Version 5 (December 2014)

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

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Note on Changes in Version 4:

Phytoplankton monitoring was in Section 6 in the previous versions but it is now Section 3 as phytoplankton monitoring is now a requirement for production areas to be assigned an open status. Other changes include additional specific official control sampling by the SFPA (see Section 4.9), new sample delivery addresses (see Section 4.10.5) and the introduction of a weekly sampling frequency to off-shore non classified scallop grounds (see Section 4.14.2).

Note on Change in Version 5:

The section on Shellfish Production Areas and Sampling Points (Section 4.7) has been updated to explain how requests for changes to shellfish production areas and sampling points are handled..'

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 (the Irish Sea-Fisheries Board),
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
EHS	Environmental Health Service, part of the HSE
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
HABS Database	Harmful Algal Blooms Database www.marine.ie/habs
HACCP	Hazard Analysis and Critical Control Point
HPLC	High-performance liquid chromatography, a chemical analytical method
HSE	Health Services Executive
INAB	Irish National Accreditation Board
ISO/IEC 17025:2005	International Standard of General Requirements for the Competence of Testing and Calibration Laboratories
ISA	Irish Shellfish Association
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
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 or a 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 Co-ordinator	The SFPO with responsibility for overseeing the operation of the sampling in the Irish Shellfish Monitoring Programme
Shellfish Manager	The SFPO or Loughs Agency Officer with responsibility for a production area
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 so 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 monitoring. A separate Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas is available on the Seafood Safety Section of the SFPA website (www.sfpa.ie/SeafoodSafety/Shellfish).

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

1.4 Stakeholders

The stakeholders listed below are members of the MSSC and the committee chair is held by the FSAI. The Management Cell of the MSSC is comprised of representatives from the FSAI, SFPA, MI and the ISA.

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 signed service contracts with the FSAI.

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 Harmful Algal Bloom (HABS) database which gives easy access to up-to-date monitoring results (www.marine.ie/habs).

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

2.0 The MSSC

2.1 Role of the MSSC

The MSSC was established, following Ministerial direction, to provide a partnership forum within which all stakeholders (see Section 1.4) involved in the production, processing, development, analysis and regulation of shellfish can frankly express their views in the interests of collective learning. It facilitates the discussion of the safety of the product and the management of the industry from risk management and consumer protection perspectives. The MSSC is an open forum and anyone with a relevant matter to discuss is free to attend and participate.

The MSSC acts as a consultative body from which the 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; and,
- Supporting the long term sustainable development of the shellfish industry and to maximize its export potential.
- Ensuring that any changes in legislation are introduced into the monitoring programme in a co-operative and open manner.

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

The MSSC can also delegate some of this work or some of its functions to sub-groups or sub-committees, constituted by members of the MSSC and anyone not a member of the MSSC, but co-opted to become a member of a sub-group or sub-committee.

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 held in the FSAI Offices (Dublin), with one meeting each hosted by the SFPA (Clonakilty) and the MI (Galway). Other regional meetings may also be organised from time to time.

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

2.4 The Management Cell

The MSSC operates a "Management Cell" to proactively assess the risk to public health presented by shellfish from production areas in Ireland. The objective of the Management Cell is to facilitate rapid decision making in non-routine situations. The operation of the Management Cell is described in Appendix 2.

3.0 Phytoplankton Monitoring

(Moved from Section 6)

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 Phytoplankton Monitoring pages of the MI website provides details of the species of phytoplankton that are of significance in Irish waters, along with 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, they indicate the

- 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 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 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 Marine Institute.

Samples from south of the Shannon estuary should be submitted to:

Marine Institute Phytoplankton Laboratory,

c/o Fastnet Mussels,

Gearhies,

Bantry,

Co Cork.

Sample from north of the Shannon estuary should be submitted to:

Marine Institute,

Rinville,

Oranmore,

Co. Galway.

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. Every classified shellfish production area must collect weekly phytoplankton samples in order to remain on 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. 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 weekly samples of phytoplankton (in addition to the shellfish samples) in advance of their expected week of recommencing harvesting.**

Any production area not meeting the minimum of 3 out of 4 weekly phytoplankton samples will not be assigned an open biotoxin status. There will be no management cell decisions for production areas where phytoplankton sampling is not at the minimum phytoplankton sampling frequency.

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.

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3.4 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 HABs webpage (www.marine.ie/habs). and can be accessed by choosing the Toxic Phytoplankton option on the option on the Report Type list.

