



Protocol for Classification of Shellfish Production Areas, Northern Ireland

August 2023

This protocol reflects policy decided by the Food Standards Agency (FSA) as Central Competent Authority in Northern Ireland 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 Community Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice](#). The protocol cannot cover every situation, where circumstances are not covered, the relevant legislation and guidance will be considered when making a decision.

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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. 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.

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 [relaying for at least one month](#) 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 [EC Community Guide](#), 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.** Food Safety 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

2.1 Food Standards Agency (FSA)

The FSA in Northern Ireland is responsible for the classification and monitoring of production and relay areas. This includes undertaking the sanitary survey process in the new production areas, establishing representative monitoring points (RMP) and reviewing existing sanitary surveys. The FSA can reclassify an area based on monitoring results. The FSA is also responsible for policy development.

2.2 District Councils (DCs)

District Councils are responsible for undertaking enforcement action where the health standards for shellfish have been exceeded or where there is a risk to human health. This includes where necessary, closure of a production area via a Temporary Closure Notice (TCN).

2.3 Official Control laboratories

Northern Ireland Public Health Laboratory (NIPHL) carry out FSA's OC microbiological testing.

2.4 Sampling bodies

Official control shellfish samples for microbiological analysis are collected by DCs, a private sampling contractor and the Loughs Agency in NI. The results of these samples are used to inform FSA's classification of production and relay areas.

2.5 Food Business Operator

Food Safety Regulations stipulate that the primary responsibility for food safety rests with the Food Business Operator.

2.6 Aquafact

Private contractor who carry out sanitary survey assessments on behalf of the FSA.

3 Application process for the classification of a new bed

- 3.1. Live bivalve molluscs can only be harvested or gathered from production or relaying areas with fixed locations and boundaries that the competent authority has classified. Scallops, non-filter feeding gastropods and holothuroidea are an exception to this requirement and may be harvested outside classified areas, however they are subject to land-based controls.
- 3.2. 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 district council and submitted to the FSA.
- 3.3. 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.
- 3.4. 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 and there is stock for commercial harvesting and official control sampling.
- 3.5. Harvesters should note that commercial harvesting cannot be carried out until the classification process has been completed. The classification process includes FSA verification, a completed sanitary survey (if required) and ten pre-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.
- 3.6. Shellfish harvesters who have requested classifications for multiple species in a single area 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 provisional, annual or seasonal classification.

Provisional classification

- 4.2. May be awarded to new shellfish areas where there is no 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 pre-classification samples, taken at least seven days apart.
- 4.3. Classification of an existing production area for a new species may be progressed quicker where there is existing monitoring data for a suitable indicator species. Similarly, classification of an area that has been declassified **within** the past 2 years and where existing or historic monitoring data allows a robust risk assessment. The FSA will review the data and confirm the approach in these circumstances.
- 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 classification

- 4.5. May be awarded to an area after a full 12 months of routine monthly monitoring and where 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.

Classification of scallop areas

4.7. Regulation (EC) No 853/2004 permit scallops (pectinidae) to be harvested from unclassified waters providing they are placed on the market via fish auction, dispatch centres or processing establishments. 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 district councils should conduct verification checks.

4.8. Scallop harvesting grounds may be classified where monitoring data is available and the responsible district council 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 Regulation 853/2004, Annex III, Section VII, Chapters I to VIII.

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 [FSA website](#) and the [EC Community 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 pre-classification 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:
 - 5.4.1. Detailed co-ordinates for the production area boundary;
 - 5.4.2. Detailed *E. coli* RMP(s) for the area;
 - 5.4.3. 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 Department of Agriculture, Environment and Rural Affairs (DAERA) fisheries and Northern Ireland Water (NIW) are utilised, as well as historical official control *E. coli* results, where available.

Additional notes

- 5.6. Until the FSA issues a classification 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

- 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 classification sooner.
- 6.2.** Information contained in the most recent sanitary survey report carried out in the production area will be used in the assessment process. A review of existing or historic monitoring data will also be considered in this process.
- 6.3.** An assessment of monitoring results will be reviewed and a provisional classification awarded.

