

Protocol for the Classification of Shellfish production and relaying areas in Northern Ireland



Version 1 – July 2017

Protocol for Classification of Shellfish Production and Relaying Areas in Northern Ireland

This protocol reflects policy decided by the Food Standards Agency (FSA) as Competent Authority in Northern Ireland for this area of work. It is intended to meet the legislative requirements of EC Regulation 854/2004 and take into account the recommendations contained in the European Good Practice Guide at: <https://eur.cef.eu/public-documents/official-control-guides.aspx>

1.0 Introduction

1.1 Regulation 854/2004 lays down the official control (OC) requirements for the Competent Authority (CA) concerning Live Bivalve Molluscs (LBMs). These controls include the classification and monitoring of production and relaying areas from which the CA authorises the harvesting of LBMs. The classification of a production area determines the treatment required before the molluscs may be marketed: -

Table 1: Shellfish classification categories

<input type="checkbox"/> Class A – 80% of sample results ≤ 230 <i>E.coli</i> /100g, no results exceeding 700 <i>E.coli</i> /100g – molluscs can be harvested for direct human consumption provided the end product standard is met.
<input type="checkbox"/> Class B - 90% of sample results must be less than or equal to 4600 <i>E. Coli</i> /100g with none exceeding 46000 <i>E. Coli</i> /100g - molluscs can go for human consumption after: <ul style="list-style-type: none">• purification in an approved establishment, or• relaying in a classified Class A relaying area, or• an EC approved heat treatment process.
<input type="checkbox"/> Class C - ≤ 46000 <i>E. Coli</i> /100g - molluscs can go for human consumption only after either: <ul style="list-style-type: none">• relaying for at least two months in a classified relaying area (followed by, where necessary, treatment in an approved purification centre, or• an EC approved heat treatment process.
<input type="checkbox"/> Prohibited areas ¹ (>46000 E. Coli/100g) - molluscs must not be subject to production or be harvested.

1.2 If the Food Standards Agency (FSA), as CA, decides to classify a production or relaying area, it must first establish the location and fix the boundaries of the area to be classified and assess the area for likely sources of contamination and identify a Representative Monitoring Point (RMP) and sampling plan. This is achieved through a sanitary survey being carried out.

1.3 As part of the sanitary survey process, for new areas, an initial assessment may be carried out to establish an appropriate monitoring point for the purposes of gathering

¹ Not a legal definition but used to denote areas which are unfit for commercial harvesting of LBMs for health reasons e.g. those consistently returning prohibited level results

indicative data on the hygiene status of the fishery (Provisional Representative Monitoring Point (pRMP) assessment).

1.4 The faecal coliform indicating bacteria, *E. coli*, is used to establish the degree of contamination in areas where LBMs are to be harvested and classifications are awarded by FSA, according to the levels of contamination detected in samples of LBM flesh (Table 1).

1.5 The EU Food Hygiene Regulations require relaying areas to be classified and monitored in a similar manner to production areas. They must have clearly identifiable boundaries by the use of 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.

2.0 Types of Classification

2.1 Shellfish production or relaying areas may be awarded a preliminary, provisional, annual, seasonal or part year classification.

Preliminary classification

- May be considered for an area which is currently classified for another species or has been declassified less than 2 years. Furthermore, it may be considered if the production area has had a sanitary survey carried out and where existing or historic monitoring data allows for a robust risk assessment and immediate preliminary classification to be awarded.

Provisional Classification

- Will be awarded to new shellfish areas where there is no existing or historic monitoring data and where no sanitary survey has been carried out. An interim sanitary survey of the new area will need to be undertaken and completion of a specified sampling plan will be required. An interim desk based assessment may be undertaken while a sanitary survey is carried out to enable a provisional classification to be awarded.

Annual Classification

- Will be awarded to an area after a full 12 months of routine (monthly) monitoring and where historical and current results allow for annual A, B or C classification to be awarded.

Seasonal Classification

- May be awarded when at least 2 full years' worth of routine monitoring data shows a consistent, seasonal trend of results. The area/site may be classified as an A or B for one period of the year and B or C for the other.

