Protocol for Classification of Shellfish Production Areas, England and Wales

March 2026

This protocol reflects policy decided by the Food Standards Agency (FSA) as Central Competent Authority in England and Wales for this area of work[1]. It is intended to meet the official control requirements of Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2019/627 in the interests of public health and considers the recommendations contained in the European Union Reference Laboratory (EURL) Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice (Issue 3). This 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] References to EU Regulations in this Protocol are references to the assimilated EU law as found at the legislation.gov.uk website and should be read alongside any domestic legislation which amends it.

Contents

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 in Article 14 of Regulation (EC) 178/2002 and more specific requirements in Annex II of Regulation (EC) 853/2004 and the microbiological criteria adopted under [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
   - relaying 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[2]
      OR
   - an approved heat treatment

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[2] 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.   Legislation 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.

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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.

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
- Providing support to Official Laboratories (OLs) as the National Reference Laboratory (NRL) for bacterial contamination of bivalve molluscs

Local authorities (LAs)
- Carry out official controls including undertaking microbiological, phytoplankton and biotoxin sampling.

Official laboratories (OIs)
- Carry out testing for the microbiological monitoring programme[3]

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[3] Approval of laboratories for shellfish control is <u>not</u> undertaken by UKHSA, Public Health Wales (PHW) or the NRL. In order to become an Official Laboratory for monitoring *Escherichia coli* in shellfish, the Local Authority has to show that they wish to use that particular laboratory for official controls and request the FSA to designate the laboratory as an official laboratory **as long as it meets the required criteria**. In the case of *E. coli* testing, LAs 'instruct' the designated OLs to undertake the testing. A list of designated OLs for monitoring *E. coli* in shellfish can be found on the FSA website.

3 Getting Started

3.1. For a production or relaying area to be classified, a shellfish classification 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 local authority 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 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 being 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 provisional, annual, seasonal or long-term classification.

Provisional Classification

4.2.   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

4.3.   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 but with monitoring having continued on a quarterly frequency may be reinstated if the monitoring data allows for 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/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. 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 Regulation (EC) No. 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 determine a 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.

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;
- *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 routine monitoring results.

Remote harvesting areas

5.6. If a new sanitary survey (or review of an existing sanitary survey) determines a production or relaying area is not impacted by direct sources of animal or human pollution and therefore is assumed to be homogenous with respect to microbiological contamination, it shall be designated a 'remote area'. A remote designation is not linked to distance of the harvesting area from the coast.

5.7. The agreed sampling plan derived from the sanitary survey (or review of an existing sanitary survey) will use one of two alternative approaches for *E. coli* monitoring compared to the fixed RMP used for harvesting areas impacted by direct sources of contamination.

5.8. The first allows sampling at the centroid of the harvesting area. The second

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allows sampling from anywhere within the boundaries of the harvesting area, with classification assessed as though all samples originate from a 'virtual monitoring point'. The definitions below apply:

- 'Remote area' is a production or relaying area where a new sanitary survey (or review of an existing sanitary survey) determines there are no direct impacting sources of animal or human pollution and that microbiological contamination is assumed to be homogenous within its boundary.
- 'Non-fixed sample' is a sample collected anywhere within the boundary of a 'remote area' in accordance with an agreed sampling plan (virtual monitoring point). The classification of a 'remote area' will be assessed as though all non-fixed samples originate from the same virtual monitoring point.
- 'Centroid' is the visual (fixed) centre of a polygon.

5.8   For samples collected from a virtual monitoring point (VMP), the actual location of sampling should be noted on the sample submission form accompanying each official control sample collected from a 'remote area' and submitted for testing. This information will also be logged on the monitoring programme.

5.9   A 'remote area' designation is retained until a subsequent review of the sanitary survey indicates that there are newly identified contamination sources directly impacting on the area.

Additional notes

5.10   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.

5.11   As well as *E. coli* monitoring, biotoxin monitoring (two satisfactory samples taken at least a week apart) will also be required 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 and quarterly monitoring has been in place during this time), 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 a classification sooner.

6.2. Information contained in the most recent sanitary survey undertaken in the production area will be used in the assessment process. Monitoring data will also be considered.

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 for microbiological analysis. 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 during initial monitoring, may result in the area being designated as 'prohibited' and the classification application rejected.

Annual (full) classifications

6.8. 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.

6.9. Monthly monitoring is usually expected to maintain a full classification unless otherwise agreed. 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 declassified by the FSA (see section 6.14).