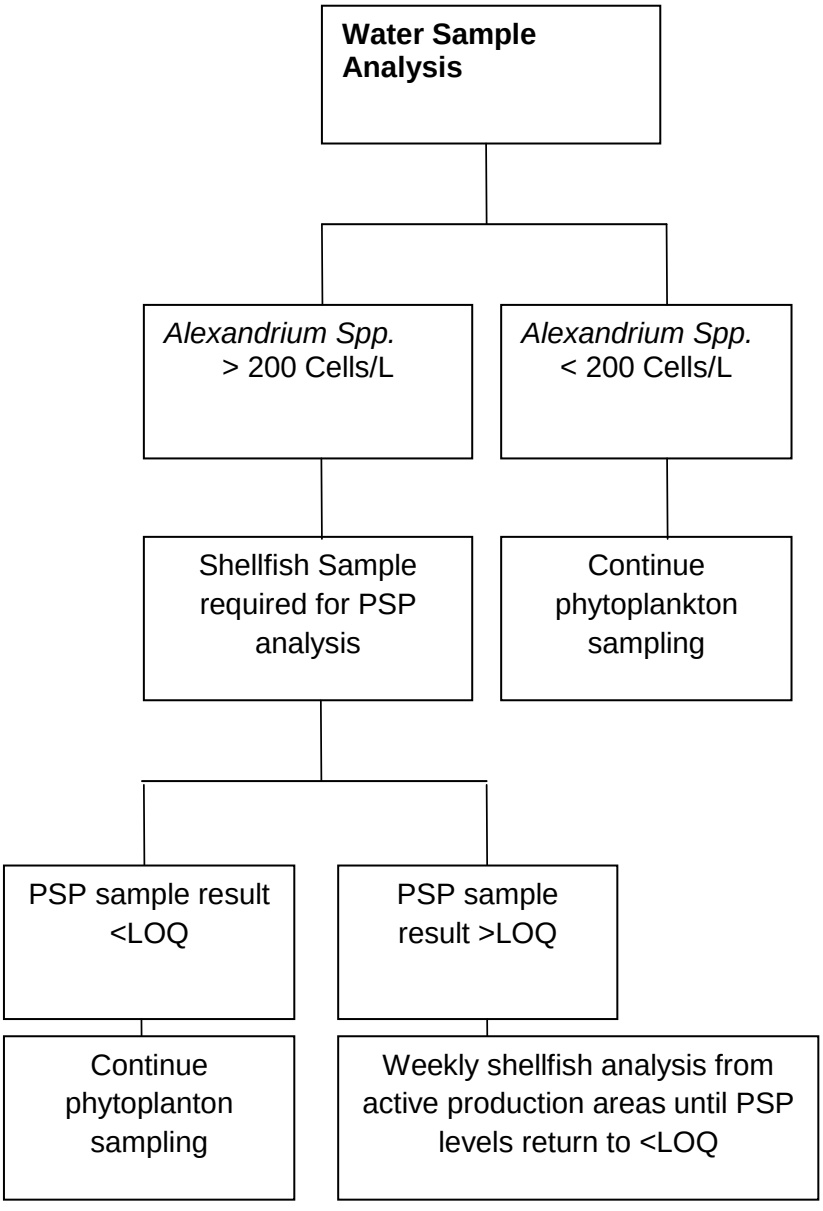
3.5 Additional Monitoring When Toxic Phytoplankton are Identified

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 for PSP in areas outside of Cork Harbour, see Figure 1.

Figure 1. The Decision Tree for the monitoring of *Alexandrium spp*. and PSP in production areas outside of Cork Harbour.



ASP Phytoplankton

If phytoplankton cell counts of Pseudonitzschia spp. reach a level of greater than 1 million (1 x 10^6) cells per litre this will trigger a request by the MI for shellfish samples for ASP from that production area.

4.0 Shellfish Sampling, Analysis and Reporting

4.1 Organisation of Shellfish Sampling

Shellfish production areas are under the Official Control of the SFPA. 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 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 Shellfish Samplers and all other relevant documents.

4.1.2 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.

4.2 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 3. The regulatory limits apply to both wild and farmed shellfish. Specific requirements for scallops are outlined in Section 4.14. 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. Other frequencies may also be set if conditions necessitate. Sampling should only take place when shellfish harvesting is expected.

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 each week, with no more than **12 days** between sample dates. The sampling week starts on a Sunday and ends the following Saturday.
- When the sampling frequency is **fortnightly** a sample should be submitted each week, with no more than **19 days** between sample dates. The sampling week starts on a Sunday and ends the following Saturday week.
- When the sampling frequency is **monthly** a sample should be submitted each calendar month, with no more than **38 days** between sample dates.

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 Mandatory Phytoplankton sampling, ***Dormant areas that wish to re-open, must send in 2 weekly samples of phytoplankton (in addition to the 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. Gastropods require 1 clear sample to open an area in advance of harvesting.

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 SFPA Shellfish Co-ordinator who will in turn inform all the Sample Managers and Samplers. The MI will also highlight the sampling frequency change in their laboratory analysis reports. The interval between any decision on sampling frequency variation and its application is normally at least 2 weeks to allow the necessary arrangements be made to ensure a smooth transition. This interval may be reduced, as necessary, following discussion between the MI and the SFPA Shellfish Co-ordinator.

