

# Protocol for Classification of Shellfish Production Areas, England and Wales

September 2022

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 retained Regulation (EU) 2017/625 and retained 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 \(Issue 3\)](#)<sup>1</sup>.

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<sup>1</sup> References to EU Regulations in this Protocol are references to the retained EU law as found at the [legislation.gov.uk](https://www.legislation.gov.uk) website and should be read alongside any domestic legislation which amends it.

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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  
**OR**
  - after 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 in a Class B relaying area followed by purification in an approved establishment  
**OR**
  - relaying in a Class A relaying area<sup>2</sup>  
**OR**
  - an approved heat treatment

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<sup>2</sup> 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 monitoring programme<sup>3</sup>

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<sup>3</sup> 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 OC laboratory **as long as it meets the required criteria**. In the case of *E.coli* testing, LAs 'instruct' the designated OCLaboratories 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 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](mailto:shellfish@food.gov.uk) in England or [lasupportwales@food.gov.uk](mailto: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 be awarded a 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.** Retained Regulation (EC) No 853/2004 permits scallops (pectinidae) to be harvested from unclassified waters providing they are placed on the market via a fish auction, a dispatch centre or a processing establishment. Such consignments must be subject to a system of checks by food business operators in these establishments to demonstrate compliance with health standards (for marine biotoxins and the microbiological end product standard) and local authorities should conduct verification checks.
- 4.9.** Scallop harvesting grounds may be classified where monitoring data is available and the responsible local authority wishes classification to occur. In such cases, similar rules to those applied to live bivalve molluscs will apply to scallops harvested from classified production areas i.e. classified scallop production areas will be incorporated into the microbiological and biotoxin monitoring programmes and harvesters must comply with the requirements in retained Regulation 853/2004, Annex III, Section VII, Chapters I to VIII.

### **Additional notes**

- 4.10.** 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 [FSA website](#) and the [EU Good Practice Guide](#).
- 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 or '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.<br>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 re-classify, 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 laboratories<sup>4</sup>. Results are reported to Cefas and published on [its website](#).
- 8.2. Retained Regulation 2019/627 specifies the Most Probable Number, ISO 16649 part 3 as the reference method for analysis of *E.coli* and permits the use of alternative methods if they are validated against this reference method in accordance with the criteria in ISO 16140.
- 8.3. The OC laboratories are accredited by the UK Accreditation Service (UKAS) and take part in external quality assessments and UK National Reference Laboratory (NRL) ring trials.

### Supplementary samples

- 8.4. 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.
- 8.5. 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.
- 8.6. 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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<sup>4</sup> [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".

