

# ALGAL TOXINS IN SHELLFISH MONITORING PROGRAMME SCOTLAND

### **GUIDANCE FOR FOOD AUTHORITIES**

Local Authority Food Law Enforcement Branch Issue July 2009

#### INDEX

- 1 Background
- 2 Algal Toxin Monitoring
- 3 Local food authority responsibilities
- 4 Action when shellfish flesh results exceed maximum permitted levels
- 5 Closure of the affected areas
- Tracing and dealing with any shellfish harvested after the date of gathering the actionable sample and prior to closure action
- 7 Action required to open a closed production area
- Local food authority liaison with FSAS and Centre for Environment, Fisheries and Aquaculture Science (Cefas)

#### **ANNEXES**

Glossary of Terms

ANNEX A: Implementation of EC 854/2004 in relation to Official Control Biotoxin

Testing in Classified Shellfish Production Areas

ANNEX B: Shellfish Biotoxin Sampling programme for 2009/10

ANNEX C: Algal Toxin Monitoring and Surveillance Programme -

Shellfish Sample Collection Protocol & submission form.

Wild Pectinidae Sample Collection Protocol & Sample submission

form

ANNEX D: Local Food Authority named contact officer details

ANNEX E: Information concerning Temporary Closure Notices

ANNEX F: Temporary Closure Notices (TCN) – model Notice

ANNEX G: Suggested text for warning notices to casual gatherers

ANNEX H: Action following tracing of product harvested after date of sample

ANNEX I: Revocation of Temporary Closure Notices (TCN) – model Revocation

Notice

ANNEX J: Food Standards Agency Scotland contact details

ANNEX K: Laboratory contact details

ANNEX L: NRL Transport SOP

ANNEX M: Protocol on application of earlier testing at closed areas

#### **BACKGROUND**

- 1.1 Regulation (EC) No 853/2004 lays down the hygiene requirements for the production and placing on the market of live bivalve molluscs. In addition, Regulation (EC) No 854/2004 sets out the official controls concerning live bivalve molluscs from classified production areas. They are enabled by the Food Hygiene (Scotland) 2006 Regulations.
- 1.2 Marine biotoxins produced by phytoplankton can accumulate in the tissues of shellfish. If these species are consumed by humans, toxin related illness can occur.
- 1.3 As part of the controls to protect public health, Regulation 854/2004 requires a monitoring programme of shellfish relaying and production areas to be established to check for the possible presence of toxin producing plankton in the water and biotoxins in the shellfish flesh.
- 1.4 As the Competent Authority in Scotland, the Food Standards Agency Scotland (FSAS) is responsible for carrying out monitoring of classified production areas in Scotland for the presence of phytoplankton in samples of water and for marine biotoxins in samples of shellfish flesh. Similar monitoring programmes are carried out in England, Wales and Northern Ireland. Within FSAS the Local Authority Food Law Enforcement Branch (LAFLEB) implements and manages the Official Control Monitoring Programmes.
- 1.5 This guidance summarises the operation of the monitoring programme in Scotland, and outlines what action should be taken when either ASP (Amnesic Shellfish Poisoning), DSP (Diarrhetic Shellfish Poisoning) and PSP (Paralytic Shellfish Poisoning) toxins are found to exceed the maximum permitted levels in flesh samples.
- 1.6 Before bivalve molluscs may be harvested for human consumption the production area needs to be classified. Tests for levels of *E.coli* on the bivalve molluscs that are to be harvested from the proposed production area is undertaken and an assessment carried out before the classification is made. The classification of a production area is specific to the area and for the species concerned. The FSAS publishes the details of the designated bivalve mollusc production areas in Scotland each year. The only exception to this is natural scallop beds which are outwith the scope of classification requirements. All details are available on the Agency's web site.
- 1.7 These classified areas require to be monitored additionally for biotoxins by the FSAS. A timetable is developed each year between Centre for Environment, Fisheries and Aquaculture Science (CEFAS), who currently hold the contract with FSAS for this work, and FSAS to ensure monitoring of Representative Monitoring Points (RMPs) indicator sites within classified production areas. Samples of shellfish for biotoxin monitoring purposes are taken from these classified production areas.

#### 2 ALGAL TOXIN MONITORING

#### **FLESH SAMPLING**

- 2.1 On the 1 April 2000 the Food Standards Agency 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.
- 2.2 ANNEX A details in full the new programme design.
- 2.3 Most bivalve mollusc production areas have one sampling point although some will have more than one which will be monitored simultaneously. Sampling sites and sampling frequency for 2009/2010 are shown in ANNEX B.
- 2.4 At present, shellfish samples for flesh bioassays are collected by local food authority (LFA) Authorised Officers or shellfish harvesters and are sent to the flesh testing laboratory at Centre for Environment, Fisheries and Aquaculture Science (Cefas) for testing. The shellfish sample collection protocol is shown at ANNEX C.
- 2.5 Centre for Environment, Fisheries and Aquaculture Science (Cefas) will provide boxes and postage labels for sending flesh samples to the laboratory. Tests are carried out using methods specified by the EC.
- 2.6 Centre for Environment, Fisheries and Aquaculture Science (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.
- 2.7 See section 4 for action to be taken when results exceed these levels. The weekly results will be available on the FSA web site on Tuesday afternoons.

#### PHYTOPLANKTON SAMPLING

2.8 In addition to the flesh sampling, FSAS also monitor phytoplankton, which is carried out by Scottish Association for Marine Science (SAMS). SAMS will provide boxes and postage labels for sending water samples to the laboratory. The results of the phytoplankton monitoring may be used to increase frequency in flesh sampling where weekly testing is not already taking place. See Annex A para 6 for details of Alert levels.

#### 3 LOCAL FOOD AUTHORITY RESPONSIBILITIES

- 3.1 Regulation (EC) 854/2004 requires the FSAS to undertake or to require food authorities to undertake on its behalf the monitoring of bivalve mollusc production areas to determine whether toxin producing plankton are present in waters and whether biotoxins are present in live bivalve molluscs.
- 3.2 The Regulations allow provision (under Article 6 and paragraph C of Chapter II of Annex II) for the LFA to make a Temporary Closure Notice (TCN), where it is satisfied that the consumption of the live shellfish taken from a production area is likely to cause a risk to public health.

