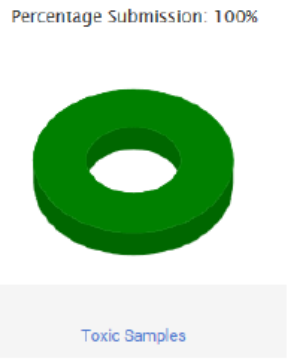
The **Sample Progress Tracker** table shows any samples which have been received in the lab, at which % stage of analysis the sample is at and when the result is estimated to be available, samples which have been reported are at 100% with a green tick in the completed column

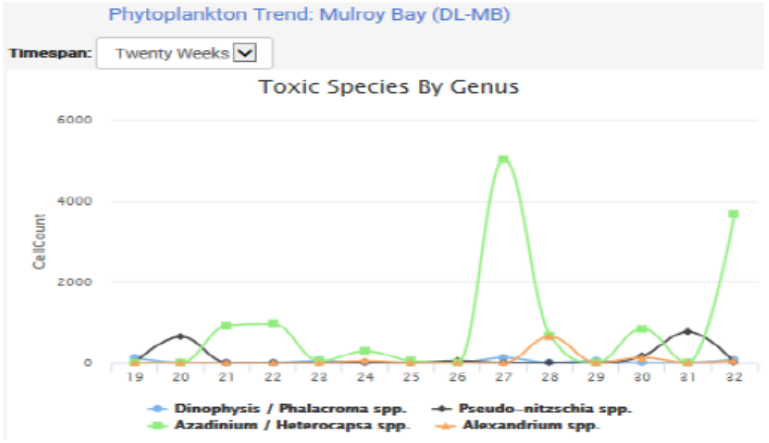
The **Biotoxin Trend** graph shows the levels of the different biotoxin groups (AZP, DSP etc.) and if they are increasing / decreasing over the last 20 weeks

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 8 – The Shellfish Registration Document

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

Serial No. IE 20000[6 digit]

SHELLFISH REGISTRATION DOCUMENT

DATE OF HARVEST: (1) 03 MARCH 2018	PRODUCTION AREA HARVESTED: (2) CASTLETOWNBERE	HARVEST LOCATION CODE (3) Ck-CE-CE
BIOTOXIN STATUS: (4) OPEN	WEEK NUMBER: (5) 14	PREVIOUS TEST STATUS: (7) OPEN
CLASSIFICATION OF PRODUCTION AREA: (6)	A	B ✓ C
NAME AND REGISTRATION OF VESSEL (if applicable): (8)		
EU LOGSHEET NUMBER (if applicable, vessels>10m):	ICES AREA: (9)	ICES Statistical Rectangle (9)
FISHING START TIME	END OF FISHING TIME	LANDING PORT
DREDGE TYPE (r)	NO. OF DREDGES	DREDGE WIDTH (cm)

SHELLFISH SPECIES HARVESTED: (11)

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

DESTINATION OF SHELLFISH HARVESTED: (8) (Name, Address in Block Capitals)	Destination 1:	Destination 2: (If applicable)
	Pure Irish Oysters	
	CASTLEBAR	
	Co Mayo	
Market Category (s)		

GATHERER'S NAME: (13) (Block Capitals)	JOE SMITH
GATHERER'S ADDRESS: (14) (Block Capitals)	Main Street Adrigole Co. Cork
TELEPHONE NUMBER: (14)	027 70439
Signature: (15)	
Date: (17)	4/3/2018

Company Date Stamp: (18)

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 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: (i)	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 Heaven Barrs 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 42985
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.