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MANAGING SHELLFISH TOXIN RISKS

GUIDANCE FOR HARVESTERS AND PROCESSORS

Reviewed April 2014

For all queries about this guidance — including if, you require the information in an alternative format such as audio, large print or Braille — please use the number below.

CONTACT TELEPHONE 01224 285157 Jennifer Howie

Summary

Intended audience:	• Shellfish harvesters • Approved shellfish establishments • Local Authorities
Which UK nations does this cover?	This guidance has been developed for Scotland but it can be applied by anyone selling live bivalve molluscs in the UK.
Purpose:	This document provides tools which will help the shellfish industry in Scotland better manage the risks associated with toxic algal blooms
Legal status:	This document provides guidance on compliance with applicable food hygiene legislation contained within Regulations (EC) No 852/2004 and 853/2004
	Best practice recommendations are highlighted in grey boxes
Key words:	• Shellfish, Live Bivalve Molluscs • Food law, monitoring and controls • Hygiene and food safety
Review date:	This guidance will be reviewed in 2015.

Revision history

If you have any comments on the guidance itself, please call us using the contact number on the front page of this guidance or complete our ongoing Guidance survey: https://www.surveymonkey.com/s/55QQDCG

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
1	April 2014	Amendments following initial consultation Feb – March 2014. Including: - amended phytoplankton trigger levels - inclusion of details regarding enforcement approach	Jennifer Howie

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General Introduction

1. Shellfish biotoxins can make people ill and in some cases can result in fatalities. That is why it is important that the risks associated with biotoxins in live bivalve molluscs (LBMs; or filter-feeding shellfish) are managed appropriately by everyone involved in the supply chain.

2. EU Regulations require the Food Standards Agency (FSA) to undertake an extensive programme of Official Control (OC) monitoring of shellfish. The purpose of this monitoring programme is to determine whether an area should be open or closed for harvesting, depending on the levels of microbiological and other contaminants, including marine biotoxins. The monitoring programme is not designed to provide confirmation of the health status of the final product placed on the market – this is the legal responsibility of the food business operator (FBO).

3. EU Regulations define the legal obligations of food businesses to ensure shellfish placed on the market is safe to eat. These include a requirement to ensure that LBMs do not exceed the legal limits for the three groups of marine biotoxins which are known to present a risk to human health. These are Amnesic Shellfish Poisoning toxins (ASP), Lipophillic toxins (which include Diarrhetic Shellfish Poisoning toxins or DSP, azaspiracids or AZAs, and yessotoxins or YTXs), and Paralytic Shellfish Poisoning toxins (PSP). All three groups of biotoxins are regularly detected in shellfish growing waters around the UK.

4. The uptake of biotoxins by shellfish is highly variable, therefore even when OC monitoring indicates that the levels present in an area are below regulatory limits, there may be occasions when harvested product could still lead to illness. This is a particular risk during the summer months when phytoplankton blooms are most prevalent. For this reason, it is important that FBOs are aware of the biotoxin status of their harvesting area and ensure that they are responding appropriately to control the potential risk that may be associated with their product.

5. This guidance is intended to provide a framework to assist all food businesses involved in the production, processing and sale of shellfish to assess the biotoxin risks associated with their products, and assist them in designing harvesting and testing regimes that will help to minimise the risks of placing harmful product on the market.

Intended audience

6. This guidance is primarily intended for shellfish harvesters, and FBOs handling and processing LBMs, but will also be useful for Local Authorities (LAs).

Purpose of guidance

7. This guidance document is intended to help food businesses manage those risks and provides a 'traffic light' tool kit which can be applied by either harvesters or approved establishments. The guidance will also help LAs to assess food safety management procedures in the businesses they inspect.

Legal status of guidance

8. These guidance notes have been produced to provide advice on how to comply with:

    - the legal requirements of Regulations (EC) 852/2004 and 853/2004 (as amended) as enforced by the Food Hygiene (Scotland) Regulations 2006 (as amended). Specifically Chapter II, Article 5 (Hazard analysis and critical control points) of 852/2004 and Section VII, Chapter V (Health Standards for LBMs) of 853/2004.

9. These guidance notes cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances.

10. The guidance also covers areas of best practice, which, although not explicitly required by the legislation, will assist FBOs and LAs in ensuring the legal requirements are met.

11. Businesses with specific queries may wish to seek the advice of their LA. Details of relevant contacts in Foods Standards Agency in Scotland (FSAS) are provided below.

Contacts

FOOD SAFETY MONITORING & POLICY BRANCH – SHELLFISH MONITORING TEAM		
Name	**Topics**	**Contacts**
Jennifer Howie	• Shellfish unit - contract management and policy responsibility	☎ 01224 285 157 jennifer.howie@foodstandards.gsi.gov.uk
Caroline Thomson	• Biotoxin • Phytoplankton • E. coli management and classification • Sampling Officers	☎ 01224 288 378 caroline.thomson@foodstandards.gsi.gov.uk
Kasia Kazimierczak	• Scientific Advice • Testing methods • Depuration • Sanitary Surveys • Chemical contaminant monitoring	☎ 01224 285 111 kasia.kazimierczak@foodstandards.gsi.gov.uk
Graham Ewen	• Classifications applications/ • Classification appeals • E.coli contract support	☎ 01224 285 190 graham.ewen@foodstandards.gsi.gov.uk
Karolina Mikrut	• Shellfish Official Control Results Manager	☎ 01224 288 360 karolina.mikrut@foodstandards.gsi.gov.uk

Review

12. This guidance will be reviewed in 2015. Feedback from users, including completion of Guidance survey: https://www.surveymonkey.com/s/55QQDCG, is welcome.

Glossary

ASP	Amnesic Shellfish Poisoning
AZA(s)	Azaspiracid(s) - group of lipophilic toxins
CA	Competent Authority
DSP	Diarrhetic Shellfish Poisoning
EC	European Commission
EPT	End Product Test
EU	European Union
FBO(s)	Food Business Operator(s)
FSA	Food Standards Agency
FSAS	Food Standards Agency in Scotland
HACCP	Hazard Analysis and Critical Control Point. An internationally recognised food safety management system that identifies, evaluates, and controls hazards that are significant for food safety. European food law requires every FBO (except primary producers) to implement a food safety management system based on HACCP principles.
LA(s)	Local Authority(ties)- the local competent authority responsible for enforcement of food safety legislation
LBM(s)	Live Bivalve Mollusc(s)
LC-MS/MS	Liquid Chromatography with tandem Mass Spectrometry
OA/DTX(s)/PTX(s)	Okadaic Acid / Dinophysistoxin(s) / Pectenotoxin(s) – group of lipophilic toxins
OC(s)	Official Control(s)
PSP	Paralytic Shellfish Poisoning
YTX(s)	Yessotoxin(s) - group of lipophilic toxins

Chapter 1 - Algal Toxins – official control monitoring

Introduction

13. Marine biotoxins produced by phytoplankton can accumulate in the tissues of filter-feeding bivalve shellfish. Toxin related illness can occur, if contaminated shellfish are consumed by humans.

