Food Standards Scotland protocol for appointed sampling officers for the collection and transport of shellfish samples for the purpose of Official Control Monitoring of classified shellfish production areas in Scotland

Version 4 FINAL
For implementation from 31 August 2020

26 pages

Document prepared by:	Cefas, SSQC, Fera, HMMH
Document quality checked by:	Myriam Algoet, Lesley Bickerstaff, Lewis Coates, Michelle Price-Hayward, May-June 2020
Document approved by:	Karen Litster, Cefas Project Manager Graham Ewen, FSS Operations Manager
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1. INTRODUCTION

Current laws require that classified shellfish production areas are monitored for microbiological contamination, marine biotoxins, harmful algae and chemical contamination. This forms part of an official control monitoring programme. In Scotland, Food Standards Scotland is the Competent Authority with responsibility for the implementation and delivery of the shellfish official control monitoring programme. Cefas is the laboratory contracted by FSS to co-ordinate this programme, arrange the collection of samples and deliver the required testing. Under current arrangements, the HMMH (Scotland) Ltd is responsible for sample collection and the transport of the samples to the laboratory is arranged by the laboratories responsible for testing. The only exception to this is Shetland where samples for *E.coli* monitoring are hand delivered to the laboratory by HMMH.

The laboratories currently responsible for testing are:

- **Cefas** – all toxin testing,
- **Cefas** - *E.coli* testing (Scotland other than Shetland and Orkney)
- **SSQC** – *E.coli* testing (Shetland & Orkney)
- **Fera** – all chemical contaminants testing
- **SAMS** – all water monitoring for harmful phytoplankton

Official control shellfish samples must be collected by authorised sampling officers. This defines a '**verified' sample**. The only exception to this rule will be for specific sites in Scotland where the collection of unverified samples by a harvester on behalf of the authorised sampling officer has been agreed between FSS, HMMH and Cefas and complies with the conditions further specified in section 5.

Samples collected by Industry may fall in two categories:

1. A '**verified from shore' sample** is defined as a sample collected by a harvester but where collection from the agreed monitoring point is observed by an authorised sampling officer from the shore. Note that from the date of implementation of this protocol, HMMH will record the location of the point of verification from shore.
2. An '**unverified' sample** is defined as a sample collected by a harvester from the monitoring point but when the authorised sampling officer cannot observe this happening. In most cases, this will be because of the remoteness of the monitoring point or distance from any vantage point.

The definitions of verified, unverified and verified from shore used in this protocol are those prescribed by FSS as the Competent Authority, for the purpose of the Scottish official control shellfish monitoring programme.

All samples covered within the scope described in section 2 below must be collected in accordance with this protocol and from the monitoring points designated by FSS, details of which are available from FSS. This protocol can be read in conjunction with FSS 'Guide to shellfish sample collection' DVD.

Samples which fail to meet the requirements of this protocol will not be accepted by the laboratories.

This version of the protocol (and version 3 of the Cefas shellfish sample submission form) is for implementation for samples collected from Monday 31 August 2020. Given that a number of changes have been made to the protocol and submission form, a short transition period will be implemented to ensure that all familiarise themselves with these changes. Full compliance with the protocol and use of the new submission form only is expected from Monday 28 September 2020. Please note that a revised Industry sample collection protocol (Version 3) and Industry sample submission form (Version 4) are also implemented from the same dates.

2. SCOPE OF THIS DOCUMENT

Table 1: Scope of this document

Monitoring programme	Scotland
E. coli (microbiological monitoring)	yes
Toxins	yes
Chemical contaminants	yes

This protocol is intended for use by appointed HMMH sampling officers collecting verified samples or handed over verified from shore/unverified samples collected by Industry. A separate protocol for the collection of shellfish and water samples by Industry is available from the Shellfish Partnership page of the Cefas website.

Please note that a separate protocol for the collection of water samples is available from the Shellfish Partnership page of the Cefas website. This protocol is for use by sampling officers for the monitoring of shellfish production areas for the presence of harmful phytoplankton.

3. TIME OF SAMPLING

All samples should be collected at the frequency specified by FSS monitoring plans and policies, unless sampling can be rescheduled by agreement or where circumstances are outside of the sampling officers' control. 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 the laboratories. You must comply with these requests, unless exceptional circumstances prevent the collection of these additional samples.

Where industry support is required to access sites, you must liaise with the harvesters to agree a suitable time when sampling can take place and to draw up your sampling plans. Industry have been advised that rescheduling of samples will not be accepted unless agreed in advance with HMMH.

To enable the laboratory to plan work for the forthcoming week, HMMH sample collection managers should email their **shellfish sampling schedule** each week to the

designated laboratory co-ordinators (see section 11) **by 3pm Friday** of the preceding week. The schedule should specify the day when each shellfish sample is due for collection.

It is noted that unforeseen events (weather, issue with access to site due to industry boat breakdown/staff illness) may force a change to the agreed weekly schedule and may result in last minute cancellation of sampling. Where samples are collected by Industry or Industry are assisting you by providing access to site, Industry have been asked to provide you with as much notice as possible of any change request (ideally min 24h). Where changes to the weekly plan can be agreed, you will need to confirm the new arrangements to Industry and the laboratories co-ordinators before sampling is due (preferably by email either the evening before or first thing in the morning). Should further changes to the day's schedule be required, you must make every effort to notify the laboratories. Industry have been made aware that changes to the sampling schedule will be subject to sampling officers' availability.

Please note that whilst laboratories will endeavour to accept changes to the weekly schedule, there may be times when staff/lab availability is restricted. This may lead to delays in sample processing. Where laboratory capacities are exceeded, samples will be stored at the laboratory and processed the next working day (subject to sample conditions being acceptable) so a delay in results in possible. Temporary storage by the sampling officer is allowable if delays prevent the samples from being posted or from being accepted by SSQC on the day of collection.

