

Protocol for Classification of Shellfish Production Areas, England and Wales

October 2018

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 legislative requirements of EC Regulation 854/2004 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 Practice¹.

¹<https://eur1cefass.org/public-documents/official-control-guides.aspx>

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1 Introduction

- 1.1. Regulation 854/2004² 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 clams³. 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 health standards in Annex II of European Regulation 853/2004 and the microbiological criteria adopted under European Regulation 2073/2005 must be met⁴. Local authorities (LAs) act as the Competent Authority (CA) responsible for sampling and enforcement in their areas⁵.

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*/100g, no results exceeding 700 *E. coli*/100g – molluscs 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 4600 *E. coli*/100g with none exceeding 46000 *E. coli*/100g - molluscs can go for human consumption after
- purification in an approved establishment
- OR**
- after relaying in a class A relaying area
- OR**
- after an EC approved heat treatment process.

Class C

- 1.4. less than or equal to 46000 *E. coli*/100g - molluscs can go for human consumption only after either:
- 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 area⁶
- OR**
- an EC approved heat treatment process

² <https://eur1cefafas.org/public-documents/legislation.aspx>

³ <https://eur1cefafas.org/public-documents/legislation.aspx>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R2073&from=EN>

⁵ <https://www.food.gov.uk/about-us/food-and-feed-codes-of-practice> (for England and Wales)

⁶ Harvesters may also wish to apply further purification steps to class A relayed LBMs, however this is not a requirement in legislation.

- 1.5. If the Food Standards Agency decides to classify a production or relaying area, it must first establish the location and fix the boundaries of the area to be classified and 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 EURL guidance, RMPs should be representative of the point likely to show the highest level of contamination i.e. worst-case scenario.
- 1.6. As part of the sanitary survey process, for new areas, an initial assessment may be carried out to establish an appropriate monitoring point (or points) for the purposes of gathering indicative data on the hygiene status of the fishery. This is a Provisional Representative Monitoring Point (PRMP) assessment.
- 1.7. 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 FSA according to the levels of contamination analysed in samples of LBM flesh. *The presence of E. coli indicates that other more harmful bacteria of faecal origin may also be present.*
- 1.8. *E. coli* can also indicate that viruses, such as Norovirus, are present. However, there is currently no requirement to monitor viruses under the official control programme. They do though still pose a food safety risk and FBOs should ensure they adequately control this risk with appropriate end-product testing, which should be increased following reports of sewage spills.
- 1.9. The EU Food Hygiene 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 Provisional Representative Monitoring Point (PRMP) assessments on behalf of the FSA

Centre for Environmental, Fisheries and Aquaculture Science (Cefas)

Co-ordinating the microbiological testing programme and carrying out the biotoxin monitoring programme on behalf of the FSA and providing technical advice and recommendations on classification to the FSA and local authorities

Local authorities (LAs)

Carrying out official controls - classification and monitoring sampling for microbiological and biotoxin testing.

Official Control (OC) laboratories

Carrying out testing for the microbiological testing programme⁷

⁷ Approval of laboratories for shellfish control is not 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 OCL as long as it meets the required criteria. In the case of *E.coli* testing, LAs 'instruct' the designated OCLs to undertake the testing.

3 Getting Started

- 3.1. For a production or relaying area to be classified, an application form must be completed. Before an application form is submitted there are steps to follow in accordance with the application form and checklist. The form should be completed by the applicant (harvester) in liaison with the Environmental Health Officer (EHO) from the relevant LA and submitted by the LA via email to: shellfish@food.gov.uk in England or shellfish.wales@food.gov.uk in Wales.
- 3.2. FSA will undertake a verification check of the classification application and will progress a sanitary survey/PRMP assessment if required. Further details on sanitary surveys and PRMP assessments are set out in sections 5 and 6 of this document.
- 3.3. Applications should only be made when all the steps on the application form/ checklist have been followed, there is a viable commercial fishery, it has been confirmed that there would be no restriction on harvesting from the new area and there is stock for commercial harvesting.
- 3.4. Harvesters and LAs should allow time for the FSA verification and PRMP assessment to be carried out and the ten classification samples taken at least one week apart to be completed before harvesting is anticipated. This can take several months.
- 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.

