

Protocol for Classification of Shellfish Production Areas, England and Wales

July 2020

This protocol reflects policy decided by the Food Standards Agency (FSA) as Central Competent Authority in England and Wales for this area of work. It is intended to meet the official control requirements of Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2019/627 in the interests of public health and considers the recommendations contained in the European Union Reference Laboratory (EURL) Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice.

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1 Introduction

1.1. Commission Implementing Regulation (EU) 2019/627 lays down the official control (OC) requirements for the Food Standards Agency (FSA) as Central Competent Authority (CCA) concerning Live Bivalve Molluscs (LBMs), which are filter feeding shellfish such as oysters, mussels and clams. These controls include the classification and monitoring of shellfish production and relaying areas, from which the FSA authorises the harvesting of LBMs. The classification of a production area determines the treatment required before the molluscs may be marketed. In all cases the general food safety requirements of Regulation (EC) 178/2002, Article 14 and more specific standards in Annex II of Regulation (EC) 853/2004 and the microbiological criteria adopted under Commission Regulation (EC) 2073/2005 must be met. Local authorities (LAs) act as the Competent Authority (CA) responsible for sampling and enforcement in their areas.

Shellfish classification categories and permitted levels of *E. coli |*100g flesh and intravalvular liquid

Class A

1.2. 80% of sample results less than or equal to 230 *E. coli* per 100g, no results exceeding 700 *E. coli* per 100g during the review period – LBMs can be harvested for direct human consumption provided the end product standard is met.

Class B

- **1.3.** 90% of sample results must be less than or equal to 4,600 *E. coli* per 100g with none exceeding 46,000 *E. coli* per 100g LBMs can go for human consumption after
 - purification in an approved establishment
 - after <u>relaying for at least one month</u> in a class A relaying area OR
 - after an approved heat treatment.

Class C

- **1.4.** All samples must be less than or equal to 46,000 *E. coli* per 100g LBMs can go for human consumption only after:
 - relaying for at least two months in a Class B relaying area followed by purification in an approved establishment

 OR
 - relaying for at least two months in a Class A relaying area¹
 OR
 - an approved heat treatment

¹ Harvesters may also wish to apply further purification steps to relayed LBMs, however this is not a requirement in legislation.

- 1.5. If the FSA decides to classify a production or relaying area, it must first establish the location and fix the boundaries of the area to be classified, assess the area for likely sources of contamination and identify a representative monitoring point (RMP). This is achieved through a sanitary survey being carried out. In line with the European Union Reference Laboratory (EURL) guidance, RMPs for establishing classification should be representative of the point likely to show the highest level of contamination i.e. worst-case scenario.
- **1.6.** The faecal indicator bacterium, *E. coli*, is used to establish the degree of faecal contamination in areas where shellfish are to be harvested. Classifications are awarded by the FSA according to the levels of contamination analysed in samples of shellfish flesh. The presence of *E. coli* may indicate that other bacteria and viruses of faecal origin may also be present.
- **1.7.** Although the presence of *E. coli* can indicate that viruses, such as Norovirus, could be present, there is currently no requirement to monitor viruses under the official control programme. Food Business Operators (FBOs) should ensure they adequately take this risk into account, especially following reports of sewage spills.
- **1.8.** EU Regulations require relaying areas to be classified and monitored in a similar manner to production areas. They must have clearly identifiable boundaries using poles, buoys or other fixed means and operate on a batch basis i.e. 'all in all out' system. Batches and species may not be mixed at any one time.

2 Organisations – roles and responsibilities

Food Standards Agency (FSA)

Central Competent Authority for food safety including shellfish hygiene in England and Wales, makes all final classification decisions and sets out overall policy

Carcinus

Carrying out sanitary surveys on behalf of the FSA

Centre for Environmental, Fisheries and Aquaculture Science (Cefas)

- Co-ordinating the microbiological and biotoxin monitoring programme on behalf of the FSA
- · Carrying out biotoxin and phytoplankton testing
- Providing technical advice to the FSA and local authorities

Local authorities (LAs)

Carrying out official controls including undertaking microbiological, phytoplankton and biotoxin sampling

Official Control laboratories

Carrying out testing for the microbiological testing programme²

² Approval of laboratories for shellfish control is <u>not</u> undertaken by PHE or the NRL. In order to become an Official Control Laboratory, the Local Authority has to show that they wish to use that particular laboratory for official controls and then request the FSA to designate the laboratory as an OC laboratory as long as it meets the required criteria. In the case of *E.coli* testing, LAs 'instruct' the designated OC laboratories to undertake the testing.