Please be aware of the arrangements agreed with FSS for the submission and testing of samples around bank holidays and Christmas. These are communicated 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 specific programmes:

Samples for microbiology (*E.coli*) testing:

- You must collect these samples, where practical, on as random a basis as possible with respect to likely influencing environmental factors e.g. tidal state, rainfall, wind etc. to avoid introducing any bias to the results.
- The frequency of testing of each site is specified by FSS and indicated on the classification listing which they maintain and publish on the FSS website.
- We may request additional samples from a classified area. This may be because the previous sample was rejected on arrival at the laboratory or because of a high result requiring further investigations. When required, this will be notified to you by Cefas.
- **You must schedule your collections so that shellfish samples for this programme arrive at the laboratories (Cefas *E.coli* Testing Laboratory or SSQC– see details below) after 7 am Monday, Tuesday, Wednesday and no later than 3 pm Thursday each week (excluding bank holidays or other days when the laboratories may be closed). Samples may be submitted on Friday if agreed in advance.** If you are unable to arrange for arrival at the laboratory within this timeframe, please contact the relevant laboratory (see contact information in section 11 of this protocol).

- **Shellfish samples from Orkney should be collected on Sunday, Monday, Tuesday or Wednesday to comply with the transport procedures specified in section 9.**
- If you collect samples between 07:45 and 09:00am and submit these to Cefas, we ask that you notify us. This will best be done by sending a text message providing details of area sampled, time and date of sampling to 07919 696857. This will help the laboratory ensure that staff are available to receipt these samples and limit the risk of samples exceeding the maximum 48h allowance for time elapsed between sample collection and start of test.
- Please note that if you collect samples before 07:45am and you are sending these on to Cefas, there is a risk that these samples will be rejected on arrival at the laboratory if they are delayed in the post. This is because they will then exceed the maximum 48h allowance for time elapsed between sample collection and start of test. It is noted that sampling at such time may not be avoidable but where possible, samples should be collected later to reduce the risks of rejection.

Samples for toxin analyses:

- You must collect these samples at the frequency specified by FSS and in accordance with the routine sampling schedule set out by Cefas for each toxin pod.
- We may ask you to collect additional samples. When required, this will be notified by Cefas when either phytoplankton levels or flesh results reach or exceed the agreed trigger levels shown in Table 2.

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	
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*	50,000	≥10 mg/ kg shellfish flesh

- We may also request additional samples if the previous sample you submitted was found to be unsuitable/insufficient for analysis on receipt at the laboratory We will notify you directly.
- You should schedule your sample collection for this programme, ideally on **Monday, Tuesday or Wednesday so that they arrive at Cefas Tuesday to Friday**. Flexibility for collection and reception throughout the week is in place, however so if you are unable to comply with the above specifications, please contact the laboratory to discuss your requirements (see contact information in

section 11 of this protocol).

Samples for chemical contaminant analysis:

- The FSS chemical contaminants programme is defined in October/November each year and communicated to HMMH 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
- 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 FSS (see Section 7).

4. EQUIPMENT

Collection by sampling officers:

The following equipment is required for shellfish sampling and will be provided by the laboratories. Please contact them if you are running low on equipment. For contact information please see the section at the end of this protocol:

a. Food grade polythene bags
b. Cable ties
c. Coolboxes
d. Ice packs
e. Insulating foam
f. Spray water bottle
g. Strong adhesive tape
h. Return address labels
i. Gloves or antibacterial wipes
j. GPS have been loaned by Cefas to HMMH sampling officers

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

a. Thermometer
b. Scrubbing brush
c. Rulers/calipers
d. Colander or other draining vessel
e. Absorbent paper towel
f. Disinfectant (see section 12)
g. Safety equipment as per HMMH risk and Coshh assessments

Collection by Industry on behalf of sampling officers:

When samples are collected by industry, on behalf of the sampling officer, the following equipment will need to be provided to the industry collector by HMMH:

a. Food grade polythene bags
b. Cable ties
c. Industry sample submission form (please note that a blank template of this form is available on the Cefas website)

Industry will be expected to provide the rest including GPS/plotter/Nautical charts; thermometer; cool box/bag for temporary storage; disinfectant for industry own use (see Industry protocol on the Cefas website for details)

5. SAMPLING METHOD

Wherever possible, you should collect a shellfish sample using the method normally used for commercial harvesting as this can influence the degree of microbial contamination.

Sampling location:
You must use the FSS Representative Monitoring Point (RMP) or Representative Monitoring Zone (RMZ) location as the starting point to identifying the position from which samples should be taken. FSS maintains the list of production areas currently classified, dormant, provisionally classified or in pre-classification status and circulates updates when changes occur. A list of the current RMP/RMZ list is available on the FSS website and should be used by HMMH to plan sampling activities.

If sampling at a monitoring point listed by FSS is no longer possible (no harvesting activity, lack of stock, access issue), you must inform the Cefas programme co-ordinator. Discussions will take place with FSS so that monitoring arrangements can be amended and the RMP/RMZ list updated.

If you are aware that a harvester wishes to suspend harvesting in an area (>3 weeks), then please advise them to contact FSS direct to agree monitoring arrangements. FSS will then confirm these with Cefas and HMMH.

For sampling for microbiological monitoring, you must collect from the *E.coli* RMP or within the tolerance set around this RMP as shown on FSS classification list. If sufficient shellfish of the required size are not available within the area prescribed by the tolerance, you must contact Cefas so that a revised tolerance or alternative sampling location can be considered.

Where a Representative Monitoring Zone (RMZ) is given in the sampling plan, you must collect the sample from within the boundaries of the zone.

