Food Standards Agency protocol for the collection and transport of shellfish samples for the purpose of Official Control Monitoring of classified shellfish production areas in England & Wales

Marine biotoxins and chemical contaminants

FINAL Version 4

July 2022

For implementation from 01 August 2022

16 pages

Document classification:	Official
Document review date:	Not applicable
Date of issue of this version:	27/07/2022

1. INTRODUCTION

There is a current regulatory requirement to monitor classified shellfish production areas to check for microbiological contamination, marine biotoxins, harmful algae and chemical contaminants.

In England and Wales, the Food Standard Agency (FSA) is the Central Competent Authority (CCA) with overall responsibility for the implementation and delivery of the shellfish official control monitoring programmes. Cefas is the contracted laboratory with responsibility for the coordination of the toxin and chemical contaminants monitoring programme and the delivery of all associated shellfish and water testing (where relevant). Toxin testing is undertaken by Cefas in Weymouth and chemical contaminants testing by Fera in York.

Local Enforcement Authorities (LEAs), the Competent Authorities (CAs), are responsible for collecting shellfish (and water) samples from the designated representative monitoring points in harvesting areas and sending these to the Cefas & Fera laboratories for analysis.

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.

2. SCOPE OF THIS DOCUMENT

Table 1: Scope of this document

Monitoring programme	England & Wales
E. coli (microbiological monitoring)	No[1]
Toxins	Yes
Chemical contaminants	Yes

1: Testing delivered by other official laboratories designated by FSA – see generic sampling protocol and sample submission form on the Cefas website. Please consult with the appointed official laboratories for details of their submission forms.

This protocol is intended for use by authorised sampling officers (referred to as 'YOU' in this document), for the official control monitoring of shellfish production areas in England and Wales for the presence of harmful marine biotoxins and chemical contaminants. Please note that a separate protocol for the collection of water samples is available from on the Cefas website.

You should use this protocol in conjunction with the Cefas sample submission form which is available on the Cefas website. The submission form can be used for samples for both toxin and chemical contaminants monitoring – please tick the relevant section on the form.

3. TIME OF SAMPLING

You must collect samples at the frequency specified by the FSA monitoring plans and policies, unless sampling can be rescheduled by agreement or where circumstances are outside of your control.

a) Please note that where a sample is assessed as unsuitable by the laboratory or where a high result has been recorded, additional samples will be requested by Cefas. A sample may be recorded as unsuitable if, for example, it contains an insufficient number of live shells or insufficient weight (see section 7), shellfish have been frozen or they are dead on arrival at the laboratory.

You must comply with these requests, unless exceptional circumstances prevent the collection of these samples.

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

If you are unable to collect samples on the planned dates, please notify the Cefas programme co-ordinators with the reason and your revised sampling date.

Please be aware of the arrangements agreed with FSA for the submission and testing of samples around bank holidays and Christmas. Cefas will communicate these arrangements to all at the start of each calendar year. Late samples will not be accepted, unless discussed and agreed in advance with Cefas.

There are specific conditions which you must be aware of when collecting samples for programmes covered in this protocol:

Samples for chemical contaminant analyses:

- The FSA chemical contaminants programme is defined in October/November each year and communicated to LEAs and Fera by early December. The programme defines which area must be monitored and for which contaminants.
- Samples collected for chemical contaminant analysis must be collected in **January – March** as this is prior to shellfish spawning.
- Other ad-hoc collections may be required and arrangements for these will be communicated to LEAs in advance of any sampling being required.
- You should schedule your sample collection so that samples arrive at the Fera – York laboratory between **9am Tuesday to 3pm Thursday**.
- The volume of shellfish required for chemical contaminants analyses will be defined by the number and nature of tests requested by FSA (see Section 7).
- We may request a new sample if the sample you submitted was found to be unsuitable for analysis on receipt at the laboratory.

Samples for toxin analyses:

- You must collect samples at the frequencies specified by FSA.
- You may be required to collect additional samples when either phytoplankton levels or toxin results reach or exceed the agreed trigger levels shown in Table

2. Cefas will notify you if additional samples are required.

- You should ideally schedule your shellfish sample collection on a **Monday, Tuesday or Wednesday so that samples arrive at Cefas on Tuesday to Friday**. Flexibility for collection and receipt throughout the week is in place. If you are unable to comply with the above specifications, you should contact the laboratory to discuss your requirements. For contact information, please see section 11 of this protocol.
- We may request a new sample if the sample you submitted was found to be unsuitable for analysis on receipt at the laboratory.