Notes

- 3.6. Application forms and guidance on other permissions to consider and site selection can be found at:

<https://www.food.gov.uk/business-guidance/shellfish-production-area-assessments>

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 a production area has had a sanitary survey carried out and where existing or historic monitoring data allows for a robust risk assessment and immediate preliminary classification to be awarded.

Provisional Classification

- 4.3. Will be awarded to new shellfish areas where there is no existing monitoring data and where no sanitary survey has been undertaken, once the following has taken place:

- a desk based PRMP assessment.
- completion of a specified sampling plan and
- a minimum of ten classification samples, taken at least seven days apart will be required before a provisional classification is awarded based on the results of those classification samples.

- 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 biotoxins (and chemical contaminants where required). A full sanitary survey may still need to be undertaken

Annual/full Classification

- 4.5. Will 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. Further detail on sampling is in section 8.

Seasonal Classification

- 4.6. May be awarded when at least 2 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 one period of the year and B or C for the other. The season must be at least 3 months in length and of benefit to local industry.

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

- 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 LBMs harvested

from these areas are more likely to reflect this. Harvesters benefit from a more consistent classification, which is less vulnerable to single events.

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 providing the controls specified in Regulation 853/2004 (testing by the food business at fish auction, dispatch or processing establishment) are carried out to ensure that the end product standards are met.

Notes

- 4.9.** See section 7 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.

5.2. More information on sanitary surveys can be found at the links below:

<https://www.food.gov.uk/business-guidance/shellfish-production-area-assessments>

<https://eur1cefas.org/public-documents/official-control-guides.aspx>

5.3. On receipt of accepted shellfish classification applications, FSA will determine whether a sanitary survey is required. If a sanitary survey is required, FSA will initially carry out a Provisional Representative Monitoring Point (PRMP) assessment whilst awaiting the completion of the sanitary survey. This will identify a production area boundary and a monitoring point to allow sampling to begin as soon as possible.

6 Provisional Representative Monitoring Point (PRMP) Assessment

- 6.1. The PRMP assessment process takes the form of a desk top survey of the area to facilitate the classification process and enable classification sampling to begin as soon as possible. A full Sanitary Survey builds on this assessment with further verification steps (see below). It will assess the location and type of the shellfishery, location and types of sewage discharges, river inputs, harbours and available microbiological data from nearby areas.
- 6.2. The PRMP assessment report will:
- Detail provisional co-ordinates for the production area boundary;
 - Detail provisional *E. coli* RMP(s) for the area;
 - Detail the frequency and number of samples to be taken from each *E. coli* RMP as part of a provisional sampling plan;
 - Be reviewed later in the sanitary survey process as further information becomes available.
- 6.3. As much relevant information as possible is obtained from existing sources of publicly available information. Records from bodies such as the Environment Agency and Natural Resources Wales are utilised, as well as historic official control *E. coli* results.
- 6.4. Once the PRMP assessment is complete and the sampling plan is agreed by all parties, classification sampling by local authorities can begin.

Notes

- 6.5. Please note that until FSA issues a formal notification or interim update to confirm the classification status of an area, the area remains unclassified.
- 6.6. 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).

7 Further information on classification awards

Preliminary classifications

- 7.1. If a production area has been previously classified (within two years of new application), is currently classified for another species, and a sanitary survey has been carried out where there is sufficient data in order to make a robust assessment, then it may be possible to award an immediate preliminary classification to enable harvesting to commence.
- 7.2. Such classifications will be awarded based on the precautionary principle, to ensure public health is not jeopardised. 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.
- 7.3. 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.
- 7.4. Following the award of a preliminary classification a total of 10 samples are required to be collected by the applicant from the area 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.
- 7.5. 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 PRMP assessment of the production area may be carried out (**see section 6**) to determine future monitoring.