14. As part of the controls to protect public health, Regulation (EC) 854/2004 requires the Competent Authority (CA) for food safety to establish an OC monitoring programme of classified shellfish relaying and production areas to check for the possible presence of toxin producing phytoplankton in the water and biotoxins in the shellfish flesh.

15. FSAS is the CA for food safety in Scotland and as such is responsible for carrying out this OC monitoring programme in Scotland. Similar monitoring programmes are carried out in England, Wales and Northern Ireland.

Biotoxin monitoring: Maximum permitted levels

16. When any of the following maximum permitted levels are breached in an OC sample the shellfish areas concerned must be closed. These closures are applied by LAs and harvesting from an area closed by a statutory notice is an offence.

    - ASP - 20 milligrams of domoic acid per kilogram flesh
    - Lipophilic Toxins:
        - 160 micrograms OA/DTX/PTX per kilogram flesh
        - 160 micrograms AZA per kilogram flesh
        - 3.75 milligrams YTX per kilogram flesh
    - PSP - 800 micrograms per kilogram flesh.

17. Monitoring frequency for flesh testing is based on a risk assessment. As a rule, monitoring for all biotoxins is undertaken on a weekly basis where historic data has indicated toxin may be present in an area. In some areas at certain times of the year, this testing frequency has been reduced, as there is evidence that the risk associated with the presence of toxins is lower.

18. The frequency of FSAS testing should not in itself determine the level of end product testing (EPT) required by food businesses. However, the results from such monitoring should be used to inform decisions taken by the FBO regarding harvesting activity and the need to increase the amount of EPT that may be required to demonstrate product safety and reduce the risk of toxic shellfish being placed on the market.

Phytoplankton monitoring

19. The FSAS also oversees a programme of sampling and analysis of water column for presence of toxin producing phytoplankton species: *Pseudo-nitzschia* spp., *Alexandrium* spp., *Dinophysis* spp., *Prorocentrum lima*, *Prorocentrum cordatum*, *Lingulodinium polyendrum* and *Protoceratium reticulatum*.

20. Sampling is currently carried out at 40 areas at the frequency provided in **Table 1**.

Table 1. Phytoplankton Monitoring Schedule

March to September	**All areas weekly**
October	**All areas fortnightly**
November to February	**7 selected areas, one sample per month (selected based on phytoplankton levels in Sept/Oct and historic data)**

21. During periods of reduced frequency of OC biotoxin monitoring (i.e. at any time where shellfish flesh monitoring is fortnightly or monthly), the results of phytoplankton analysis is used by the FSAS to trigger additional biotoxin shellfish flesh sampling. Elevated phytoplankton levels can also be used by the FSAS to advise LAs to close areas where flesh monitoring has not been undertaken. This tends to apply to wild shellfisheries where insufficient flesh sampling has been undertaken. The phytoplankton trigger levels for the Scottish OC programme are provided in **Table 2**.

Table 2. Phytoplankton OC trigger levels

Species	Trigger level (cells per litre)	Toxin produced
Pseudo-nitzschia spp.	50,000	Domoic Acid (ASP)
Alexandrium spp.	Presence	Saxitoxins (PSP)
Dinophysis spp.	100	Okadaic Acid / Dinophysistoxins (DSP)
Prorocentrum lima	100	Okadaic Acid / Dinophysistoxins (DSP)

Where are my nearest OC monitoring points?

22. FSAS undertakes OC biotoxin flesh monitoring on the basis of a 'Pod' system. A pod usually comprises a number of classified production areas. Each pod contains a representative monitoring point (RMP) from which most samples will be collected. For OC monitoring purposes these RMPs are considered to be representative of all of the production areas within that pod, and any result over the regulatory limit at an RMP will close all associated areas within the pod. There are approximately 80 such pods in Scotland and every harvesting area belongs to one of these pods. Phytoplankton monitoring is undertaken in fewer areas but these are targeted both to provide good geographic and species coverage across the country, as well as targeting areas where high levels of toxicity and harvesting production have taken place in the past.

All harvesters and processors should make themselves familiar with the results from OC monitoring in their own and neighbouring area as well as from the nearest phytoplankton monitoring point or points. All OC monitoring results are published weekly on the shellfish-monitoring page of the FSA Website. Historical data for harvesting areas can also be accessed on the *Aquaculture website* by selecting 'classified shellfish harvesting areas' on the left hand side of the screen. Type the name of your area in the 'place of interest' and then 'select a result' from the options given. Then use the map to identify neighbouring classified areas which will be hatched in red on the screen. **Remember** – not all classified areas are sampled for flesh or for phytoplankton, but there will be classified areas locally which are being monitored. You should use data from these areas to inform your risk management plan. You can also request to receive all shellfish toxin results on a daily basis from FSAS in order to keep your own records if you wish.

23. Further information on OC monitoring for toxins can be found on the FSA website here. Information from the FSA OC programme is sent to the Aquaculture website on a weekly basis. Should you wish to receive any information in hard copy please contact FSAS directly.

Chapter 2 - Toxin risk management 'traffic light' tool kit

24. The 'traffic light' matrices at **Annex A**, **B**, **C** and **D** are a decision tool kit which can be populated with information from both the FSAS OC monitoring programme and any EPT undertaken by harvesters or food businesses themselves. Once information has been entered, the 'traffic lights' suggest the harvesting action and testing considerations that should follow.