In many cases, the *E.coli* RMP will also be the RMP for toxin and chemical contaminants monitoring but not always. Please refer to the FSS classification list for details of the RMPs for these programmes. For consistency across the programmes, you must use, where possible, the same tolerances around the agreed RMPs of the toxin or chemical contaminant monitoring programmes. Where this is not possible, you may collect from another point within the boundaries of the production area for the purpose of the toxin and chemical contaminants programmes.

Samples collected outside of the RMP tolerance/RMZ (Ecoli samples) or out of the boundaries of the area (other samples) will not be rejected but discussions will subsequently take place between HMMH and Cefas/FSS to understand why this is occurring and to try and address it to prevent further occurrences.

Recording of actual sampling location:

- **Verified samples**: you must report the *actual* location of sampling to a **10m accuracy** in Ordnance Survey national grid reference (NGR) format i.e. **AB 1234 5678**. A GPS device must be used for this purpose. To achieve the maximum level of accuracy the WAAS/EGNOS option must be enabled.
- **Samples collected by industry**: the collector must fill in an Industry sample submission form for each sample they collect and hand this over to you together with the sample. You must ensure that you have blank forms available to hand out to collectors.
    - Where a GPS is available to the boat operator, they must provide details of actual sampling location as described above.
    - When no GPS is available, Industry can use a plotter or an Admiralty Chart (or similar) and the location of sampling must be recorded in degrees and decimal minutes format i.e. 00°00.001'N, 00° 00.001'W (or E as appropriate) or in degrees, minutes and seconds format i.e. 00°00'01''N, 00°00'01''W (or E as appropriate). It is important that the format of the latitude and longitude position is recorded accurately. If the position is provided by the operator for unverified or verified from shore samples in another format (e.g. decimal degrees), this should be noted on the sample submission form. For example:
        - a location in degrees and decimal minutes is: 54°59.062'N, 5°2.132'W.
        - The same location recorded in degrees, min, sec is: 54°59'3.73''N, 5°2'7.9''W.
        - And the same location recorded in decimal degrees is: 54.98437, -5.03553

      For samples where the location is provided in latitude and longitude format, you must convert this position to the OS national grid reference format and write this on your sample submission form. The online converter nearby.org.uk must be used to convert the coordinates. Screenshots of this converter & examples of use are shown in Appendix 1.

Recording of location of verification from shore:

- **Verified from shore samples**: you must report the *actual* location of the vantage point from which you verify Industry sampling activity to a 10m accuracy in Ordnance Survey national grid reference (NGR) format i.e. AB 1234 5678. A GPS device must be used for this purpose. To achieve the maximum level of accuracy the WAAS/EGNOS option must be enabled. The time of the observation must also be noted.

Exceptional situations where sampling by industry for official control purposes may be authorised:

FSS recognises that there are situations where industry sampling may have to be considered for the purpose of the Scottish shellfish official control monitoring. To allow industry sampling, you must be of the clear view that you cannot undertake sampling for reasons of either practicality or health and safety.

Practicality reasons could be:

- extreme difficulties in the timing of sampling (e.g. short notice through necessity of specific weather, environmental conditions that mean fitting in with sampling officer work schedules is impractical, harvest times which authorised sampling officers cannot reasonably be expected to meet) or
- extremely long sampling runs. This will most likely occur in sites conforming to the following definition of '*Remote area*':

An area where no human or animal sources had been shown to impact on the fishery in the sanitary survey and where no potential changes to sources have been identified during the annual review process. An offshore bivalve shellfishery (≥5 km from shore) not impacted by long sea outfalls is an example of a remote area.

The use of specialist equipment such as dredges (for example oyster dredges), mechanical winches (for example as used in rope mussel fisheries) is not in itself grounds for industry lone sampling as it may be quite possible for you to supervise or observe the industry operating such equipment to take the sample. Similarly, it may also be possible for you to accompany an industry operator on a boat where diver-gathered sampling may be necessary. Each of these scenarios have been employed under the programme in Scotland and have worked successfully.

Health and safety reasons could be:

- From 09th July 2018, Cefas and FSS request that sampling officers only board vessels that show a valid small vessel certificate issued by the Maritime and Coastguard Agency (MCA) (or other authorised certifying authority) ("coded vessel"), as per the requirements of MCA Code of Practice for the safety of small workboats or pilot boats (workboat code) or MGN280 (M), and are maintained to this MCA standard by the operator and are suitable insured. These codes are applicable to vessels of up to 24m load line length which are engaged at sea in commercial activities; where larger vessels are used for sample collection, compliance with the MCA code of practice(s) relevant to these vessels will be required.
- From this date, you must request from the industry evidence of coding or dispensation from the MCA and compliance with the MCA code for each vessel made available to sampling officers. You must keep a record of this evidence.
- Where it has been established that the vessel is suitably coded or dispensed from coding, you will undertake a succinct check of the vessel safety before boarding, in accordance with HMMH's vessel safety checklist. This check will be a quick confirmation of vessel safety. Where all checks are satisfactory, you will be authorised to board the vessel and undertake verified sampling. You will not be allowed to board the vessels if the safety check cannot be completed or if they reveal that the vessel does not meet minimum safety requirements in accordance with the checklist.
- Working with the industry, HMMH have established a list of sites from which verified sample collection should be the norm or alternatively where onshore verification can be organised. Unverified samples collected by the industry and handed over to sampling officers will be accepted only if no suitable coded vessel is available and no onshore verification by sampling officer can be implemented for the site.
- For the following, *E.coli* samples, investigation samples collected following

possible human illness and toxin samples collected in order to achieve a 2nd negative result prior to reopening of an area, the expectation will remain that these will be verified samples collected by sampling officers (from suitably coded vessels) or collected by harvesters with collection verified from the shore by sampling officers. This is subject to suitably coded vessels being available.