## 4 ACTION WHEN SHELLFISH FLESH RESULT EXCEEDS MAXIMUM PERMITTED LEVEL

- 4.1 On receipt of results that are positive for DSP or exceed the maximum permitted level for ASP or PSP, the LAFLEB will contact the relevant LFA named contact officer by telephone as soon as possible. At times outwith the LFA's stated working hours, the LAFLEB will make use of the emergency contact number supplied by the LFA. All verbal information will then be supported by a fax or email to provide the LFA with the necessary information with which to take action. Discussion with the LFA will include where necessary:
  - Mathematical Problem 2 by How, dependent on local circumstances, the affected area should be closed to prevent shellfish harvesting (see section 5);
  - Tracing of product already harvested (see section 6);
  - Follow up sampling requirements, e.g. the area(s) from which to collect samples, the species to be sampled (where the area is represented by an indicator species) and the sampling frequency (see also paragraph 5.4).
- 4.2 ANNEX D lists all relevant LFA named contact officer details. Any changes to these should be notified to the LAFLEB as soon as possible to ensure that the programme can be run efficiently.

#### 5 CLOSURE OF THE AFFECTED AREAS

- 5.1 Classified Production Area To administer a closure in a classified area, a Temporary Closure Notice (TCN) has to be made by the LFA to comply with the requirements of Regulation 854/2004 enabled by the Food Hygiene (Scotland) 2006 Regulations. Further information is at Annex E and a model TCN is at Annex F. A TCN administers closure prohibiting the collection of any live bivalve molluscs from a designated area. A TCN remains in force until revoked. A TCN is administered and enforced by the LFA.
- 5.2 **Unclassified Production Area** To close an unclassified area an Order is made under Part I of the Food and Environment Protection Act 1985 (FEPA).
- 5.3 A FEPA is a statutory instrument made by the Scottish Ministers. FEPA Orders come into force immediately but require to be confirmed by the Scottish Parliament within 28 days in order to remain in force. Once confirmed they continue in force until revoked, again by the Scottish Ministers. FEPA Orders are administered by the FSAS and enforced by the relevant competent body i.e. Fisheries Protection Agency or LFA.
- The Food Standards Agency may seek advice from Centre for Environment, Fisheries and Aquaculture Science (Cefas) to determine the size of the area to be closed under a TCN, taking into account hydrography and other factors. Appropriate advice will be passed to the relevant LFA directly by the FSAS.
- 5.5 Algal toxins usually only affect bivalve molluscan shellfish. Therefore, it is not generally necessary to take action to prevent the harvesting and marketing of other shellfish (e.g. crustacea). However, where levels of PSP in bivalve molluscs exceeds 150ug/100g, scientific advice is that gastropods and crustacea may become affected. Therefore, when levels of PSP exceed this limit, the LAFLEB will:
  - request the LFA to collect and submit to Centre for Environment, Fisheries and Aquaculture Science (Cefas) samples of crustacea on an advised basis until the level of PSP detected falls below this limit.
  - discuss with the LFA whether there is a need to take local action to prevent harvesting, trace product and warn local industry and consumers.
- 5.6 Where a production area is not a private laying, and so may be accessible by the public for casual gathering, general notices affixed in the vicinity of the area are required. A model warning notice is at ANNEX G. The LFA should also consider the issue of a press release to warn casual gatherers.
- 5.7 It is recommended that the TCN is laid within 1 working day of receipt of results which require action.

- 6 TRACING AND DEALING WITH ANY SHELLFISH HARVESTED AFTER THE DATE OF GATHERING THE ACTIONABLE SAMPLE AND PRIOR TO CLOSURE ACTION
- 6.1 The LAFLEB will discuss with food authorities the need, on a case by case basis;
  - to trace product;
  - whether an incident report should be completed under Code of Practice and sent to the FSAS to consider the issuing of a Food Alert.
- 6.2 ANNEX H offers guidance on suggested action and enforcement powers when dealing with traced product.

#### 7 ACTION REQUIRED TO OPEN A CLOSED PRODUCTION AREA

- 7.1 A closure may be lifted when there have been two consecutive satisfactory results taken at least 7 days apart. The FSAS recommends that at least 7 days be left before a sample is taken at a newly positive production area. This will allow some time for toxin levels to subside. Currently FSAS is applying a one-year pilot period for early re-testing in certain circumstances. Where these have been approved the early re-test protocol applies. This protocol is found at annex M and includes an application form for harvesters wishing to apply via their LFA to be considered for an early re-test.
- 7.2 ANNEX I provides a model TCN revocation notice.
- 7.3 It is, however, worth bearing in mind that there may be occasions when further consideration will need to be given prior to re-opening an area, e.g. where neighbouring areas need to remain closed and opening selected beds may lead to enforcement problems.
- 7.4 The LAFLEB will provide all food authorities with all results from the algal toxin monitoring programme. The LFA should determine when two consecutive satisfactory results have been received for an area in which a TCN is in force. The LFA should decide, with assistance by the LAFLEB if necessary, when a TCN can be revoked. A formal revocation notice should be issued and sent to members of the industry who were originally advised that harvesting should cease. Similarly, where a press release was issued notifying of restrictions in fishing activity, a further press release should be issued announcing the revocation of the TCN. Any notices erected in the area should also be removed.
- 7.5 Copies of all revocation Notices should be sent to the LAFLEB by fax or email within 5 working days.

- 8 LOCAL FOOD AUTHORITY LIAISON WITH FSAS AND CENTRE FOR ENVIRONMENT, FISHERIES AND AQUACULTURE SCIENCES (CEFAS)
- 8.1 The LAFLEB should be the first point of contact for food authorities to:
  - discuss the need for local action following actionable results from the monitoring programme;
  - find out when sample results will be available;
  - obtain general information about the algal toxin-monitoring programme.
- 8.2 A list of Food Standards Agency contacts is given in ANNEX J.
- 8.3 Centre for Environment, Fisheries and Aquaculture Science (Cefas) may be contacted directly regarding the submission of routine samples, advice on sampling and requests for sampling kits and equipment. Centre for Environment, Fisheries and Aquaculture Science (Cefas) contact points are at ANNEX K. SAMS contact points are also included in ANNEX K.

#### **ANNEXES**

#### **Glossary of terms**

**Representative Monitoring Point (RMP)** -Official Control Monitoring point representative of a classified shellfish Production Area/s. This relates to a point which will be monitored to the timetable for all toxin groups throughout the year.

**RMP species** - the species used for monitoring at the RMP site. In some circumstances this may differ from the species harvested at the same site (e.g. mussels may be monitored at a queen scallops site).

**Associated Harvesting Area/a (AHA)** -Harvest area/s represented by a representative monitoring point (usually classified shellfish areas denoted by a SIN).

**Open harvest status (Green)** – RMP shows no evidence of toxin levels, phytoplankton cell counts are below alert status and historic data suggests a low risk.

**Alert harvest status (Yellow)** - RMP indicates evidence of alert levels of toxin production as specified and/or toxic phytoplankton species detected above alert levels or historical data suggests heightened probability of toxic event.