Table 2: Set phytoplankton and toxin trigger levels

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

4. EQUIPMENT

The following equipment is required for shellfish sampling and will be provided to you by Cefas. Please contact Cefas if you are running low on equipment. You must return damaged transport boxes to Cefas.

a. Food grade polythene bags
b. Cable ties
c. Coolbox
d. Ice packs
e. Insulating foam
f. Spray water bottle
g. Strong adhesive tape
h. Return address labels and pre-paid delivery labels
i. Gloves or antibacterial wipes
j. Sample submission form

The following equipment should also be available (to be provided by LEAs):

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)
h. Pen

5. COLLECTION OF SAMPLES

Sampling method:
Wherever possible, you should collect a shellfish sample using the method normally used for commercial harvesting. Deviations from this must be discussed in advance with Cefas and the sampling plan will be amended. Please complete the method of collection section of the submission form.

Sampling location:
You must use the Representative Monitoring Point (RMP) location (as stated in the agreed sampling plans). FSA maintains the list of production areas currently classified on the FSA website and publishes updates when changes occur.

Sampling for toxin monitoring:

- You must collect your sample from the toxin RMP (or within the agreed *E.coli* tolerance for that point).

Sampling for chemical contaminants monitoring:

- The annual FSA chemical contaminants programme which FSA specifies in November/December each year provides details of the monitoring points or areas which must be sampled. Where other ad-hoc monitoring is agreed, the details of the monitoring points/areas will be provided by FSA.
- You must collect your sample from the specified RMP (or within the agreed *E.coli* tolerance for that point).

You will need to confirm on the sample submission form that you have complied with the protocol and that the sampling meets the above requirements. If you cannot comply with the sampling requirements for your toxin or chemical contaminants samples (for example, because of no harvesting activity, lack of stock, access issue), you must inform the Cefas programme co-ordinators. Discussions will take place with FSA so that monitoring arrangements can be amended and the sampling plan updated. This should take place before you collect a sample from the affected area.

Recording of actual sampling location:
You must record your *actual* location of sampling to a 10m accuracy in Ordnance Survey national grid reference (NGR) 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 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 indicate which datum is used (OSGB 36 or WGS 84) as positional errors of up to 200m can occur if the incorrect datum is reported.

6. SIZE OF INDIVIDUAL ANIMALS

The shellfish you collect must only comprise animals that are within normal commercial size range. Immature, juvenile, old or excessively large animals may provide results that are unrepresentative of mature stock that will be harvested for commercial sale/human consumption and should therefore be avoided.

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

A minimum sample size (in terms of number of live animals by species or weight in shell) is required for analysis. This is summarised in Table 3 below.

You must not use open, gaping or damaged shells in your sample. Also note that the laboratories will need a minimum of ten live animals to accept a sample as suitable for analysis. If this criterion cannot be met, the sample will 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 or animals than those recommended below to ensure sufficient animals remain available for analysis.

Table 3: Minimum sample size (in terms of number of live animals by species or weight in shell) recommended for submission for each type of analysis

Shellfish species	Toxin - to provide 50g flesh[1]	Chemical Contaminants – to provide 100g flesh[2]	Chemical Contaminants – to provide 500g flesh[3]
King scallops (*Pecten maximus*)	12 to 15	12 to 15	50 to 70
Queen scallops (*Aequipecten opercularis*)	15 to 30	20	80 to 100
Oysters (*Crassostrea gigas* or *Ostrea edulis*)	12 to 18	20	80 to 100
Hard clams (*Mercenaria mercenaria*)	12 to 18	20	80 to 100
Manila clams (*Tapes philippinarum*)	18 to 35	16 to 25	80 to 125
Otter clams (*Lutraria lutraria*)	12 to 15	12 to 15	50 to 70
Pullet carpet shell (*Venerupis senegalensis*)	20 to 25	40 to 50	100 to 140
Palourdes or carpet shell clams (*Tapes decussatus or Venerupis decussata*)	18 to 35	16 to 25	80 to 125

Surf clams (*Spisula solida*)	30 to 50	16 to 25 or 1 kg shells	80 to 125
Sand Gapers (*Mya arenaria*)	N/A	10 to 15	50 to 70
Razor clams (*Ensis* spp.)	12 to 15	10 to 15	50 to 70
Rope grown mussels (*Mytilus* spp.)	15 to 30	60 or 600g shells	300 or 3kg shells
Shore mussels (*Mytilus* spp.)	25 to 40	80 or 800g shells	400 or 4kg shells
Cockles (*Cerastoderma edule*)	35 to 55[4]	100 or 600g shells	500 or 3 kg shells

Notes:

1. Minimum 50g of flesh is required for all samples submitted for toxin analyses, regardless of the type of analysis required.
2. Minimum 100g of flesh is required for heavy metals or PAHs testing.
3. Minimum 500g of flesh is required for a full suite of chemical contaminants testing (heavy metals, PAHs and PCBs or dioxins) or PCBs and dioxins testing alone.
4. Where minimum landing sizes have been reduced, more individuals may be required.