The nature of the sample (unverified (that is a sample that is collected by harvesters, on behalf of and without direct supervision by an authorised sampling officer) or verified from the shore (that is a sample that is collected by harvesters and collection from the RMP is observed by an authorised sampling officer from the shore)) must be recorded on the sample submission form by filling in the relevant section of that form. Actual co-ordinates must be provided for all samples. For unverified or verified from shore samples, this information is provided by Industry on the Industry submission form. You must not accept any samples provided without co-ordinates or submitted with forms showing pre-printed locations.

In summary, if the taking of samples by the appointed sampling officer is not possible, then the next consideration should be officer supervision of the industry taking the sample. Only in the exceptional situations outlined above, could industry take the OC samples unsupervised. Ultimately the decision rests with FSS as the Competent Authority.

Unless exceptional circumstances, unverified samples must be collected at the point of landing. You will be requested to provide a justification for collections other than at point of landing (to be recorded on the sample submission form).

Specific considerations for the collection of razor clams:

Following adoption of the Razor Clams (Prohibition on Fishing and landing (Scotland) order 2017 ((Scottish Statutory Instrument 2017/49) (https://www.legislation.gov.uk/ssi/2017/419/pdfs/ssi_20170419_en.pdf), you must ensure that for the duration of the Scottish electrofishing on razor clams trial, sample of razor clams are only collected using vessels that have been issued a formal derogation to participate in the trial by Marine Scotland Science and only at times when the trial is live and fishing is permitted by Marine Scotland Science. A list of approved vessels has been provided to HMMH and is updated when required.

6. SIZE OF INDIVIDUAL ANIMALS

The shellfish you collect for the sample must be 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

We need you to collect a minimum sample size (in terms of number of live animals by species or weight in shell) 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 non moribund or dead 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	E.coli	Toxin - to provide 50g flesh[1]	Chemical Contaminants – to provide 500g flesh[2]	Chemical Contaminants – to provide 100g flesh[3]
King scallops (*Pecten maximus*)	12 to 15	12 to 15	50 to 70	12 to 15
Queen scallops (*Aequipecten opercularis*)	15 to 30	15 to 30	80 to 100	20
Oysters (*Crassostrea gigas* and *Ostrea edulis*)	12 to 18	12 to 18	80 to 100	20
Hard clams (*Mercenaria mercenaria*)	12 to 18	12 to 18	80 to 100	20
Manila clams (*Tapes philippinarum*)	18 to 35	18 to 35	80 to 125	16 to 25
Otter clams (*Lutraria lutraria*)	12 to 18	12 to 15	50 to 70	12 to 15
Palourdes (*Tapes decussatus*)	18 to 35	18 to 35	80 to 125	16 to 25
Surf clams (*Spisula solida*)	30 to 50	30 to 50	80 to 125	16 to 25 or 1 kg shells
Sand Gapers (*Mya arenaria*)	12 to 18	N/A	50 to 70	10 to 15
Razor clams (*Ensis* spp.)	12 to 18	12 to 15	50 to 70	10 to 15
Rope grown mussels (*Mytilus* spp.)	15 to 30	15 to 30	300 or 3kg shells	60 or 600g shells
Shore mussels (*Mytilus* spp.)	N/A	25 to 40	400 or 4kg shells	80 or 800g shells
Cockles (*Cerastoderma edule*)	35 to 55	35 to 55[4]	500 or 3 kg shells	100 or 600g shells

Notes:

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

Other species:	**E.coli**
Abalone (*Haliotis* spp.)	12-18
Purple sea urchins (*Paracentrotus lividus*. up to 7cm diameter)	50-60
Common sea-urchins (*Echinus esculentus*, up to 20 cm diameter)	12-15
Green sea-urchins (*Psammechinus miliaris*, up to 11 cm diameter)	35-55

8. PREPARATION AND PACKAGING OF SAMPLES

Preparation of unverified and verified from shore samples collected by Industry:
Please see the protocol for collection of shellfish by Industry for details of the preparation of samples collected by Industry. This protocol is available on the Cefas website.
Under this protocol, Industry will:

- Collect, prepare, bag and clearly label shellfish samples for the purpose of the FSS programme, from the RMP/RMZ specified by FSS and as agreed with you. They will take and bag & label separate samples for toxin, microbiological and chemical analyses. They must attach an industry sample submission form to each sample and ensure it is completely in full and accurately.
- Place the labelled bagged sample(s) in a temporary storage container promoting the cooling of the sample whilst the sample is in their possession.
- Hand over the samples to you as quickly as possible after collection to ensure that you have time to finish preparing the samples, complete the paperwork and pack the samples for dispatch to the laboratories on that day.

You will:

- Measure the temperature of the shellfish sample when handed over to you and record this on your sample submission form. This is to provide the laboratory with additional information on the conditions of the sample prior to shipping.
- Fill in a Cefas submission form for each unverified/VFS sample you accept, filling in the unverified/VFS section and general sections of the form**.** This form must be attached to the sample, together with the Industry form.
- **Check the submission form provided by Industry. You must ask Industry to complete the form if some details are missing. You must not accept a sample without a completed, accurate and signed Industry sample submission form. The form must show the correct details for the sample, including the actual location of the sample and not a pre-printed location. You must not correct Industry forms.**
- Pack the sample(s) in accordance with Cefas sampling and transport protocol (Follow points 11 to 13 of the guidance below for preparation of verified samples) and
- Send these samples to the testing laboratories.
- You must be personally handed the sample by an Industry representative. You must not accept samples left unattended; you must not arrange for samples to be left unattended before you can collect them.

Please note:

- Handover of samples by Industry will be in person (no unattended samples) and Industry must make themselves available in person to answer any query you may have on the samples or forms you are handed over.
- Overnight storage of samples by Industry is allowable for razor and surf clams as it is noted that harvesting may take place at night or at weekends and return to harbour at times when sampling officers may not be available. In this case, the samples must be stored by Industry in their closed bag (to avoid cross contamination), in a secured (to avoid tampering of samples) cold storage (at a temperature of 2 to 10°C) and handed over to you at a time that you arrange.