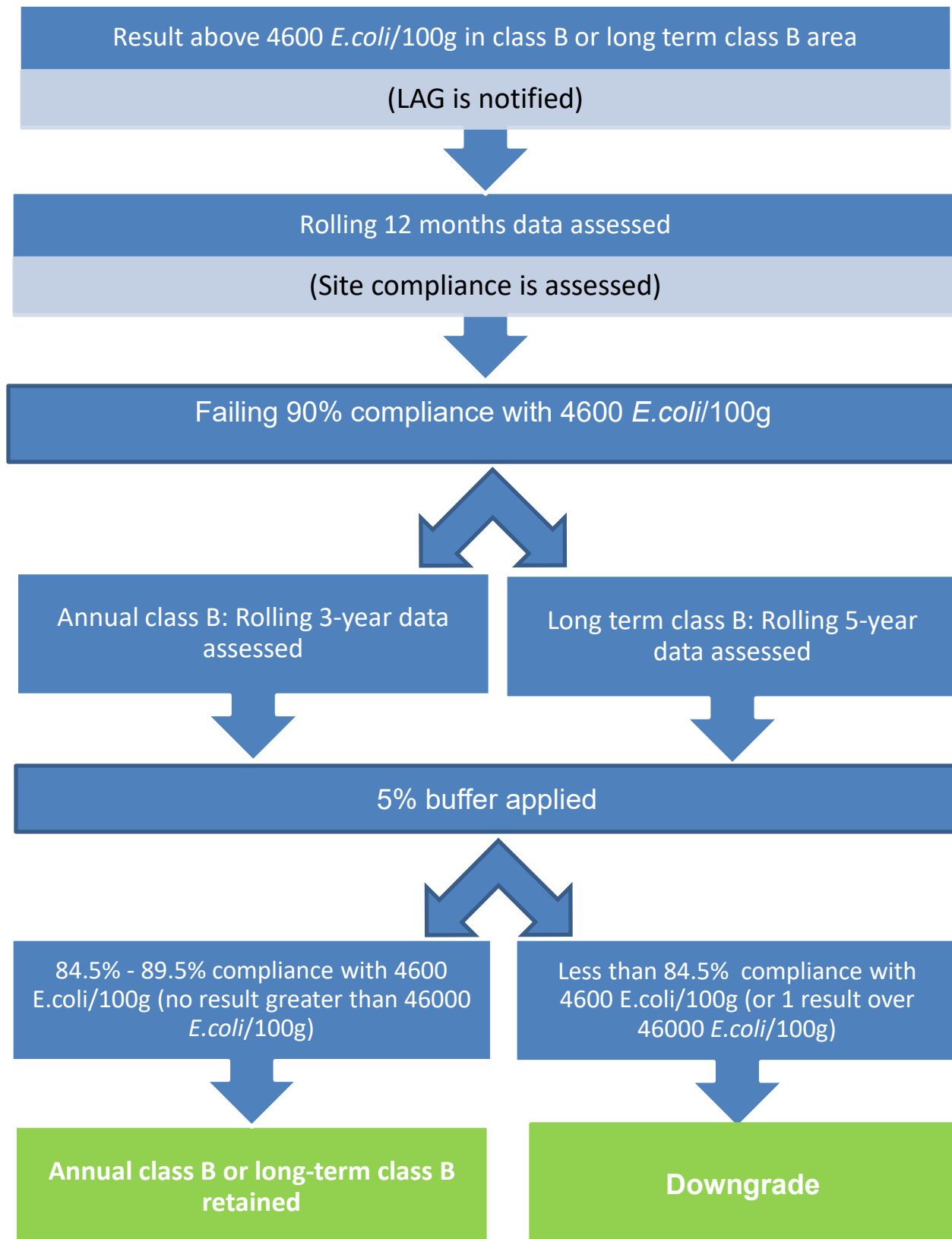
## **9 Classification Review**

- 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.

## In-year assessment of Class B areas with results above 4600 *E. coli* per 100g





## 10 Handling high results

- 10.1. When results above classification maximums are returned, an investigation state is implemented for Class A & B beds (Class A – results between 230-700 *E.coli* per 100g, B – results between 4,600 – 18,000 *E. coli* per 100g).
- 10.2. For **results above trigger levels (i.e. high results)** an action state for all classifications (Class A – above 700 *E.coli* per 100g, Class B – above 18,000 *E. coli* per 100g & Class C – above 46,000 *E. coli* per 100g) will be instigated. A notification will be sent to the LA advising what action is required. This will depend on both the magnitude of the result and the bed's current compliance. The LA is expected to initiate the Local Action Group (LAG) for the area. Further guidance is available in the [FSA guidance for LAGs](#).
- 10.3. Additional food safety 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 the risks to public health are controlled.
- 10.4. A Temporary Closure Notice (TCN)<sup>5</sup> or temporary downgrade 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 or downgrade period, sampling should be increased to weekly and temporary restrictions lifted following two consecutive satisfactory sample results compliant with the area's classification.

### Actions following outcome of investigations

- 10.5. OC results falling outside classification maximums are investigated following procedures in [FSA guidance for LAGs](#). The results and their potential impact on classification will be reviewed following the outcome of investigations and statistical analysis. If deemed appropriate by the FSA, results may be waived if there is sufficient justification to support that.
- 10.6. 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

<sup>5</sup> Made under Retained Commission Implementing Regulation (EU) 2019/627 prohibiting the collection of any live bivalve molluscs from a designated area.

Will not recur will be removed from the dataset. This will not, however, preclude the possibility of short-term control measures being applied to protect public health e.g. a temporary closure notice.

**10.7.** Examples of events that may lead to results being removed from the dataset are:

- Sewage treatment works failure\* or other pollution events
- 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/or samples arriving above the permitted temperature

**10.8.** Results above permitted classification thresholds where a cause during action state investigations cannot be found but that are markedly higher (or lower) than those previously recorded in the area may be considered 'statistically anomalous'. A statistical analysis will be carried out for sites with at least thirty samples over a representative minimum period of 30 months. Results falling more than 3 standard deviations (SD) above the mean contamination levels of a representative 30-month, log transformed dataset will be disregarded for the purpose of classification. Whilst these results will not lead to a downgrade in classification, they will remain within the dataset to ensure future statistical analyses are valid.

**10.9.** In addition for Class A and seasonal class A areas, occasional results slightly above the threshold (780 *E. coli* per 100g) may also be considered anomalous where monitoring data demonstrates that at least 80% of the samples contain *E. coli* less than or equal to 230 *E. coli* per 100g and an analysis of the 1 and 3 year dataset shows that the area is on-track to remain within the Class A criteria. These results will not lead to a change in classification unless compliance falls below 80% and will remain within the dataset for future compliance assessments.

