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**ALGAL TOXINS IN OFFICIAL CONTROL SHELLFISH
MONITORING PROGRAMME SCOTLAND: PROTOCOL ON
APPLICATION OF EARLIER TESTING AT CLOSED AREAS**

Shellfish Unit

April 2010

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Abbreviations

FSAS	Food Standards Agency in Scotland
OC	Official Control
RMP	Representative Monitoring Point
AHA	Associated Harvesting Area
LC-MS	Liquid Chromatography Mass Spectrometry
HPLC	High Performance Liquid Chromatography
MBA	Mouse Bioassay
TCN	Temporary Closure Notice
Cefas	Centre for Environment, Fisheries and Aquaculture Science
EPT	End Product Test
DSP	Diarrhetic Shellfish Poisoning
ASP	Amnesic Shellfish Poisoning
PSP	Paralytic Shellfish Poisoning

1. Introduction

Since 1 April 2000 the Food Standards Agency in Scotland (FSAS) assumed responsibility for monitoring and surveillance of bivalve mollusc harvesting areas and the FSAS monitoring and surveillance programme came into operation on that date. The programme is targeted to cover active shellfish production areas in Scotland and is undertaken with assistance from food authorities and shellfish harvesters. Shellfish samples for flesh bioassays are collected at representative monitoring points by local food authority shellfish sampling officers and are sent to the flesh testing laboratory at the Centre for Environment, Fisheries and Aquaculture Science (Cefas) for testing. Cefas inform the FSAS of all results as they occur and will report as soon as possible whenever flesh samples exceed the following maximum permitted levels:

- ◆ ASP - 20µg of domoic acid per gram flesh
- ◆ DSP- Presence
- ◆ PSP - 80µg per 100 gram flesh.

For full details on the current monitoring programme please refer to the FSAS guidance document 'ALGAL TOXINS IN SHELLFISH MONITORING PROGRAMME SCOTLAND GUIDANCE FOR FOOD AUTHORITIES', last published in April 2010 <http://www.food.gov.uk/scotland/regsscotland/regsguidscot/guidancealgaltoxins>

Historically The Agency in the UK has applied a seven day sampling policy. In effect this means that any area closed must provide two consecutive samples below the regulatory limits each taken seven days apart before a closure can be lifted allowing harvesting to resume.

FSAS has been approached by a number of harvesters requesting a review of this procedure. In response and following a pilot, the Agency in Scotland will apply in particular stated circumstances earlier testing when an area is closed. This decision is aligned with the Scottish Government's fundamental aim of economic growth as well as the Agency's better Regulation and Simplification process. Unless the stated circumstances are met, the two consecutive samples will continue to be taken seven days apart.

2. Legal Considerations

EU Regulation 854/2004 stipulates that openings be determined by at least two consecutive results below the regulatory limit, separated by at least 48 hours in sample collection time. It is known that other member states operate a 48 hour re-opening regime. The procedure will apply to all RMP areas closed where they conform to the criteria set in the protocol.

3. Technical and operational considerations

The protocol will only be applied to RMP's or AHA's that have been granted temporary RMP status at which there is an intention to harvest shortly after opening. If there is no intention to imminently harvest, then sites are not deemed to be suitable for consideration under the protocol. Harvesters who wish to utilise this protocol should inform their sampling officer of their intention to do so and submit a fully completed application form (annex 2) to FSAS. FSAS will determine suitability of each application. Where the area is eligible for inclusion in the protocol, samples will be gathered at a frequency agreed at local level and will be dependant upon local resource and laboratory capacity. Every effort will be made to accommodate requests.

Please be advised that where earlier re-testing is permitted and has resulted in an area opening earlier, there will be a lag in resumption of standard monitoring programme testing to bring the area back into line with regular testing at the prescribed frequency. This is particularly important for DSP testing in order to comply with Home Office licence conditions. In effect, this means that any assay performed on the area in question, is performed earlier rather than more frequently.

The example below outlines an earlier testing scenario and how it is envisaged to be implemented in practice. In this example an area will be opened 6 days earlier than under the existing regime.