Preparation of Verified samples:

You must follow this guidance to prepare your shellfish samples:

1. Collect enough suitable shellfish 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 toxin, microbiological and chemical analyses. To do this, place the shellfish inside a strong food grade plastic bag (blue for *E. coli* samples and clear for toxins samples; any colour for chemical contaminants) and tie the bag leaving some air space. 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 Cefas sample submission form, circling at the top of the form what type of testing the sample(s) is/are for.
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 sampling officers.
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[1]*. 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
9. Use insulating material (for example newspaper) to ensure that samples do not come into direct contact with the coolpacks and freeze. Frozen samples will be rejected by sampling officers.
10. 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 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**

[1] *The NRL for microbiological contaminant in bivalve shellfish has carried out a significant body of work in this area, to underpin the time-temperature criteria used for E. coli testing purposes in the UK for shellfish classification purposes. This data, derived over numerous laboratory studies, as well as previous published work in this area indicated that E. coli concentrations do not significantly deviate under short-term conditions of moderate warming (up to 20°C), however longer term temperature abuse may impact recovery of E. coli from bivalve shellfish tissues*

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

11. Once correctly packed, secure the box lid with adhesive tape to prevent leakage and 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.
12. 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.

Re-immersion of shellfish post collection from the monitoring point

You or Industry **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 microbial contamination.

Method for packing of coolboxes

Please note that two separate types of Coleman boxes and the Igloo profile 16 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.

Packing of 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:

Top 2 layers of foam

Top layer of 3 ice packs

Layer of foam

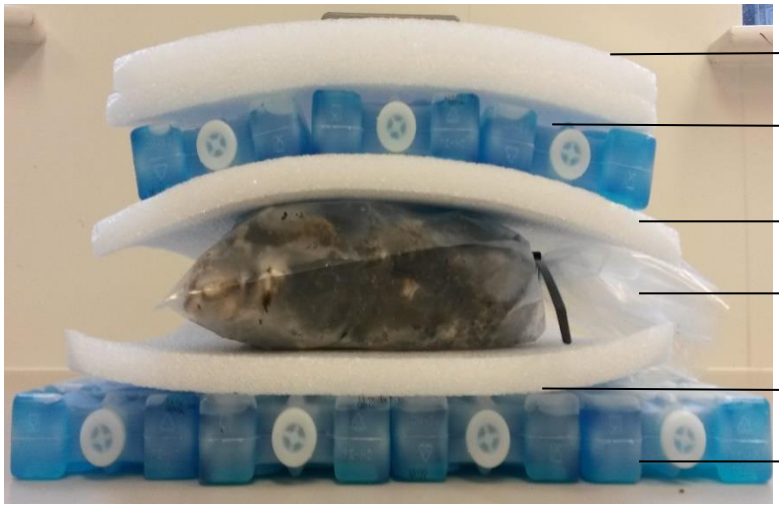
Sample(s) in polythene

Layer of foam

Bottom layer of 3 ice packs

Coleman box model number 5877

The boxes may be used for biotoxin and/or chemical contaminants analyses **BUT not E. coli samples as they will not maintain sufficient temperature control over 48h**. 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:



Top 2 layers of foam

Top layer of 3 ice packs

Layer of foam

Sample(s) in polythene

Layer of foam

Bottom layer of 4 ice packs

Please note:

- If submitting multiple samples on any given day, it is 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 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.

- Submitting *E.coli* and toxin samples to Cefas: Cefas has sourced suitable labels and bag markers to allow toxin and *E.coli* samples to be placed in the same box. Green cable ties should be used to tie bags containing shellfish for toxins testing and yellow cable ties should be used to tie bags containing shellfish for *E.coli* testing. Clear plastic bags should be used to package shellfish for toxins testing and blue plastic bags should be used to package samples for *E.coli* testing. The type of testing required for the samples in the box should be marked on the outside of the box for boxes that contain samples for toxins and E. coli testing, by placing a tick next to the relevant 'T' for toxins and/or 'EC' for *E.coli* on the box label. Clear cable ties should not be used for these samples.
- The volumes of shellfish required for chemical contaminants analyses are much greater than for toxin or E. coli 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, 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.**

Short term storage of samples

There may be times when you are unable to send samples on the day of collection. If you have to store samples overnight prior to dispatch/delivery, you must keep the samples in a correctly packed validated coolbox. You must not store samples in your own appliances. Samples must not be frozen.

The samples should then be re-packed with new icepacks 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)/duration of storage on the sample submission form.

9. SAMPLE TRANSPORT

You must dispatch samples to the laboratories as soon as practically possible after sampling. For the purposes of the monitoring programmes sampling locations have been designated as either **NOT REMOTE** or **REMOTE**. Remote areas are defined by Royal Mail special delivery terms and conditions. HMMH have be advised of the status of each production area and will be informed if this changes.

Samples from areas designated as NOT REMOTE

Samples should be delivered to the designated courier drop off point in time for next day delivery to the laboratory.

Samples from areas designated as REMOTE

For sampling locations with agreed **REMOTE** designation, samples must be delivered to the designated courier drop off point in time for dispatch on the day of sampling or following day, for arrival at the laboratory on the next day.

Specific note relating to samples for *E.coli* testing: Samples from areas designated as NOT REMOTE should arrive at the laboratory in order that analysis can be commenced within 24 hours of collection. Samples from REMOTE areas must arrive at the laboratory in order that analysis can be commenced within 48 hours of collection. Samples cannot be tested if the time elapsed between collection and onset of analysis exceeds 48 hours and these samples will be rejected on arrival at the laboratory.