**10.10.** Results not meeting the defined waiver criteria described above remain valid and are used to assess overall compliance. If compliance of an area is less than required for the classification then a downgrade may be appropriate. The flowcharts below illustrate the data assessment procedures.

## **Downgrade criteria**

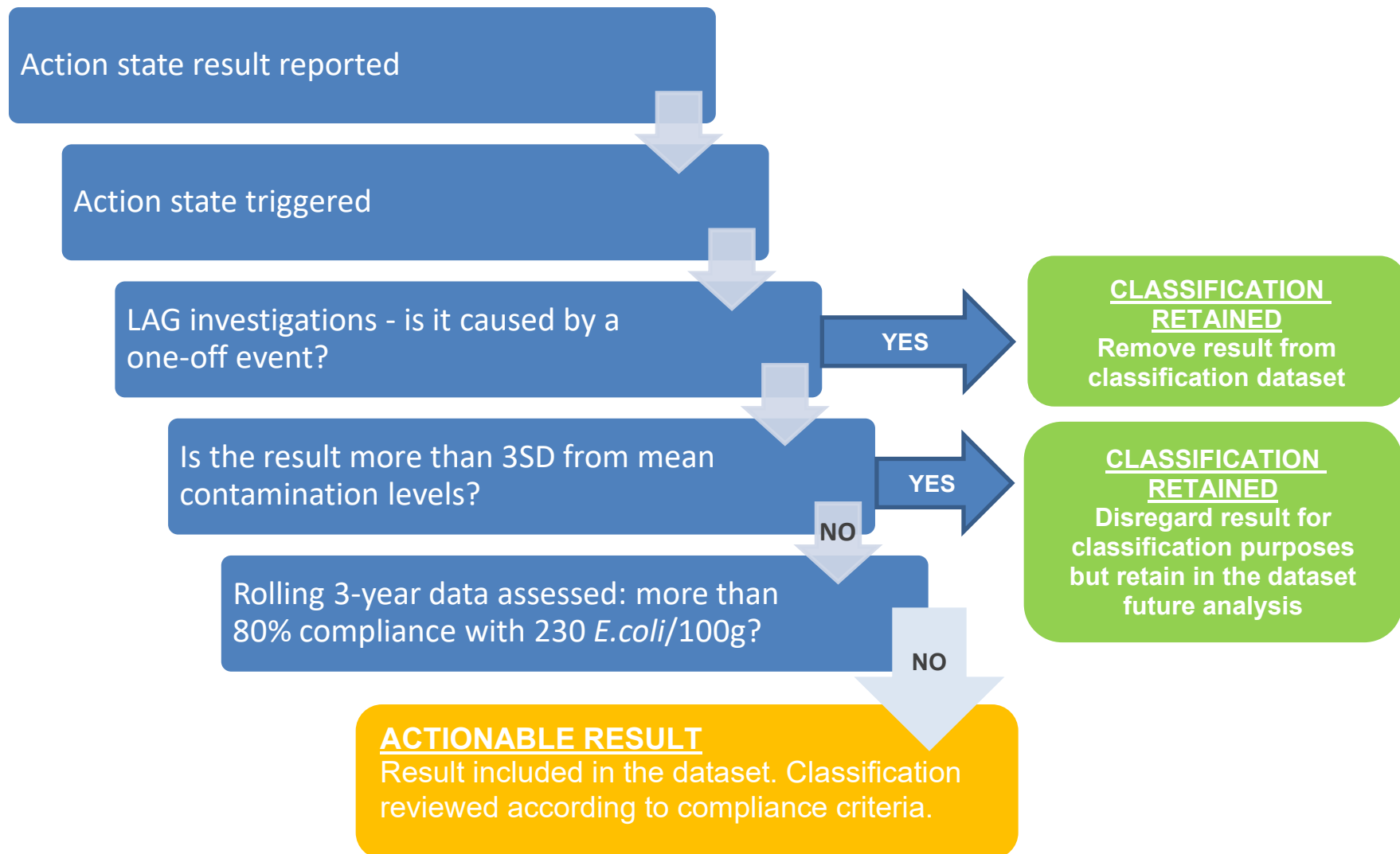
- 10.11.** Cefas will review the dataset to determine whether the overall compliance warrants a downgrade and advise the FSA by issuing interim update recommendations. Cefas will also notify the EA/NRW and the LA and ask them to inform industry of the recommendation. The FSA will make the final decision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