Provisional classifications

- 7.6. For new production or relaying areas, a sanitary survey is required to be undertaken.
- 7.7. Whilst awaiting the full sanitary survey for the production area, a PRMP assessment will be carried out to determine a provisional representative monitoring point and sampling plan for the new area to facilitate sampling for provisional classification.
- 7.8. 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 are to be harvested, the microbiological quality of **all** species must be determined separately.

- 7.9.** Compliance with the EU legislative classification criteria (see section 1) is required for provisional classifications.

Notes

- 7.10.** Sample results returning prohibited levels (over 46,000) of microbiological contamination during initial monitoring towards provisional classification, may result in the area being designated as 'prohibited' and the classification application rejected at that time.

Annual (full) classifications

- 7.11.** Following the award of the provisional classification, routine official control sampling will be carried out by LAs at the frequency recommended by the PRMP assessment or sanitary survey (this is generally monthly). The results of the samples collected from the established RMP(s) will contribute to an annual classification of the area.
- 7.12.** Within the calendar year, a minimum of 8 monthly sample results are required to award and maintain annual B and C area classification, whereas, to award and maintain an annual class A classification status, 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 FSA. (see section 7.14)

Seasonal classifications

- 7.13.** At least 2 years' worth of data 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 local industry (at a time they would usually harvest). Routine monthly monitoring should continue throughout the full calendar year.
- 7.14.** A transitional period before the start of the season is required. This is two months for Class C/B areas and one month for Class B/A areas. During this period two samples, taken at least a week apart must show compliance with the higher classification. Once these two samples show compliance, harvested products may be processed at the higher classification, even if it is still within the transitional period.

- 7.15.** If one or both samples in the transition period are not compliant, the LA can continue to sample until two consecutive compliant samples (at least 7 days apart) are obtained before the season at the 'better' classification may commence. 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 transitional samples) for two consecutive years then the seasonal classification period will be reviewed. Transitional results will normally be included in the classification dataset (i.e. used for classification assessments).

De-classification

- 7.16.** For classified areas that fail to submit the required number of sample results in a calendar year, or where there is insufficient stock for sampling, 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.
- 7.17.** 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 taking place, a preliminary classification may be awarded (see section 7.1) providing there are no issues with the quarterly monitoring data and once monthly monitoring recommences. If after two years there is no request to classify the area again, or there is unlikely to be commercial interest, it will be removed from the listing. A new classification application would need to be submitted to FSA if there was a request to classify the area after the production area has been removed from the listing.

8 Classification sampling and number of samples

- 8.1. 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: www.cefas.co.uk/cefas-data-hub/food-safety/classification-and-microbiological-monitoring/england-and-wales-classification-and-monitoring/current-sampling-plans/
- 8.2. Once a provisional classification has been awarded, official control sample collection will be carried out at a frequency recommended by the sanitary survey (usually monthly) over a calendar year.
- 8.3. All samples are required to be collected in accordance with FSA's shellfish sampling and transport protocols which include further detailed information including on temperature requirements.
- https://www.food.gov.uk/sites/default/files/sp-transport-of-samples-flesh_1.pdf
 - <https://www.cefas.co.uk/cefas-data-hub/food-safety/the-shellfish-partnership/guide-to-shellfish-sampling-protocols/>

Notes

- 8.4. 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 FSA.
- 8.5. If there are other circumstances which do not fit with these scenarios, Local Authorities (LAs) should contact the FSA/Cefas to discuss what sampling arrangements are necessary and this will be considered on a case by case basis. 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).
- 8.6. However:
- A minimum of 10 samples are required to award an A classification in any calendar year.
 - A minimum of 8 samples are required to award a classification B/C in any calendar year.
 - This also applies to seasonal areas

9 Sample analysis

- 9.1. Official control (OC) microbiological samples are analysed in designated OC laboratories⁸. Results are reported to Cefas and published on its website⁹
- 9.2. All testing undertaken by the OC laboratory is in accordance with the agreed 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.
- 9.3. EU Food Hygiene legislation permits the Competent Authority to consider results from FBOs' sampling to supplement those from official control (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.
- 9.4. 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.
- 9.5. 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). See link to the protocol:

<https://www.food.gov.uk/business-guidance/shellfish-supplementary-sampling>

⁸ 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”.