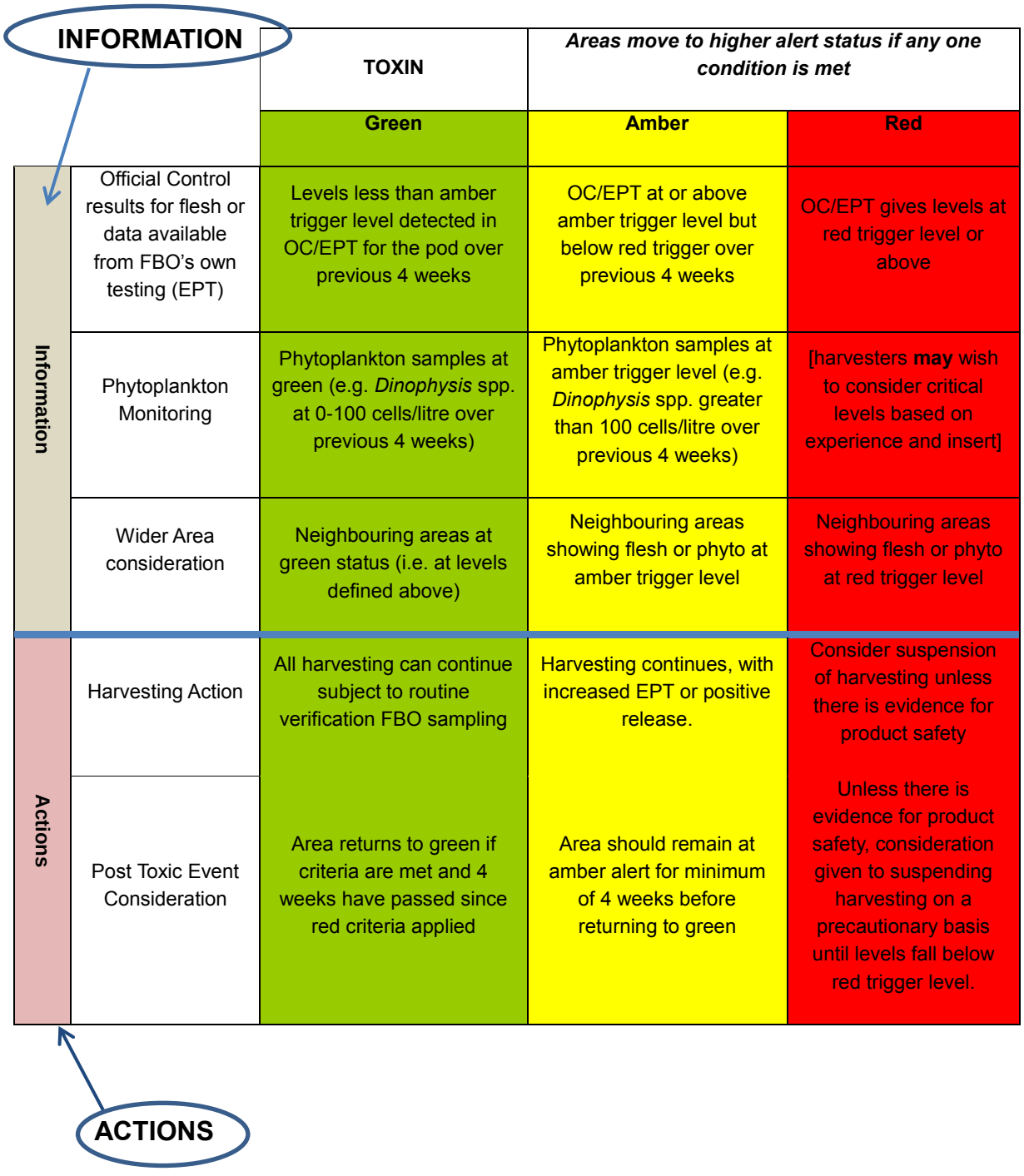
25. Please note that the parameters suggested within the matrices, e.g. 2-4 weeks at amber following a flesh or phytoplankton trigger result, are based on an analysis of historic data from the OC programme. For the limited period that data was analysed, higher biotoxin results in the flesh have almost always been preceded by biotoxin and/or phytoplankton levels at the trigger levels proposed.

These matrices are not guaranteed to be 'fail safe'**.** They have been tested by FSAS against a limited historic dataset only and are intended as a platform upon which food businesses can build appropriate risk management systems.

26. Please note that the trigger levels proposed in the matrices for PSP and ASP producing phytoplankton (*Alexandrium* spp. and *Pseudo-nitzschia* spp.) are higher than those advised by the National Reference Laboratory for OC monitoring purposes. These higher trigger levels were selected following analysis of historic (4-year) datasets, which found them to be sufficient to flag up toxicity over the regulatory level in subsequent flesh samples. The application of these trigger levels will be reviewed and amended in light of future research or OC monitoring. If harvesters have information based on their own monitoring which allows different triggers to be applied, then that evidence should be provided to Environmental Health Officers on request.

How to use the matrices

27. Each matrix can be divided into two key sections titled Information and Actions (see below and overleaf).



		TOXIN	*Areas move to higher alert status if any one condition is met*	
		Green	**Amber**	**Red**
Information	Official Control results for flesh or data available from FBO's own testing (EPT)	Levels less than amber trigger level detected in OC/EPT for the pod over previous 4 weeks	OC/EPT at or above amber trigger level but below red trigger over previous 4 weeks	OC/EPT gives levels at red trigger level or above
	Phytoplankton Monitoring	Phytoplankton samples at green (e.g. *Dinophysis* spp. at 0-100 cells/litre over previous 4 weeks)	Phytoplankton samples at amber trigger level (e.g. *Dinophysis* spp. greater than 100 cells/litre over previous 4 weeks)	[harvesters **may** wish to consider critical levels based on experience and insert]
	Wider Area consideration	Neighbouring areas at green status (i.e. at levels defined above)	Neighbouring areas showing flesh or phyto at amber trigger level	Neighbouring areas showing flesh or phyto at red trigger level
Actions	Harvesting Action	All harvesting can continue subject to routine verification FBO sampling	Harvesting continues, with increased EPT or positive release.	Consider suspension of harvesting unless there is evidence for product safety
	Post Toxic Event Consideration	Area returns to green if criteria are met and 4 weeks have passed since red criteria applied	Area should remain at amber alert for minimum of 4 weeks before returning to green	Unless there is evidence for product safety, consideration given to suspending harvesting on a precautionary basis until levels fall below red trigger level.

INFORMATION: The three information rows in each matrix can be populated using data from the FSAS OC programme and/or any EPT results that harvesters may have for the batch concerned. This information will result in a risk rating (green, amber, red) which can be applied to the batch under consideration.

ACTIONS: The information determines the risk rating which can then be used by FBOs to inform appropriate actions which would assist them in controlling the risks. Whilst the actions proposed by this guidance are not specifically required by legislation, they will assist FBOs in meeting their legal obligations to ensure safe shellfish is placed on the market.

Rather than apply this 'traffic light' system, harvesters may decide to test all product before it is sold, without reference to OC results or other relevant information. This would reduce the time spent managing toxic risk variables, but would be more expensive.