8. PREPARATION AND PACKAGING OF SAMPLES

You must follow this guidance to prepare each of your shellfish samples:

1. Collect enough shellfish of the correct size to satisfy the requirement for one or more samples to be collected from the site.
2. Remove the mud and sediment adhering to the shellfish. To do this, rinse or scrub the shellfish with fresh water of potable quality or seawater from the immediate area of sampling.
3. Allow to drain.
4. Ensure that if samples are required for more than one analysis, you prepare, bag and label separate samples for each set of analyses. To do this, place the shellfish inside a strong food grade plastic bag (see below for further details). Place the first bag in a second bag if the sample is likely to puncture the first plastic bag.
5. Using a permanent marker pen, label each bag with the origin of the sample (site name) and fill in the sample submission form.
6. Sign, date and add your name to the form.
7. Securely attach the form to the correct sample bag (ideally the bagged sample and form should be placed in a second/third bag and resealed). Samples which are not correctly labelled will be rejected by the laboratory. You may place the submission form in a small, sealed plastic bag to help keep it clean/dry.
8. Where required, place the labelled bagged sample in a temporary container to promote the cooling of the sample. This may be required when the location of sampling makes the immediate use of a validated cool box difficult or impractical. For example, if out on extensive mud flats or on a small boat etc. In such cases, it would be acceptable to place samples for a short period of time (up to 4 hours) in a more easily portable non-validated container prior to packing in a validated cool box for final transport to the laboratory. The temporary storage container should promote cooling of the sample. For example, a ruck sack, bag or box with

cool packs where necessary (e.g. in summer) suitably separated so as not to come into direct contact with the shellfish should be adequate. Use insulating material (for example newspaper) to ensure that samples do not come into direct contact with the coolpacks and freeze.

9. As soon as practically possible after collection from the harvesting area, place the sample(s) in the cool box provided by the laboratory and pack the box in accordance with this protocol (see below). This should ensure that samples are maintained at a temperature not exceeding 10°C. Care must be taken to correctly place the coolpacks 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.**
10. Once correctly packed, secure the box lid with adhesive tape to prevent leakage/sample loss.
11. Attach a prepaid postage label before posting to the relevant laboratory. Shellfish samples sent using Royal Mail must be labelled as "**perishable**", to comply with Royal Mail labelling rules. 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. Affix a sender's address label to the tape used to secure the sample box. Do not write on the box or affix any label to the box itself.
12. Follow the instructions listed in Section 9 to send the samples to the correct laboratory.

Re-immersion of shellfish after collection from the monitoring point:

You **must not** re-immerse shellfish in water (for example for short-term storage) once you have collected them from the monitoring point. This may cause the shellfish to open or introduce a source of contamination.

Method for packing of coolboxes:

Please note that two separate types of Coleman boxes and the Igloo Profile 16 box are used by Cefas for the purpose of the programmes covered by this protocol. You must use the correct packing instructions for the boxes delivered to you, to ensure optimal performance of the boxes.

Coleman box model number 6216/6215 and Igloo Profile 16 box:

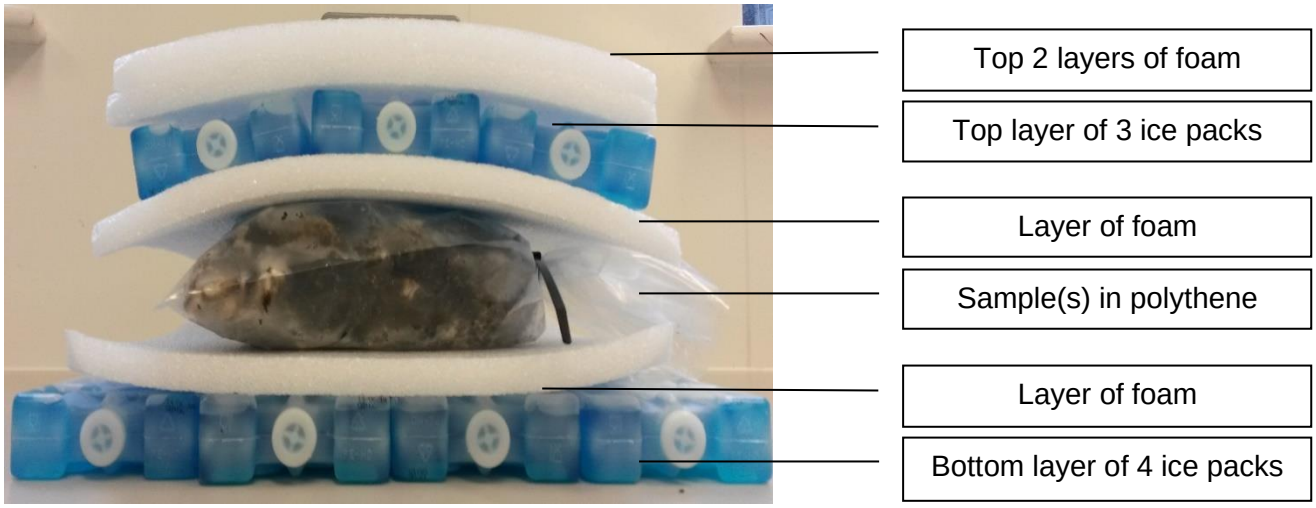
Prior to shellfish collection, the provided Campingaz M10 cool packs (**6** per box) must be chilled in a freezer for a minimum of 24 hours.

Boxes of these types should be packed according to the diagram below:

<u>Coleman box model number 5877:</u>

Prior to shellfish collection, the provided Campingaz M10 cool packs (**7** per 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:



You must be carefully when slotting the cool packs and foam spacers 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.**

Please note:

- If you submit multiple samples on any given day, it may be possible to place more than one sample in the coolbox (packaged as above) providing the box can be securely sealed and the total weight of the box (including sample(s), cool packs and spacers) does not exceed 10kg. If you cannot fit two/three samples securely into the box, or the total weight exceeds 10kg, you must send these samples in separate boxes. When packing more than one sample per box, you must ensure that each bagged sample is correctly sealed and identified.
- The volumes of shellfish required for chemical contaminants analyses are much greater than for toxin analyses. This means that some samples are likely to have to be split between 2 if not 3 boxes per sample. When this is required, you must ensure that all boxes are accompanied by a completed submission form marked 1 out of 3, 2 out of 3, ...
- **Incorrectly packaged or unidentified samples cannot be analysed by the laboratory.**

Each coolbox is marked with an ID logo. Please do not remove these as they are used as a logging system by laboratory staff responsible for replenishing your stock of boxes.

Use of other coolboxes:

Cefas will issue specific packing instructions and coolboxes to those authorities with whom the use of these coolboxes has been agreed.

Short term storage of samples prior to dispatch to laboratories:

There may be times when you cannot make the cut-off time for sample dispatch on the day of sample collection. In those circumstances, you should store the samples overnight prior to dispatch the following day and keep them in their Coleman or Igloo box, packed as described in the above section. You must not store samples in home appliances. Samples must not be frozen.

The following day, the samples should be re-packed with new coolpacks immediately before final box sealing and posting/transfer to the laboratory in the morning.

Where short term storage has been required, you must record the temperature (prior to repacking) and duration of storage on the sample submission form.

9. SAMPLE TRANSPORT

You must dispatch your prepared samples to the correct laboratory as soon as practically possible after sampling. Samples should be sent using Royal Mail Special Delivery (unless alternative courier arrangements have been agreed) to the following laboratories:

- Toxins samples: Cefas Weymouth
- Chemical contaminants samples: Fera York

See section 8. for situations when you may be able to store samples prior to dispatch/delivery.

Samples destined for Cefas, Weymouth: Samples should be sent using the relevant prepaid labels to:

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

Response License with special delivery license number NAT24456/PB1

Samples destined for Fera, York: Samples should be sent using the relevant prepaid labels to:

FAO Sean Panton,
Fera Science Limited,
York Biotech Campus
Sand Hutton,
YORK, North Yorkshire
YO41 1LZ
Please note that old address labels may be used up until new labels are issued.

In case of emergency (for example in case of industrial action by Royal Mail or Post Office), the alternative courier service will be either TNT or Parcelforce. Cefas will advise you of the revised transport arrangements if contingency measures are required.