**Closed harvest status (Red)** - RMP is subject to biotoxin test results which exceed the statutory biotoxin levels prescribed in 853/2004.

**Active Harvesting area** - a classified site which is currently harvesting or has the potential to harvest molluscs and place these on the market.

**Wild harvest area** - a classified Harvest area which is not a managed aquaculture site and may be exploited by more than one harvester.

**Local Food Authority (LFA)** – Local competent body responsible for enforcement of food safety Regulation.

**Temporary Closure Notice (TCN)** - Administrative notice which is provided to all harvesters within a RMP and AHA by the LFA to provide detail of a statutory closure.

**FBO** - Food Business Operator

Cefas - Centre for Environment, Fisheries and Aquaculture Science

**SAMS** - Scottish Association for Marine Science

**LAFLEB** - Local Authority Food Law Enforcement Branch

**SOP** - Standard Operating Procedure

**NRL** - National Reference Laboratory

**EPT** - End Product Testing

#### ANNEX A

## Implementation of EC 854/2004 in relation to Official Control Biotoxin Testing in Classified Shellfish Production Areas

#### 1. Introduction

- 1.1. FSAS is required as Central Competent Authority to conduct an Official Control Monitoring Programme for Biotoxins in Classified Shellfish Production Areas.
- 1.2 An implementation plan to deliver the Regulatory requirements under EC 854/2004 in relation to biotoxin monitoring in classified shellfish production areas has been agreed. The main driver of the plan is the inshore biotoxin risk assessment undertaken by the Agency in 2004.
- 1.3 FSAS has determined that the overall objective of the Monitoring Programme is:

'to verify compliance with health standards in order to meet our Community obligations under EC 854/2004 as Central Competent Authority'

1.4 EC 854/2004 requires all shellfish production areas to be sampled weekly through representative monitoring points (RMP). An assessment of suitable RMP was undertaken in 2006 and again in 2008. These RMP's represent all of our classified production areas. These will be sampled at different frequencies depending on seasonal risk.

#### 2. Proposed Monitoring and Management System

- 2.1 The backbone of the system is the chain of Representative Monitoring Points. These are monitored weekly for PSP and according to season for DSP and ASP. This will take place for the regulated toxins. RMPs are also harvest areas. The RMPs are chosen with regard primarily to their geographical relevance. This is both in terms of their ability to cover a representative area (the Associated Harvesting Area/s) and how representative they are of the area chosen. Other factors that are used to choose RMPs include previous toxin history, ease of access and the species present at the site.
- 2.2 The FSAS decision is that we will endeavour to monitor all classified harvesting areas. Wild harvest areas will be sampled when they are being actively harvested and the LFA will be best placed to judge when this is happening.
- 2.3 In most cases, the representative species are mussels (*Mytilus edulis*). There is evidence from the risk assessment and from other sources that mussels are more likely to have elevated levels of toxins than other species, oysters for example. Further Regulation 854/2004 allows for the use of a representative species for the purposes of monitoring. Where mussels are not available then the species of harvest will be the representative species.

- 2.4 The primary purpose of the RMP is to give timely information on the levels of toxins within their area and AHA. In particular, early detection of toxin production events is a useful part of the monitoring programme. For this reason, the flesh monitoring programme will closely liase with the phytoplankton monitoring programme to help give early warning of toxic events. Historical data may also be used in conjunction with the RMP data. An additional benefit of this design is that it may encourage more focused end product testing (EPT) by industry which will enhance public protection.
- 2.5 If we could be certain that the RMP was truly and equally representative of the toxin status of all of AHA then we could manage all of the harvest areas solely by reference to the RMP. However, the available scientific data does not allow us to make such assumptions and, further, 854/2004 prescribes that the RMP should be as representative as possible and therefore acknowledges that flexibility is necessary. The purpose of our use of RMPs is therefore to assist in ensuring that proportionate monitoring resources are used in the most effective manner whilst meeting our requirements under Community Law.

#### 3. Rotation of RMP

3.1 Where an RMP is accompanied by AHA/s, the LFA may sample from the AHA if they have had prior agreement from the LAFLEB. This will allow flexibility to allow for harvesting and site accessibility. Where the RMP is not to be sampled Centre for Environment, Fisheries and Aquaculture Science (Cefas) should be advised to assist in sample management.

#### 4. RMP on its own

- 4.1 Some RMP cover only a single harvest area due to the scattered nature of Scotland's shellfish aquaculture industry. Management of these sites is straightforward. When there is no evidence of toxins or phytoplankton at above the alert or statutory level then the area is assigned an Open (Green) status. An Open harvest status does not mean that harvesters are in anyway released from their obligation to ensure the safety of their product, it merely indicates that with the information available to the Agency that no toxin activity is taking place at the point and time of sampling.
- 4.2 When evidence of toxin production is detected below statutory levels but at levels of alert the RMP will be provided with an Alert status (Yellow). This will allow the harvester to ensure his risk assessment reflects this increased risk and that subsequent adequate EPT or other suitable precautions as determined by the FBO are employed if the area is actively harvesting.
- 4.3 If toxin levels exceed the statutory limits then the site is closed and assigned a Closed (Red) status. The LFA will administer a Temporary Closure Notice. Weekly monitoring for the toxin affecting the closure will continue, after one clear sample all toxins will be subject to analysis and when two consecutive samples, seven days apart have been obtained below the statutory limits the site can be re-opened for harvesting. Where an area has been subject to successful application for re-test during the pilot period (until end October 2009) then the frequency will be as stated in this protocol which is detailed in Annex M.

4.4 Where the positive sample originates from a representative species, the area will be closed on the basis of the result and the classified species submitted for toxin analysis at the next opportunity. Closure decisions will thereafter be made on the species classified.

#### 5. RMP with AHA

- 5.1 Most RMPs have one or more AHA's within the area. 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 and there is no historical reason to expect a toxin event then the RMP and AHA have 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, toxins are detected at alert level or the RMP or AHA has a history of toxic events at that time then the RMP and affected AHA moves to Alert status (Yellow). The Alert status again indicates to harvesters the increased risk and their risk assessments should accommodate this by their EPT level or other appropriate control measures.
- 5.4 If toxin levels at the RMP exceed the statutory limits then the RMP and all related AHA's are closed and assigned a Closed status (Red). The LFA will administer a TCN. Weekly monitoring for the toxin affecting the closure will continue. After one clear sample all toxins will be subject to analysis and when two consecutive samples seven days apart have been obtained below the statutory limits the area can be reopened for harvesting.
- 5.5 During this closure any FBO wishing to harvest in an AHA, should submit evidence that the AHA is potentially below the statutory level for **all** of the toxins. This will consist of an EPT result indicating potential absence of biotoxin levels or levels below the statutory levels prescribed in Chapter 5 of 853/2004. These end product test results should relate to a sample taken after the previous official control negative result.
- 5.6 Upon evidence of this, FSAS will fund OC samples via the appropriate Control Body to determine whether it is safe for the TCN to be lifted for this AHA. The AHA will require to have two samples, seven days apart at below the statutory level before the TCN will be partially revoked to cover the AHA. This will also apply to other species being harvested within the RMP/AHA.
- 5.7 Where AHA are not active harvest areas they need only follow the open or closed status of the RMP.
- 5.8 In some cases an RMP will exceed statutory toxin levels without warning (i.e. the RMP is on Open harvest status). In this case the closure is dealt with as above.
- 5.9 Where an AHA is being used as surrogate RMP the AHA will adopt RMP status and the same rules will apply.

