

**Protocol for the Collection and Transport
of Shellfish samples from England & Wales
for the purpose of Official Control Toxin Monitoring
of classified shellfish production areas under
Regulation EC 854/2004**

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1. INTRODUCTION

Regulation EC (No.) 854/2004 requires the monitoring of classified shellfish production areas, as part of the Competent Authority's official controls, to check for microbiological contamination, marine biotoxins and chemical contamination.

In England and Wales, the Food Standard Agency (FSA) is the Central Competent Authority with overall responsibility for the implementation and delivery of the shellfish official control monitoring programmes. Cefas is the contracted laboratory with delegated responsibility for the coordination of the toxin monitoring programme and the delivery of all associated shellfish and water testing. Local Enforcement Authorities (LEAs), the Competent Authorities, are responsible for collecting shellfish (and water) samples from the designated harvesting areas and sending these to Cefas for analysis. It is recognised that there may be exceptional situations where Food Business Operator (FBO) sampling may have to be considered. This should only be the case where the LEA is of the clear view that it cannot undertake sampling for reasons of either practicality or health and safety e.g. extreme difficulties in the timing of sampling and/or extremely long sampling runs. If an LEA deems there to be a production area that may meet the above exceptional criteria then agreement on the way forward should be discussed with the FSA as the CCA. Decisions will be made on a case-by-case basis.

All samples covered within the scope described in section 2 below should be collected in accordance with this protocol and from the monitoring points designated by the FSA, details of which are available on the Cefas website (<https://www.cefas.co.uk/cefas-data-hub/food-safety/classification-and-microbiological-monitoring/england-and-wales-classification-and-monitoring/current-sampling-plans/>). This protocol can be read in conjunction with the FSA 'Guide to shellfish sample collection' DVD¹, viewable at: <http://www.cefas.defra.gov.uk/our-science/animal-health-and-food-safety/food-safety/shellfish-partnership/guide-to-shellfish-sampling-protocols.aspx>.

2. SCOPE OF THIS DOCUMENT

Monitoring programme	England	Wales
	Not applicable ¹	
Toxins	X	X

1: Testing delivered by Starcross, Public Health England and Public Health Wales – see sampling protocol and sample submission form on [Cefas website](#)

Please note that a separate protocol for the collection of water samples required by Cefas for the monitoring of shellfish production areas for the presence of harmful phytoplankton is available from the [Cefas website](#).

¹ DVD produced by FSS but sampling guidance applicable to England & Wales

3. TIME OF SAMPLING

All samples should be collected at the frequency specified by the FSA monitoring plans and policies, unless sampling can be rescheduled by agreement or where circumstances are outside of the sampling officers' control.

Sampling officers should notify the Cefas programme co-ordinators (see details in section 11) of their **monthly sampling schedule before the start of each month or when additional sampling has been requested, before the end of each week.**

Sampling officers are requested to note the arrangements agreed with FSA for the submission and testing of samples around bank holidays and Christmas. These will be communicated to all at the start of each calendar year.

Shellfish samples should be collected at the stated frequency and in accordance with the FSA monitoring plan. In addition to the routine testing arrangements, and when shellfish testing is not weekly, additional shellfish samples will be requested by the FSA when either phytoplankton levels or flesh results reach or exceed the following agreed trigger levels:

Biotoxin produced	Phytoplankton species	Phytoplankton trigger level (in cells/litre)	Flesh trigger levels
PSP	<i>Alexandrium spp</i>	40	≥400 µg [STX eq.]/kg shellfish
OA/DTX/PTX	<i>Dinophysis & Phalochroma spp</i>	100	≥80 µg [OA eq.]/kg shellfish
OA/DTX	<i>Prorocentrum lima</i>	100	
AZA	<i>Azadinium & Amphidoma spp</i>	Not monitored for No trigger set	≥80 µg [AZA1 eq.]/kg shellfish
YTX	<i>Protoceratium reticulatum</i> <i>Lingulodinium polyedrum</i>	No trigger set	≥1.8 mg [YTX eq.]/kg shellfish
ASP	<i>Pseudo-nitzschia spp</i>	150,000	≥10 mg/ kg shellfish flesh

If samples have been found unsuitable/insufficient for analysis on receipt at the laboratory, additional sampling requirements will be notified to the sampling officers by the toxin programme co-ordinators.