Provisional classifications

- 6.4.** 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.
- 6.5.** To award a new provisional classification, a minimum of 10 samples, taken at least a week apart, are required to be collected by the FBO for microbiological analysis. More samples may be required for potential 'provisional A' classifications. Where more than one species is to be harvested, the microbiological quality of **all** species must be determined separately.

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

Additional notes

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

Annual classifications

- 6.8. Following the award of the provisional classification, routine official control sampling will be carried out by FSA 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.
- 6.9. Within a 12-month period, a minimum of 8 monthly sample results are required to award and maintain annual B and C area classifications. 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, and the area being awarded a dormant status or de-classified by the FSA (see section 6.15).

Seasonal classifications

- 6.10. 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.
- 6.11. A buffer period before the start of the 'better classification 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 official control monitoring sample must show compliance with the 'better' classification prior to the 'better' season commencing.

The 'better' classification is awarded 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:

| Example of seasonal classifications | | | | |
|--|------------------------|-------------------------------------|--|---|
| Stage | Date | Classification status | Required monitoring results | Shellfish treatment requirements |
| 1 | 1 April – 30 September | Class C season | Monthly samples contribute to rolling assessment of class C season | Shellfish must be treated in accordance with Class C requirements |
| 2 | 1 October – 31 October | Class B Buffer (area still Class C) | Monthly sample must be compliant with Class B standard | Shellfish must be treated in accordance with Class C requirements |
| 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. | Shellfish must be treated in accordance with Class B requirements |

- 6.12.** If the sample in the buffer period is not compliant with the ‘better’ classification, further samples may be taken 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.

Dormant status

- 6.13.** For classified areas that become commercially inactive for a temporary period of time, 6 months up to two years, FSA may remove the classification and award a ‘dormant’ status. During this period, if required, FSA will agree a reduced frequency of monitoring (quarterly) with the harvesters, provided there is sufficient stock to continue sampling. Dormant status will allow shellfish areas to quickly resume harvesting activity following a period of inactivity.
- 6.14.** If a harvester wishes to re-commence harvesting and a classification request is made for an area that has been dormant for less than the two year period, and at least quarterly monitoring was maintained, FSA may award a preliminary classification or re-instate the classification (depending on the sampling plan of the area prior to it going into dormancy).

De-classification

- 6.15.** If after two years there is no request to re-commence harvesting, or there is unlikely to be commercial interest, the area will be de-classified. Classified areas that fail to submit the required number of sample results in a calendar year or

where there is no stock available for sampling will also be de-classified. These areas will be placed on FSA's de-classified list for up to two years and no longer monitored. 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, pre-classification sampling will be undertaken by the FBO and the samples analysed for microbiological contamination.
- 7.2.** Once a provisional classification has been awarded, official control sampling will be carried out by FSA at a frequency recommended in the sampling plan in the sanitary survey (usually monthly) over the classification year (January to December).
- 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.

8 Sample analysis

- 8.1. Official control (OC) microbiological samples are analysed in a designated OC laboratory. The [microbiological results](#) are reported to FSA and published on our website.
- 8.2. Regulation 2019/627 specifies the Most Probable Number (MPN), 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 laboratory is accredited by the UK Accreditation Service (UKAS) for this method and takes part in external quality assessments and UK National Reference Laboratory (NRL) ring trials.

Supplementary samples

- 8.4. Food Safety 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 the [supplementary sampling guide](#) 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).