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 SFPA Shellfish 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. Where phytoplankton counts of *Pseudonitzschia spp*. are elevated or low level toxicity indicates a risk, this frequency will be increased. When the presence of the *Pseudonitzschia spp.* is detected at levels of 1 million (1 x 10^6) cells/litre in phytoplankton samples the MI will request additional phytoplankton and shellfish samples from these areas for ASP testing (see Section 3.5, Additional Monitoring When Toxic Phytoplankton Species are Identified).

Scallops in classified production areas are sampled for ASP (see Section 4.14.1,Scallops from classified production areas) and if ASP is detected sampling of other species in that area may be initiated. Scallops from offshore areas are sampled in accordance with Section 4.14.2 (Scallops from offshore areas that are not classified). 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 on the MI website (www.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 should be sent to the SFPA Shellfish 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 SFPA Shellfish 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, PSP, YTX 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.
- Whole scallops from approved FBOs are sampled on a quarterly basis
- Marine gastropods from approved FBOs are sampled 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. Samplers should refer to Appendix 3 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, leading to a delay in the reporting of results.

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

An example of a label is shown here:

For Biotoxin Analysis:

Name of Area Sampled:	**Ballinakill, Co Galway**
Sample Point Code:	**GY-BL-BL**
Date of Sampling:	**11 – Nov – 2014**
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,

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.

Aquafact Limited,

12 kilkierrin Park,

Liosbaun Estate,

Tuam Road,

Galway.

Any changes to the sample delivery information will be posted on the MI website (www.marine.ie/habs).

Shellfish samples should normally be submitted to arrive no later than Wednesday evening where the result is needed 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 report will be issued the following day. Shellfish arriving on Friday may be held over the weekend depending on laboratory schedule. PSP and ASP analyses may take longer.

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 4). 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 Database (www.marine.ie/habs).

4.14 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 (June 2014 Vers 3) which is available from the SFPA (SFPA.ie 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 4.14.1 Scallops harvested within 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 4.14.2 (Scallops from offshore areas that are not classified).

Documentation

All batches of harvested or fished scallops must be accompanied by a completed Shellfish Registration Document which records date of harvesting, quantities harvested, location of harvesting, biotoxin status, name of fishing vessel, EU logsheet etc. Shellfish Registration Documents are available from any SFPA office.

4.14.1 Scallops from Classified Production Areas

Live Scallops from a classified production area may only be placed on the market for retail sale when the production area has an Open 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 (SFPA Classified Shellfish Production 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 5)

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 'Harvest Restricted' Biotoxin status when only shucked product of those parts of the scallop which have tested below regulatory limits for Marine 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 'Harvest 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.

Scallop processors or approved dispatch centres handling scallops from classified production areas should agree with fishing vessel operators to identify the vessel(s) which will act as scallop shellfish samplers. The scallop shellfish samplers are responsible for the collection of scallop samples and phytoplankton samples. This

identification of scallop shellfish samplers is to avoid duplicate sampling where different vessels fishing in the same classified production area submitting samples. 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).

Sample Protocol for scallop from classified areas

Sample size should be 12 – 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:

*Available on the MI website at: Production Area Maps and Sample location codes

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 Marine Institute PO BOX 430 Galway Mail Centre, Tuam Road, Galway.

Additionally the MI biotoxins lab must be informed of the submitted samples by Fax 091 387201 or by email to; dave.clarke@marine.ie or conor.duffy@marine.ie

Phytoplankton monitoring: There is a requirement for phytoplankton samples to be submitted from classified production areas that are fished for scallops.

Biotoxin Results

The Marine Institute publishes the biotoxin results on the MI HABS Database (www.marine.ie/habs). For further information on results see Section 5.4 (ASP). The Marine Institute will also inform samplers of the scallop biotoxin status of a production area via text alert and by email, by arrangement.

4.14.2 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 will be required.

Documentary Requirements

Scallops harvested from offshore sites 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 5, Examples of Gatherers Registration Documents).

Fishermen landing scallops from offshore sites should record ‘Not tested’ in the Biotoxin Status on the Shellfish Registration Document.

Sampling frequency for scallops harvested from offshore areas that are not Classified:

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.

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:

*The Location Codes for offshore areas are the ICES statistical rectangles which are available on the MI website at: Production Area Maps and Sample location codes

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

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.