3 Getting Started

- 3.1. For a production or relaying area to be classified, an <u>application form</u> must be completed. Before an application form is submitted there are steps to follow in accordance with the application form and guidance. The form should be completed electronically by the applicant (harvester) in liaison with the relevant food authority and submitted by the food authority via email to: shellfish@food.gov.uk in England or lasupportwales@food.gov.uk in Wales.
- **3.2.** FSA will undertake a verification check of the classification application and will commission a sanitary survey if required. Further details on sanitary surveys are set out in section 5 of this document.
- **3.3.** Applications should only be made when all the steps on the application form have been completed, it has been confirmed that there are no barriers to proceeding with the application, all necessary permissions have been sought by other regulators, there is stock for commercial harvesting and the food authority confirms that official controls samples can be obtained according to protocol.
- 3.4. Harvesters and food authorities should note that commercial harvesting cannot be carried out until the classification process has been complete. The classification process may include FSA verification, a completed sanitary survey and ten classification samples, taken at least one week apart. The minimum time from the application being received to the harvesting area receiving classification is likely to be around 16 weeks, and this may be longer if issues arise at any stage of the process.
- **3.5.** Shellfish harvesters who have requested classifications for multiple species in a single area with no other classifications should apply to have **each** species classified. Samples of each species may need to be submitted for analysis.

4 Types of classification

4.1. Shellfish production areas may be awarded a preliminary, provisional, annual, seasonal or long-term classification.

Preliminary classification

4.2. May be considered for any area which is currently classified for another species or has been declassified within the past 2 years. Furthermore, it may be considered if an adjacent production area has had a sanitary survey carried out (and data supports this) and where existing or historic monitoring data allows for a robust risk assessment and immediate preliminary classification to be awarded.

Provisional Classification

- **4.3.** May be awarded to new shellfish areas where there is no existing monitoring data and where no previous sanitary survey has been undertaken, once the following has taken place:
 - a full sanitary survey
 - completion of a specified sampling plan and
 - a minimum of ten classification samples, taken at least seven days apart
- **4.4.** A provisional classification will allow commercial harvesting to begin, subject to compliance with the criteria for the classification awarded and subject to other necessary controls being put in place for marine biotoxins and phytoplankton monitoring (and chemical contaminants where required).

Annual/full Classification

4.5. May be awarded to an area after a full 12 months of routine monthly monitoring and where historical and current results allow for annual A, B or C classification to be awarded for a 12-month period. The FSA reviews all classifications annually. It also analyses monitoring data throughout the year, which can result in changes to classification being notified via interim updates as necessary.

Seasonal Classification

4.6. May be awarded when at least 3 full years' worth of routine monitoring data shows a clear seasonal trend of results. The area may be classified as an A or B for part of the year and B or C for the rest of the year. The season must be at least 3 months in length and of benefit to industry.

Long-term Classification (B-LT) (class B only)

4.7. When a Class B production area has stable compliance over a 5-year period, a long-term classification can be awarded, indicated as B-LT. This demonstrates that water quality is more stable in these production areas and shellfish harvested from these areas are more likely to reflect this. Harvesters benefit

from a more consistent classification, which is less vulnerable to single testing results.

Classification of scallop areas

4.8. The current approach in England and Wales is to classify farmed scallop areas within or surrounded by an existing classified shellfish production area, i.e. grown in lanterns or by other aquaculture methods. Data for other species in existing classified beds in the vicinity may be used (depending on evidence base) to enable classification. If scallops are growing wild, they can be harvested without classifying the production area. However, harvesting is only permitted by Commission Delegated Regulation 2019/624, Article 11 when the competent authorities carry out official controls on such animals in fish auctions, dispatch centres and processing establishments.

Additional notes

4.9. See section 6 for more information on the types of classification.

5 Sanitary surveys

- 5.1. Sanitary surveys are required for new shellfish production or relaying areas prior to classification. The surveys are intended to provide a thorough assessment of microbiological pollution sources that may affect the new area and to develop the most representative sampling plan. The survey will also consider the possibility of using 'indicator species' to represent more than one species of shellfish in an area if there is evidence to support this.
- **5.2.** More information on sanitary surveys can be found on the <u>FSA website</u> and the <u>EU Good Practice Guide</u>.
- 5.3. On receipt of a completed shellfish classification application form, the FSA will determine whether a sanitary survey is required. This will identify a production area boundary and a RMP to allow sampling to begin. Please note the sanitary survey may identify more than one RMP required to classify an area.
- **5.4.** The sanitary survey will assess the location and type of the production or relaying area, location and types of sewage discharges, river inputs, harbours and available microbiological data from nearby areas. The final report will include:
 - Detailed co-ordinates for the production area boundary;
 - Detailed *E. coli* RMP(s) for the area;
 - Detail the frequency and number of samples to be taken from each RMP as part of the sampling plan.
- 5.5. As much relevant information as possible is obtained from existing sources of information. Records from bodies such as the Environment Agency (EA) and Natural Resources Wales (NRW) are utilised, as well as historic official control *E. coli* results.