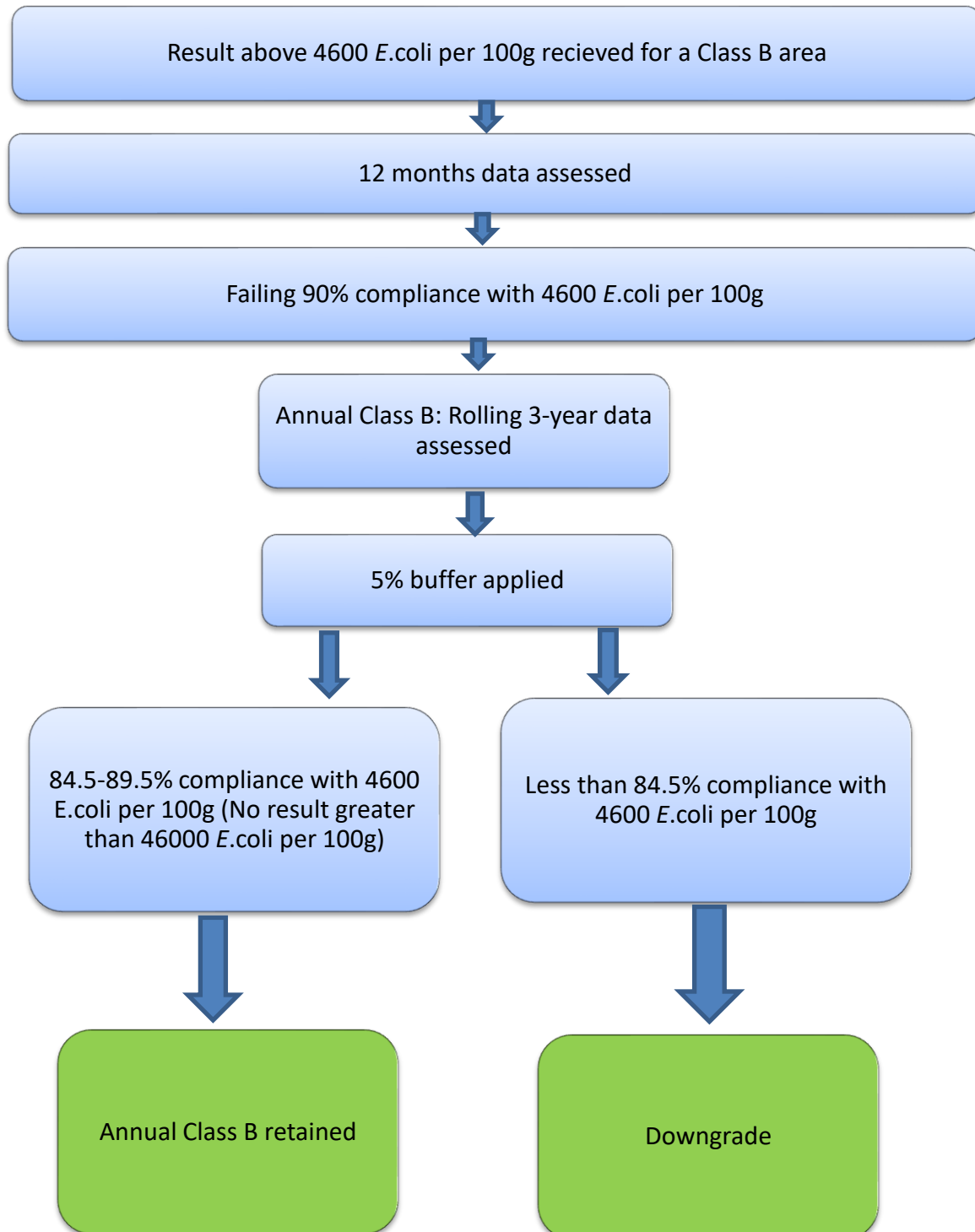
9. Classification Review

- 9.1.** Each year, the FSA carries out an annual review of all shellfish classifications utilising the one year and three year dataset or all data if less than 3 years worth of monitoring has been carried out.
- 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 investigated and acted upon. 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 issued to all relevant stakeholders.
- 9.4.** Class B production and relaying areas showing marginal compliance will be reviewed in-year accordance the flowchart below.