During periods of high toxicity in their or neighbouring areas, harvesters may wish to cease harvesting on a voluntary basis. Voluntary closure is a precautionary measure which may not be necessary, providing evidence is available from the harvester that the product is safe. Alternative measures such as batch testing/positive release using regulatory methods may be acceptable depending on individual circumstances, providing the FBO can demonstrate product safety.

Application of the risk matrix is described in more detail below:

Information: What do we know about…	**OC results for flesh or data available from FBO's own testing (EPT)**	Results in the weeks preceding the OC programme and/or EPT should be considered here. The results of this flesh analysis will determine whether your harvesting area should be considered 'low', 'medium' or 'high' risk (i.e. green/amber/red respectively) and your harvesting action will be determined accordingly. Any result over trigger level in your area in the previous 4 weeks should be considered indicative of increased risk.
Information: What do we know about…	**Phytoplankton Monitoring**	Phytoplankton can be a good early indicator of future toxicity in shellfish flesh. Results from the OC programme (or any monitoring carried out by the FBO) should be considered here. These results will also help to determine whether your harvesting area should be considered low, medium or high risk (green/amber/red respectively). If there is no phytoplankton available for your own area or neighbouring sites then only flesh results can be considered to inform the type of action that may be required.
Information: What do we know about…	**Wider Area considerations?**	Not all production areas have an associated phytoplankton monitoring point. Neighbouring phytoplankton results should always be considered by harvesters, as these can be indicative of an increased risk in the area, even when it is open for harvesting. Toxin history in the immediate or neighbouring area should also be considered, particularly for ASP and PSP toxins which can lead to serious illness.
Actions: What do we do now?	**Harvesting Action**	The results from phytoplankton and flesh monitoring in preceding weeks will inform the need to increase the levels of EPT necessary to demonstrate the safety of shellfish harvested from the area or indeed other measures, including whether harvesting should be suspended voluntarily on a precautionary basis. In the absence of access to EPT, consideration may be given to withholding batch movement pending subsequent OC results being made available. For example, where there is an increased risk from biotoxins for which no commercial testing kit is available (e.g. AZA).
Actions: What do we do after the toxic event?	**Post Toxic Event Consideration**	When an area falls into the red category (i.e. it meets any of the 'red' conditions highlighted in the information section of the matrix) all actions should remain at 'red' until the levels of biotoxins and phytoplankton at the area or nearby areas fall below red trigger levels. After this point, it is recommended that the area moves to amber status for a period of 4 weeks, regardless of the levels detected. If the green criteria are met at the end of those 4 weeks the area may revert back to green.

Traffic light summary

28. As mentioned above, the information received in the previous four weeks (i.e. a flesh or phytoplankton result) will then determine whether the action falls into a 'green', 'amber' or 'red' alert status:

Risk rating (by colour)	***Action***
Green	No increase in EPT. FBO should maintain routine verification checks
Amber	Increase frequency of EPT or positive release
Red	Cease harvesting unless evidence is available that product is safe

Proposed toxin flesh and phytoplankton trigger levels

29. Proposed trigger levels for use in the matrices are summarised in **Table 3**. The trigger levels proposed for DSP in the matrix are based on those currently applied by FSAS for OC purposes. However more precautionary trigger levels are proposed for ASP and PSP toxins for use in the matrix. This is because ASP and PSP can accumulate in shellfish very quickly and are more toxic than DSP in humans. When ASP and PSP toxins reach red trigger levels (particularly in shellfish flesh where levels of 10 mg/kg ASP and 400 µg/kg PSP are proposed), FBOs are recommended to take particular care to ensure they do not place unsafe product on the market, even though the regulatory limit has not been breached. This may involve voluntarily suspending harvesting until there is evidence that toxin levels have reduced, or positive release of product, with EPT undertaken using regulatory analytical methods. To note that whilst FSAS monitor for 2 out of 3 of the suspected YTX producers; *Protoceratium reticulatum* and *Lingulodinium polyedrum*, there is no recognised trigger level. FSAS does not currently monitor for the other suspected YTX producer *Gonyaulax spinifera*, or any azaspiracid-producing phytoplankton, as these cannot currently be identified using conventional techniques (light microscopy). Therefore only flesh trigger levels can currently be used to inform actions for these toxin groups.

Table 3. Proposed toxin and phytoplankton trigger levels

Toxin	Regulatory level	Amber flesh trigger level	Red flesh trigger level	Phytoplankton indicator	Amber phyto trigger level
Paralytic Shellfish Poisoning (PSP)	800 micrograms/kilogram	**>RL***	**400 µg/kg**	*Alexandrium* spp. (saxitoxin)	Greater than or equal to **40 cells/litre** of Alexandrium
Amnesic Shellfish Poisoning (ASP)	20 of domoic acid milligrams/kilogram	**>LOQ**	**10mg/kg**	*Pseudo-nitzschia* spp. (domoic acid)	Greater than or equal to **150,000 cells/litre**
Diarrhetic Shellfish Poisoning (DSP) OA/DTXs/PTXs	160 micrograms of okadaic acid equivalents/kilogram	**80 µg/kg**	**160 µg/kg**	*Dinophysis* spp. *Prorocentrum lima* (okadaic acid, dinophysistoxin);	Greater than or equal to **100 cells/litre**
Azaspiracids (AZAs)	160 micrograms of azaspiracid equivalent /kg	**80 µg/kg**	**160 µg/kg**	Not currently monitored	NA
Yessotoxins (YTXs)	3.75 milligrams of yessotoxin equivalent/kilogram	**1.8 mg/kg**	**3.75mg/kg**	*Protoceratium reticulatum* and *Lingulodinium polyedrum*	NA

*Quantifiable levels of PSP biotoxins detected by OC

Voluntary trigger levels

30. FSAS is aware that some producers have set their own critical (i.e. red) alert levels for phytoplankton and are applying that in their HACCP plans. If harvesters have information based on their own monitoring which allows different triggers to be applied then that evidence should be provided to Environmental Health Officers on request.

Harvesters may wish to consider the toxin history of their area and associated levels of phytoplankton. If, in your area, there is evidence that particular levels of phytoplankton have historically indicated high toxicity in shellfish flesh harvesters can consider introducing their own critical level for phytoplankton which would result in increased testing or a voluntary suspension of harvesting.

Wild Shellfisheries

31. This guidance is intended for use by anyone placing LBMs on the market. Whilst OC monitoring results are available for classified shellfish production areas, this data is not available for wild fisheries which are not routinely monitored (e.g. offshore scallop grounds). In such cases then harvesters and food businesses should utilise the results of their own monitoring to inform their risk management decisions. Harvesters and FBOs should always bear in mind that bivalves, as

filter-feeding organisms, carry inherent risks and biotoxin risk tends to increase significantly during the summer months.