Shellfish samples should ideally be collected on **Monday, Tuesday or Wednesday and posted to Cefas for reception on Tuesday to Friday.** Flexibility for collection and reception throughout the week is in place, however. Sampling officers unable to comply with the above specifications should contact the laboratory to discuss requirements. For contact information, please see section 11 of this protocol.

4. EQUIPMENT

The following equipment is required for shellfish sampling. Please contact the laboratory if you are running low on sampling equipment. For contact information please see the section at the end of this protocol:

- a. Food grade polythene bags
- b. Cable ties
- c. Cool box/Biotherm Box/Coleman Box
- d. Ice packs
- e. Insulating foam
- f. Spray water bottle
- g. Strong adhesive tape
- h. Return address labels
- i. Gloves or antibacterial wipes

The following equipment should also be available:

- a. Device for identification of fixed sampling points (e.g. GPS).
- b. Temperature measuring equipment.
- c. Scrubbing brush.
- d. Rulers/calipers.
- e. Colander or other draining vessel
- f. Absorbent paper towel
- g. Disinfectant (see section 12)

5. SAMPLING METHOD

Wherever possible, shellfish should be sampled by the method normally used for commercial harvesting as this can influence the degree of contamination.

Sampling location:

The Representative Monitoring Point (RMP) location (as stated in the sampling plan) should be used as the starting point to identify the position from which samples should be taken.

For consistency across the programmes, sampling officers are asked to use the same tolerances as those defined for E. coli RMPs around the agreed RMPs of the toxin monitoring programme.

Sampling officers must report the *actual* location of sampling to a 10m accuracy in Ordnance Survey grid reference format i.e. AB 1234 5678. A suitable GPS device or Ordnance survey 1:25,000 map should ideally be used for this purpose. Alternatively, if samples are taken offshore by boat then, instead of an OS map, an Admiralty Chart (or

similar) should be used with position recorded in Degrees and decimal minutes format i.e. 00° 00'.001N, 000° 00'.001W (or E as appropriate). Please record locations to 3 decimal places (as in the example above) and record which datum is used (OSGB 36 or WGS 84) as positional errors of up to 200m can occur if the incorrect datum is reported.

For sites where samples are, with FSA's agreement, collected by harvesters/industry for exceptional reasons, on behalf of and without direct supervision by an authorised sampling officer, the samples should be clearly marked as UNVERIFIED by ticking the box in the OS Grid reference section of the sample submission form. If known, the actual location of sampling should still be recorded.

6. SIZE OF INDIVIDUAL ANIMALS

Samples should only consist of animals that are within the normal commercial size range. Immature/juvenile animals may provide results that are unrepresentative of mature stock that will be harvested for commercial sale/human consumption. In circumstances where less mature stock is being commercially harvested for human consumption then samples of these smaller animals may be collected for analysis.

7. SAMPLE COMPOSITION

The following sample sizes (in terms of number of live animals by species or weight in shell) are recommended for submission for analysis (following NRL guidance):

Species	Toxin
	For 50g flesh ¹
King scallops (<i>Pecten maximus</i>)	12 to 15
Queen scallops (<i>Aequipecten opercularis</i>)	15 to 30
Oysters (<i>Crassostrea gigas</i> and <i>Ostrea edulis</i>)	12 to 18
Hard clams (<i>Mercenaria mercenaria</i>)	12 to 18
Manila clams (<i>Tapes philippinarum</i>)	18 to 35
Otter clams (<i>Lutraria lutraria</i>)	12 to 15
Palourdes (<i>Tapes decussatus</i>)	18 to 35
Surf clams (<i>Spisula solida</i>)	30 to 50
Sand Gapers (<i>Mya arenaria</i>)	N/A
Razor clams (<i>Ensis</i> spp.)	12 to 15
Rope grown mussels (<i>Mytilus</i> spp.)	15 to 30
Shore mussels (<i>Mytilus</i> spp.)	25 to 40
Cockles (<i>Cerastoderma edule</i>)	35 to 55 ²

Notes:

1. Min. 50g of flesh is required for all samples submitted for toxin analyses, regardless of the type of analysis required.
2. Where minimum landing sizes have been reduced, more individuals may be required.