<https://www.food.gov.uk/about-us/food-and-feed-codes-of-practice>

⁹ <https://www.cefas.co.uk/cefas-data-hub/food-safety/classification-and-microbiological-monitoring/england-and-wales-classification-and-monitoring/shellfish-monitoring-results/>

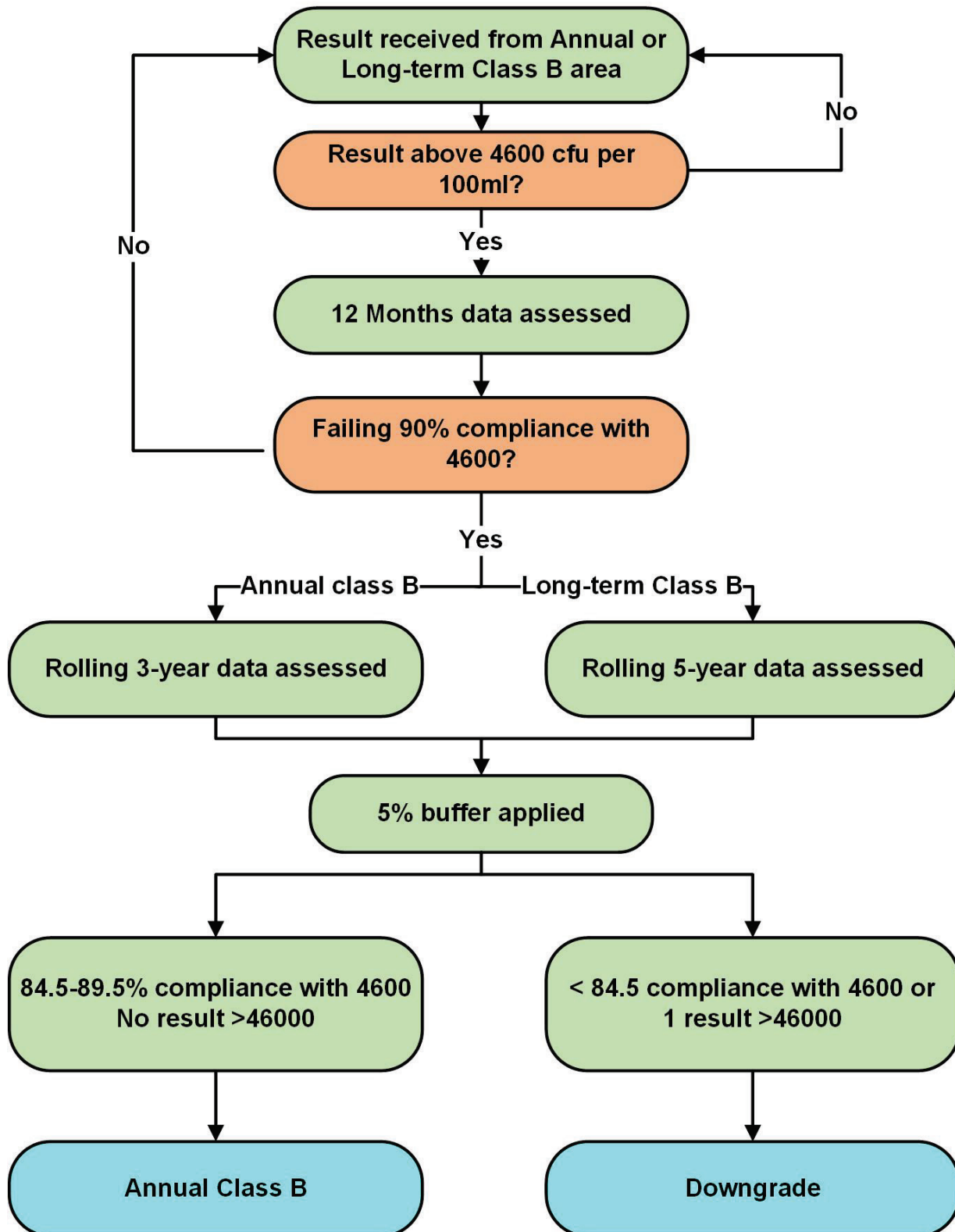
10 Classification Review

- 10.1.** Each year, FSA carries out an annual review of all shellfish classifications utilising the previous five year/ three year dataset (or all data if less than 3 years).
- 10.2.** 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.