32. In the case of wild scallops (pectinidae) which are not required to come from classified areas, biotoxin controls are placed at the approved establishment, i.e. processing or dispatch centres. Scallops are known to accumulate higher levels of domoic acid (which can cause ASP in humans) than other bivalves and routine testing for all toxins, and especially ASP, should be incorporated into the HACCP plan of all premises approved to dispatch whole, live scallops.

An absence of local OC monitoring data does not equate to an absence of risk. When OC monitoring data is unavailable, FBOs may need to consider increased testing to demonstrate product safety, particularly during summer months.

33. Further guidance on the OC programme for biotoxins is available here. Guidance to LAs for premises dealing with wild pectinidae is available here.

Chapter 3 - Questions and Answers

Q. Why use the previous 4 weekly results?

A: Analysis of historic OC monitoring data shows that subsequent toxicity in the flesh is usually flagged up to 4 weeks in advance by either phytoplankton or biotoxin flesh results. As the high biotoxin levels detected in 2013 showed, biotoxin events can arise very quickly.

Q. Do I have to use these matrices?

A: Use of the matrices and this guidance is not a statutory requirement; however, the law requires food businesses to apply 'due diligence' at all stages of harvesting and production. Application of this guidance will not guarantee the safety of your product – but it will help you to demonstrate that you have considered and are managing the risks associated with shellfish biotoxins accordingly. See also Section on 'Risk Management for Small Businesses' below.

Q. How do I choose which test or analysis to use?

A: The FSAS has produced information for harvesters and food businesses which will help when deciding which type of kit or test is appropriate [see link and Appendix A]. Some of these kits are antibody based, and are designed to be used by harvesters themselves. However, other analyses such as functional assays must be undertaken in appropriate laboratory based facilities. In all cases, the use of kits or results from third party laboratory

based analysis should be undertaken to the satisfaction of the LA and appropriate records made available on request. Undertaking appropriate levels of EPT and maintaining good records associated with all batches tested will help to ensure that product remains on the market despite any subsequent area closure which may occur.

Q. What if no commercial (rapid) EPT kits are available?

A: It is acknowledged that for some toxins no rapid kits exist (for example for YTXs and AZAs). The regulations require that food businesses take all reasonable measures to mitigate against toxin-contaminated product being placed on the market. Where the OC monitoring results indicate a rising trend for such toxins, harvesters (at their own expense) can send samples for LC-MS/MS analysis which utilises the same methodology as the OC programme. Where no EPT is carried out, the only means of evaluating the risk associated with harvested shellfish is to refer to the subsequent OC result before placing it on the market. Such an approach would not provide the same level of assurance as EPT, but will be considered in limited circumstances where access to testing is restricted. Harvesters should also be aware of the potential for enforcement action when there is insufficient evidence to verify product safety (see **Appendix D**)

A quick reference guide to the type of tests available can be found at **Appendix A**, and a list of laboratories who may be able to offer commercial testing services can be found at **Appendix B**. Please note that this list is not exhaustive.

Q. If I test my product, will it remain on the market even if the area subsequently closes?

A: Provided that food businesses selling shellfish can demonstrate that they have taken all reasonable measures to ensure that the product placed on the market is safe to the satisfaction of their LA, then that product can remain on the market. The regulations do not specify the type of analysis that harvesters must undertake, but testing should be undertaken in a competent and verifiable manner.

Appendix C contains a draft batch record document which some businesses may wish to adapt for their own use.

Risk management for small businesses

34. The guidance presented in this document provides a model which has been tested against limited data from the OC monitoring programme. FSAS is aware however that some businesses may already be applying alternative risk management models. In such cases food businesses should present those to LAs who will consider whether or not these deliver similar levels of public health protection.

FSAS will provide advice to LAs on the robustness of any alternative risk management models presented.

Enforcement action

35. As highlighted, it is the legal responsibility of every shellfish business to be able to demonstrate the safety of the products they place on the market. When businesses have not been adequately managing biotoxin risks, and are unable to verify to the satisfaction of the enforcing LA that shellfish is safe to eat, it may be necessary to instigate a product recall.

Appendix D provides an outline of the enforcement steps that will be taken by LAs when risk management systems prove inadequate.

As highlighted, this guidance is not fail-safe and there may be exceptional circumstances whereby the FSAS has information which indicates that, despite best endeavours of the harvester, for public health reasons the product should be removed from the market. In such cases full discussion with the food business concerned will be undertaken.

In all cases, before shellfish are sold, harvesters and processors need to stop and think – what are the risks associated with my product? What does the available data tell me? Can I afford not to test my product?

Relevant information should never be ignored – use of all trigger levels and wider monitoring data should mean that harvesters stop and think before supplying shellfish without a supportive test result. Testing should be a default consideration and only when risk factors have been actively ruled out should testing <u>not</u> take place.

Useful information

1. Annual toxin reports from the FSAS programme provide details of toxicity by area and is useful when looking at historic patterns.
2. The Scottish Aquaculture website provides a map based interface allowing access to shellfish toxin and monitoring results. These are updated every Monday.
3. The Food Standards Agency website also provides weekly results from the FSAS OC programme.
4. Information for harvesters on EPT is available here.

Data Protection Statement

The Food Standards Agency complies with UK Privacy Laws, including the Data Protection Act 1998 and is registered as a data controller with the Information Commissioner (Reg Z477519). Any personal data that you provide to us will be used only for the purpose for which it was obtained. We will take all steps necessary to protect your personal data from unauthorised or accidental loss. We will also not pass on your personal data to others outside our organisation unless the Data Protection Act allows us to do. If you have any data protection queries please contact the FSA Data Protection Officer at:

Email: Data.Protection@foodstandards.gsi.gov.uk
Tel: 01904 455119

Annex A - Diarrhetic Shellfish Poisoning Matrix[1]