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 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. Any non-compliant results will trigger a review of the eligibility of the season.	Class B

6.12. 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. 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).

6.13. The minimum sample numbers stated in 6.9 apply to seasonal classifications.

Declassification

6.14. A classified area may be declassified if the required number of sample results in a calendar year fail to be submitted, where there is insufficient stock for sampling, or the area is closed to harvesting by other authorities. It will be placed on the FSA's declassified list and can be either unmonitored or monitored quarterly. The list is reviewed as part of the annual review process.

6.15. Where a classification request is made for a declassified area (see Section 6.1), a classification can be awarded provided that:

- The area has been declassified for less than two years
- Quarterly sampling has been undertaken
- Routine monitoring has recommenced

6.16. 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 (1 October to 30 September).

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.   The minimum sample numbers in 6.11 may be reviewed by FSA if areas are for instance, formally closed/have low stocks for an extended period of time.

7.5.   If there are other circumstances which do not fit with these scenarios, local 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).

8   Sample analysis

8.1.   Official control (OC) microbiological samples must be analysed by designated OLs[4]. Results are reported to Cefas and published on [their website](#).

8.2.   Regulation 2019/627 specifies the Most Probable Number, ISO 16649 part 3 as the reference method for analysis of *E.coli* in live bivalve molluscs. The legislation permits the use of alternative methods if they are validated against the reference method and meet the criteria in ISO 16140. The modified Colony Count ('Pour Plate') method[5] and the Impedance method meet these requirements and may be used for official control testing.

8.3.   The OLs are accredited by the UK Accreditation Service (UKAS) and take part in external quality assessments, proficiency testing schemes and UK National Reference Laboratory (NRL) training.

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 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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[4] [The Food Law Code of Practice](#) defines official laboratory as "A laboratory accredited for the purposes of analysis, and which appears on the list of official food control laboratories".

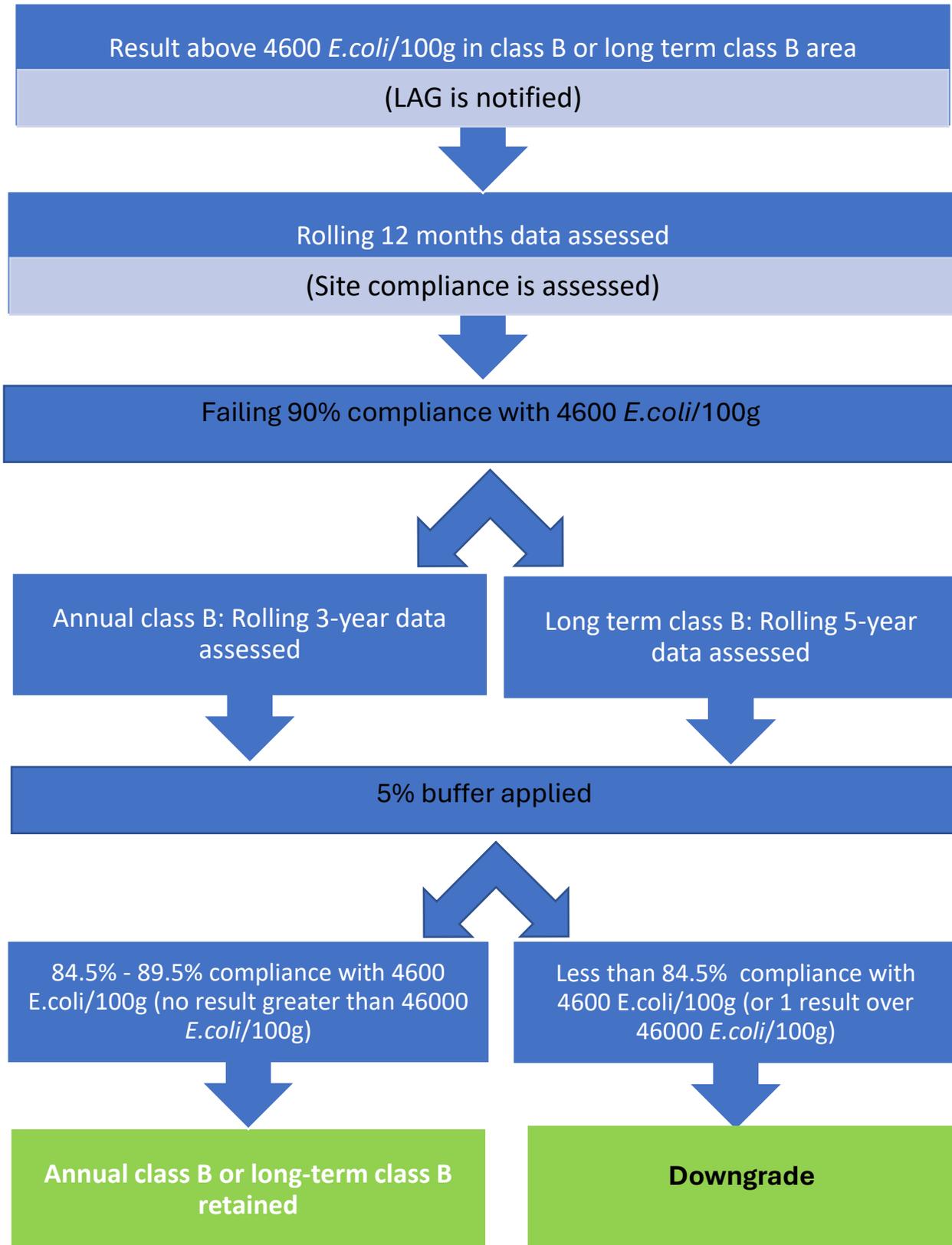[5] Using the protocol published by the [National Reference Laboratory](#)