	Mon 1st	Tues 2nd	Wed 3rd	Thurs 4th	Fri 5th	Sat 6th	Sun 7th
Area Open	Sample gathered	Sample at laboratory	Analysis and result showing positive	Area closed	Area closed	Area closed	Area closed
	Mon 8th	Tues 9th	Wed 10th	Thurs 11th	Fri 12th	Sat 13th	Sun 14th
Area Closed	Sample gathered	Sample at laboratory	Analysis and result showing negative. Sample gathered	Sample at laboratory	Analysis and result showing negative Area open	Area open	Area open
	Mon 15th	Tues 16th	Wed 17th	Thurs 18th	Fri 19th	Sat 20th	Sun 21st
Area Open	Area open No sample gathered	Area open	Area open	Area open	Area open	Area open	Area open
	Mon 22nd	Tues 23rd	Wed 24th	Thurs 25th	Fri 26th	Sat 27th	Sun 28th
Area open	Sample gathered						

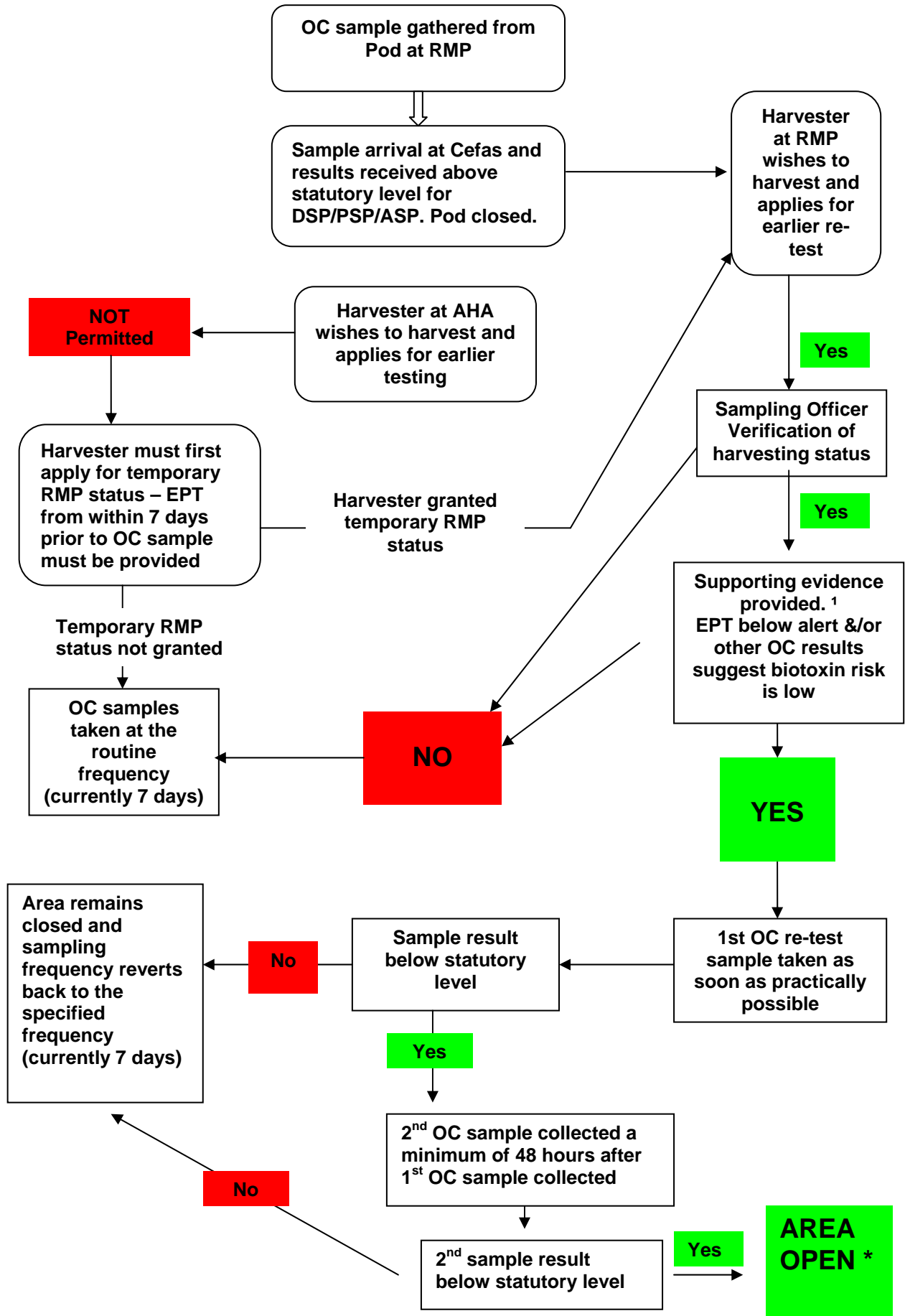
4. Protocol for earlier testing for opening of classified shellfish production areas following closure due to a toxic event