		DSP	*Areas move to higher alert status if any one condition is met*	
		Green	**Amber**	**Red**
Information	**Official Control results for flesh or data available from FBO's own testing (EPT)**	FSA OC/EPT less than 80 micrograms of OA/DTXs/PTXs equiv /kg flesh detected for the pod in previous 4 weeks	FSA OC/EPT between 80 and 160 micrograms of OA/DTXs/PTXs equiv /kg flesh detected for the pod in previous 4 weeks	FSA OC/EPT above 160 micrograms of OA/DTXs/PTXs equiv /kg flesh
	Phytoplankton Monitoring	Phytoplankton samples (*Dinophysis* spp. /*Prorocentrum lima*) at <100cells/litre	Phytoplankton samples (*Dinophysis* spp. /*Prorocentrum lima*) equal to or greater than 100 cells/litre in previous 4 weeks	Harvesters may consider critical levels based on experience and insert
	Wider Area consideration	Neighbouring areas at green levels	Neighbouring areas showing flesh or phyto at amber trigger level	Neighbouring areas closed or showing flesh or phyto at red trigger level
Actions	**Harvesting Action**	All harvesting can continue subject to routine verification sampling	Harvesting continues with increased EPT /positive release	No harvesting (Area closed due to toxin levels exceeding legal limits)
	Post Toxic Event Consideration	Area returns to green if all green criteria are met and 4 weeks have passed since red criteria applied	Once area been in red it must stay at amber alert for minimum of 4 weeks before returning to green	Unless there is evidence for product safety, consideration to be given to suspending harvesting on a precautionary basis until toxin levels fall below red trigger levels in neighbouring areas

[1] Okadaic acid, dinophysistoxins and pectenotoxins together

Annex B - Paralytic Shellfish Poisoning Matrix

		PSP	*Areas move to higher alert status if any one condition is met*	
		Green	**Amber**	**Red**
Information	**Official Control results for flesh or data available from FBO's own testing (EPT)**	FSA OC/EPT are below reporting level (<RL)	FSA OC/EPT between RL and 400 micrograms/kg flesh in previous 4 weeks	FSA OC/EPT between 400 and 800 micrograms/kg flesh
	Phytoplankton Monitoring	Phytoplankton samples (*Alexandrium* spp.) at below 40 cells/litre.	Phytoplankton samples (*Alexandrium* spp.) equal to or greater than 40 cell/litre in last 2 weeks	Harvesters may consider critical level and insert level here
	Wider Area consideration	Neighbouring areas at green levels	Neighbouring areas showing flesh or phyto at amber trigger level	Neighbouring areas closed or flesh or phyto at red trigger level.
Actions	**Harvesting Action**	All harvesting can continue subject to routine verification sampling	Harvesting continues with increased EPT/positive release.	Unless there is evidence for product safety, cease harvesting on a voluntary basis
	Post Toxic Event Consideration	Area returns to green if all green criteria are met and 4 weeks have passed since red criteria applied	Once area been in red it must stay at amber alert for minimum of 4 weeks before returning to green	Unless there is evidence for product safety, consideration to be given to suspending harvesting on a precautionary basis until toxin levels fall below red trigger levels

Annex C - Amnesic Shellfish Poisoning Matrix

		ASP	*Areas move to higher alert status if any one condition is met*	
		Green	**Amber**	**Red**
Information	**Official Control results for flesh or data available from FBO's own testing (EPT)**	FSA OC/EPT are below limit of quantitation (LOQ)	FSA OC/EPT between LOQ and 10 milligrams DA/kg flesh in previous 4 weeks	FSA OC/EPT between 10 and 20 milligrams DA/kg flesh
	Phytoplankton Monitoring	Phytoplankton samples (*Pseudo nitzschia* spp.) at 0-150,000 cells/litre	Phytoplankton samples (*Pseudo nitzschia* spp.) >150,000 cells/litre in last 2 weeks	Harvesters may consider critical level and insert level here
	Wider Area consideration	Neighbouring areas at green levels	Neighbouring areas showing phyto or flesh at amber trigger level.	Neighbouring areas closed or flesh or phyto at red trigger level.
Actions	**Harvesting Action**	All harvesting can continue subject to routine verification sampling	Harvesting continues with increased EPT/positive release.	Unless there is evidence for product safety, cease harvesting on a voluntary basis
	Post Toxic Event Consideration	Area returns to green if all green criteria are met and 4 weeks have passed since red criteria applied	Once area been in red it must stay at amber alert for minimum of 4 weeks before returning to green	Unless there is evidence for product safety, consideration to be given to suspending harvesting on a precautionary basis until toxin levels fall below red trigger levels.

Annex D - Azaspiracids and Yessotoxins matrix

		AZA & YTX	*Areas move to higher alert status if any one condition is met*	
		Green	**Amber**	**Red**
Information	**Official Control results for flesh or data available from FBO's own testing (EPT)**	FSA OC/EPT less than 1.8 milligrams YTX /kg flesh in previous 4 weeks FSA OC/EPT less than 80 micrograms AZA /kg flesh in previous 4 weeks	FSA OC/EPT between 1.8 and 3.75 milligrams YTX /kg flesh in previous 4 weeks FSA OC/EPT 80 - 160 micrograms AZA /kg flesh previous 4 weeks.	FSA OC/EPT above 3.75 milligrams YTX /kg flesh FSA OC/EPT above 160 micrograms AZA /kg flesh
	Phytoplankton Monitoring	For YTX: *Protoceratium reticulatum* and *Lingulodinium polyedrum* NA for AZA	NA	NA
	Wider Area consideration	Neighbouring areas at above levels	Neighbouring areas showing flesh at amber trigger level	Neighbouring areas at above levels
Actions	**Harvesting Action**	All harvesting can continue subject to routine verification sampling	Await OC result before releasing product for sale or arrange LC-MS analysis	No harvesting (Area closed due to toxin levels exceeding legal limits)
	Post Toxic Event Consideration	Areareturns to green if all green criteria are met and 4 weeks have passed since red criteria applied	Once area been in red it must stay at amber alert for minimum of 4 weeks before returning to green	Unless there is evidence for product safety, consideration to be given to suspending harvesting on a precautionary basis until toxin levels fall below red trigger levels in neighbouring areas

APPENDIX A End product testing – quick reference

Toxin Group/ Regulatory Limit	Test methods and regulatory status	Method characteristics	Considerations
PSP Paralytic Shellfish Poisoning 800 micrograms saxitoxin equivalents/kg	Antibody based lateral flow tests, such as Jellett® Rapid PSP Test.	Dip-stick type tests - suitable for farm-based testing and implementation in a laboratory. Kits available from commercial companies. Will provide a qualitative result - presence/absence test (positive/negative, yes/no for PSP). May have some limitation in toxin coverage, e.g .may not detect all toxins from the PSP family	Antibody based kits are suitable for EPT, but the results only provide an indication of the levels of PSP toxins that may be present in shellfish. A measure of total levels of all toxins from the PSP family can be only achieved with a use of a fully quantitative method, such as HPLC FBO should contact a test kit provider or a laboratory offering testing to confirm full method characteristics.
	Antibody based ELISA kits, such as: Biopharm AG RIDASCREEN®FAST PSP SC, Abraxsis®Saxitoxin (PSP) ELISA Test Kit, ZEULAB SaxiTest ELISA Kit, Bioo Scientific MaxSignal® Saxitoxin (PSP) ELISA Test Kit.	Competitive enzyme immunoassay tests - suitable for implementation in a laboratory. Kits and testing available from commercial companies. Will provide a semi-quantitative result - will measure (quantify) levels (concentration) of some of the toxins from the PSP family in a sample and sensitivities of tests vary for some of the toxins from the PSP family. May have some limitation in toxin coverage, e.g. may not detect/measure all toxins from the PSP family.	