#### 6. Alert status triggers

6.1 DSP - Closures without an Alert status are most likely to occur with DSP samples since the method does not quantify toxins it provides only a negative or positive result. It is hoped however that future LC-MS trial will allow some quantification and thus the adoption of a useful Alert status for this toxin. Alert status for this toxin will also be assigned on the number of phytoplankton cells detected, 100 cells/litre, and by historical data. Alert levels for PSP, DSP and ASP are shown below.

#### **Alert and Action Table**

Biotoxin	Phytoplankton	Alert (Yellow)	Action (Red)
PSP	Alexandrium	Greater than 0 cells/litre of	HPLC or MBA at
		Alexandrium, HPLC and/or MBA at 40-79μg/100g	80μg/100g
DSP	Dinophysis	Greater than or equal to 100 cells/litre of Dinophysis, and/or MBA clinical signs and by historical data.	MBA positive
ASP	Pseudo-nitzschia	Greater than or equal to 50,000 cells/litre of Pseudo-nitzschia, half the Regulatory level (=10µg/g) and /or historical data	20μg/1g by HPLC

This information may be used to increase frequency in sampling where weekly testing is not already taking place. Additionally this information should be of use for Industry to assist them in their assessment of risk when considering harvesting.

#### 7. Wild Classified Production Areas

- 7.1 Sampling from these areas may be problematic since gathering requires good tides or a diver's assistance to collect them. Harvesting is infrequent, sporadic and may be difficult to detect. Obtaining weekly samples may be difficult.
- 7.2 However, if such areas are not monitored then FSAS may not be effectively meeting its requirements under Community legislation.
- 7.3 Where possible these wild harvest areas are included as an AHA covered by a RMP that uses an aquaculuture species as the RMP species. Monitoring of wild pectinidae falls outwith this guidance document and can be found within the document entitled; "Official Controls of Wild pectinidae for Biotoixns. Implementation of EC Regulations 854/2004 and 882/2004".
- 7.4 Where there are no practical aquaculture sites to act as RMP for wild harvest areas the OC sampling will be the responsibility of the LFA who will collect samples at the stated frequency during periods when harvesting is permitted. EC 853/2004 requires all shellfish batches to be accompanied by a Registration document, unless an exemption known to the LFA is in use. This requirement should ensure that the LFA

is at all times aware of the harvesting activity at their wild production areas and that the requisite weekly sampling is implemented during the period of classification.

#### 8. Resource Issues

#### 8.1 Resource

The requirements of the programme follow mainly from the need to provide weekly monitoring of the RMP and are thus driven by the overall number of these. We currently have 94 RMPs on the list to cover all of the Classified Production Areas in Scotland. We intend for sampling to be carried out every week where harvesting is taking place. It is intended that the programme be reviewed at agreed periods to allow for further refinement.

#### 8.2 Laboratory

The programme is co-ordinated and managed by Centre for Environment, Fisheries and Aquaculture Science (Cefas) in conjunction with FSAS and SAMS. Samples for biotoxin analysis will be sent direct to Centre for Environment, Fisheries and Aquaculture Science (Cefas) where ASP, DSP and PSP analysis will be undertaken..The Biotoxin National Reference Laboratory (NRL) (FRS Aberdeen) has issued guidance in relation to the transport of samples for biotoxin. The aim of this Standard Operating Procedure (SOP) is to ensure UK uniformity in sample transport, in particular in relation to temperature control. FSAS aims to implement this SOP in full using the recommended cool box system or validated equivalent. This SOP is provided at Annex L. Centre for Environment, Fisheries and Aquaculture Science (Cefas) will advise on its full implementation and provide necessary equipment.

#### 8.3 FSAS

FSAS will report samples as required. It has been decided that RMP and AHA will be reported as Green, when on an open status, Yellow when on alert status and Red when on a closed status. This will be undertaken for each toxin. The public report will continue to be made available every Tuesday, with interim results being provided to the LFA on a daily basis. This guidance will be made available to all interested parties and on our website.

#### 8.4 Sample collection

It is felt that to meet our obligations under EC 882/2004 that the OC samples be verified by Sampling Officers (SO) of the LFA. Such a system working in cooperation with the harvesters will allow good, high quality sample return.

#### ANNEX C

## ALGAL TOXIN MONITORING AND SURVEILLANCE PROGRAMME SHELLFISH SAMPLE COLLECTION PROTOCOL

- 1 Shellfish samples should be collected from identified sites at the stated frequency.
- The sites and collection frequency may change depending upon the prevalence of algal toxins but any changes will be notified beforehand.
- Ideally, shellfish samples should be collected on Monday or Tuesday of each week and posted to Cefas. Flexibility for collection throughout the week is in place, however. Should you be unable to sample on these days, we request you contact the programme coordinator (Ben Stubbs) to discuss.
- 4 Shellfish sample size should be such that at least 200g of meat can be provided for the ASP, DSP and PSP assays. This is usually achieved by the following minimum numbers of suitable commercial size animals:

Rope Grown Mussels 100 animals (1 kilo) Shore Mussels 1½ kilo **Pacific Oysters** 30 Native Oysters 35 Cockles 2 kilo Queen Scallops 35 King Scallops 15 Razor Shells 20 50-100 Periwinkles (Littorina spp) Whelks (Buccinum spp) 5-10

Lobster single animals

Nephrops 6-12

Brown Crabs single animals

Green Crabs 6
Velvet Crabs 6
Otter Shells 15
Sand Gapers 10
Surf Clams 2 kilo
Dog Cockles 15

- Shellfish must be placed in the polythene bags provided and the bags tied with an air space above the shellfish to allow the animals to breathe. The sample submission form should be completed with the date of collection, site identification number and production area, name of collector, and other relevant data e.g. OS grid reference, state of tide, water temperature, weather conditions and the number of sample collection boxes remaining.
- The bagged sample and form should then be placed in the container provided along with frozen cool packs and foam. The box must be sealed with adhesive tape and a prepaid postage label attached before posting to Cefas, Weymouth Laboratory, Barrack Road, The Nothe, Weymouth, Dorset, DT4 8UB (for purposes of Royal Mail Special Delivery, we have been assigned the postcode DT4 8BF).