- The protocol allowing earlier sampling will be provided for harvesters who are known to be planning for immediate active harvest should a site be opened.
- The system is subject to application (see annex 2) and will not be applied as a blanket approach at this time.
- Confirmation of harvesting practices will be verified by the Scottish Shellfish Sampling Officers who are generally on site on a weekly basis.
- Harvesters should, where legally required to do so, provide evidence of end product testing which indicates that toxin levels are at least below half of the regulatory limits before they become eligible for inclusion in the procedure. Verification of sample location i.e. area and site name, date of sample gathering will be required to be provided.
- Earlier sampling will be considered if the first official control (OC) sample from a closed area is negative and there is an intention to harvest.
- Decisions on earlier sampling will not be made exclusively on end product test results. Earlier sampling will not be considered if previous OC results suggest that toxin levels may be increasing. Where possible, supporting evidence via phytoplankton cell counts, from the sampling point nearest to the area, (which should fall below alert levels) and/or results from any other official samples e.g. use of LC-MS will also be taken into account when decisions on re-sampling are made.
- Where an area is accepted for inclusion in the protocol the area will be sampled as soon as practically possible after the positive result has been received or after the first OC sample has been reported as negative.
- Where the first re-sample is negative or below the statutory maximum level prescribed, the second re-sample will be taken as soon as practically possible after the minimum 48 hour period prescribed by Regulation. Please note that under the normal monitoring regime sites will continue to be re-sampled 7 days after the first negative unless there is an intention to harvest.
- All re samples must be taken by the Official Control Officer and the timings of earlier re- sampling arrangements will be in agreement with these officers and their timetabled sampling schedule. Therefore where a harvester is accepted for inclusion in the protocol the area will be sampled as soon as practically possible.
- Earlier sampling will only be considered for RMP's or AHA's temporarily granted RMP status. Please refer to Annex A, Section 5.5 of the Algal Toxins in Shellfish Monitoring Programme Scotland for guidance on how AHA's can challenge RMP status. Copy of the relevant section is attached at Annex 2.

The flow diagram at annex 1 illustrates the practical workings of the proposal.

Annex 1

Testing of Closed RMP Area Frequency Procedure



Supporting evidence should indicate that the risks of a toxic event during the intended harvesting period are minimal.

This will include results of end product tests with levels as prescribed below.

Test method	Toxin	Acceptable result to trigger more frequent sampling
PP2A assay	DSP	<LOD
Elisa	DSP	LOD
Ridascreen	PSP	<40µg/100g
HPLC	ASP	<10µg/g
Phytoplankton		
Dinophysis Sp	DSP	= to or < 100 cells/litre
Alexandrium Sp	PSP	LOD
Pseudo - nitzschia Sp	ASP	= to or < 50,000 cells/litre

**Annex 2
APPLICATION FORM FOR EARLIER BIOTOXIN RE-SAMPLING**

APPLICANT DETAILS			LOCAL AUTHORITY DETAILS		
Name:			Name of Authority and Officer:		
Address:			Address:		
Contact Information:	Tel No:		Contact Information:	Tel No:	
	Mobile Tel No:			Mobile Tel No:	
	Fax No:			Fax No:	
Email:			Email:		