Additionally the MI biotoxins lab must be informed of the submitted samples by Fax 091 387201 or by email to; dave.clarke@marine.ie or conor.duffy@marine.ie

The MI publishes the biotoxin results on the MI HABs database (www.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 4 (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
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

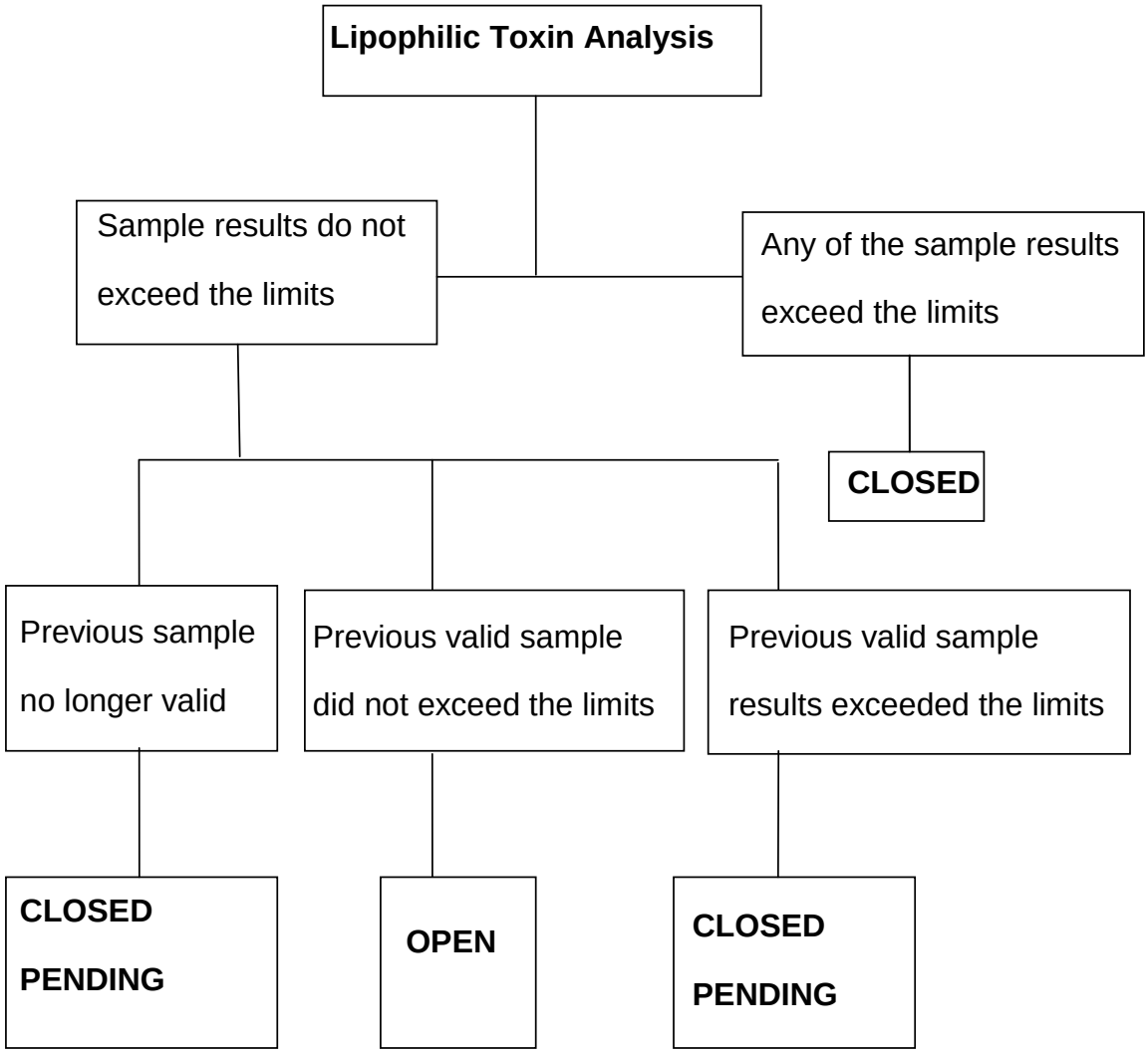
Samples must normally be taken in the same or successive production period for an Open status to be maintained, although variations to this may be agreed by the Management Cell (see Appendix 2, The Management Cell).

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 2, 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).