#### Sample Submission Form: Wild Pectinidae Biotoxin Monitoring Please ensure that samples are accompanied by this sheet and that all sections have been completed - thank you. Date of Collection from Processors: Name of LFA Officer: Contact Telephone Number: Name and Address of Premises: Premises Approval No.: Origin of Sample ie sea box no./area: Sample details (please tick box): Minimum requirement: Whole King Scallop (in shell) 30 Shucked King Scallop 30 White Meat Only King Scallop 30 50 Whole Queen Scallop (in shell) Shucked Queen Scallop (whole or adductor/gonad) 50 Adductor (white) meat of Queen Scallop 50 Other Information eg Dates of Harvesting: Date of Landing of Catch: Where Landed: Number of sample boxes remaining: (please circle) 5+ To be completed by Cefas

PLEASE ENSURE THAT COOL-PACKS ARE FROZEN BEFORE PUTTING IN SAMPLE BOX

Time of arrival:

Date of arrival:

Cefas Sample ID:

#### Sample Submission Form: Inshore Biotoxin Monitoring

Please ensure that samples are accompanied by this sheet and that <u>all</u> sections have been completed - thank you.

Name and Signature of Collector:					
Contact Telephone Number:					
	C	ef	as		
Production Area:					
Site Name:					
OS Grid Reference (eg NM 85812 29	534):		Pod no.:		
Species sampled: (enter in box below)		]		ox. number of	
Other information			*		
Number of sample boxes remaining: (please	1	2	3	4	5+
Other information  Number of sample boxes remaining: (please circle)  To be completed by Cefas	1	2	3	4	5+

#### **ANNEX D**

### Local food authority named contact officer details

LOCAL FOOD AUTHORITY	CONTACT OFFICER(S)	EMAIL	TELEPHONE	FAX
Argyll & Bute Council	Andrew MacLeod	andrew.macleod@argyllbute.gov.uk	01631 562125	01631 570861
Argyll & Bute Council	Alan Morrison	alan.morrison@argyll-bute.gov.uk	01546 604292	01546 604410
Argyll & Bute Council	Karen MacLeod	karen.macleod@argyll-bute.gov.uk	01546 604134	01546 606897
Argyll & Bute Council	Patrick Mackie	patrick.mackie@argyll-bute.gov.uk	01700 505339	01700 503331
Argyll & Bute Council	Christine Mclaughlin	Christine.mclaughlin@argyll- bute.gov.uk	01631 567920	01631 70861
Argyll & Bute Council	Ian MacKinnon	iain.mackinnon02@argyllbute.gov.uk	01631 567922	01631 567917
Argyll & Bute Council	William Mcquarrie	Sampling Officer		
Argyll & Bute Council	Ewan McDougal	Sampling Officer		
Argyll & Bute Council	Donald Campbell	Sampling Officer		
Dumfries & Galloway Council	David A Grant	EHHQ@dumgal.gov.uk	01557 330291	01557 331982
Dumfries & Galloway Council	Leslie C Paton	EHHQ@dumgal.gov.uk	01557 330291	01557 331982
Dumfries & Galloway Council	John Arthington	john.arthington@dumgal.gsx.gov.uk (Sampling Officer)		
East Lothian Council	Malcolm Elliott	melliott@eastlothian.gov.uk	01620 827918	01620 827233
East Lothian Council	George Fairgrieve	gfairgrieve@eastlothian.gov.uk	01620 827305	01620 827918

Edinburgh City Council	Colin Sibbald	colin.sibbald@edinburgh.gov.uk	0131 4695784	0131 4695849
Fife Council	John Lecyn	john.lecyn@fife.gov.uk	01592 417730	01592 417717
	Ronnie Vaughan	Ronnie.vaughan@fife.gov.uk (Sampling Officer)	01592 417746	
Highland Council Ross and Cromarty	Clifford Smith	clifford.smith@highland.gov.uk	01349 868498	01349 868594
Highland Council Ross and Cromarty	Sandy Fraser	sandy.fraser@highland.gov.uk	01862 812024	01862 812024
-	William Steven	bill.steven@highland.gov.uk (Sampling Officer)	01463 703964	
Highland Council Lochaber	Mark Phillips	mark.phillips@highland.gov.uk	01397 707013	01397 707009
	Stephen Lewis	Stephen.lewis@highland.gov.uk (Sampling Officer)	01397 707013	
Highland Council Sutherland	Chris Ratter	chris.ratter@highland.gov.uk	01862 812024	
	Sandy Fraser	sandy.fraser@highland.gov.uk (Sampling Officer)	01408 635324	
	Anne Grant	anne.grant4@highland.gov.uk (Sampling Officer)	01408 635326	
Highland Council Inverness	Alan Yates	alan.yates@highland.gov.uk	01463 702532	01463 702233
	William Steven	bill.steven@highland.gov.uk (Sampling Officer)	01463 703964	
	James Spence	hamish.spence@highland.gov.uk (Sampling Officer)	01463 703963	
Moray Council	James McLennan	james.mclennan@moray.gov.uk	01343 563360	01343 563483
North Ayrshire Council	Kevin McMunn	kmcmunn@north-ayrshire.gov.uk	01294 324355	01294 324360
North Ayrshire Council	Catherine Reilly	creilly@north-ayrshire.gov.uk	01294 324384	01294 324360
North Ayrshire Council	Francis Gemmel	FGemmell@north-ayrshire.gov.uk	0194 324358	01294 324360
North Ayrshire Council	Andrew Miller	andrew.miller@north-ayrshire.gov.uk	01294 324359	