Samples should be sent to the following laboratories:

- *E.coli* samples from Scotland other than Shetland and Orkney: Cefas Weymouth
- *E.coli* samples from Shetland and Orkney: SSQC LTD, Shetland
- Toxins samples: Cefas Weymouth
- Chemical contaminants samples: Fera York

Samples destined for SSQC Ltd, Shetland

Shellfish samples from Shetland should be hand delivered to SSQC Ltd (see address below). Samples from Orkney should be handed over to Streamline at Kirkwall in time for loading onto the Tuesday pm or Thursday pm (seasonal) Northlink sailings to Lerwick. The sampling officer must notify the laboratory of the sailing used so that laboratory staff can arrange the collection of the sample from Lerwick.

Samples should be addressed to:

SSQC Ltd,
Port Arthur,
SCALLOWAY,
Shetland, ZE1 0UN

Samples destined for Cefas, Weymouth:

Shellfish samples should be sent via Royal Mail Special Delivery (unless alternative courier arrangements have been agreed), using the relevant prepaid labels (marked with a tick next to ‘T’ for toxins samples and/or a tick next to ‘EC’ for E. coli samples) to:

Shellfish Microbiology and BTX
Cefas Weymouth laboratory
Barrack Rd,
WEYMOUTH, Dorset
DT4 8UB

Please note that old address labels may be used up until new labels are issued. In this case, write ‘EC’ and/or BTX’ on the shipping label accordingly if the box contains E. coli and/or Biotoxin samples so that they can be directed to the correct laboratory on arrival at Cefas.

Samples destined for Fera, York:

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

FAO Sean Panton/Liz Greene,
Fera Science Limited,
National Agri-Food Innovation Campus

Sand Hutton,
YORK,
North Yorkshire, YO41 1LZ

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. We will advise you of the revised transport arrangements if contingency measures are required.

10. SAMPLE SUBMISSION FORM

Unverified/verified from shore samples: each sample collected by Industry must be accompanied by an Industry sample submission form, completed in full and accurately by the industry collector and signed. The template for this form is available on the Shellfish Partnership page of the Cefas website. **Sampling officers are asked not to accept samples if not accompanied by a fully completed, accurate and signed form. The form must include the actual location of the sample (not a pre-printed location).**

All samples: You must fill in a Cefas Sample submission form for each sample that you submit**.** Blank Sample submission forms are provided to sampling officers and are also available on Shellfish Partnership page of the Cefas website. The form must be completed in full and accurately. Incomplete or inaccurate submission forms may lead to the rejection of samples.

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

- Sample testing required; *E.coli*, toxins or chemical contaminants
- Details of site: production area, site name, SIN, Pod number, actual OS Grid reference
- Date and time of collection (date must be as dd/mm/yy and time in 24h clock)
- Method of collection (for verified samples only). (please note that samples should be collected in a way that is as representative as possible of normal harvesting conditions. The sampling method may impact on the level of contamination of the bivalves and information on sampling practice should be considered during analysis of historical monitoring results in subsequent surveys or reviews. Please note that the option “hand-picked” should be ticked when samples are collected from a sampling box or when shellfish are manually removed from a shellfish line)
- Your name and contact details
- Nature of sample: verified, verified from shore, unverified and reason why the sample was not verified.
- For sites verified from shore: your location of when verifying and time when sampling was verified.
- The date and time when the verified from shore/unverified sample was handed over to you
- Temperature*
- Storage of sample prior to dispatch
- Specific details for *E.coli* samples*
- Date of last/next harvesting if known. If this information is not known, leave blank

on the form. This information will support discussions with FSS and local authorities about follow up monitoring should a high result be recorded with the sample.
- Any other relevant information*

* See details below

Temperature:

- Verified samples: You must 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.
- Unverified and verified from shore samples: the same measurement will be requested from Industry for all samples that they collect. In addition, you must measure the between-shellfish temperature for all VFS/unverified samples at the time they are handed to you. To do this the temperature probe should be placed in the centre of the bagged shellfish sample.
- The temperature (and for industry samples the time when it was taken) should be recorded on the **Sample submission form**.

Additional details for samples submitted for *E.coli* testing:

- Where you/Industry is asked to collect an additional sample for example for further dilution testing, you should tick the relevant box to indicate a **resample**.
- Where you/Industry is asked to submit a sample from a site undergoing classification, you should tick the relevant box on the **Sample submission form**.

Any other relevant information:

- In addition to the information requested, you must 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.
- For razor samples: you must provide the name and licence number (PLN) of the vessel used to collect these samples to verify that these were acquired in compliance with the new legislation on razor clam fishing.

11. CONTACT INFORMATION

Enquiries relating to the delivery of the FSS monitoring programmes (including monitoring points, frequency of sampling, actions in case of breach of pre-defined levels, general queries or problems relating to sampling) should be referred to the Cefas Programme Co-ordinators listed in Table 4.

Table 4: Name and contact details of the Cefas programme co-ordinators responsible for the delivery of the *E.coli*, toxins and chemical contaminants programmes

Monitoring programmes	Cefas Programme Co-ordinators
***E. coli* Monitoring Programme**	**Michelle Price Hayward** Tel. 01305 206627, Fax. 01305 206601 michelle.price-hayward@cefas.co.uk copied to mailbox: ecoliscotland@cefas.co.uk
Chemical Contaminant Monitoring Programme	**Myriam Algoet** Tel. 01305 206696, Fax. 01305 206601 myriam.algoet@cefas.co.uk
Toxin Monitoring Programme	**Lewis Coates** Tel. 01305 206744, Fax. 01305 206601 biotoxinmonitoring@cefas.co.uk or Toxin laboratory Tel. 01305 206600

Weekly sampling schedules (and their updates when changes have been agreed) must be submitted to the following generic email addresses: biotoxinmonitoring@cefas.co.uk, microlab@ssqc.co.uk, toxicalgae@sams.ac.uk, liz.greene@fera.co.uk, ecoliscotland@cefas.co.uk

Enquiries relating to sample collection/delivery should be submitted to the laboratories' contact listed in Table 5.