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 less than 3 years' monitoring data.

In-year reviews

9.3.   OC microbiological results and shellfish classifications are also examined on an on-going basis during the year considering the appropriate 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

Result above 4600 *E.coli*/100g in class B or long term class B area

(LAG is notified)

Rolling 12 months data assessed

(Site compliance is assessed)

Failing 90% compliance with 4600 *E.coli*/100g

Annual class B: Rolling 3-year data assessed

Long term class B: Rolling 5-year data assessed

5% buffer applied

84.5% - 89.5% compliance with 4600 E.coli/100g (no result greater than 46000 *E.coli*/100g)

Less than 84.5% compliance with 4600 E.coli/100g (or 1 result over 46000 *E.coli*/100g)

Annual class B or long-term class B retained

Downgrade

10 Handling high results

10.1. When results above classification threshold 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). A notification will be sent to the responsible LA. The notification type sent will depend on the compliance of the site. Further guidance is available in the FSA guidance for LAGs

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 Plan (LAP) and alert 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)[6] 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 have already been distributed locally or nationally. During a closure or downgrade period, additional samples returning results compliant with the classification of the area will be required to revoke short term control measures (see 10.5 and 10.6 for details).

10.5. In Class A and Class B areas where the trigger result is below 46,000 *E. coli*/100g, additional sampling may be undertaken as soon as practicable:

- If the result of the first re-sample is below the lower compliance threshold (230 and 4,600 *E. coli*/100g, respectively), and there are no other risks to public health, short-term control measures may be revoked.

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

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- If the result of the first re-sample is above the lower compliance threshold (230 and 4,600 *E. coli*/100g, respectively), further sampling should continue and short-term control measures remain in place until a compliant result (i.e. a result below the lower compliance threshold) is obtained. Additional sampling may be undertaken as soon as practicable in all circumstances.

10.6. Where the trigger result is above 46,000 *E. coli*/100g, short-term control measures must remain in place until two results below the lower compliance limit from consecutive samples taken at least 7 days apart are reported. Additional sampling should commence at least one week (7 days) after the action state trigger sample was collected.

Actions following outcome of investigations

10.7. 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.

10.8. Results that can be attributed quite clearly to very unusual or "one-off events" (usually up to 120 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 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.

10.9. 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

10.10. 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.

10.11. Occasional results slightly above the threshold (780 *E. coli* per 100g) in Class A and seasonal class A areas will be considered anomalous where those results have been generated using the Most Probable Number (MPN) method and where monitoring data demonstrates that at least 80% of the samples contain *E. coli* less than or equal to 230 *E. coli* per 100g. This provision does not apply to results generated using the validated Colony Count (Pour Plate) method.

10.12. Results of 780 *E. coli* per 100g recorded using the MPN method will not lead to a change in classification unless compliance falls below 80%. These results will remain within the dataset for future compliance assessments.