In-year reviews

- 10.3.** 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 (sample results above the threshold of the classification awarded to the area – see below) and depending on the outcome of investigations these results may be disregarded from the dataset. Shellfish classifications may be revised at any point in year as needed and interim updates are sent to update stakeholders and LAs who should ensure all local industry members within their area of responsibility are aware of the changes.
- 10.4.** 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 flowcharts below illustrate how data from class A and B areas are assessed in-year.
- 10.5.** If significant changes in contaminating sources (e.g. significant known changes in sewage discharge arrangements) have occurred, then only the data obtained since the change(s) will be included in the review. This will be assessed on a case by case basis.

Assessment of Annual and Long-term Class B harvesting areas



11 Handling results

- 11.1.** When results above classification levels are returned, an investigative state is implemented for class A & B beds. For results about trigger levels an action state for all classifications (A, B & C) will be instigated. Procedures are set out in Annex 1. 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 FSA guidance for LAGs.
- 11.2.** Additional control measures may be required following elevated results, e.g. voluntary cessation of harvesting, increased end product testing or product withdrawal. The LA will liaise with the harvesters on such additional controls.
- 11.3.** A Temporary Closure Notice (TCN)¹⁰ may be put in place by LAs following any result that exceeds the classification threshold. LAs should share a copy of the TCN with the FSA. During a closure period, sampling is increased to weekly and the area re-opened following 2 consecutive satisfactory sample results. The classification of the area will be reviewed.

Actions following outcome of investigations

- 11.4.** OC results will be reviewed in the light of the outcome of investigations. If deemed appropriate by the FSA, results may be waived if there is sufficient justification to support that.
- 11.5.** 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 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 (TCN).
- 11.6.** Examples of events that may lead to results being disregarded are:
- Sewage treatment works failure*
 - 1 in 5 year (or longer) return period storm event*

¹⁰ Made under EC Regulation 854/2004 prohibiting the collection of any live bivalve molluscs from a designated area.

- Failure to comply with the standard sampling protocol – in practice this has meant the exclusion of results for samples that have exceeded the 48-hour limit between sampling and testing.

* Where it is deemed that the resulting discharges will have markedly impacted on the shellfish bed(s) – information obtained from the Environment Agency (EA) and LA is used to assist in this determination.

11.7. If, however, all results remain valid and overall compliance is less than that the EU legislative classification criteria then a re-classification /downgrade may be appropriate.

Downgrade criteria

11.8. Cefas will notify FSA and EA and advise the LA of the situation and ask them to inform industry. Cefas will review the dataset and data from neighbouring RMPs to determine whether the overall compliance warrants a downgrade and advise FSA via interim update recommendations. FSA will decide on whether to downgrade and will send out an interim update to confirm any downgrades.

Class A areas

3 results over 230 but less than 7,00, or 1 result over 700 in the rolling review year.

Class B and Long-term B areas

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

- 1 & 3 year compliance is less than 89.5%
or a result over 46,000 is returned
or
- 1 and 5 year (B-LT) compliance is less than 84.5% or a result over 46,000 is returned.

The site may be downgraded to class C following one result over 46,000 after the outcome of investigation into high result if compliance is failing (if this is the second result over 46,000, the site may be recommended for prohibition, however, each situation will be assessed on a case-by-case basis).

Class C areas

2 results over 46,000 (site will normally be recommended for prohibition, however, each situation will be assessed on a case-by-case basis)

Upgrade criteria

- 11.9.** Areas showing an improvement in compliance with regard to potential upgrade for all classifications 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 FSA.

Upgrade criteria Class B – A

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

Upgrade criteria Class C – B

- 11.11.** 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 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)

- 11.12.** Mandatory requirement: All results must be less than or equal to 46,000 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.

12 Contact details

FSA

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

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