## **Class A areas**

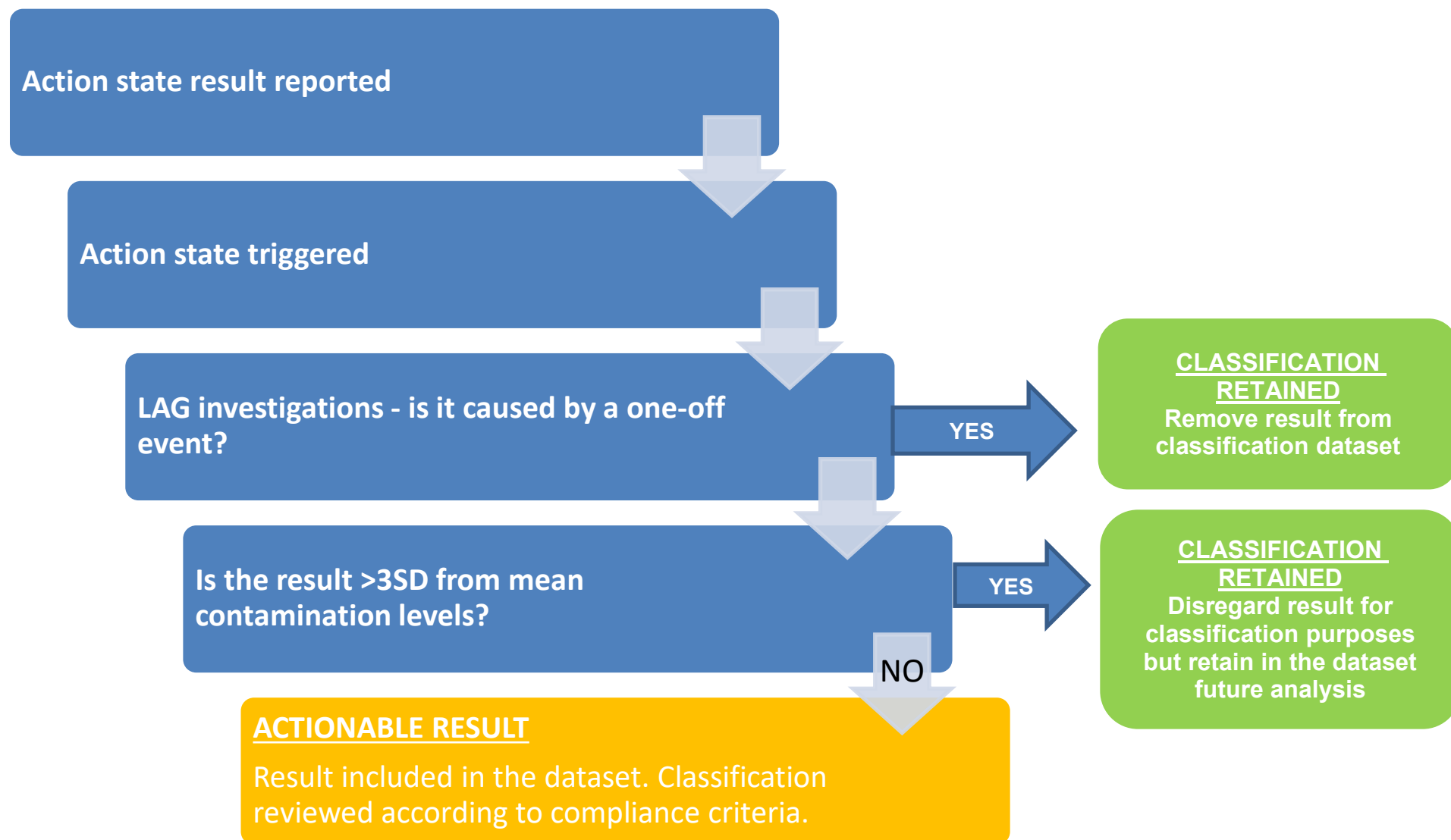
Site meets downgrade criteria as set out in Class A flowchart if:

- 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 not exceeding 3 standard deviations above the mean contamination levels for a log transformed dataset.  
**Or**
- 1 result between 700 *E. coli* per 100g and 780 *E. coli* per 100g and monitoring data indicates the area is failing to meet the Class A compliance

## Assessment of Class A areas with results between 700 -780 *E.coli* per 100g



**Results above action state thresholds (Class A, B and C areas)**



## **Class B and Long-term Class 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 over 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**

- 10.12.** 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**

- 10.13.** 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 [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**

- 10.14.** 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)**

- 10.15.** 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**

- 10.16.** In all cases, final decisions on designating or changing classification rest with the FSA. Decisions will be made based on available information.

## **11 Contact details**

### **FSA**

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[lasupportwales@food.gov.uk](mailto:lasupportwales@food.gov.uk) (Wales)

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