10.13. 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. A flowchart illustrating the data assessment procedures is on p. 23.
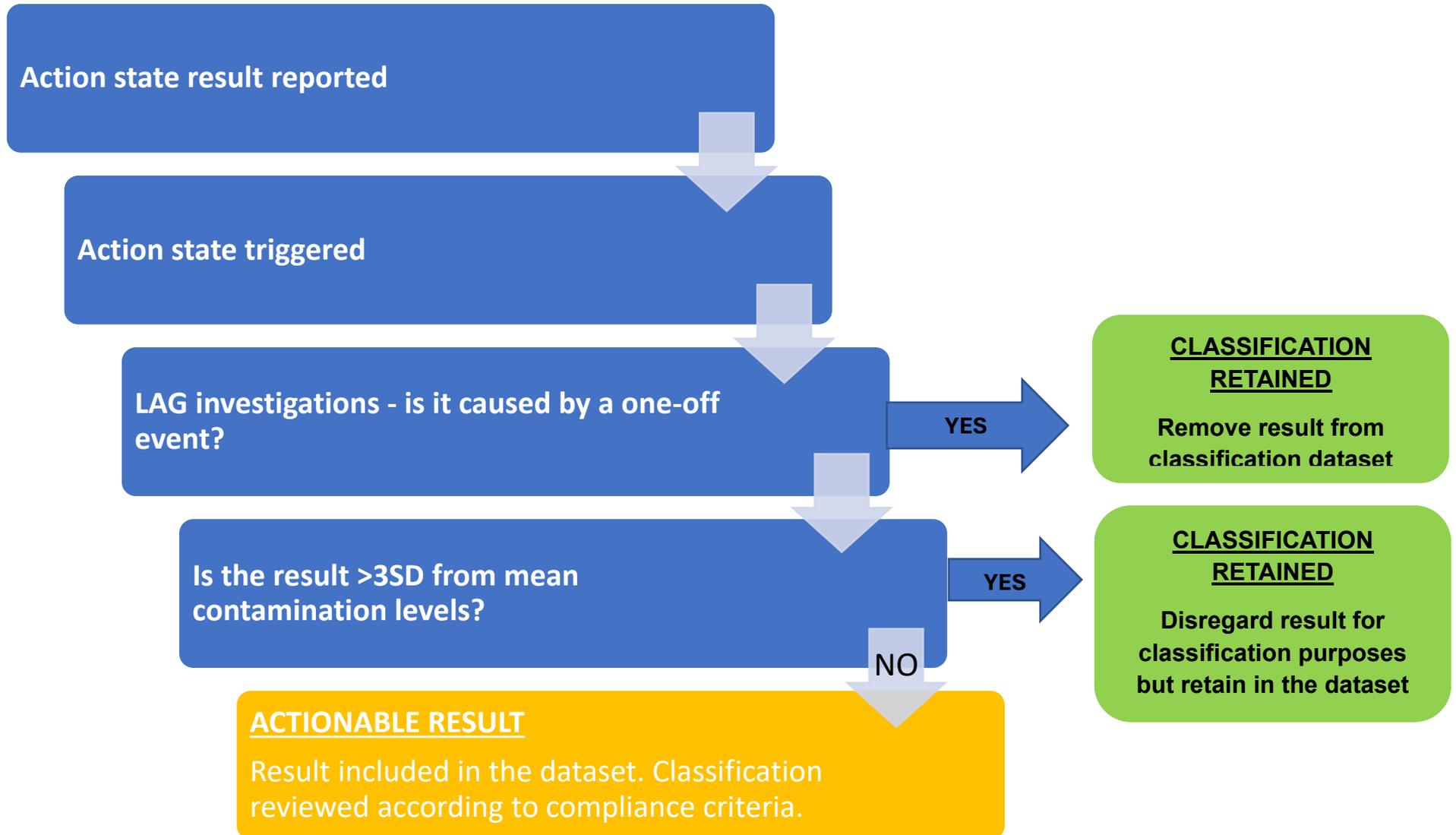
Downgrade criteria

10.14. 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 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 MPN 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. Flowchart for MPN decision-tree is available in the Annex.

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

Action state result reported

Action state triggered

LAG investigations - is it caused by a one-off event? — **YES** → **CLASSIFICATION RETAINED** — Remove result from classification dataset

Is the result >3SD from mean contamination levels? — **YES** → **CLASSIFICATION RETAINED** — Disregard result for classification purposes but retain in the dataset

NO → **ACTIONABLE RESULT** — Result included in the dataset. Classification reviewed according to compliance criteria.