	HPLC Regulatory method	Chemico-physical tests. Only available from specialised testing laboratories. Will provide a fully quantitative result – will measure (quantify) levels (concentration) of all toxins from the PSP family in a sample. Official Control testing method in the UK.	
DSP & PTX Diarrhetic Shellfish Poisoning (DSP) (okadaic acid [OA] and dinophysis [DTX] toxin group) and pectenotoxins (PTX) together, 160 micrograms of okadaic acid equivalents/kg.	Antibody based lateral flow tests, such as Jellett® DSP Rapid Test and Neogen Reveal® for DSP.	Dip-stick type tests - suitable for farm-based testing and implementation in a laboratory. Kits available from commercial companies. Will provide a qualitative result - presence/absence test (positive/negative, yes/no for DSP). Have some limitation in toxin coverage - do not detect pectenotoxins and will require hydrolysis step to detect some of the toxins from DSP family (ester forms of the DSP toxin group).	Antibody based kits are suitable for EPT, but the results only provide an indication of the levels of DSP toxins that may be present in shellfish and do not detect/measure pectenotoxins. Functional tests are suitable for EPT and give a good indication of the total toxicity of a sample due to DSP toxins, but do not detect/measure pectenotoxins. A measure of total levels of all toxins from the DSP family and pectenotoxins can be only achieved with a use of a fully quantitative method, such as LC-MS. FBO should contact a test kit provider or a laboratory offering testing to confirm full method characteristics.
	Antibody based ELISA kits, such as Abraxis® Okadaic acid (DSP) ELISA Test Kit and Bioo Scientific – MaxSignal® Okadaic Acid (DSP) ELISA Test Kit.	Competitive enzyme immunoassay tests - suitable for implementation in a laboratory. Kits and testing available from commercial companies. Will provide a semi-quantitative result - will measure (quantify) levels (concentration) of toxins from the DSP family in a sample, but sensitivities of tests vary for some of the toxins for the DSP family. Have some limitation in toxin coverage, do not detect pectenotoxins and will require hydrolysis step to detect/measure some of the toxins from DSP family (ester forms of -toxin group).	

	Functional assay - Phosphatase Inhibition Assay (PP2A), such as Zeulab OkaTest (DSP) kit, Abraxis® Okadaic Acid (DSP) PP2A Plate Kit and Sceti K.K. DSP rapid kit. Zeulab OkaTest (DSP) kit complies with the criteria stipulated by the European Reference Laboratory on Marine Toxins and Commission Regulation 15/2012 for determination of OA-group toxins in molluscs, according to the European Commission (DG-SANCO)	Functional, colorimetric assay - suitable for implementation in a laboratory. Kits and testing available from commercial companies. Will provide a quantitative result for the DSP family of toxins, but will not detect or measure pectenotoxins - will only measure (quantify) levels (concentration) of DSP family toxins (sum of okadaic acid and dinophysistoxins 1, 2 and 3) in a sample. Tests give a good indication of the total toxicity of a sample due to DSP toxins, but do not detect pectenotoxins. May require hydrolysis step to detect/measure some of the toxins from DSP family (ester forms of okadaic acid-toxin group).	
	LC-MS/MS Regulatory reference method	Chemico-physical tests. Only available from specialised testing laboratories. Will provide a fully quantitative result – will measure (quantify) levels (concentration) of all toxins from the DSP family and pectenotoxins in a sample. Official Control testing method in the UK .	
AZP Azaspiracid Poisoning (AZP) 160 micrograms of azaspiracid equivalents / kg	LC-MS/MS Regulatory reference method	Chemico-physical tests. Only available from specialised testing laboratories. Will provide a fully quantitative result – will measure (quantify) levels (concentration) of all toxins from the AZP family in a sample. Official Control testing method in the UK .	A measure of total levels of AZP toxins. FBO should contact a laboratory offering testing to confirm full method characteristics.

YTX Yessotoxin 3.75 miligrams /kg	LC-MS/MS Regulatory reference method	Chemico-physical tests. Only available from specialised testing laboratories. Will provide a fully quantitative result – will measure (quantify) levels (concentration) of all yessotoxins in a sample. Official Control testing method in the UK .	A measure of total levels of yessotoxins. FBO should contact a laboratory offering testing to confirm full method characteristics.
ASP Amnesic Shellfish Poisoning 20 milligrams domoic acid/kg.	Lateral flow tests, such as Jellett® ASP Rapid Test and Neogen Reveal® for ASP .	Dip-stick type test - suitable for farm-based testing and implementation in a laboratory. Kits available from commercial companies. Will provide a qualitative result - presence/absence test (positive/negative, yes/no for ASP).	Antibody based kits are suitable for EPT, the results provide a good indication of the levels of ASP toxins that may be present in shellfish. An HPLC will provide an accurate measure of total levels of ASP. FBO should contact a test kit provider or a laboratory offering testing to confirm full method characteristics.
	Antibody based ELISA kits, such as Biosense® ASP ELISA kit for quantitative determination of domoic acid and Zeulab DomoTest ELISA Kit. Biosense® ASP ELISA is a regulatory method to be used for screening purposes only (AOAC 2006.02)	Competitive enzyme immunoassay tests - suitable for implementation in a laboratory. Kits and testing available from commercial companies. Will provide a quantitative result - will measure (quantify) total content of ASP in a sample. Although an approved regulatory method, Biosense® ASP ELISA is not used for Official Control samples in the UK.	
	HPLC Regulatory reference method	Chemico-physical tests. Only available from specialised testing laboratories. Will provide a fully quantitative result – will measure (quantify) levels (concentration) of ASP. Official Control testing method in the UK .	