Part Year Classification

- May be awarded when harvesting is restricted to a stipulated period in a year (by another authority) and where current and historical results allow for a straight A, B or C classification to be awarded for the period when the area is open for harvesting.

2.2 For more information on classifications see section 7.0.

3.0 Getting started

3.1 For a production or relaying area to be classified, an application form must be completed. Before an application form is completed there are steps to follow in accordance with the information sheet which accompanies the application form: <https://www.food.gov.uk/sites/default/files/classification-application-form-nov-16.pdf>. The form should be completed by the applicant in liaison with the Environmental Health Officer (EHO) from the relevant district council and submitted by email to: executive.support@foodstandards.gsi.gov.uk.

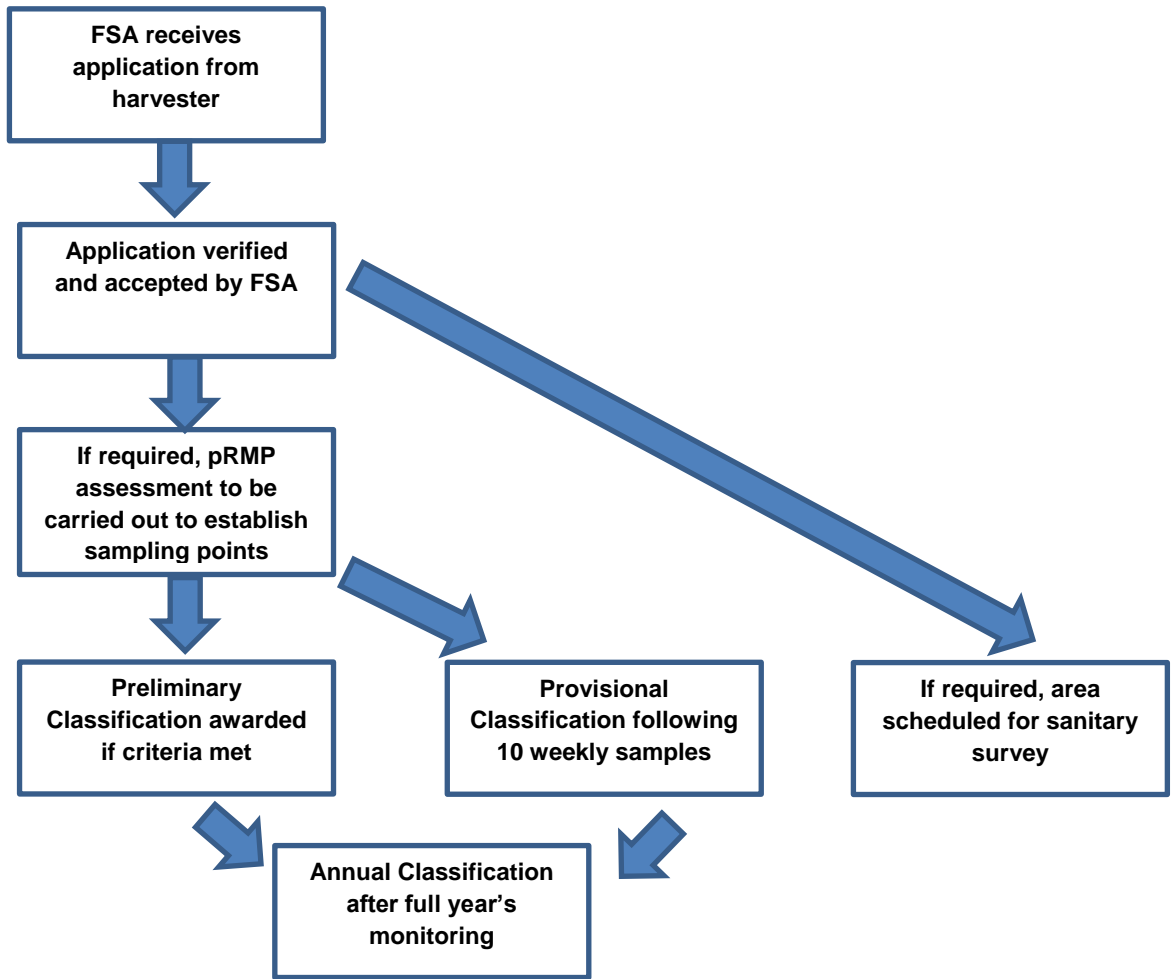
3.2 On receipt, FSA will consult with all relevant interested parties to validate the classification application and will progress the classification as necessary.