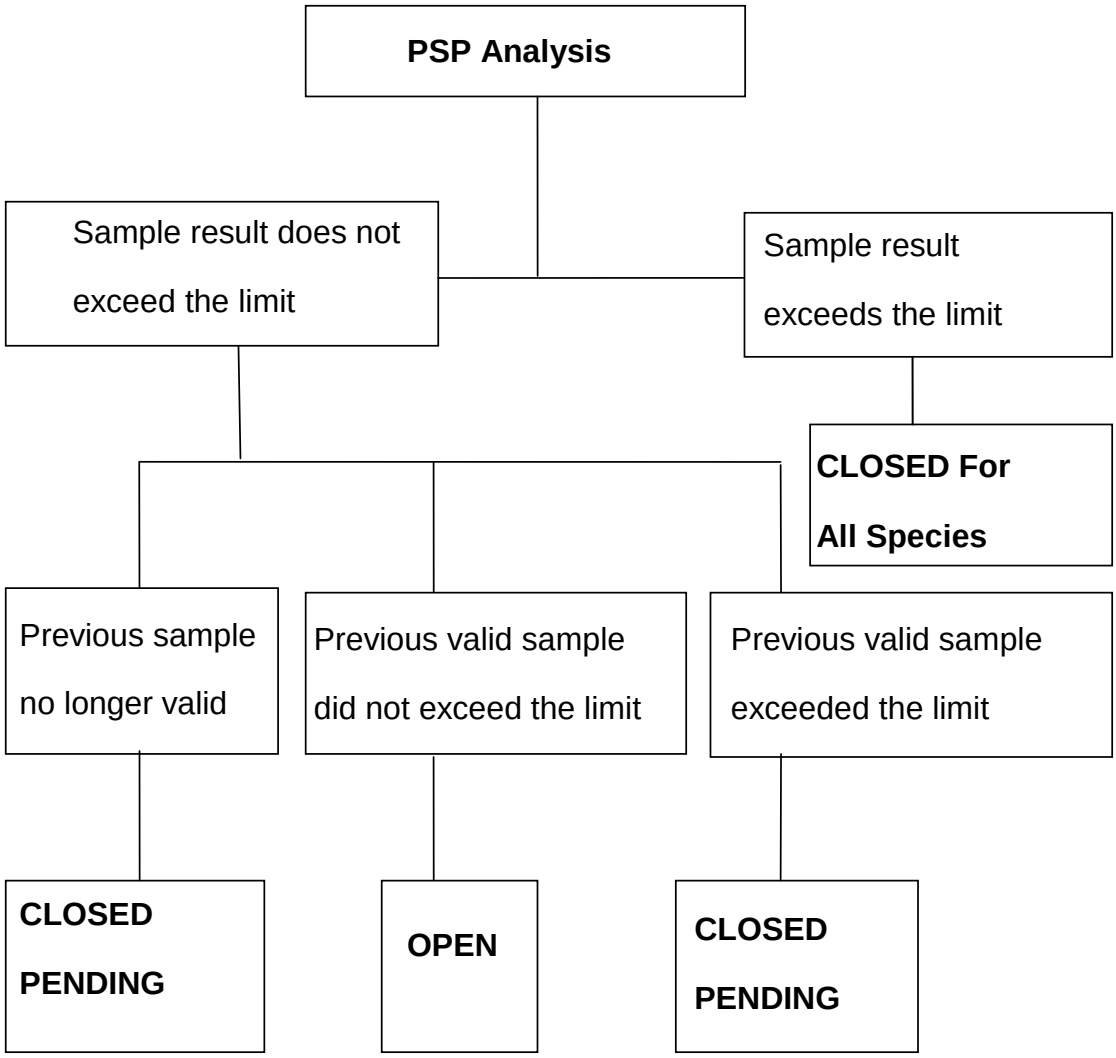
Figure 2. Lipophilic Toxin Decision Tree



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 3. The phytoplankton monitoring decision tree for *Alexandrium spp.* and PSP in production areas outside of Cork Harbour is shown in Figure 1 (see Section 3.5, Additional Monitoring when Toxic Phytoplankton are Identified).

Figure 3 PSP Decision Tree



5.4 ASP Results

5.4.1 Live bivalves - Excluding Scallops

Shellfish from sentinel sites are tested for ASP. 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 Fig. 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 Fig 1, 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 2 & 4). 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 4 ASP Decision Tree for scallops from classified production areas

(See also the requirements for Lipophilic Toxins, Figure 2)