APPENDIX B

UK and Republic of Ireland laboratories offering commercial services for shellfish biotoxin testing		
Laboratory	**Commercial testing offered**	**Accreditation***
Agri-Food Biosciences Institute (AFBI), **Marine Biotoxin Unit,** **Chemical Surveillance Branch** Stoney Road Stormont Belfast Northern Ireland BT4 3SD Tel: +44 (0)2890 525785 E-mail: info@afbini.gov.uk Website: www.afbini.gov.uk/	ASP by HPLC-UV	Yes
	PSP by HPLC-FLD	Yes
	DSP (okadaic acid, dinophysistoxin) by MBA	Yes
	Lipophilic toxins (okadaic acid, dinophysistoxins, pectenotoxins, azaspiracids and yesotoxins) by LC-MS/MS	Yes
Cefas Shellfish Testing The Cefas Weymouth Laboratory The Nothe Barrack Road Weymouth DT4 8UB Tel: +44 (0)1305 206600 Email: cst@cefas.co.uk Website: www.cefas.defra.gov.uk	ASP by HPLC-UV	Yes
	PSP by HPLC-FLD	Yes
	Lipophilic toxins (okadaic acid, dinophysistoxins, pectenotoxins, azaspiracids and yesotoxins) by LC-MS/MS	Yes
Neogen Europe Ltd - trading as VeroMara European Headquarters of Neogen Corporation The Dairy School Auchincruive Ayr KA6 5HW Tel:+44(0)1292 525610 E-mail: info_uk@neogeneurope.com Website: www.neogeneurope.com	ASP by HPLC-PDA	Yes
	PSP by ELISA	Yes
	DSP (okadaic acid, dinophysistoxin) by Phosphate Inhibition Assay	No

Marine Institute Headquarters Rinville, Oranmore, Co. Galway Republic of Ireland Email: institute.mail@marine.ie Website: http://www.marine.ie/home/services/operational/seafood/Shellfish+Biotoxins.htm Phone: +353 91 387 200 Fax +353 91 387 201	ASP by HPLC-UV	Yes
	PSP by HPLC-FLD	Yes
	Lipophilic toxins (okadaic acid, dinophysistoxins, pectenotoxins, azaspiracids and yesotoxins) by LC-MS/MS	Yes

* check with the laboratory which species are currently covered by the accreditation

This is not an exhaustive list. Please note that other laboratories may offer commercial services but may not be accredited.

Reference to accreditation means an accreditation by an official organisation to ISO17025 standard (in the UK, the United Kingdom Accreditation Service (UKAS)). Accreditation to this standard means that testing laboratories bodies have been assessed against internationally recognised standards to demonstrate their competence, impartiality and performance capability.

APPENDIX C

Pre Harvest Form - to be filled out for each harvest event

Person Ordering/ Risk Assessing					BATCH NO.						
Date of Order / Risk Assessment											
Site name					DATE OF HARVEST						
Toxin Closure Notice		Yes		No	HARVESTED BY						
Nearest phyto site											
Date of Last OC flesh		Result of OC			ASP		PSP		DSP		AZA
Date of Last OC plankton		Plnktn result			**Pseudo-nitzschia** (cells/l)		**Alexandrium** (cells/l)		**Dinophysis/P.Lima** (cells/l)		
Date of last EPT sample		result of EPT									
ALERT STATUS RISK ASSESSMENT											
Condition of toxin in flesh in order to remain green			Green		asp < RL		psp < RL		dsp < 80		
Condition of plankton in order to remain green			Green		Psud-nitz 0-150000		Alex'm <40		Dinophysis < 100		
Condition of toxin in flesh in order to be amber (daily EPT)			Amber		asp >RL<15		psp >RL<400		dsp 50-160		YTXs 1.8< 3.75mg/kg
Condition of plankton in order to be amber (daily EPT)			Amber		Psud-nitz >150,000		Alex'm >=40		Dinophysis >=100		
Were any of amber conditions met in last 4 weeks?***					Yes	No	Yes	No	Yes	No	
Conditions for flesh which would require harvesting to stop			Red		>10 FSA Sample or +ve EPT		> 400 FSA Sample or +ve EPT		> 160 FSA Sample or +ve EPT		YTXs >3.75mg/kg AZAs >160µg/kg
Plankton conditions which would require harvesting to sto			Red								

*Amber conditions in previous 4 weeks mean amber actions apply except for P Nitzchia (ASP) and Alexandrium (PSP) where amber conditions apply to previous 2 weeks only.

**Neighbouring area profiles should also be considered especially during high risk periods.

APPENDIX D

ENFORCEMENT ACTIONS IN RESPONSE TO POSITIVE MONITORING RESULT

1. Where Food Business Operators (FBOs) have adopted the 'traffic light' model outlined in this document, Local Authorities (LAs) can be satisfied that risks are adequately controlled. Where this model has not been adopted, LAs must be satisfied that the alternate controls implemented are effective in ensuring that only safe products are placed on the market.

2. Where the food business is unable to satisfy the LA that adequate controls are in place in relation to marine biotoxins, formal enforcement action including withdrawal of approval should be initiated.

3. Where an Official Control (OC) monitoring sample results in a closure of a classified area the FSA in Scotland Incidents Team will contact the relevant LA to confirm details of any harvesting and distribution of LBMs since the previous monitoring sample date, and details of End Product Testing (EPT) undertaken. It will be expected that the FBO will initiate a recall of all products placed on the market since the last point where products were known to be compliant (the last known point of safety). This will normally be the last satisfactory relevant EPT result. In the absence of appropriate EPT, all products harvested since the last 'clear' OC monitoring sample will require to be recalled. This is in line with processes employed across the rest of the food supply chain.

4. This revised recall timeline is greater than previously applied, where only products harvested subsequent to the failed sample being collected were recalled. Previous recall practise allowed products for which there was no evidence of compliance with the food safety requirements to remain on the market and did not provide adequate public health protection.

Article 19 of EC Regulation 178/2002 requires that:

'if a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers

products already supplied to them when other measures are not sufficient to achieve a high level of health protection.'

5. In the absence of evidence to the contrary, e.g. a more recent EPT result, an OC monitoring sample above maximum permitted level will provide the basis for recalling all products harvested since the previous satisfactory OC monitoring sample due to the lack of any confirmatory data to demonstrate that such products were in compliance with food safety requirements.

6. Subsequent to any recall or withdrawal of products from the market, it will be necessary to undertake a review of the HACCP to ensure that appropriate controls are implemented to prevent a recurrence. As indicated earlier, if the LA is not satisfied that appropriate controls are in place, formal enforcement action including withdrawal of approval should be initiated.

For all queries regarding food incident handling please email:

ScottishIncidents@foodstandards.gsi.gov.uk