There may also be times when emergency situations affect laboratories and when samples need to be directed to an alternative testing laboratory. Cefas will advise you of the revised arrangements if such emergency arises.

10. SAMPLE SUBMISSION FORM

An individual sample submission form must accompany each sample to the laboratory. You must complete the form in full and accurately. Incomplete or inaccurate submission forms may lead to the rejection of samples. Blank Sample submission forms are provided to sampling officers and are also available on the Cefas website.

You must record the following information on the **Sample submission form**:

- Production area, site name, Cefas Bed ID, actual location of sampling (OS Grid reference)
- Date and time of collection
- Method of collection
- Name and contact details of sampling officer
- Temperature*
- Storage of sample prior to dispatch
- Any other relevant information*

* See details below

Temperature:
You should take the temperature of the surrounding seawater at the time of sampling. 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. Record the temperature on the submission form.

Any other relevant information:
In addition to the information requested, you should 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 would also be useful.

When filling in the sample submission form:

- **Please use black ink and capital letters, where possible.**
- **All dates must be recorded as dd/mm/20yy and times in 24h clock.**
- **All OS NGR must be recorded to 10 m accuracy minimum (e.g. NS12345678)**
- **All temperatures must be recorded in °C.**

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:

FSA contacts
England: shellfish@food.gov.uk **Wales**: shellfish.wales@food.gov.uk

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**
Chemical Contaminants	myriam.algoet@cefas.co.uk
Toxins	biotoxinmonitoring@cefas.co.uk

Sampling schedules (and their updates when changes have been agreed or made on the day of collection) must be submitted to the following distribution list:

- Toxin samples: biotoxinmonitoring@cefas.co.uk,
- Chemical contaminants samples: sean.panton@fera.co.uk, myriam.algoet@cefas.co.uk

12. HEALTH, SAFETY & BIOSECURITY ADVICE

You must comply with the Health and Safety policies and procedures of your organisation. This includes compliance with all safety measures prescribed in risk assessments relevant to you 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 the Competent Authority.

When undertaking sampling duties, you must be mindful of the risks of introduction or transfer of aquatic pathogens and invasive species to the areas being visited, through your sampling activities. You must comply with minimum biosecurity measures such as cleaning and disinfection of instruments, equipment and shoes/boots between sites and you must not drive/park 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 Cefas Fish Health Inspectorate (FHI) (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/.

You should also be mindful of the health status of the sites that you visit and schedule your 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 Cefas FHI 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 you familiarise yourself 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 with you as soon as reasonably practicable, following notification by the Cefas FHI.

If you wish to transfer shellfish between sites for the purpose of the FSA official control monitoring programmes, you must contact the Cefas FHI and obtain written approval prior to any transfer taking place.

For further advice on biosecurity measures, please contact:

Fish Health Inspectorate
Cefas
Barrack Road
The Nothe
Weymouth
Dorset DT4 8UB
Tel: 01305 206700
Email: fish.health.inspectorate@cefas.co.uk

Change record

Version	Date released	Change
1	March 2018	New protocol released
2	June 2020	Remove reference to EU regulation Igloo Profile 16 added to transport box details Added requirement for actual sample location for samples collected by FBO Royal Mail license number added to delivery details Update to links throughout document Minor editing updates to text in all sections
3	Dec 2020	Addition of sampling for chemical contaminants monitoring to scope of protocol and update throughout the document to specify requirements for this sampling Document updated throughout to comply with Accessibility Laws and list of abbreviations added Document title amended
4	July 2022	Further update to text format to conform to accessibility guidance Removed reference to FSS DVD, now archived Update to format of Table 2 to remove merged cells Update to section 5 to include: • reference to collection of information about method of sampling • update to sampling location specifications for toxin and chemical contaminants samples • new reference to confirmation of compliance with sampling plan when filling in the submission form and what to do if the sampling plan cannot be adhered to. Change to formatting of Table 3 and notes to Table 3 Update to laboratories, FHI and FSA contact details in Sections 9 & 11

List of abbreviations used in this document:

CA:	Competent Authority
CCA:	Central Competent Authority
Cefas:	Centre for Environment Fisheries and Aquaculture Science
Fera:	Fera Science Limited
FBO:	Food Business Operator
FSA:	Food Standards Agency
GPS:	Global positioning system
Lat/Long:	Latitude and Longitude coordinates
LEA:	Local enforcement authority
Min.:	Minimum
OC:	Official control
PAHs:	polycyclic aromatic hydrocarbons
PCBs:	polychlorinated biphenyls
RMP:	Representative monitoring point