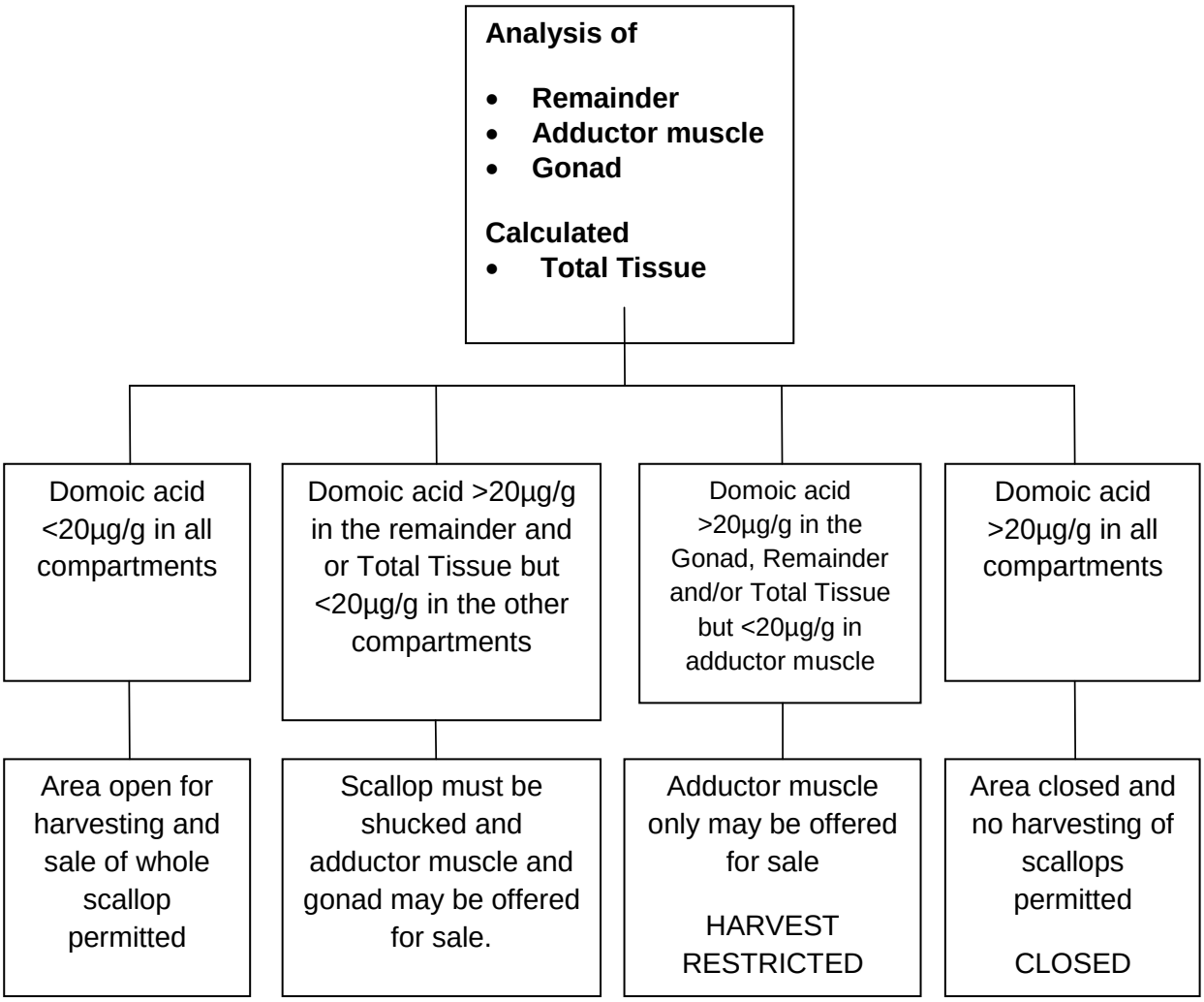


Table 2 Production Area Status for Scallops from Classified Areas

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 unless the express permission of the SFPA has been obtained for the movement of shellfish.
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 limts 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 Reports for scallops from classified production areas

Biotoxin Analysis Result	MI Report 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 Lipophilc 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 Lipophilc 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	"(Insert applicable Location code) is under a restricted harvesting regime and scallops from it must be processed before only the Adductor Muscle maybe

Lipophilic Toxin limits in the Remainder Tissue	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 Lipophilc 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 and Gonad are marketed"
Scallops from a production area <20 µg/g Domoic Acid in all compartments and > associated Lipophilc Toxin limits in the Remainder Tissue but < associated Lipophilc 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 Lipophilc Toxin limits in the Remainder and Gonad tissue < associated Lipophilc 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 5). 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.