Orknov Islands	Alan Tait	alan.tait@orkney.gov.uk	01856 873535	01856 87649
Orkney Islands Council	Alan Tall	alan.tait@orkney.gov.uk	extn 2808	01000 07049
Shetland Isles	Dawn Manson	dawn.manson@sic.shetland.gov.uk	01595 744831	01595 74480
Council				
Shetland Isles Council	Louise Moar	louise.moar@sic.shetland.gov.uk	01595 744857	01595 744802
Shetland Isles Council	George Williamson	George.williamson@nafc.uhi.ac.uk	01595 772313	
Shetland Isles Council	Sean Williamson	Sean.williamson@nafc.uhi.ac.uk	01595 772433	
Shetland Isles Council	Kathryn Winter	Kathryn.winter@nafc.uhi.ac.uk	01595 772313	
Shetland Isles Council	Marion Slater	Marion.slater@nafc.uhi.ac.uk		
South Ayrshire Council	Gerry Fallon	Gerry.fallon@south-ayrshire.gov.uk	01292 618222	01292 28875
South Ayrshire Council	Brian Lawrie	Brian.Lawrie@south-ayrshire.gov.uk (Sampling Officer)	01292 618222	01292 61635
South Ayrshire Council	Sabrina Kelly	Sampling Officer		
Western Isles Council (Lewis, Harris & Barra)	Colm Fraser	cfraser@cne-siar.gov.uk	01851 703773 x357	01851 709287
Western Isles Council (Benbecula)	Alistair MacEachen	amaceachen@cne-siar.gov.uk	01870 602425 x827	01870 60233
Western Isles Council (Stornoway)	Christine Schofield	cschofield@cne-siar.gov.uk	01851 709255	01851 70928
			1	

#### **ANNEX E**

#### INFORMATION CONCERNING TEMPORARY CLOSURE NOTICES

- 1. If the Notice is to apply on a specified future date, it will be effective as from midnight of that day. If the Notice is to apply on the day it is issued, it will come into force at the time of making and this should be stated on the Notice. TCNs should be made and apply within one working day of any actionable result.
- 2. Subject to territorial restrictions, a TCN can apply to any sea, estuarine or lagoon area containing natural deposits of shellfish or to other sites used for the cultivation of shellfish.
- 3. After making a Notice the LFA is required under paragraph C of Chapter II of Annex II of Regulation 854/2004 to inform affected parties as follows:
- in the case of a private laying a written notice should be served on every owner and tenant drawing their attention to the Notice made, giving reasons as to why it was made.
- in every other case, i.e. anywhere a public place is involved, the LFA shall put notices in the
  affected area and, in addition, may take other appropriate steps to publicise the Notice, e.g. local
  press. The notices used should draw attention to the fact that a TCN is in place (a copy of the
  Notice could be included) and give appropriate reasons.
- 4. In each case, the Notice must be brought to the attention of anybody likely to be affected by its implementation. This can be done by displaying warning notices in the affected area, the issue of a press release or by writing to the affected parties.
- 5. In all cases, a copy of the Notice and notice(s) should be sent to the LAFLEB by fax/email within 5 working days.
- 6. The TCN may cover 'any' shellfish. This means a TCN may cover a particular species or all species of shellfish.
- 7. The LFA will require to determine whether the notice should cover marine gastropods, echinoderms or tunicates.
- 8. The TCN should state clearly which shellfish are covered by the Notice. TCNs, or any associated publicity, may also clarify that certain shellfish and crustacea are not covered by the Notice.

#### **Temporary Closure Notice (TCN) MODEL NOTICE**

#### NOTICE OF TEMPORARY CLOSURE OF PRODUCTION AREA(S)

Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

#### Food Hygiene (Scotland) Regulations 2006 S.S.I. 2006/3

Pursuant to the power conferred on it by Article 6 of, and paragraph C of Chapter II of Annex II to the above EC Regulation, being satisfied that [the results of sampling show that the health standards for molluscs are exceeded] [there may be a risk to human health] –

As Competent Authority for the purposes of the above EC provision by virtue of regulation 4 of the Food Hygiene (Scotland) Regulations 2006 S.S.I. 2006/3 –

[Insert authority] has temporarily closed the production area identified in the Schedule to this notice for the production of [insert list of all affected species] by food business operators until further notice. <sup>2</sup>

[Insert official position of signatory] On behalf of the [insert authority]	Signed: 200[ ]	Dated this [ ] day of [ ]

<sup>&</sup>lt;sup>1</sup> Recent analysis of samples taken by [insert authority] from the affected area has shown that [insert animals] are affected by [insert problem].

<sup>[</sup>insert authority] will continue to take samples for analysis and keep its decision to close the area under review. To check the current status of the area you may contact [insert authority] by [insert preferred method of contact, e.g. telephone no.]

#### **SCHEDULE**

Area[s] in which the production of [insert list of all species affected] by food business operators is prohibited by reason of this Notice:

[Insert area] [Insert area]

Food business operators must not collect the affected animals from this area by any method, it is unsuitable for their production for health reasons and has been temporarily closed. For a food business operator to collect affected animals from the area that is temporarily closed amounts to the commission of a criminal offence under Regulation 17 of the Food Hygiene (Scotland) Regulations 2006

S.S.I. 2006/3. On conviction a fine or imprisonment for a term of up to two years or both may be imposed.

[PRIVATE INDIVIDUALS ARE STRONGLY ADVISED NOT TO GATHER [insert description of affected animals] FOR THEIR OWN CONSUMPTION FROM THE AFFECTED PRODUCTION AREA. THERE MAY BE A RISK TO HUMAN HEALTH IN DOING SO.]

#### **ANNEX G**

#### SUGGESTED TEXT FOR WARNING NOTICES FOR CASUAL GATHERERS

#### 'NATURALLY OCCURRING ALGAL POISON'

[Mussels/cockles/oysters/etc] taken from this beach as from the date of this notice should not be eaten.

They may be contaminated and therefore pose a risk to health.

For further information, contact:

**Environmental Health Department** 

Address

Tel

[Date of notice]'

#### ANNEX H

## ACTION FOLLOWING TRACING OF PRODUCT HARVESTED AFTER THE DATE OF SAMPLING

- 1. Measures must be taken where necessary to prevent consumption of shellfish landed after the date the positive sample was taken and already in public supply or in the processing/distribution chain.
- 2. The enforcement options which should be considered by the LFA on tracing product harvested after the date of a positive sample are:
- Redeposit the shellfish from where they were harvested this option is only really available if the shellfish have not been placed on the market and that the LFA has confidence that the product has been suitably controlled during any transport that has taken place.
- Allow product to market subject to satisfactory end product testing. This option would be considered best for occasions where the product has reached the final processor or handler. This testing could be undertaken by the harvester/processor or the LFA.
- Destroy the product. For example, if there was a very high PSP reading destruction might be the only option available.
- 3. If local industry will not co-operate voluntarily with the option above, the LFA should consider taking statutory enforcement action which may involve certifying the product as unfit under Regulation 27 of the Food Hygiene (Scotland) 2006 Regulations and seizure and detention of product under Section 9 of the Food Safety Act 1990. The LFA may consider it necessary to test the product to be able to conclude that it does not comply with these end product standards. Product which requires destruction must be destroyed as animal by product in an appropriate manner.
- 4. It is the view of the Agency that it would be reasonable to conclude that product harvested during the intervening period between the collection of the positive sample and the making of the TCN would be likely to be contaminated and may cause food poisoning, unless there is sufficient evidence to the contrary. The Agency would consider sufficient evidence to be sight of a fully acceptable risk assessment which should include, but not be confined to, end product test results. Where an FBO wishes to present evidence of suitable risk assessment/HACCP, they should provide these details within a timescale specified (the time allowed for this will depend upon the severity of the potential incident and the market situation for example). FSAS and the LFA will determine the suitability of this assessment. FBO's should of course have suitable risk assessment/HACCP in place already, however in light of this guidance and the fact that such evidence will be required quickly we would recommend that they ensure that these are fully up to date and in a condition for use at all times.
- 5. There may be occasions when, in consultation with the LFA, the Food Standards Agency Scotland might consider a Food Alert should be issued e.g. if product has already been sold to consumers and there is absence of a sufficient risk assessment from the business.