Additional notes

- **5.6.** Until the FSA issues a formal interim update to confirm the classification status of an area, the area remains **unclassified and harvesting must not take place**.
- **5.7.** As well as *E. coli* monitoring, biotoxin monitoring will also be required before harvesting can commence (two satisfactory samples taken at least a week apart before the area can open and harvesting commence).

6 Further information on classification awards

Preliminary classifications

- **6.1.** If a production area has been previously classified (within two years of a new application), is currently classified for another species, and a sanitary survey has been carried out where there is sufficient data to make a robust assessment, then it may be possible to award an immediate preliminary classification to enable harvesting to commence.
- 6.2. Such classifications will be awarded based on a precautionary principle, to ensure public health is not put at risk. Therefore, a previous Class A area may receive an immediate B classification, which will be subject to review. Immediate preliminary Class A classifications will not be awarded. The applicant may wish to refuse an immediate preliminary classification, if unfavourable and pursue provisional classification instead.
- **6.3.** Information contained in any sanitary survey report already carried out in the production area will be used in the process of awarding the preliminary classification.
- **6.4.** Following a preliminary classification, a total of 10 samples are required to be collected by the LA at least a week apart for microbiological analysis. Where more than one species has been classified, the microbiological quality of **all** species will need to be determined.
- 6.5. An assessment of the sample results will then be reviewed against the sampling plan derived from the sanitary survey and, if appropriate, a provisional classification awarded. If the sampling plan is considered appropriate, the new area will be represented by the relevant RMP of the production area. However, if the sampling plan is not considered appropriate, a sanitary survey of the production area may be carried out (see section 5) to determine future monitoring.

Provisional classifications

- **6.6.** For new production or relaying areas, a sanitary survey is required to be undertaken. This will determine the area's boundary, RMP(s) and monitoring plan.
- 6.7. To award a new provisional classification, a minimum of 10 samples, taken at least a week apart, are required to be collected for microbiological analysis. More samples may be required for 'provisional A' classifications. Where more than one species is to be harvested, the microbiological quality of **all** species must be determined separately.

6.8. Compliance with the classification criteria (see section 1) is required for provisional classifications.

Additional notes

6.9. Sample results returning levels over 46,000 *E.coli* per 100g of flesh and intravalvular liquid during initial monitoring, may result in the area being designated as 'prohibited' and the classification application rejected.

Annual (full) classifications

- **6.10.** Following the award of the provisional classification, routine official control sampling will be carried out by LAs at the frequency recommended in the sanitary survey (this is generally monthly). The *E.coli* test results for the samples collected from the established RMP(s) will contribute to an annual classification for the area.
- 6.11. Within a 12-month period, a minimum of 8 monthly sample results are required to award and maintain annual B and C area classification. To award and maintain an annual class A classification, a minimum of 10 monthly sample results are required. Anything less than the minimum sample requirement may result in no classification being awarded, or the area being de-classified by the FSA (see section 6.15).

Seasonal classifications

- **6.12.** At least 3 years' worth of data (and a minimum 24 sample results within the 'better' season) showing a clear seasonal trend is necessary for a seasonal classification to be awarded. Seasonal classifications should comprise at least 3 consecutive months and be of benefit to industry (at a time they would usually harvest). Routine monthly monitoring is required throughout the full calendar year to provide sufficient compliance data.
- 6.13. A buffer period before the start of the season is required. This is one month for Class C to B areas and for Class B to A areas (two months for C to A). During the buffer period the monthly monitoring sample must show compliance with the higher/'better' classification prior to the 'better' season commencing. Harvested products may only be processed at the 'better' classification at the start of the season and not during the buffer period. This is to allow for clearance of contamination during the buffer month/s. The example in the following table demonstrates a seasonal classification. Once stage 3 is complete, stage 1 is repeated:

Stage	Date	Classification status	Required monitoring results	Processing requirements for commercially fished shellfish
1	1 April – 30 September	Class C season	Monthly samples contribute to rolling assessment of class C season	Class C
2	1 October – 31 October	Class B Buffer (area still Class C)	Monthly sample compliant with Class B	Class C
3	1 November - 31 March	Class B Season	Monthly samples contribute to rolling assessment of class B season. Any non-compliant results will trigger a review of the eligibility of the season.	Class B

6.14. If the sample in the buffer period is not compliant with the better classification, the LA must sample again until a compliant sample is obtained before the month of the 'better' classification may commence (sampling should be at least 7 days apart). This may mean the start of the season is delayed. Such decisions will be made on a case-by-case basis by the FSA. If the season is delayed (following non-compliant buffer samples) for two consecutive years, then the seasonal classification period will be reviewed. Buffer period results will be included in the classification dataset (i.e. used for classification assessments).

De-classification

- 6.15. For classified areas that fail to submit the required number of sample results in a calendar year, where there is insufficient stock for sampling, or the area is closed to harvesting by other authorities, the area may be de-classified. It will be placed on the FSA's declassified list and can be either monitored quarterly or not monitored. The list is reviewed as part of the annual review process.
- **6.16.** If a classification request is made for an area that has been de-classified for less than the two year period and at least quarterly sampling has been undertaken, a preliminary classification may be awarded (see section 6.1) providing there are no issues with the quarterly monitoring data and once monthly monitoring recommences. If after two years there is no request to reclassify, or there is unlikely to be commercial interest, it will be removed from the listing. A new classification application would then need to be submitted to the FSA if there was a request to classify the area.

7 Classification sampling and number of samples

- **7.1.** For a provisional classification to be awarded, classification sampling will be undertaken by LAs and the samples must be analysed for microbiological contamination. Cefas, on behalf of the FSA, will advise the LA of the sampling plan and RMPs to be used. The sampling plans are available here
- 7.2. Once a provisional classification has been awarded, official control sampling will be carried out at a frequency recommended in the sampling plan in the sanitary survey (usually monthly) over the classification year (July to June).
- **7.3.** All samples are required to be collected in accordance with the FSA's shellfish sampling and transport protocols which include further detailed information including the temperature requirements.

Additional notes

- **7.4.** At least 12 samples a year (on a monthly basis) are usually expected to maintain a full classification unless otherwise agreed. If areas are for instance, formally closed/have low stocks for an extended period of time, a reduced frequency may be agreed with the FSA.
- 7.5. If there are other circumstances which do not fit with these scenarios, food authorities should contact the FSA/Cefas to discuss what sampling arrangements are necessary and this will be considered on a case by case basis for a decision by the FSA. Some examples may be where the harvesting season is restricted, sometimes for less than 3 months, for reasons other than hygiene compliance, and are beyond industry control (i.e. Inshore Fishery Conservation Authority byelaws).

7.6. However:

- A minimum of 10 samples are required to award an A classification in any classification year.
- A minimum of 8 samples are required to award a B or C classification in any classification year.
- These minima also apply to seasonal classifications.

8 Sample analysis

- **8.1.** Official control (OC) microbiological samples must be analysed in designated OC laboratories³. Results are reported to Cefas and published on <u>its website</u>.
- 8.2. All testing undertaken by the OC laboratory is in accordance with the EU reference method. Results obtained using other methods are not acceptable for classification purposes. The OC laboratories are accredited by the UK Accreditation Service (UKAS) for this method and take part in external quality assessments and UK National Reference Laboratory (NRL) ring trials.

Supplementary samples

- **8.3.** The legislation permits the Competent Authority to consider results from FBOs' sampling to supplement those from OC sampling in order to determine the classification, opening or closure of shellfish harvesting areas following a protocol agreed by the FSA and the FBO.
- **8.4.** FBO supplementary sampling and analysis must be conducted under conditions comparable to sampling and analysis for official controls and is as representative as possible of the area being monitored.
- **8.5.** For supplementary samples to be considered, the FSA must have designated the laboratory carrying out the analysis as an official control laboratory. In addition to this, the sampling must have taken place in accordance with FSA's official control sampling and transport protocol (as above).

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³ The Food Law Code of Practice defines official control laboratory as "A laboratory accredited for the purposes of analysis, and which appears on the list of official food control laboratories".