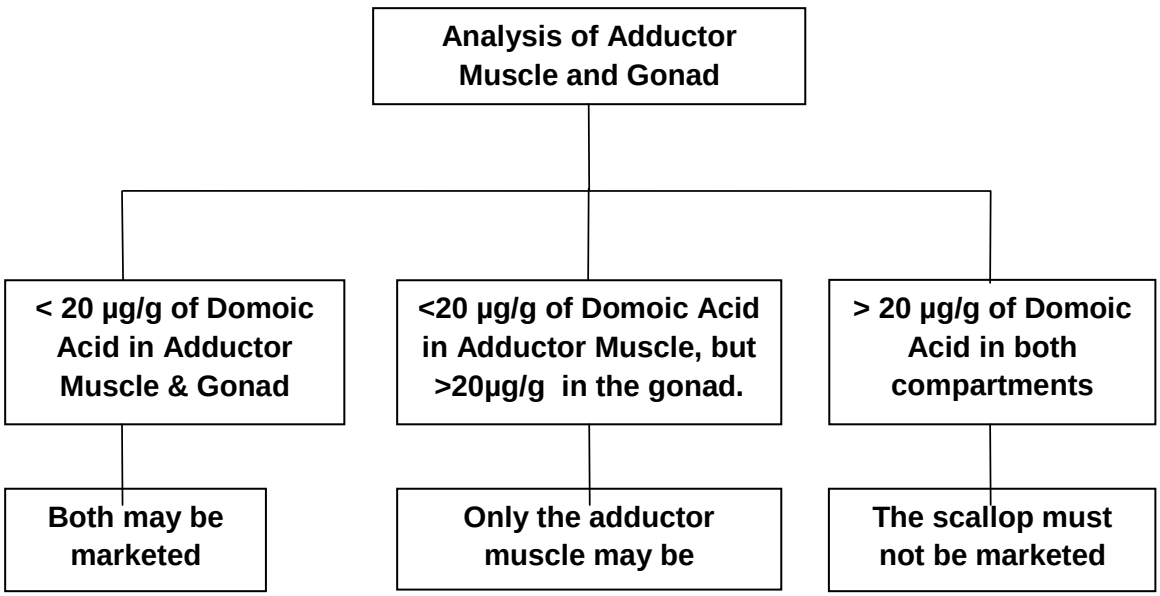
If the amount of Domoic Acid is found to be >20µg/g in both compartments then the batch must be rejected and must not be placed on the market for human consumption.

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 reports for scallops from offshore areas

Analysis Result	**MI Report 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 5. 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 MI website. 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.

6.2 Production Period for Harvesting

The production period is the period of time that a valid sample relates to during harvesting. The production period is set to match the sampling frequency assigned to the shellfish in the production area. For example, when the sampling frequency is weekly then the production period will be weekly. 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.

Sampling Frequency Is Weekly:

When sampling frequency is weekly then the production period is a period of seven days from Sunday to 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.

Sampling Frequency Is Fortnightly:

When sampling frequency is fortnightly then the production period is a period of fourteen days from Sunday to Saturday. 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.

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.

For example, when the sampling frequency is weekly then both the sampling week (see Section 4.4) and production period for harvesting (Section 4.9) run from Sunday to Saturday

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 **classified** production areas, except for the offshore scallop fishery.
2. Harvesting should only take place when a **classified** production areas is **not subject to a temporary closure** (e.g. due to pollution events)
3. Harvesting should only take place from production areas that have a current open status on the basis of biotoxin results.
4. Before any processed shellfish are placed on the market, robust product recall and traceability procedures must be in place (see FSAI Guidance Note No.10 on Product Recall and Traceability). Any product recall or withdrawal must be handled in accordance with 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 Guidance Note No.10 on Product Recall and Traceability).

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 products 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 webpage (www.marine.ie/habs).

7.2 Communication to Recreational Gatherers

Permanent bilingual signage (Irish and English) have been erected around the coast, close to production areas. These alert members of the public engaged in recreational gathering to the possible presence of biotoxins in shellfish. When any new signage is planned the HSE is consulted. The HSE may, when it considers it appropriate, issue advice to the general public through local radio and media of the potential dangers of harvesting and eating contaminated shellfish, where there is a history of recreational gathering in or near a closed production area. For this purpose support will be available to the HSE from the FSAI.

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 (Revision 2).

Appendix 1 – Live Bivalve Legislation

The farming and the placing on the market of live bivalve molluscs is regulated under EU and Irish Legislation. The FSAI website includes a Legislation Section which is kept uptodate with the latest legislation including consolidated versions. An overview of the specific legislation relevant to molluscan shellfish safety is available in the Aquaculture-Bivalve Molluscs pages of the Legislation Section.

EU Legislation

The EU Food Legislation relevant to this COP is shown in Table 5. All the legislation in the table are Regulations, apart from the Shellfish Water Quality and Animal Health Rules which are both Directives. The EU has produced consolidated versions for all the legislation, apart from the Animal Health Rules. These consolidated versions include all the amendments to each piece of legislation.

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 Official Controls - Classification & monitoring of areas - Controls on wild scallops and gastropods Biotoxin Methods Microbiological Criteria	 853/04 Annex III, Section VII - Chapters I, VI & VIII - Chapter II - Chapters III & IV - Chapter V - Chapter IX 854/04 Annex II - Chapter II - Chapter III 2074/05 Article 3, Annex III* 2073/05 Annex I, Chpt I (1.17,1.24)
Fishery Products Specific Hygiene Rules - Requirements for vessels - Landing and first sale - Establishments and vessels - Cooked crustaceans and molluscs - Health standards including biotoxins - Wrapping, storage & transport Official Controls Microbiological Criteria	 853/04 Annex III, Section VIII - Chapter I - Chapter II - Chapter III - Chapter IV - Chapter V - Chapters VI, VII & VIII 854/04 Annex III 2073/05 Annex I (1.2, 1.16, 1.25, 1.26, 2.4)
Animal Health Rules Aquaculture Diseases	 2002/99 (Directive) Annex I
Water Water Framework Directive	 2000/60
Official Controls Verification of compliance	 882/04

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

- **Irish Legislation**

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 relevant SIs are shown in Table 6.