#### **ANNEX I**

#### MODEL TEMPORARY CLOSURE REVOCATION NOTICE

## The Food Hygiene (Scotland) Regulation 2006 TEMPORARY CLOSURE NOTICE - REVOCATION

Reference No	Date
To:	[proprietor of the business/harvester]
At:	[address of proprietor / harvester]
I am satisfied that the production area or SIN]	/ site identified in the Notice as [insert area name
Is now determined to be within the sta	tutory levels for algal toxins.
The Temporary Closure Notice relating	g to this area is therefore revoked and
harvesting of (spec	cies) at this site can now resume.
Signed:	(authorised officer)
Name:	Date:

#### **ANNEX J**

## FOOD STANDARDS AGENCY SCOTLAND CONTACT DETAILS FSAS, 6th Floor,

#### St Magnus House, 25 Guild Street, Aberdeen. AB41 6NJ

#### FSAS Local Authority Food Law Enforcement Branch CONTACT LIST

Name	Title	Tel.	Email	Ar	eas of work
Lorna Murray	Senior Enforcement Advisor Lead Officer - Official Controls	01224 285114	Lorna.Murray@foodstandards.gsi. gov.uk	•	Regulatory/ Enforcement Advice Official Controls co- ordination, management and contract management
Jackie McCann	Enforcement Support Officer	01224 288378	jackie.mccann@foodstandards.gsi .gov.uk	•	Regulatory/Enforcement assistance
Lisa Harper	Enforcement Support Officer	01224 288378	Lisa.Harper@foodstandards.gsi.g ov.uk	•	Regulatory/Enforcement assistance Communication with Local Food Authority and Harvesters/other stakeholders
Kirsten Black	Administrative Officer	01224 285510	kirsten.Black@foodstandards.gsi. gov.uk	•	Program administration and reporting of results
Graham Ewen	Administrative Officer	01224 288360	Graham.Eweo@foodstandards.gs i.gov.uk	•	Program administration and reporting of results

#### **ANNEX K**

#### LABORATORY CONTACT DETAILS

Cefas, HABS (Biotoxins Dept), Barrack Road, The Nothe, Weymouth, Dorset, DT4 8UB, UK. Advice of ASP, DSP and PSP sample analysis, Programme co-ordination and sampling equipment

Name	Title or Department	Telephone	E-mail Address
Myriam Algoet	Project Manager	T: 01305 206600 Fax: 01305 206601 01305 206696	Biotoxinmonitoring @Cefas .co.uk
Ben Stubbs	Deputy Project  Manager	01305 206713	

#### SAMS, Dunstaffnage, Marine Laboratory, Oban, Argyll, PA37 1QA.

Advise on all aspects of phytoplankton sampling

Name	Title or Department	Telephone	E-mail Address
		T:01631 559000	info@sams.ac.uk
		Fax: 01631 559001	
Keith Davidson	Microbial & Molecular Biology	01631 559256	kda@sams.ac.uk
Sarah Swan	Project Manager	01631 559223	scs@sams.ac.uk

#### **ANNEX L**

#### **UK-NRL**

TITLE:

STANDARD OPERATING PROCEDURE (SOP) FOR THE TRANSPORT, RECEPTION AND SHORT TERM STORAGE OF BIVALVE MOLLUSCS PRIOR TO TESTING FOR MARINE BIOTOXINS IN THE UK'S STATUTORY BIOTOXIN MONITORING PROGRAMMES

#### **Production Summary**

Author:	UK-NRL Network <sup>3</sup>
Reviewed by:	UK-NRL Network
Date:	May 02 2006
Issue Authorisation	UK-NRL for Marine Biotoxins <sup>4</sup>

#### **Distribution of copies**

Copy No:	Authorised recipient	Location
1 (Master)	Fiona Mackintosh	UK-NRL @ FRS
2	Susan Gallacher	UK-NRL @ FRS
3	Cowan Higgins	AFBI
4	Myriam Algoet	CEFAS
5	Kevin Hargin	FSA UK
6	Claudia Martins	FSA UK
7	Jacqui McElhiney	FSAS
8	Lorna Murray	FSAS
9	Kirsten Dunbar	FSANI
10	Michael Williams	Integrin
11	Wendy Higman	CEFAS
12	Louise Richens	CEFAS

#### **History of procedure**

Issue	Date issued	Changes
1	May 02 2006	

United Kingdom National Reference Laboratory Network

United Kingdom National Reference Laboratory for Marine Biotoxins (FRS Marine Laboratory, Aberdeen)

#### 1 INTRODUCTION

The SOP applies to bivalve molluscs, echinoderms, tunicates and gastropods to be tested for marine biotoxins listed in EU Regulation 853/2004 within the UK statutory biotoxins monitoring programme. It is based on recommendations of the UK-NRL Network Working Group on transport/storage for statutory biotoxin monitoring (6 and 7th October 2004). It aims to standardise storage conditions of shellfish samples during transport to the test laboratory and receipt at the laboratory. The SOP also aims to standardise short term sample storage requirements prior to testing.

The SOP sets out time and temperature criteria to ensure as far as possible, animals taken for analysis arrive at the laboratories in the best possible condition, and the possibility of the total toxin content changing during transport and storage is minimised.

To aid in regulation of temperature control the UK-NRL recommends use of Biotherm boxes for transport of shellfish (UK-NRL Transport Trials Report) where the time from harvest to receipt at the laboratory exceeds 12 hours. However, it is recognised that for some geographical locations less than 12 hours can elapse from sample collection to receipt at the laboratory, for some geographical locations, in which case use of coolboxes is adequate. Laboratories providing evidence that samples are received from specific sites within 12h of harvest may use coolboxes instead of Biotherm boxes for these sites.

Relevant instructions from this SOP should be included in sample collection documents issued to parties responsible for collection and packing of samples at the harvesting point.

