



Processes and flowlines for establishing classification and bio–toxin status of new offshore shellfish growing areas.

Background / Rationale

It is anticipated that over the coming decades, offshore aquaculture¹ will become increasingly important, allowing aquaculture to maintain its reputation as the fastest growing food production sector. This is evidenced by both growth and R&D projects in New Zealand, USA, Canada, Norway and the UK, including England. Within the UK, offshore shellfish aquaculture production is currently quite rare and classification of the first of these sites initially required processes and procedures to be developed accordingly. Due to the nature of offshore sites, there may also be specific logistical issues, which will need to be considered by the Food Standards Agency (FSA) and the responsible Local Enforcement Authority (LEA) on a case by case basis.

History

Until recently most shellfish aquaculture around the coast of England has been situated in near-shore environments or along intertidal zones. This has made collection of samples by the LEA relatively straight forward in that they could collect samples quickly and easily in liaison with the local aquaculture farmer. However, with the arrival of offshore shellfish farms this has become more problematic in that it might not be clear just which LEA is responsible and how far its legal remit extends. In addition, collection of samples becomes far more onerous due to the distance and time involved. The availability of suitable vessels can also be problematic.

Objective

The objective of this document is the clarification of processes and flowlines for establishing classification and bio–toxin status of new offshore shellfish growing areas and their ongoing sampling.

Initial site selection

¹ *Offshore is not a defined term under EC Regulation 854/2004 (the legislation covering classification of harvesting areas), however, the European Good Practice Guide https://eur1cefas.org/media/14034/gpg_issue-6-final-170117.pdf quotes an offshore shellfishery as being an example of a 'remote area' the definition for which is as follows: '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.'

One issue facing any prospective offshore shellfish farmer is knowing what the classification status of their proposed site is likely to be in advance of the significant investments required for this type of operation. The factors affecting water quality at a particular site can be complex. Whilst better water quality might be expected the further offshore you go, influences from long sea sewage outfalls and river plumes can extend over long distances so good water quality cannot be assumed. Consequently, it is highly advised that an adequate amount of investigatory shellfish *E.coli* testing (i.e. prior to any testing for classification purposes) is carried out at an early stage, prior to full investment in either construction or licensing of the selected site.. The responsibility for this investigative testing of potential new areas falls to the prospective shellfish farmer.

Depending on the precise details of the aquaculture proposal, the testing would most probably need to include placing trial ropes or bags within the proposed site for given periods and then testing these shellfish by approved methods. Whilst there is some older documentation that gives general guidance on site selection, the section on the microbiological contamination aspects is very limited (<https://www.cefas.co.uk/publications/techrep/techrep136.pdf>).

However, Cefas and FSA have recently published joint guidance on site selection from a microbiological perspective:

<https://www.cefas.co.uk/media/180291/20170329-selection-of-a-bivalve-shellfish-cultivation-site.pdf>

It is recommended that the new aquaculture business carries out its own sampling as early as possible, long before the classification application has been submitted in order to determine potential contamination levels. In addition, it may be useful to consult any reports for sanitary surveys that may have been carried out for relevant adjacent sites but exercising caution with any assumptions that water quality will be better.

Other statutory requirements

Prospective shellfish farmers will need to obtain all other regulatory permits, licences and leases relevant for the type of shellfish farming to be employed. It is recommended that the new farmer should engage in all these processes as early as possible in order to avoid delays in establishing the full range of legal permissions. These are available at

<http://www.seafish.org/industry-support/aquaculture/aquaculture-regulatory-toolbox-for-england>

Current Processes

The actual processes to go through for obtaining classification and biotoxin status remain the same for offshore shellfish farming areas as they are for inshore areas and these are documented on the the FSA website e.g.

1. The application document for beginning this process:

<https://www.food.gov.uk/sites/default/files/applicationfornewbivalvemolluscharvestingarea.pdf#overlay-context=user>

The responsibility for submitting this application form lies with the LEA as they are taking on responsibility for the monitoring and sampling of this shellfish classification area. This needs to be done in conjunction with the prospective shellfish farmer. However, it should be noted that acceptance of an application does not guarantee classification. The final level classification will be

based on the shellfish *E. coli* data obtained from the official classification samples; the taking of these is the responsibility of the LEA.

2. The classification protocol for England and Wales:

<https://www.cefas.co.uk/media/52553/classification-protocol-revised-version-07-june-2017-fsa-final.pdf>

For the purposes of classification, offshore areas will be treated as new production areas i.e. an area that does not contain any existing classified beds and/or data from previous microbiological monitoring.

To comply with the requirements of EC Regulation 854/2004, a sanitary survey (an assessment of all the sources of faecal contamination potentially impacting the production area of interest) must be carried out prior to classification of new areas. The primary objective of this survey is to allow identification of representative monitoring points (RMPs) from which shellfish *E.coli* monitoring should take place to define a sampling plan for initial and ongoing (monthly) monitoring.

Classification of a production area is based on the results of this monitoring according to the criteria set out in the Regulation. The procedures for sanitary survey are under review by the FSA and provisional RMP assessments currently fulfil this role in England and Wales.