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



10. Handling results

- 10.1.** When results above classification maximums are returned (outwith results), an investigation is initiated (Class A – results between 230-700 *E.coli* per 100g, Class B – results between 4,600 – 46,000 *E. coli* per 100g and results above 46,000 *E. coli* per 100g. Notifications will be sent to the DC and all relevant shellfish stakeholders including sampling officers, DAERA Fisheries, NI Water and Food Business Operators to initiate investigations.
- 10.2.** Additional measures may be required following outwith results, e.g., increased end product testing or product withdrawal. The DC will liaise with the harvesters on such additional measures to ensure public health protection. The DC is expected to inform FSA in NI of the additional measures implemented.
- 10.3.** A Temporary Closure Notice (TCN)⁴ may be put in place by DCs following any result that exceeds the regulatory limit for microbiological contamination. FSA will liaise with DCs immediately on any closures and will give consideration to whether any action should be taken to withdraw any LBMs from sale that has already been distributed locally or nationally. During a closure period, additional sampling demonstrating results compliant with the classification of the area will be required to revoke the additional measures implemented (see 10.4 and 10.5 for details.)
- 10.4.** In Class A areas where the outwith result is below 46,000 *E.coli* per 100g, additional sampling may be undertaken as soon as is practicably possible:
- If the result of the first re-sample is **below** the lower compliance threshold 230 *E. coli*/100g for Class A, and there are no other risks to public health, additional measures may be revoked.
 - If the result of the first re-sample is **above** the lower compliance threshold 230 *E. coli*/100g, sampling should continue and additional measures remain in place until a compliant result is obtained.
- 10.5.** Where the result is above 46,000 *E. coli*/100g, sampling will be increased to weekly and the area re-opened following two consecutive satisfactory sample results compliant with that area's classification.

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

Actions following outcome of investigations

10.6. OC results will be reviewed following the outcome of investigations.

10.7. 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.

10.8. 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
- 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 DAERA Fisheries, NI Water and DC is used to assist in this determination.

** In practice this has meant the exclusion of results for samples that have exceeded the 24-hour limit between sampling and testing and samples arriving above the permitted temperature.

- 10.9.** If, however, all results remain valid and overall compliance is less than required for the classification then a downgrade may be required.
- 10.10.** Results above classification maximums where a cause cannot be found but that are markedly higher (or lower) than those previously recorded may be considered 'statistically anomalous'. A statistical analysis will be carried out for sites with at least 30 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 analysis is valid.
- 10.11.** In addition for Class A areas, occasional results slightly above the threshold for Class A harvesting areas (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 a statistical 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.
- 10.12.** 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 more appropriate. The flowcharts below illustrate the data assessment procedures for Class A (including seasonal Class A).

Downgrade criteria

- 10.13.** FSA will review the dataset to determine whether the overall compliance warrants a downgrade. FSA will also notify all relevant stakeholders. The FSA will make the final decision on whether to downgrade and will send out an interim update to confirm.