Please note that open, gaping or damaged shells should not be included in the sample. Also note that the laboratories will need a minimum of 10 non moribund/dead animals to accept a sample as suitable for analysis. When this criterion cannot be met, the sample may be rejected on receipt at the laboratory. Where the shellfish show an unusually low yield or where morbidity may be an issue, please consider providing more shells/animals than those recommended above to ensure sufficient animals remain available for analysis.

8. PREPARATION AND PACKAGING OF SAMPLES

It is imperative that mud and sediment adhering to the shellfish is removed. This is best achieved by rinsing/scrubbing with fresh water of potable quality or seawater from the immediate area of sampling (to avoid contamination). Do **not** totally re-immerses the shellfish in water as this may cause them to open or introduce a source of microbial contamination. Allow to drain.

Shellfish must be placed inside a strong food grade plastic bag and the bag tied leaving some air space. A second bag may be used if required (in particular if the sample is likely to puncture the first plastic bag). The sample submission form should be completed. The bagged sample and form should then be placed in a second/third bag and resealed, then placed in the container provided along with frozen cool packs and foam. Freezer packs should not come into direct contact with the samples or sample bags.

After collection from the harvesting area, samples should be placed as soon as practically possible in the cool box provided by the laboratory and packed in accordance with this protocol. This should ensure that the sample is maintained at a temperature not exceeding 10°C. Care should be taken to ensure that the sample is not frozen.

Samples that do not comply with the packaging protocols may be rejected by the laboratory.

Method for packing Coleman boxes

Please note that two separate types of Coleman boxes are used by Cefas for the purpose of the programme covered by this protocol. Sampling officers must use the correct packing instructions for the boxes delivered to them, to ensure optimal performance of the boxes.

Coleman box model number 6216/6215

Prior to shellfish collection, the provided Campingaz M10 cool packs (6 per Coleman box) must be chilled in a freezer for a minimum of 24 hours.

Boxes of this type should be packed according to the diagram below:



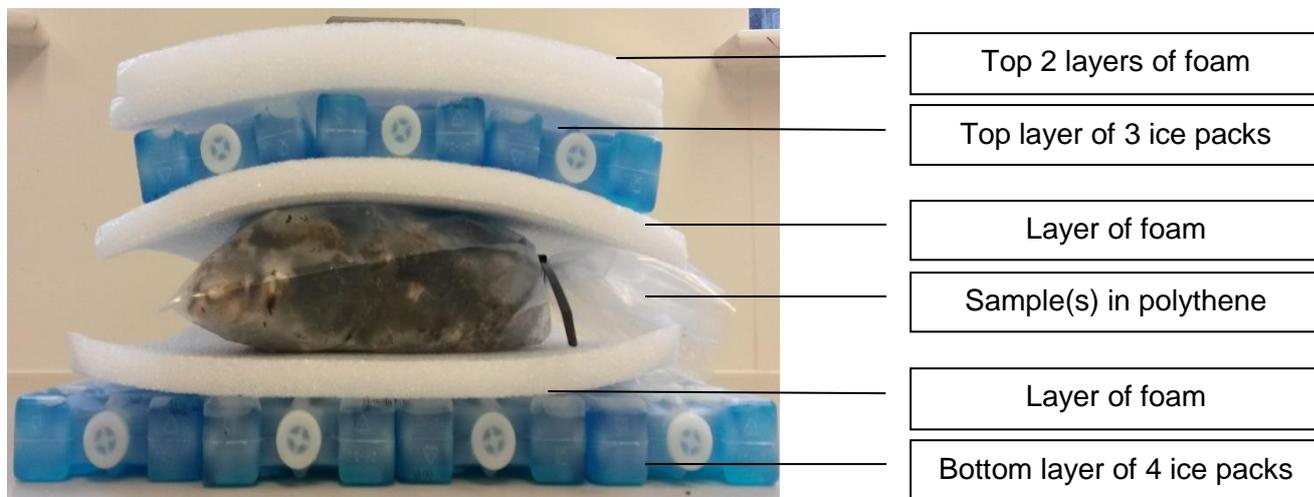
- Top 2 layers of foam
- Top layer of 3 ice packs
- Layer of foam
- Sample(s) in polythene
- Layer of foam
- Bottom layer of 3 ice packs

Coleman box model number 5877

Prior to shellfish collection, the provided Campingaz M10 cool packs (7 per Coleman box) must be chilled in a freezer for a minimum of 24 hours.