3.3 Applications should only be made when all the steps, outlined on the information sheet, have been followed and it has been confirmed that there would be no restriction on harvesting from the new area, there is stock on the site for commercial harvesting and when harvesting is anticipated.

3.4 Shellfish harvesters who have requested classifications for multiple species in a single area should apply to have **each** species classified.

TREE 1:

FLOW DIAGRAM DETAILING THE PROCEDURES FOR CLASSIFICATION OF SHELLFISH PRODUCTION AND RELAYING AREAS



4.0 Sanitary Surveys

4.1 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.

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

<http://www.food.gov.uk/enforcement/monitoring/shellfish/ssurveys>

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

4.3 On receipt of accepted shellfish classification applications, FSA will determine whether a sanitary survey is required. If a sanitary survey is required, FSA may carry out an interim assessment whilst awaiting the completion of the sanitary survey in order to identify a monitoring point for sampling prior to a provisional classification being awarded (pRMP assessment).

5.0 Provisional Representative Monitoring Point (pRMP) Assessment

5.1 The pRMP assessment process takes the form of a desk top survey of the area to facilitate the classification process and enable monitoring to begin as soon as possible. It will assess the location and type of the shellfishery, location and types of sewage discharges, river inputs, harbours and available microbiological data from nearby areas.

5.2 The pRMP assessment report will:

- Detail provisional co-ordinates for the production area boundary;
- Detail provisional *E. coli* RMP(s) for the area ensuring it is representative of the highest level of contamination;
- Detail the frequency of sampling from each *E. coli* RMP as part of a provisional sampling plan;
- Be reviewed later in the sanitary survey process as further information becomes available.

Please note that until FSA issues a formal letter to confirm the classification status of an area, the area remains unclassified.

6.0 Classification of scallop areas

6.1 FSA will classify farmed scallop areas, i.e. grown by aquaculture methods, within or surrounded by an existing classified shellfish production area. If scallops are growing wild outside a classified shellfish production area they may be harvested without classification, however harvesting is only permitted providing the controls specified in Regulation EC (No.) 853/2004 (testing by the food business at fish auction, dispatch or processing establishment) are carried out to ensure that the end product standards are met.

7.0 Further information on classification awards

Preliminary classifications

7.1 If an area has been previously classified (within two years of new application), is currently classified for another species, and a sanitary survey has been carried out where there is sufficient data in order to make a robust assessment, then it may be possible to award an immediate preliminary classification to facilitate early harvesting.

7.2 Such classifications will be awarded based on a precautionary principle, to ensure public health is not jeopardised. Therefore, a previous Class A area may receive an immediate B classification, which will be subject to review. Immediate preliminary Class A classifications will not be awarded.

7.3 Information contained in the sanitary survey report will be used in the process of awarding the preliminary classification.

7.4 Following the award of a preliminary classification a total of 10 samples are required to be collected by the applicant from the area at least a week apart for microbiological analysis. Where more than one species has been classified, the microbiological quality of **all** species will need to be determined.

7.5 An assessment of the sample results will then be reviewed against the sampling plan derived from the sanitary survey and, if appropriate, a provisional classification awarded. If the sampling plan is considered appropriate, the new area/site will be represented by the relevant RMP of the production area. If the sampling plan is not considered appropriate, a pRMP assessment of the area may be carried out (see 5.0) to determine future monitoring.

General Note: the applicant may wish to refuse an immediate preliminary classification, if unfavourable, and collect ten samples, at least a week apart, to obtain a provisional classification.