AREA AND SAMPLE DETAILS	
Production Area:	
Site Name:	
SIN:	POD No:
Species Tested:	
Date of gathering first positive sample:	
Date of closure:	
Toxin of closure:	
Period of intended harvest:	
End product test Report enclosed: Yes/No If yes – sample location and date to be provided	
Harvester signature:	Official control officer verification signature:

Please send completed applications to either:

Calum Yule calum.yule@foodstandards.gsi.gov.uk
 Graham Ewen graham.ewen@foodstandards.gsi.gov.uk
 Jennifer Howie jennifer.howie@foodstandards.gsi.gov.uk

Tel - 01224 285111 Fax – 01224 285168
 Tel - 01224 285190 Fax – 01224 285168
 Tel - 01224 285171 Fax – 01224 285168

Annex 3

PROCEDURE FOR AHA CHALLENGE ON RMP STATUS

(as per Annex A, Section 5.5 of the Algal Toxins in Shellfish Monitoring Programme Scotland Guidance)

5. RMP with AHA

- 5.1 Most RMPs have one or more AHA's within the pod. The RMP is monitored as prescribed for all toxins.
- 5.2 When no toxins are detected and there is no toxic algae present in phytoplankton samples the pod has an Open (Green) status. As described in point 4.2, an open harvest status does not mean that harvesters are in anyway released from their obligation to ensure the safety of their product.
- 5.3 If toxic algae are detected above alert levels and/or toxins are detected at alert level then the pod moves to Alert status (Yellow). The Alert status again indicates to harvesters the increased risk and their own risk assessments should accommodate this by increasing the frequency of EPT or other control measures deemed appropriate to the risk.
- 5.4 If toxin levels at the RMP exceed the statutory limits then the pod (which includes the RMP and all related AHA's) is assigned a closed status (Red). The LFA will administer a TCN. The normal frequency of monitoring for the toxin affecting the closure will continue. After the first official control sample has been analysed for the closure toxin, the second official control sample will be analysed for all toxins. The area can only be re-opened for harvesting when two consecutive samples taken at least seven days apart have been obtained below the statutory limits (unless participation in the earlier testing pilot has been agreed by FSAS – refer to the earlier testing protocol at Annex 1).
- 5.5 During this closure, any FBO wishing to harvest from an AHA is required to submit evidence to FSAS that the AHA is potentially below the statutory level for **all** toxins. This will consist of an EPT result indicating either absence or biotoxin levels below the statutory levels prescribed in Chapter 5 of 853/2004. These EPT results should relate to a sample taken after the previous official control negative result (and within 7 days prior to the official control positive result). Where the harvester has no legal responsibility to provide for EPT (i.e. they are not an approved establishment placing product on the market), FSAS will assist in collation of available results from the statutory monitoring programme which will be used to assist with making a decision. However the absence of additional data may lead to difficulty and/or delay.
- 5.6 Upon receipt of appropriate evidence, the relevant AHA will be granted temporary RMP status and FSAS will fund OC samples via the appropriate Control Body to determine whether it is safe for the TCN to be lifted for this area only. The temporary RMP will require to have two samples taken at least seven days apart at below the statutory level (unless participation in the earlier testing pilot has been agreed by FSAS) before the TCN will be partially revoked. This will only apply to the area and species covered by the temporary RMP.
- 5.7 Where AHAs are not active harvest areas they need only follow the open or closed status of the nominated pod RMP.

5.8 In some cases an RMP will exceed statutory toxin levels without warning (i.e. when the RMP is on Open harvest status). In this case, the closure is dealt with as above.

Where an AHA is being used as surrogate RMP the AHA will adopt RMP status and the same rules will apply.

*Once all AHA's with temporary RMP status and the RMP itself all have 2 consecutive negatives, the temporary RMP status is revoked and the RMP is the only point where monitoring samples are required to be collected.