Boxes of this type should be packed according to the diagram below:





Care must be taken to correctly place the cool packs and foam spacers to ensure that the sample does not come into contact with the cool packs and freeze. **Frozen samples cannot be tested and will be rejected by the laboratory.**

Once correctly assembled and the relevant sample submission forms have been included, the box lid must be secured with adhesive tape to prevent leakage and a prepaid postage label attached before posting to Cefas. Shellfish samples sent using Royal Mail must be labelled as “**perishable**”, This is for compliance with Royal Mail labelling instructions. Please note that Royal Mail has defined specific conditions for the transport of “live creatures/animals”. These are not suitable for shellfish samples destined to testing. Sampling officers are therefore advised not to log/describe the samples as live creatures for the purpose of Royal Mail. “Perishable” labels should be affixed to the tape used to secure the transport box. Alternatively, please write on the tape using a marker pen.

The address of the sender must also be shown on the sample box. It is recommended that the sender’s address label is also affixed to the tape used to secure the box. Do not write or affix any label to the box itself.

Please note:

- If submitting multiple samples on any given day, it may be possible to place more than one sample in the Coleman box (packaged as above) providing the box can be securely sealed and the total weight of the package, including cool box, sample(s), cool packs and spacers does not exceed 10kg. If two/three samples do not fit securely into the box, or the total weight exceeds 10kg, samples **must** be sent in separate boxes. If packing more than one sample in one box, care must be taken to ensure that each bagged sample is correctly sealed and identified.
- **Incorrectly packaged or unidentified samples cannot be analysed by the laboratory.**

ID logos will be marked on each cool box. Please do not remove these as they are used as a log in/out system by laboratory staff responsible for replenishing your stocks of boxes.

Use of other coolboxes

Specific packing instructions and coolboxes will be issued to those authorities with whom the use of other coolboxes has been agreed.

Short term storage of samples

Samples should not be frozen. If short term storage (particularly overnight) prior to dispatch/delivery is necessary, samples should be stored at 3±2°C. Where short term storage is required, sampling officers will be required to record this and the temperature/duration of storage on the sample submission form.

9. SAMPLE TRANSPORT

Dispatch of samples to the laboratory should be undertaken as soon as practically possible after sampling. Samples should be delivered to the designated courier drop off point preferably on the day of sampling, in time for next day delivery to the laboratory. Samples should be sent to:

Monitoring programme	Location of classified production areas	
	England	Wales
<i>E. coli</i>	Not applicable ¹	
Toxins	Cefas, Weymouth	

1: Testing delivered by Starcross, Public Health England and Public Health Wales

Shellfish samples collected for toxin monitoring should be sent via Royal Mail Special Delivery (unless alternative courier arrangements have been agreed), using the relevant prepaid labels to:

Green or uncoded label – Toxins

Cefas (Defra)
Weymouth laboratory
BTX Dept
Barrack Rd, The Nothe
WEYMOUTH,
DT4 8UB

In case of emergency (for example in case of industrial action by Royal Mail staff), the alternative courier service will be either TNT or Parcelforce. Specific instructions will be provided to sampling contractors should contingency arrangements be required.

10. SAMPLE SUBMISSION FORM

As the sampling procedure is carried out, the Sample submission form must be completed. Blank Sample submission forms are provided to sampling officers and are also available on the [Cefas website](#).

An individual sample submission form must accompany each sample to the laboratory. The form must be completed in full and accurately. Incomplete or inaccurate submission forms may lead to the rejection of samples.