Provisional classifications

7.6 For new production or relaying areas a sanitary survey is required to be undertaken.

7.7 Whilst awaiting the full sanitary survey for the production area, a pRMP assessment may be carried out to determine a provisional representative monitoring point within the new area to facilitate sampling for provisional classification.

7.8 In order to award a provisional classification, a minimum of 10 samples, taken at least a week apart, are required to be collected by the applicant for microbiological analysis. More samples may be required for potential 'provisional A' classifications and where more than one species is to be classified, the microbiological quality of **all** species must be determined.

7.9 For areas that have a preliminary classification, a provisional classification may be awarded following receipt of the required 10 sample results.

7.10 Compliance with the EU legislative classification criteria (see table 1) is required for provisional classifications.

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

Annual classifications

7.11 Following the award of the provisional classification, routine official control sampling will be carried out by FSA on a monthly basis (or alternative frequency as recommended by the sanitary survey). The results from the established RMP(s) will contribute to an annual classification of the area.

7.12 Within the calendar year, a minimum of 8 monthly sample results are required to award and maintain annual class B and C classifications, whereas to award and maintain an annual class A classification, a minimum of 10 sample results over the year are required. Anything less than the minimum sample requirement may result in site being awarded a dormant status or being de-classified by FSA (see 7.14-7.18).

Seasonal classifications

7.13 At least 2 years' worth of monitoring data showing a clear seasonal trend is necessary for a seasonal classification to be awarded. A transitional period is required before the 'better seasonal classification' – i.e. from Class C to B and B to A. The results received during the transitional period (2 results taken at least 7 days apart) must conform to the better classification category or there may be a delay in the award of the 'better seasonal classification'. Seasonal classification periods should comprise of at least 3 months and routine monthly monitoring should continue throughout the full calendar year.

Dormant Status

7.14 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, FSA will agree a reduced frequency of monitoring (quarterly) with the harvesters, provided there is sufficient stock to continue sampling. Harvesters must inform FSA and the district council EHO of their intention to re-commence harvesting to enable routine monitoring to resume one month before harvesting re-commences and for the classification to be re-instated, provided the quarterly monitoring results remain compliant with the relevant classification award. If there is insufficient stock to continuing sampling, the area may be de-classified.

7.15 If the area is still inactive after 2 years of dormancy, it will be de-classified, placed on the de-classified list for up to two years and monitoring will cease.

7.16 Dormant status will allow shellfish areas to quickly resume harvesting activity following a period of inactivity. FBOs are required to inform FSA of their temporary inactivity to enable the dormant status to be awarded and implement reduced monitoring.

De-classification

7.17 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 the area may be declassified. The area will be placed on FSA's de-classified list for up to two years and no longer monitored.

7.18 If a classification request is made for an area that has been de-classified for less than the two year period, a preliminary classification may be awarded (see 7.1). If after two years there is no request to classify the area again, it will be removed from the list.

A new classification application would need to be submitted to FSA if there was a request to classify the area after the two year period.

Classification sampling and number of samples

7.19 For a provisional classification to be awarded, classification sampling will be undertaken by the applicant (harvester) where the samples must be analysed for microbiological contamination. The applicant should liaise with FSA to agree a sampling plan and testing requirements.

7.20 Once a provisional classification has been awarded, official control (OC) sample collection will be carried out by FSA authorised sampling officers on a monthly basis (or at a frequency recommended by the sanitary survey) over a calendar year.

Please note:

A minimum of 10 samples are required to award an A classification in any calendar year.

A minimum of 8 samples are required to award a classification B/C in any calendar year.

7.21 All samples are required to be collected in accordance with FSA's shellfish sampling and transport protocols.

https://www.food.gov.uk/sites/default/files/sp-transport-of-samples-flesh_1.pdf

<https://www.cefas.co.uk/cefas-data-hub/food-safety/the-shellfish-partnership/guide-to-shellfish-sampling-protocols/>

8.0 Sample analysis

8.1 OC microbiological samples are analysed in designated laboratories. Results are reported to FSA. On receipt of the results, they are actioned, if necessary, and published on the FSA website on a weekly basis at:

<http://www.food.gov.uk/enforcement/monitoring/shellfish/nibiotxin#toc-3>

8.2 All testing undertaken by the OC laboratory is in accordance with the agreed EU reference method. Results obtained using other methods are not acceptable for classification purposes. The OC laboratory is UKAS accredited for this method and take part in external quality assessments and UK National Reference Laboratory (NRL) ring trials.