- 2 EQUIPMENT
  Use of Biotherm boxes
- 2.1 Freezer at -20 C to -10 C
- 2.2 Biotherm 10L or 25L boxes, and validated summer kit (supplied by DGP Group). Prior to shellfish collection the cool packs provided with the summer kit (3 per Biotherm box) should be chilled in a freezer for a minimum of 24 hours.

#### Use of coolboxes

- 2.3 Freezer at -20 C to -10 C
- 2.4 Coolbox
- 2.5 Cool packs previously chilled in a freezer for a minimum of 24 hours. A sufficient number of coolpacks is required to ensure that in each coolbox, the sample(s) can be placed between 2 complete layers of coolpacks.

#### At the laboratory

- **2.6** Refrigerator at 2 C to 8 C (monitored)
- 2.7 Calibrated thermometer or calibrated temperature probe

#### 3. PREPARATION OF SAMPLES FOR TRANSPORT

- 3.1 Instructions from this section (sample preparation for transport) should be issued to authorities responsible for sample harvest and transport.
- 3.2 Laboratories providing evidence that samples from specific sites are received within 12h of harvest may use coolboxes for sample transport from those sites. An evaluation period should be in place to ensure samples do

not regularly exceed 12h delivery. The temperature upon receipt should also be recorded for further evaluation.

If more than 12h routinely elapses from sample collection to receipt at the laboratory, Biotherm boxes must be used and the UK-NRL notified of this change. .

#### **USING BIOTHERM BOXES**

- 3.4 Samples should be selected which have organoleptic characteristics associated with freshness and placed inside a polythene bag which is then put inside the Biotherm™ boxes along with 3 pre-frozen cool packs (see Fig. 1) with the spacers placed to prevent the sample coming into direct contact with coolpacks.
- 3.5 The pre-printed sample information sheet should be completed and placed inside a separate polythene bag and secured within the box.
- 3.6 Once correctly assembled secure the box lid with adhesive tape to prevent leakage and send *via* the delivery option requested by the test laboratory.

#### **USING COOLBOXES**

- 3.7 Samples should be selected which have organoleptic characteristics associated with freshness and should be placed inside a polythene bag which, in turn is wrapped in newspaper (or similar medium) and placed inside the coolbox between 2 layers of pre-frozen cool packs. Samples should not be frozen or placed in direct contact with ice packs. Newspaper (or similar medium) should be used as insulation between the samples and coolpacks.
- 3.8 The pre-printed sample information sheet should be completed and placed inside a polythene bag and secured within the box
- The coolbox lid should be secured in place with tape and delivered to the test laboratory to arrive no later than 12h after harvesting.

#### 4 DELIVERY AND RECEIPT

- **4.1** The sample should be delivered to the monitoring laboratory as soon as practical after collection with the aim that:
  - no longer than 48 hours should elapse between harvest and receipt at the test laboratory for samples transported using Biotherm boxes.
  - no longer than 12 hours should elapse between harvest and receipt at the test laboratory for samples transported using coolboxes.
- **4.2** Laboratory staff should check that samples arriving in coolboxes are from those sites where use of coolboxes is approved.
- 4.3 Samples from sites where Biotherm™ boxes have not been used and application of coolboxes has not been approved should not be processed unless specific instructions to the contrary have been given by the competent authority
- **4.4** Defective or materially damaged boxes should be withdrawn from circulation.
- 4.5 Samples should be received and logged according to each laboratory's relevant SOP recording the duration of the time elapsed since collection and the temperature of the sample mass.
- **4.6** Samples arriving in Biotherm boxes or coolboxes should be within a  $2-10^{\circ}$ C window at the time of receipt,

with the exception of those samples harvested from warm waters and transported to the laboratory within 4 hours of harvest (i.e. insufficient time for coolpacks to reduce temperature).

- **4.7** Evidence suggesting that the Biotherm<sup>™</sup> system or coolboxes are no longer performing satisfactorily (i.e. sample temperature regularly exceeds 2-10°C) should immediately be brought to the attention of the UK-NRL and the FSA.
- Any defects in the manner in which the Biotherm boxes/coolboxes have been packaged (insufficient cool packs, improper placement of cool packs relative to the sample mass) will be recorded. Persistent evidence of poor packaging should be bought to the attention of the responsible Local Authority / collection centre and the UK NRL.
- 4.9 Samples that fulfil the above requirements may be further processed providing they have organoleptic characteristics associated with freshness, including, and where appropriate, shells free of excessive dirt, an adequate response to percussion and normal amounts of intravalvular liquid. Samples which do not exhibit these organoleptic characteristics should not be analysed.
- **4.10** Any animals that are frozen, gaping or are severely damaged should not be included in homogenates.
- 4.11 Samples which exceed the specified transport period and temperature requirements may be analysed with the minimum of delay providing the organoleptic properties described above are met. The time from collection to receipt at laboratory and the recorded temperature must be noted alongside the reported analysis result.

#### 5 SHORT TERM STORAGE AT THE LABORATORY

- **5.1** Whole shellfish, shellfish homogenates and shellfish extracts should not be frozen prior to analysis.
- 5.2 Shellfish should be extracted and tested within the laboratory as soon as practical upon receipt. In cases where sample storage is unavoidable storage criteria which apply are defined on Table 1. Storage details should be recorded.

Table 1: Storage criteria for whole shellfish, homogenates and extracts at 2-8°C

Matrix	Conditions to apply upon storage at 2-8°C
Whole shellfish	Whole shellfish which meet the criteria of section 4.1 may be stored so that no longer than 72 hours elapses between sample harvest and sample extraction. For example: a) a sample which takes 24 hours to reach the laboratory may be stored for a further 48 hours in the laboratory b) a sample which takes 48 hours to reach the laboratory may be stored for only 24 hours in the laboratory.
Shellfish homogenates	Should not be stored prior to extraction
1% Tween extracts from freshly prepared homogenates for analysis of lipophilic toxins	May be stored for up to 3 days
50 % (v/v) aqueous methanol for ASP analysis	Should not be stored prior to analysis
Citrate buffer extract for ASP analysis	May be stored for a maximum of 5 days
0.1 M HCl extracts, at pH 2.5- 3.5 for PSP analysis	May be stored for a maximum of 5 days

#### **LITERATURE**

Recommendations of the first meeting of the UK-NRL Network Working Group on transport/storage for statutory biotoxins monitoring. Oct 2004

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004. Laying down specific hygiene rules for the food of animal origin (Official Journal of the European Union L 139 of 30 April 2004)

UK-NRL Transport Trials Summer 2005

Provision of data on the storage of okadaic acid, DTX-1 and DTX-2 in shellfish homogenate and 1% Tween solution at 4-8°C. CSL Update Report for the FSA, Dec 2004.