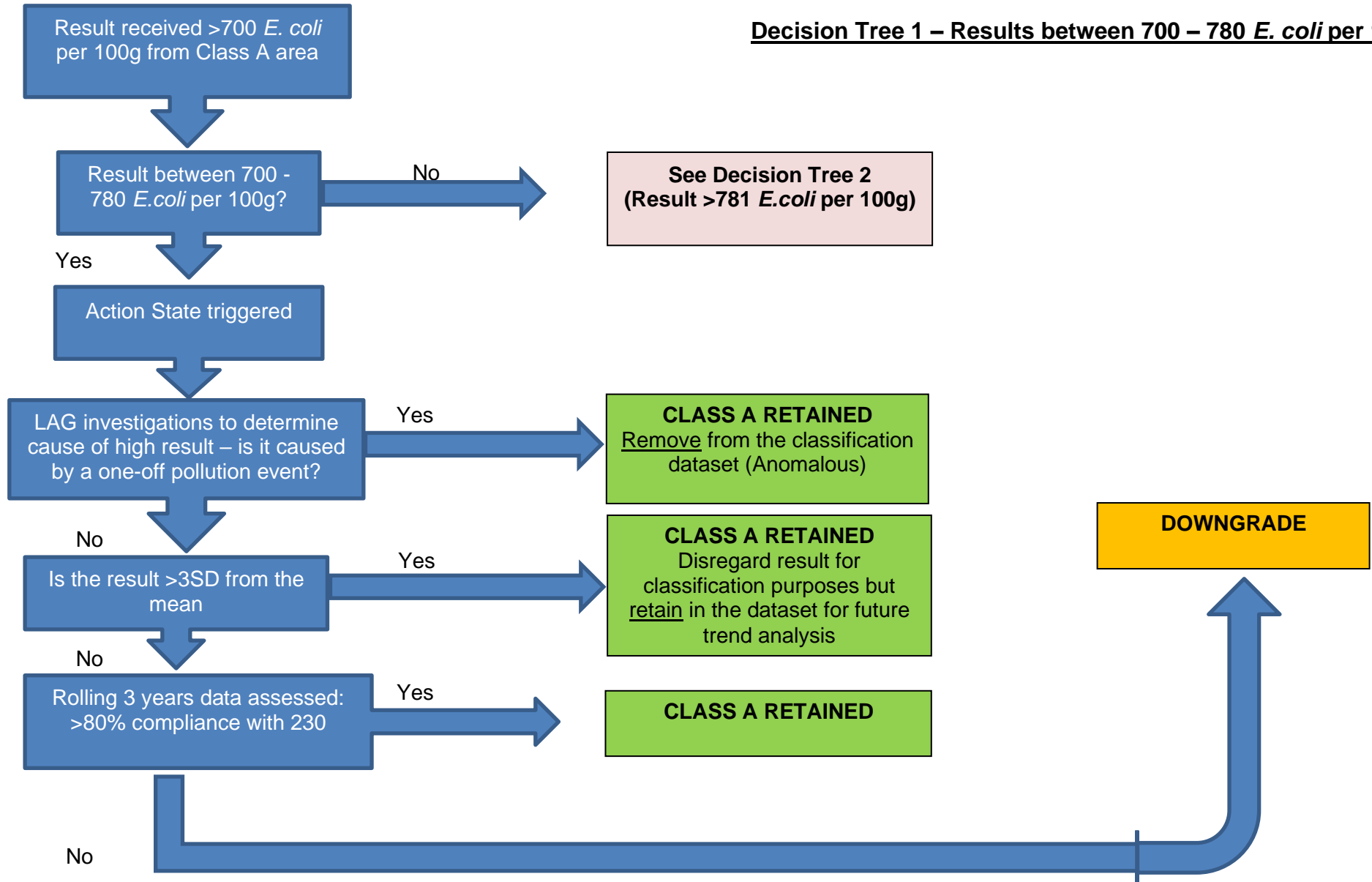
Class A areas

Site meets downgrade criteria if:

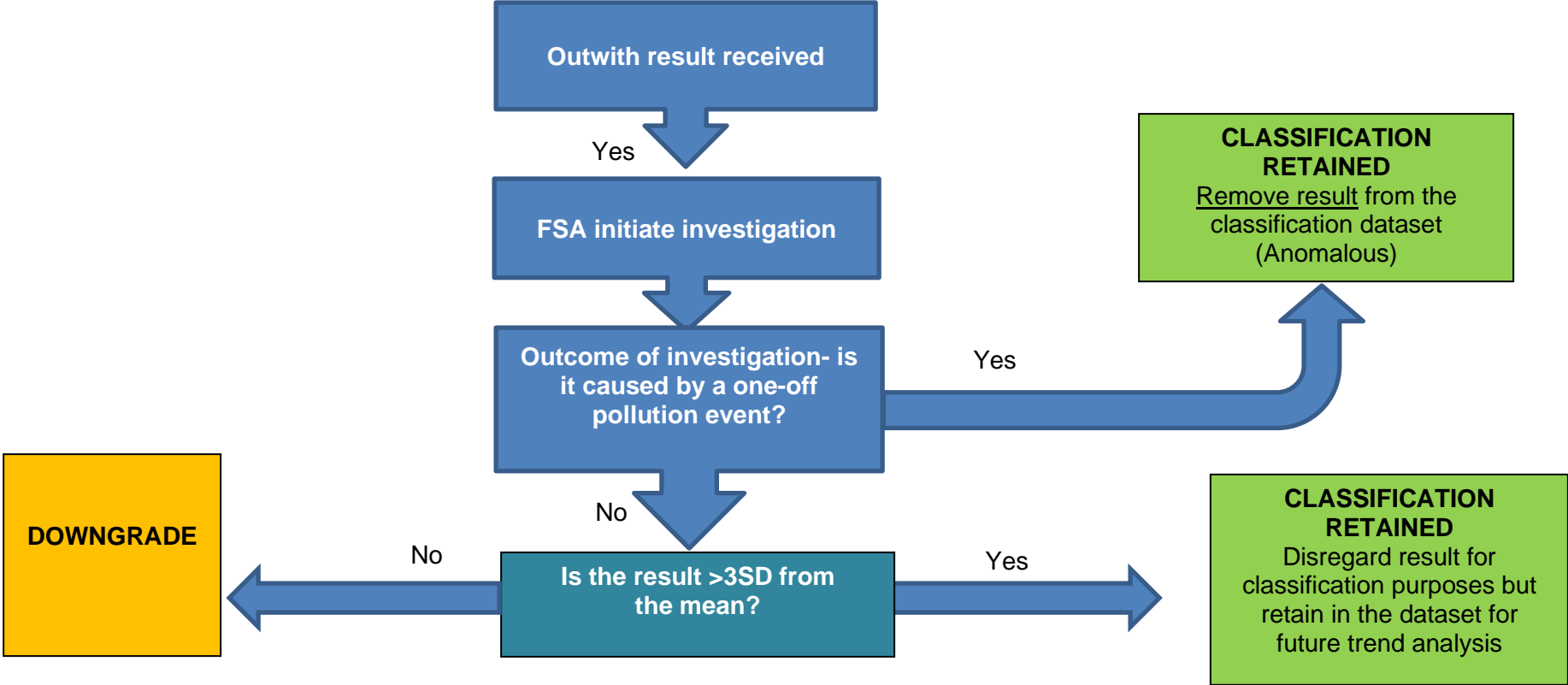
- 3 year compliance is less than 80% with 230 *E. coli* per 100 g
 - **or**
- 1 result over 700 *E. coli* per 100g not exceeding 3 standard deviations above the mean contamination levels for a log transformed dataset.
 - **or**
- 1 result between 700 *E.coli* 100g and 780 *E.coli* per 100g and monitoring data indicates the area is failing to meet the Class A compliance.

Assessment of Class A areas with results above 700 *E.coli* per 100g

Decision Tree 1 – Results between 700 – 780 *E. coli* per 100g



Decision Tree 2 – Results above classification maximums (Class A, B and C areas)



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

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.

Class C areas

- An area returning a series of results 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

10.14. Areas showing an improvement in compliance with regards to potential upgrade will be reviewed on a rolling basis following receipt of each result. If an upgrade is awarded, this will be confirmed in an interim update by the FSA.

Upgrade criteria Class B – A

10.15. 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 [EC Community Guide](#), where known discharge improvements have taken place then this period may be reduced with increased monitoring frequency.

Upgrade criteria Class C – B

10.16. Mandatory requirement: 90% of results must be less than or equal to 4,600 over the most recent 3-year period (at least 24 samples) with no result over 46,000 *E. coli* per 100g within that period. Where known discharge improvements have taken place then this period may be reduced with increased monitoring frequency.

Additional notes

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

11 Contact details

Food Standards Agency

10a-c Clarendon Road

Belfast

BT1 3BG

Email – executive.support@food.gov.uk