9.0 Use of FBOs own results in supplementing FSA's official control microbiological dataset

9.1 EU Food Hygiene legislation permits the Competent Authority to consider results from food business operators (FBOs) own sampling to supplement those from official control sampling in order to determine the classification, opening or closure of shellfish harvesting areas following a protocol agreed by the FSA and the FBO.

9.2 FBO supplementary sampling and analysis must be conducted under conditions comparable to sampling and analysis for official controls and is as representative as possible of the area being monitored.

9.3 For supplementary samples to be considered, the FSA must have designated the laboratory carrying out the analysis. In addition to this, the sampling must have taken place in accordance with FSA's official control sampling and transport protocol (as above). See link to the protocol:

https://www.food.gov.uk/sites/default/files/fbo-supplementary-sampling-guide_0.pdf

10.0 Classification Review

10.1 Classified shellfish production/relaying areas are monitored by FSA to ensure the classification award is compliant with the EU legislative classification criteria and protective of public health.

10.2 The classification of the area is determined by the OC sample results from FSA's shellfish microbiological monitoring programme, applying the requirements set down in Regulation (EC) No. 854/2004 (see table 1).

10.3 In January each year, FSA carries out an annual review of all shellfish classifications utilising the previous three year dataset (or all data if less than 3 years). This approach is in accordance with guidance issued by the European Union Reference Laboratory (EURL) Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice².

10.4 Consideration will also be given to the most recent complete year's results, if there is evidence to show that water quality has improved or deteriorated over the past 12 months.

In-year reviews and dealing with outwith results

10.5 OC microbiological results and shellfish classifications are also examined on an on-going basis during the year. Any outwith or high results will be investigated and acted upon (sample results above the threshold of the classification awarded to the area) and depending on the outcome of investigations, outwith results may be disregarded from the dataset, in accordance with the criteria laid down in the EURL GPG. Shellfish classifications may be revised at any point in year.