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

10.15. 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

10.16. 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

10.17. 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 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)

10.18. 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

10.19. In all cases, final decisions on designating or changing classification rest with the FSA. Decisions will be made based on available information.
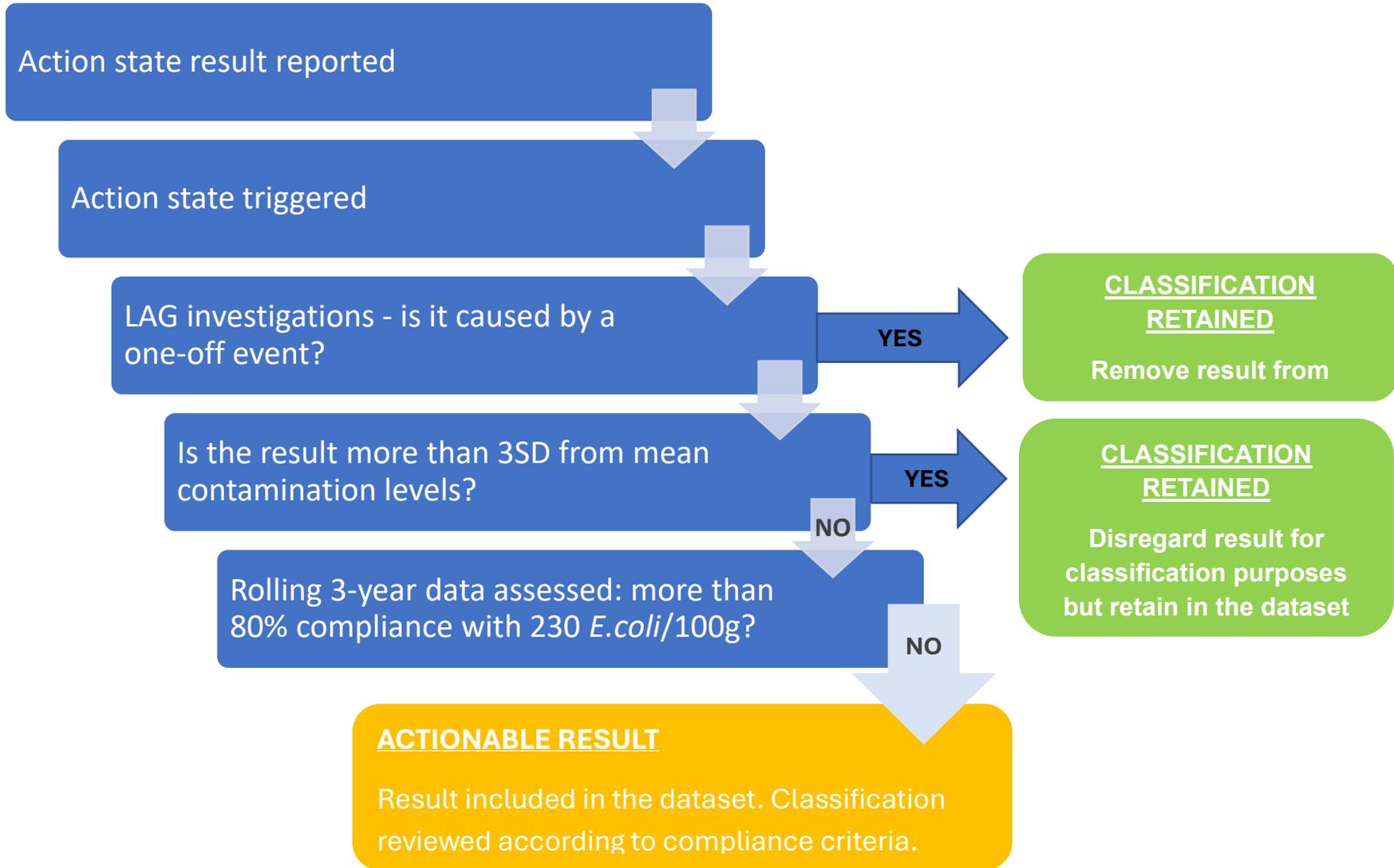
11 Contact details

FSA
shellfish@food.gov.uk (England)
shellfish.wales@food.gov.uk (Wales)

Cefas (contractor for co-ordination of the shellfish monitoring programme on behalf of the FSA)
 shellclass@cefas.co.uk

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

Action state result reported

Action state triggered

LAG investigations - is it caused by a one-off event? — **YES** → **CLASSIFICATION RETAINED**
Remove result from

Is the result more than 3SD from mean contamination levels? — **YES** → **CLASSIFICATION RETAINED**
Disregard result for classification purposes but retain in the dataset

NO

Rolling 3-year data assessed: more than 80% compliance with 230 *E.coli*/100g?

NO

ACTIONABLE RESULT

Result included in the dataset. Classification reviewed according to compliance criteria.