Table 5: Name and contact details of laboratory staff dealing with sample collection/delivery enquiries for each of FSS programmes.

Specific logistic & lab enquiries relating to:	Laboratory contact
***E. coli* samples for Cefas, Weymouth**	**Lesley Bickerstaff** Tel. 01305 206697, Fax. 01305 206601 lesley.bickerstaff@cefas.co.uk copied to mailbox: ecoliscotland@cefas.co.uk
***E. coli* samples for SSQC Ltd, Shetland**	**Jennifer Blyth** Tel. 01595 772443, Fax. 01595 880746 jennifer@ssqc.co.uk
Toxin samples for Cefas, Weymouth	**Lewis Coates** see details in above table
Chemical contaminants samples for Fera, York	**Sean Panton** Tel. 01904 462387 Sean.panton@fera.co.uk **Liz Greene** Tel. 01904 462387; liz.greene@fera.co.uk **For packaging/postage enquiries only, please contact: Myriam Algoet, Cefas (see details above)**

12. HEALTH, SAFETY & BIOSECURITY ADVICE

You must comply with the HMMH Health and Safety policies and procedures. 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 FSS monitoring programmes. The drafting, implementation and review of all relevant H&S documentations are the responsibility of HMMH.

You must comply with Government advice and restrictions on COVID19. Industry have been asked to do the same.

When undertaking sampling duties, you must be mindful of the risks of introduction or transfer of aquatic pathogens and invasive species to the areas you visit, 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 not driving/parking onto beaches or in close proximity to shellfish beds. All disposable items must be treated as clinical waste. Advice on suitable disinfectant and disinfection procedures are available from Marine Scotland Science (MSS). As a minimum, MMS recommends removing all organic matter (e.g. mud) from PPE and equipment surfaces, followed by the application of Virkon S or Virkon Aquatic S at 2% and with a minimum contact time of 10 min (or spray onto clean surface and leave to dry). You can find a list of other suitable disinfectants at: http://www.defra.gov.uk/aahm/guidance/disinfectant/list/.

You must 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. We will advise you when new designations are published. You can also find details of sites under specific designations and for which specific movement controls do apply by contacting MMS. MMS maintains up to date lists and maps of designated areas on the following links: notifiable diseases page on the Scottish Government website

You must familiarise yourself with biosecurity plans operated by operators in each harvesting area 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 Cefas programme co-ordinators and HMMH as soon as reasonably practicable following notification by Marine Scotland Science.

If you wish to transfer shellfish between sites for the purpose of the FSS official monitoring programmes, you must contact the Fish Health Inspectorate office and obtain written approval prior to any transfer taking place. The same applies if Industry wishes to transfer shellfish for the purpose of sampling for the FSS programme.

If you observe unusually high shellfish or fish mortalities during the course of your activities, you must report your findings to the Fish Health Inspectorate:

Fish Health Inspectorate,
Marine Scotland Science
PO Box 101
375, Victoria Street
Aberdeen AB11 9DB
Tel: 0131 244 3498
Email: MS.FishHealth@gov.scot

You can find information on non-invasive aquatic species and how to prevent their introduction and spread on the GB non native species Secretariat webpage. This website includes access to identification sheets for all UK invasive species.

Change record

Version	Date released	Change
1	29 March 18	New Shellfish Partnership protocol drawn up at contract start
2	6 July 18	Section 5: • Clarification as to when actual sampling location can be reported in degrees and minutes • Clarification as to where unverified samples should be collected from • Further clarification on verified from shore and unverified conditions • Clarification on the format required for reporting of latitude/longitude positions and requirement for conversion Section 8: • Introduction of provisions for sharing of transport box for E.coli and toxin samples destines to Cefas Weymouth Section 9: • Amendment to labelling of samples destined to Cefas Weymouth Section 10: • Amendment to sample submission form, now combining E.coli toxin and chemical contaminants programmes requirements. • New additions to sample submission forms • Reference to HMMH unverified sample submission form for unverified and verified from shore samples Throughout: o Reference to Industry protocol for collection of shellfish (V1 issued 06/07/18)
3	20 December 18	Section 1: • “should” replaced by” must” in a number of sentences • Addition of FSS definitions for verified, unverified and verified from shore samples • Addition of note to clarify that samples not meeting the protocol requirements will be rejected Section3: • Addition of paragraph re. liaison with industry • Addition of notes in 1st paragraph re. possible requirement for additional samples. • Addition of note referring to late samples not being accepted around bank holidays and Christmas (unless pre-arranged) Section 4: • Addition of section relating to equipment required for industry sampling Section 5: • Addition of reference to transition period (Jan 19) • Addition of notes about sampling officers having copies of blank unverified submission forms to hand out to collectors

		• Clarification of what constitutes a “verified from shore” sample • Change to recording of location of sample collection when harvesters do not provide information • Withdrawal of option where collectors do not have GPS, plotter or charts to confirm location of sampling • Addition of reference to EURL Good Practice Guide Section 7: • Minor change to wording Section 8: • Addition of section clarifying how industry will collect and hand over samples • Addition of note stating that the HMMH unverified sample submission for is available from Cefas website • Clarification on requirement for safety checks Section 9: • Update to Fera contacts Section 10: • Addition of note clarifying that unverified/verified from shore samples must be accompanied with completed unverified submission form or they will be rejected at the laboratory • Instructions for measuring shellfish temp for harvester-collected samples added Section 11: • Update to Fera contacts Section 12: • Deleted link to FRS disinfection protocol – no longer available on Marine Scotland website Appendix 1 added
4	8 August 2020	Document updated throughout to comply with UK Accessibility Laws & list of abbreviations added Document title amended Throughout the document: update to document links Section 1: • Remove reference to specific EU legislation • Add reference to sampling officers being required to record their location when verifying from shore Section 2: • Add statement to clarify protocol applies to sampling officers Section 3: • Add requirement that a minimum notice is required to a change to the weekly sampling schedule and that testing by laboratories will be subject to capacities not being exceeded • Additions to chemical contaminants section Section 5: • Reference to FSS RMP list and requirement to contact FSS if sampling at RMP is no longer possible added • Changes to Lat/Long format required • Addition of requirement to record location of verification from shore