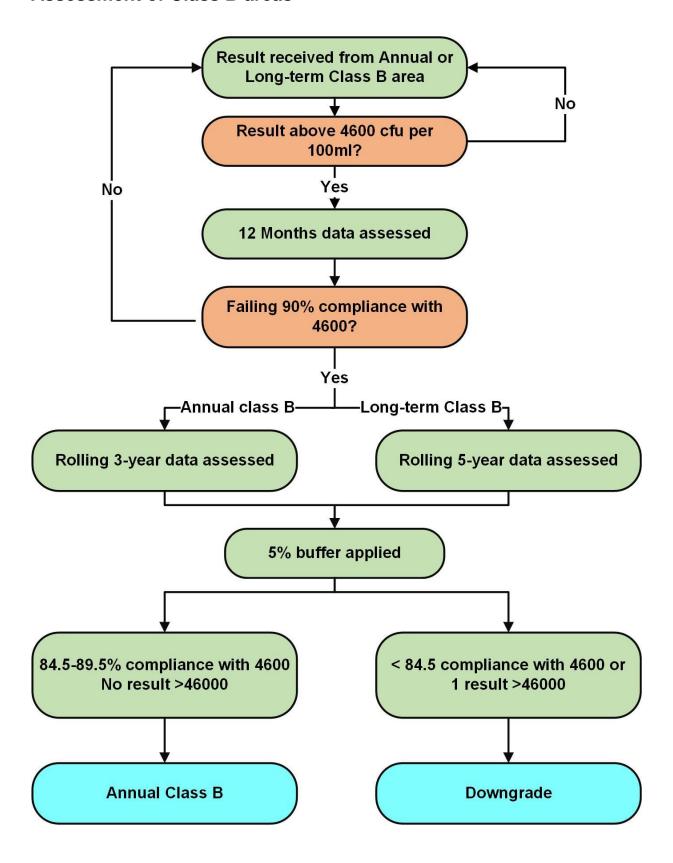
9 Classification Review

- **9.1.** Each year, the FSA carries out an annual review of all shellfish classifications utilising the previous five year and three year dataset for long term B classifications (B-LT) and one year and three year dataset for all other classifications (or all data if less than 3 years).
- **9.2.** Consideration will also be given to the most recent complete year's results, if there is evidence to show that water quality has improved or deteriorated over the past 12 months and if there is no monitoring for 3 years.

In-year reviews

- 9.3. OC microbiological results and shellfish classifications are also examined on an on-going basis during the year considering the rolling dataset. Any exceptional or high results will be acted upon according to LAs local action plans (sample results above the threshold of the classification awarded to the area see below) and the cause of the high result investigated. The outcome of these investigations may reveal evidence to disregard the result from the dataset in exceptional circumstances. (see sections 10.5 and 10.6). Shellfish classifications may be revised at any point in the year as appropriate. Interim updates are sent to LAs who should ensure all interested parties including FBOs within their area of responsibility are aware of the changes.
- **9.4.** Class B production and relaying areas showing marginal compliance with the classification criteria will be identified with an explanatory note 4 in the classification list and will be formally reviewed on an annual basis. The flowchart below illustrates how data from class B areas are assessed in-year.

Assessment of Class B areas



10 Handling results

- 10.1. When results above classification maximums are returned, an investigative state is implemented for class A & B beds. For **results above trigger levels** an action state for all classifications (A above 700 *E.coli* per 100g, B above 18,000 *E. coli* per 100g & C above 46,000 *E. coli* per 100g) will be instigated. The notification sent will depend on both the magnitude of the result and the bed's current compliance. Notifications will be sent to the FSA, LA and relevant shellfish stakeholders such as the EA/NRW and the LA are expected to initiate their Local Action Group (LAG). Further guidance is available in the <u>FSA</u> guidance for LAGs.
- **10.2.** Additional measures may be required following results that do not meet the legislative requirements, e.g., increased end product testing or product withdrawal. The LA will liaise with the harvesters on such additional measures to ensure public health protection.
- 10.3. A Temporary Closure Notice (TCN)⁴ may be put in place by LAs following any result that exceeds the classification threshold. LAs should liaise with the FSA immediately and share a copy of the TCN. Liaison with the FSA might include consideration of whether any action should be taken to withdraw any LBMs from sale that has already been distributed locally or nationally. During a closure period, sampling should be increased to weekly and the area reopened following two consecutive satisfactory sample results compliant with the area's classification.