The following information must be recorded on the **Sample submission forms**:

- Details of site: production area, site name, SIN, Pod number, actual OS Grid reference
- Date and time of collection
- Method of collection
- Name and contact details of sampling officer
- Nature of sample: unverified
- Temperature*
- Storage of sample prior to dispatch
- Any other relevant information*

* See details below

Temperature:

Sampling officers should take the temperature of the surrounding seawater at the time of sampling and record this on the collection form. Where this is not possible (e.g. for inter-tidal shellfish sampled dry) the between-shellfish temperature of the sample should be recorded immediately after collection. To do this the temperature probe should be placed in the centre of the bagged shellfish sample. The temperature should be recorded on the **Sample submission form**.

Any other relevant information:

In addition to the information requested, sampling officers are asked to report unusual observations (e.g. weather, boating activity, dredging, animals in water, plankton bloom, etc.) which can help target investigations and possible remedial actions. Information on harvesting activity will also be useful.

11. CONTACT INFORMATION

Enquiries relating to the FSA monitoring programmes (including monitoring points, frequency of sampling, actions in case of breach of pre-defined levels) should be referred to the following FSA contacts:

Monitoring programmes	FSA contacts
Toxins	England: shellfishtoxins@food.gov.uk Rebecca Watts , Tel.0788854439 Rebecca.watts@food.gov.uk Wales: Kathryn Hughes , Tel. 02920 678924 Kathryn.Hughes@food.gov.uk

Sampling schedules, general queries or problems relating to sample collection/delivery/packaging/postage should be referred to Cefas Programme Co-ordinators:

Monitoring programmes	Cefas Programme Co-ordinators
Toxin Monitoring Programmes	Lewis Coates Tel. 01305 206744, Fax. 01305 206601 biotoxinmonitoring@cefas.co.uk Rachel Parks Tel. 01305 206755, Fax. 01305 206601 biotoxinmonitoring@cefas.co.uk

12. HEALTH, SAFETY & BIOSECURITY ADVICE

Sampling officers are asked to comply with the Health and Safety policies of their respective organisation. This includes compliance with all safety measures prescribed in risk assessments relevant to their travelling to the agreed sampling locations and the collection and handling of shellfish samples from such areas for the purpose of the FSA monitoring programmes. The drafting, implementation and review of all relevant H&S documentations are the responsibility of sampling contractors.

When undertaking sampling duties, sampling officers must be mindful of the risks of introduction or transfer of aquatic pathogens and invasive species to the areas being visited, through their sampling activities. Officers are asked to comply with minimum biosecurity measures such as cleaning and disinfection of instruments, equipment and

shoes/boots between sites and not driving/parking onto beaches or in close proximity to shellfish beds. All disposable items should be treated as clinical waste. Advice on suitable disinfectant and disinfection procedures are available from the fish health inspectorates (see details below). As a minimum, Cefas recommends the use of Virkon S or Virkon Aquatic S at 2% and with a minimum contact time of 15 min (or spray onto clean surface and leave to dry). A list of other suitable disinfectants is available at: <http://www.defra.gov.uk/aahm/guidance/disinfectant/list/>.

Sampling officers should also be mindful of the health status of the sites that they visit and schedule their visits to ensure that the risk of transfer of pathogens and invasive species from site to site is minimised. Details of sites under specific designations and for which specific movement controls do apply are available from the Fish Health Inspectorate (see below) and up to date lists and maps of designated areas are published on the following links: [aquatic animal health and movements page on Defra website](#)

It is recommended that sampling officers familiarise themselves with biosecurity plans operated by the farmers in the harvesting areas and with rules that apply to site visitors.

Where new risks of transfer of specific fish or shellfish pathogens are identified, the requirement for implementation of additional biosecurity measures will be discussed between the programme co-ordinators and the sampling officers as soon as reasonably practicable following notification by the relevant competent authorities for shellfish health.

Sampling officers wishing to transfer shellfish between sites for the purpose of the FSA official monitoring programmes should contact the Fish Health Inspectorate office (see below) and obtain written approval prior to any transfer taking place.

England and Wales
Fish Health Inspectorate Cefas Barrack Road The Nothe Weymouth Dorset DT4 8UB Tel: 01305 206700 Fax: 01305 206602 Email: fhi@cefas.co.uk

Change record

Version	Date released	Change
1	March 18	New protocol drawn up