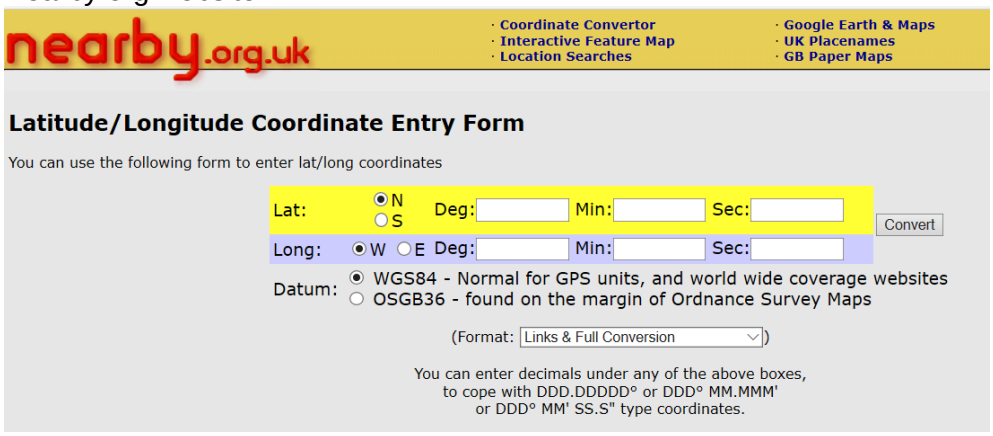
		• Removed reference to Good practice guide as this document is no longer current (revisions from EURL awaited) • Added reference to a change to the way the nature of samples is recorded on submission form • Added clarification to section on razor trial to specify that sampling can only take place when fishing is permitted by Marine Scotland Section 8: • Added that Industry submission forms must be completed in full and accurately and clarify that sampling officers must not accept samples if forms are not completed/accurate or with pre-printed locations • Clarification that sampling officers must not collect samples that have been left unattended and must not arrange for samples to be left unattended. • Clarification that samples must not be re-immersed after collection • Clarification that overnight storage by Industry is allowed for razor and surf clams but conditions apply. • Update to packing section to include reference to new box (Igloo profile 16) Section 10: • Update to details required on sample submission forms • Clarification on requirements for temperature measurements Section 11: • Update to contact details Section 12: • Reference to compliance with Government advice and restrictions re. COVID19 Appendix 1: EURL Good Practice Guide removed New Appendix 1: Nearby.org added Protocol to be implemented from 31/08/2020

List of abbreviations used in this document:

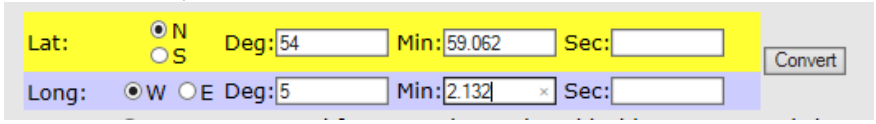
Cefas:	Centre for Environment Fisheries and Aquaculture Science
Fera:	Fera Science Limited, formerly the Food and Environment Research Agency
FSS:	Food Standards Scotland
GPS:	Global positioning system
HMMH:	Hallmark Scotland Ltd
Lat/Long:	Latitude and Longitude coordinates
MCA:	Maritime Coastguard Agency
Min.:	Minimum
NRL:	National reference laboratory for bacteriological contaminants of shellfish
OC:	Official control
PAHs:	polycyclic aromatic hydrocarbons
PCBs:	polychlorinated biphenyls
RMP:	Representative monitoring point
RMZ:	Representative monitoring zone
SAMS:	Scottish Association for Marine Science (SAMS)
SIN:	Site identification number
SSQC:	SSQC Ltd

Appendix 1: Screenshots of Nearby.org and examples of use

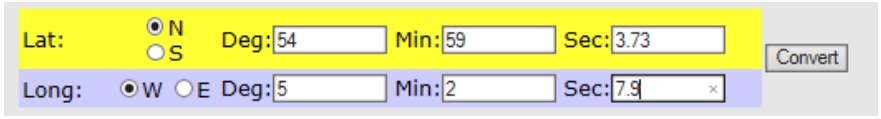
To convert Lat/Long provided by Industry into NGR, please navigate to this page of the Nearby.org website:



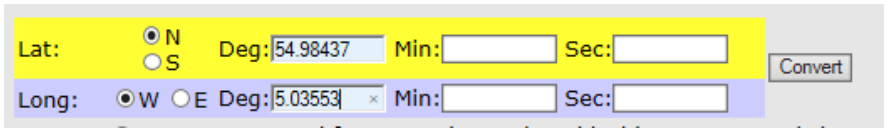
It is important that the Lat/Long coordinates are entered correctly, paying attention to the units used by Industry. For example, a location in degrees and decimal minutes is 54°59.062'N, 5°2.132'W and will be entered as:



The same location recorded in degrees, min, sec is 54°59'3.73''N, 5°2'7.9''W. and will be entered as:



And the same location recorded in decimal degrees is 54.98437, -5.03553 and will be entered as:



When pressing the "Convert" button, the conversion for all 3 sets of Lat/Long readings above will provide the same Grid Ref: NX 0586969746 – please write this NGR on your sample submission form.