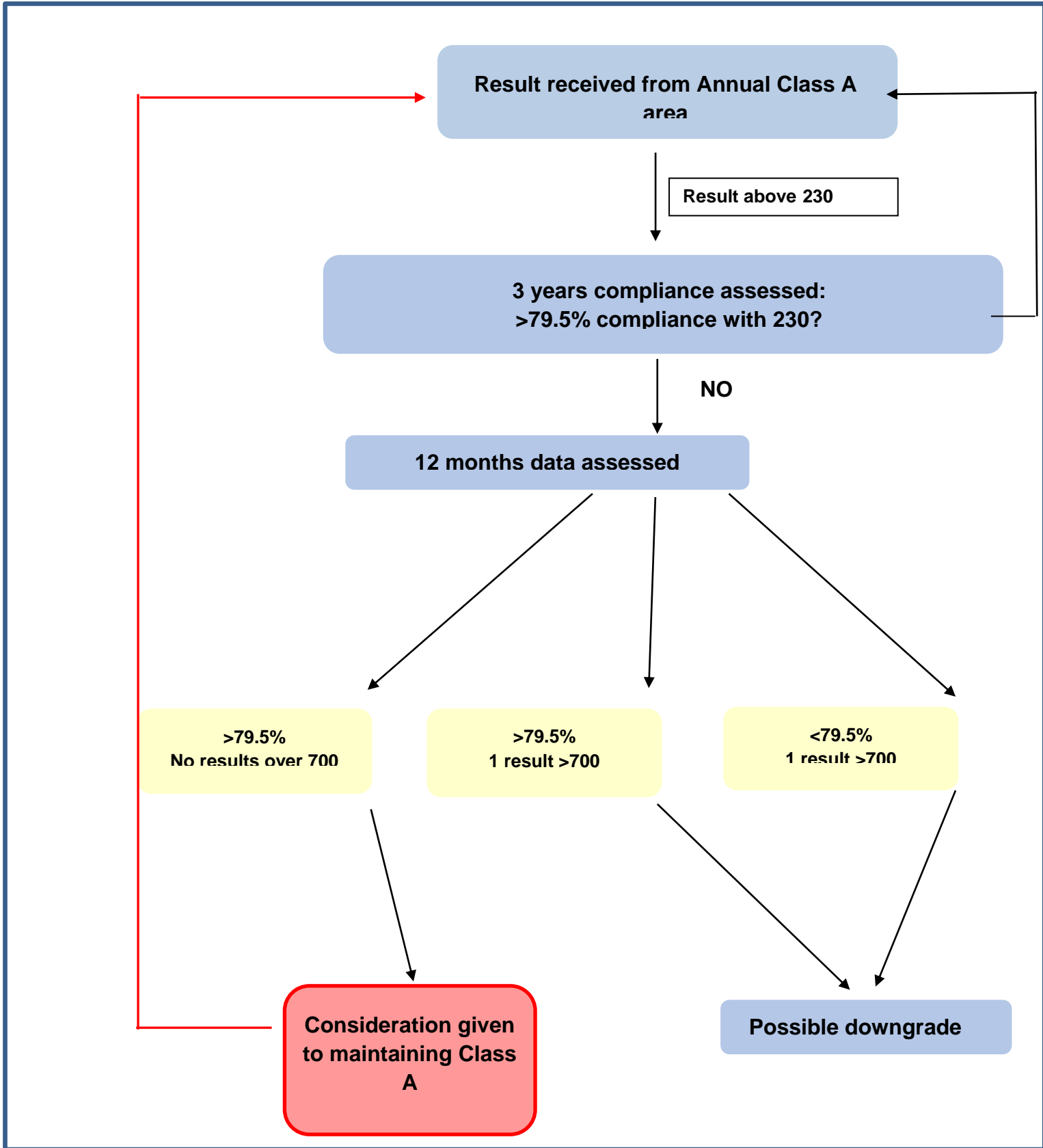
10.6 Classifications are assessed on a rolling basis following receipt of OC results. Trees 2 and 3 below illustrate how data from class A and B areas will be assessed in year upon receipt of each result.

10.7 If significant changes in contaminating sources (e.g. significant known changes in sewage discharge arrangements) have occurred then only the data obtained since the change(s) will be included in the review. This will be assessed on a case by case basis.