Actions following outcome of investigations

- **10.4.** OC results will be reviewed following the outcome of investigations. If deemed appropriate by the FSA, results may be waived if there is sufficient justification to support that.
- 10.5. Results that can be attributed quite clearly to very unusual or "one-off events" (usually up to 48 hours prior to sampling in the absence of any specific information relating to catchment retention times, etc) that are unlikely to or will not recur may be excluded. This will not, however, preclude the possibility of short-term control measures being applied to protect public health e.g. a temporary closure notice.
- **10.6.** Examples of events that may lead to results being disregarded are:

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⁴ Made under Commission Implementing Regulation (EU) 2019/627 prohibiting the collection of any live bivalve molluscs from a designated area.

- Sewage treatment works failure*
- 1 in 5 year (or longer) return period storm event
- Failure to comply with the standard sampling protocol**
 - * Where it is deemed that the resulting discharges will have markedly impacted on the shellfish bed(s) information obtained from the EA/NRW and LA is used to assist in this determination.
 - ** In practice this has meant the exclusion of results for samples that have exceeded the 48-hour limit between sampling and testing and samples arriving above the permitted temperature.
- **10.7.** If, however, all results remain valid and overall compliance is less than required for the classification then a downgrade may be appropriate.

Downgrade criteria

10.8. Cefas will review the dataset to determine whether the overall compliance warrants a downgrade and advise the FSA by issuing interim update recommendations. Cefas will also notify the EA/NRW and the LA and ask them to inform industry. The FSA will make the final decision on whether to downgrade and will send out an interim update to confirm.

Class A areas

Site meets downgrade criteria if:

- 1 and 3 year compliance is less than 80% with 230 E. coli per 100 g
 or
- 1 result over 700 *E. coli* per 100g in the rolling review year.

Class B and Long-term B areas

Site meets criteria for **downgrade in-year** as set out in the Class B flowchart. Either:

• 1 and 3 year compliance is less than 84.5% or a result over 46,000 *E. coli* per 100g is returned

or

• 1 and 5 year (B-LT) compliance is less than 84.5% or a result over 46,000 *E. coli* per 100g is returned.

Site meets criteria for **downgrade at annual review** either:

• 1 and 3 year compliance is less than 89.5% or a result over 46,000 *E. coli* per 100g is returned in the rolling review year

or

• 1 and 5 year (B-LT) compliance is less than 89.5% or a result over 46,000 *E. coli* per 100g is returned in the rolling review year.

The site will normally be recommended for prohibition following a result of 46,000 (however, each situation will be assessed on a case-by-case basis).

Class C areas

 An area returning a result over 46,000 E. coli per 100g will normally be recommended for prohibition (however, each situation will be assessed on a case-by-case basis).

Upgrade criteria

10.9. Areas showing an improvement in compliance with regards to potential upgrade will be reviewed on a rolling basis following receipt of each result. Cefas will discuss this with the relevant LA and provide data and a recommendation to the FSA for their final decision. If an upgrade is awarded, this will be confirmed in an interim update by the FSA.

Upgrade criteria Class B – A

10.10. Mandatory requirement: 80% of results must be less than or equal to 230, with no results over 700 *E. coli* per 100g over the most recent 3-year period (at least 30 samples). In accordance with the <u>Good Practice Guide</u>, where known discharge improvements have taken place then this period may be reduced with increased monitoring frequency.

Upgrade criteria Class C – B

10.11. Mandatory requirement: 90% of results must be less than or equal to 4,600 over the most recent 12-month period (at least 8 samples) with no result over 46,000 *E. coli* per 100g within that period. To give a reasonable level of confidence that a water quality improvement has actually occurred and that an upgrade is therefore justified, the EU Good Practice Guide recommends that there should ideally be at least 24 results over a minimum period of 3 years showing 90% (or better) compliance. Where known discharge improvements have taken place then this period may be reduced with increased monitoring frequency.

Prohibited areas (possible upgrade to C)

10.12. Mandatory requirement: All results must be less than or equal to 46,000 *E. coli* per 100 g over the most recent 24-month period with at least 16 samples.

Where known discharge improvements have taken place then this period may be reduced with increased monitoring frequency.

Additional notes

10.13. In all cases, final decisions on designating or changing classification rest with the FSA. Decisions will be made based on available information and recommendations from our partners.

11 Contact details

FSA

shellfish@food.gov.uk (England)
lasupportwales@food.gov.uk (Wales)

Cefas (contractor for co-ordination of the shellfish monitoring programme on behalf of the FSA)

shellclass@cefas.co.uk

Carcinus (contractor for production sanitary surveys on behalf of the FSA) shellfish@carcinus.co.uk