Transposition of EU Legislation into Irish Law

European Legislation	**National Statutory Instrument**
Water Framework Directive	E.C. (Water Policy) Regulations 2003 (S.I. No. 722 of 2003). as amended
Regulations 178/02, 852/04, 853/04, 854/04, 882/04	SI 432/2009 (Food and Feed Hygiene) (transposes the legislation for fishery products and live bivalve molluscs) as amended
Animal Health Rules, Aquaculture Diseases Directive 2002/99	SI 820/2004 (Trade in the Production, Processing, Distribution and Introduction of Products of Animal Origin for Human Consumption)

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 Service Contracts 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 (National 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 MI on behalf of the Management Cell will formally record all decisions. 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 reports.

All records relating to decisions will be retained. Where the MI are 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 – Minimum Sample Sizes

Minimum sample Sizes for shellfish for Biotoxin Testing

Scientific name	Common name	No. of individual shellfish per sample
Mytilus edulis	Blue Mussel	50 – 150
Crassostrea gigas	Pacific Oyster	15 -30
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/Native Oyster	20 – 40
Tapes philipinarum, Tapes semidecussata	Manilla Clam	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/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 senegalensis	Carpet Shell	50 – 150
Venus verrucosa	Warty Venus	50 – 150
Patella vulgata	Common limpet	20 - 40
Littorina littorea	Periwinkle	20
Buccinum undatum	Whelk	10-15
Lutraria lutraria	Otter Clam	15 - 20

Appendix 4 – 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 laboratory reports and the limits in brackets are as laid down in EU Legislation.

*Lipophilic Toxin Group

Appendix 5 – Examples of Gatherers Registration Documents

Example 1: A Gatherers Registration Document for scallop from a classified production area

Serial No. IE 100001(6 digit)

SHELLFISH REGISTRATION DOCUMENT

DATE OF HARVEST: (a)	PRODUCTION AREA HARVESTED: (b)	HARVEST LOCATION CODE (c)
31 MAY 2013	DUNMANUS BAY	Ck-DB-DO
BIOTOXIN STATUS: (d)	WEEK NUMBER: (e)	PREVIOUS TEST STATUS: (f)
OPEN	22	OPEN
CLASSIFICATION OF PRODUCTION AREA: (g)	A	B ✓ C
Fishing Vessel Details (If Applicable)	NAME AND REGISTRATION OF VESSEL: (h) DUNMANUS LADY C 123	
EU LOGSHEET NUMBER IRL 1234567	ICES AREA: (i)	ICES Statistical Rectangle (i)

SHELLFISH SPECIES HARVESTED: (j)

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

DESTINATION OF SHELLFISH HARVESTED: (k) (Name, Address in Block Capitals)	Destination 1:	Destination 2: (If applicable)
	Shellfish HAVEN	
	DURRUS	
	Co. Cork	

GATHERER'S NAME: (l) (Block Capitals)	Michael O Shea
GATHERER'S ADDRESS: (m) (Block Capitals)	Main STREET BANTRY Co Cork
TELEPHONE NUMBER: (n)	027 429851
Signature: (o)	M O Shea
Date: (p)	31 May 2013

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 2: A Gatherers Registration Document for scallop from an offshore area

Serial No. IE 100001(6 digit)

SHELLFISH REGISTRATION DOCUMENT

DATE OF HARVEST: [a]	PRODUCTION AREA HARVESTED: [b]	HARVEST LOCATION CODE [c]
01 JUNE 2013	MINE HEAD GROUND	OS - MH - MH
BIOTOXIN STATUS: [d]	WEEK NUMBER: [e]	PREVIOUS TEST STATUS: [f]
NOT TESTED.		
CLASSIFICATION OF PRODUCTION AREA: [g]	A	B C
Fishing Vessel Details (If Applicable)	NAME AND REGISTRATION OF VESSEL: [h] FULMAR D112	
EU LOGSHEET NUMBER IRL 1234567	ICES AREA: [i] VIIg	ICES Statistical Rectangle [i] 32 E2

SHELLFISH SPECIES HARVESTED: [j]

COMMON NAME	SCIENTIFIC NAME	QUANTITIES (Kg)
King Scallops	Pecten Maximus	200 kg

DESTINATION OF SHELLFISH HARVESTED: [k] (Name, Address in Block Capitals)	Destination 1:	Destination 2: (If applicable)
	Scallop Producers Ltd DUNGARVAN CO WATERFORD	

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 OShea
Date: [p]	01 Jun 2013

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.