3. The procedures for submitting samples

<https://www.cefas.co.uk/media/52551/201704-cefas-classification-sampling-protocol-for-local-authorities-final.pdf>

New areas will normally require a minimum of ten samples from each identified RMP which equates to at least ten weeks of sampling (samples for new areas must be taken at least one week apart) before a classification is given. This is initially called a provisional classification after which harvesting can begin. Once a provisional classification has been awarded, monitoring reverts to the frequency stipulated in the sampling plan (sampling plans are published on the Cefas website here:

<https://www.cefas.co.uk/cefas-data-hub/food-safety/classification-and-microbiological-monitoring/england-and-wales-classification-and-monitoring/current-sampling-plans/>

Arrangements for routine monitoring, data assessment and actions following high results applicable to all classified production areas are stipulated in the Classification Protocol (see Classification Protocol section 1.3 onwards)

Samples can be taken on a monthly basis if the need for classification is less urgent. A further full year's worth of sampling is required before a full classification can be issued.

Once classification has been awarded, regular biotoxin and phytoplankton monitoring is required to determine whether the area is prone to toxic events. Two samples are also required (taken 2 weeks apart) before harvesting can commence. In the absence of sufficient data to support a reduced sampling frequency, weekly sampling may be required.

Additional information from biotoxins sampling protocol:

EC regulation 854/2004 also carries the stipulation for sampling plans to check for the presence of toxin-producing plankton in classified production and relaying waters and for biotoxins in live bivalve molluscs (LBMs). As such, there is requirement to collect samples of LBMs and water samples from designated monitoring points within a production area. The monitoring point used for biotoxin monitoring of LBMs and water will be selected from one (or more depending on the complexity/size of the area) of the classification RMPs.

Official control monitoring should commence prior to any harvesting taking place. Two sets of flesh and water samples taken two weeks apart should be collected just prior to harvesting commencing. Ongoing/routine monitoring is required throughout periods of commercial harvesting and the frequency is dependent on several factors but may be fortnightly or monthly.

Water monitoring and the presence of toxin below the regulatory limit is used to inform when there is a higher risk of contamination, additional samples may be requested under certain circumstances. EC regulation 853/2004 stipulates the maximum permitted levels of marine biotoxins in shellfish flesh. If toxins are detected above the regulatory limit then a temporary closure notice will be issued by the relevant local authority.

Sampling requirements for a positive re-test:

Should a sample test positive for any toxin (e.g. toxin levels exceeding the regulatory limit), a re-test sample is required for subsequent weeks (normally 5-7 days apart) This will continue until two consecutive negative (or below action levels) results have been achieved. After which, routine fortnightly/monthly testing may resume unless otherwise requested by the Cefas and/or FSA.

A site may be considered for earlier re-testing if the **first** official control re-sample from a closed area returns a result below the regulatory limits for marine biotoxins. The second re-sample may then be taken as soon as *practicably possible* after at least 48 hours of the result being reported. The allowance for early retesting is dependent on harvesting activity, laboratory capacity and LEA officer availability also, so it is best to discuss this with the LEA prior to any resamples being taken. Closed areas returning a first re-sample result above the regulatory limits will not be retested early.

The FSA publish the results of official control biotoxin monitoring on their website at the following link: <https://www.food.gov.uk/enforcement/monitoring/shellfish/ewbiotoxin/>

Also included on this page is a list of current restrictions and details on the maximum permitted levels for marine toxins in shellfish flesh, along with details of phytoplankton monitoring.

Copies of the Official control biotoxin monitoring annual reports are available at the following link:

<https://www.cefas.co.uk/cefas-data-hub/food-safety/habs-surveillance-programmes-and-monitoring/>

Responsibility for sample collection.

Where a farm exists some distance offshore the LEA deemed responsible for sampling by the FSA is the Authority whose land base is most adjacent to the territorial waters in which the classified harvesting area resides. Alternatively, it may be determined this responsibility falls to the LEA in whose area the vessels will normally land the harvested product. These arrangements may take some time to agree and so, to avoid delay, a prospective aquaculture production business (APB) /food business operator (FBO) needs to begin dialogue with the FSA and relevant LEA(s) to set the necessary processes in motion at the same time as processing the other necessary environmental permissions and licencing.

In accordance with EU regulations, LEAs are responsible for collecting shellfish official control samples from the designated harvesting areas and sending these to the relevant local testing laboratory for analysis. Assistance with sampling from the FBO is permitted providing this is carried out under LEA supervision in agreement with the FSA.

It is recognised that there may be exceptional situations where APB/FBO sampling may need to be considered. For this to be the case, the LEA must be of the clear view that it cannot undertake sampling for reasons of either practicality or health and safety (e.g. the sampling process can only be undertaken safely with specialist training that would not be reasonable or practical for an LEA officer to undertake). These situations will be considered on a case by case basis by the FSA, with input from Cefas, and any agreement documented accordingly.

Industry members will need to be assessed for competency (and trained if necessary) by the LEA in order to assist in obtaining official control samples, as specified in the Food Business Operators' Supplementary Sampling Guide for official control microbiological monitoring of shellfish production areas in England and Wales:

<https://www.food.gov.uk/enforcement/monitoring/shellfish/shellharvestareas/fbo-supplementary-sampling>

And as specified in the Food Law Code of Practice:

<https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice>

Authorities will also be required to verify sampling (for microbiological and biotoxin monitoring), for instance through robust planned and unplanned visual checks along with auditing of records, procedures and equipment. Results will be used for the microbiological and biotoxin monitoring programmes, in accordance with Regulation 854/2004. Specific verification will be agreed with the FSA on a case by case basis.