²<https://eurlecefas.org/public-documents/official-control-guides.aspx>

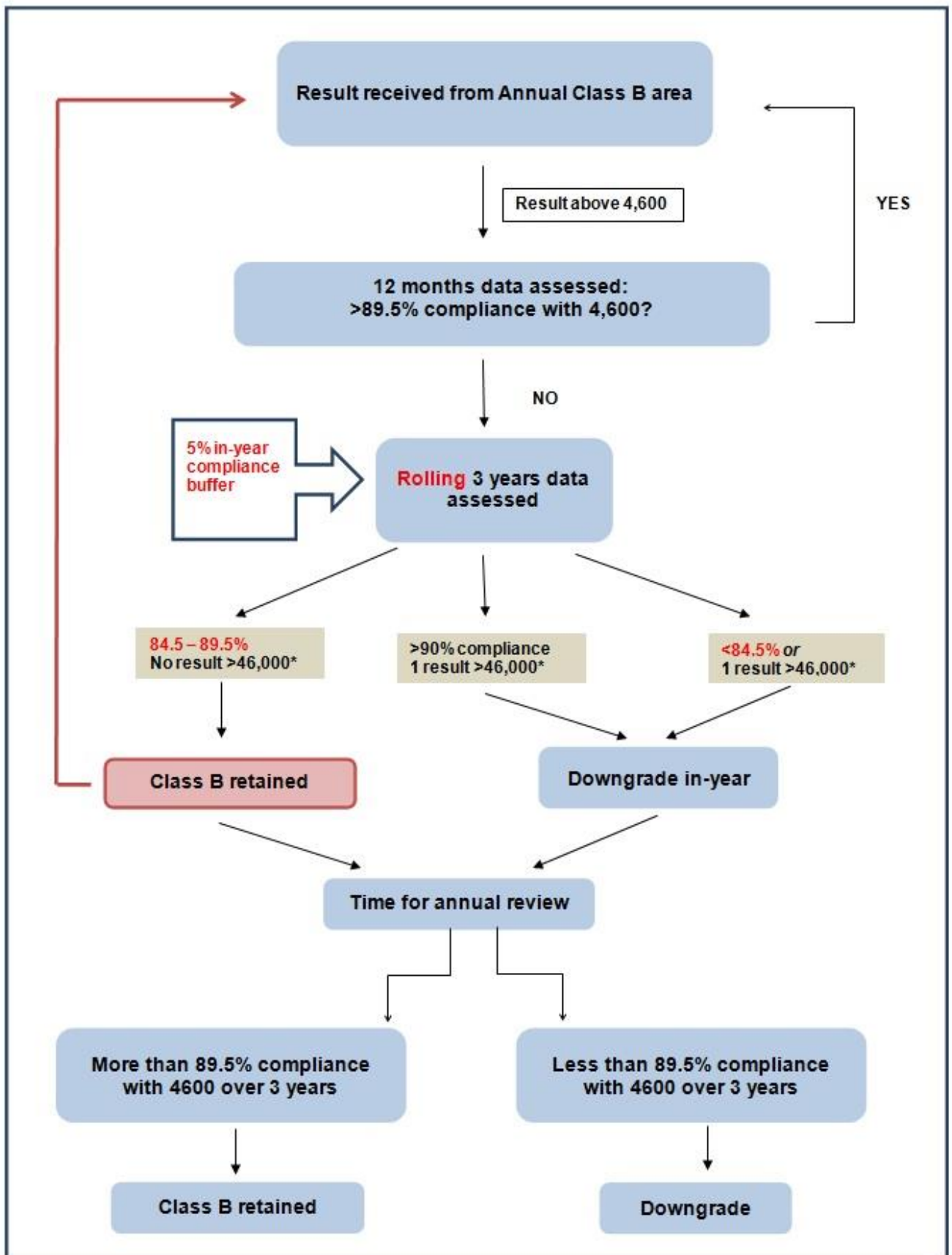
TREE 2:

Proposed assessment of class A beds



TREE 3:

Proposed assessment of Annual Class B beds



10.8 When outwith results are returned, an investigation will be instigated by FSA (and action taken if levels exceed regulatory limits). Notifications will be sent to relevant shellfish stakeholders, including sampling officers, DAERA, NI Water, NIEA, District Council, cross border authorities (if appropriate) and industry bodies, seeking information as to the possible cause of the elevated result

- A class - >230 E. coli/100g of flesh;
- B class - >4,600 E. coli/100g of flesh;
- C class - >46,000 E. coli/100g of flesh (closure)

10.9 Additional control measures may be required during elevated results, e.g. voluntary cessation of harvesting, increased end product testing or product withdrawal. The District Council EHO, as enforcement officer, will liaise with the harvesters on such additional controls.

10.10 A Temporary Closure Notice will be put in place by enforcement authorities (District Councils) following any result that exceeds 46,000 E. coli/100g of flesh (written voluntary agreements may be appropriate for certain fisheries). During a closure period, sampling is increased to weekly and the area re-opened following 2 consecutive satisfactory sample results less than the regulatory limit. The classification of such area will also be reviewed.

Actions following outcome of investigations

10.11 OC results will be reviewed in the light of the outcome of investigations. If deemed appropriate by the FSA, results may be waived if there is sufficient justification to support the Criteria for disregarding results section in the EURL GPG. If, however, all results remain valid and overall compliance is less than that the EU legislative classification criteria then a re-classification may be necessary.

Upgrade criteria

10.12 Areas showing an improvement in compliance with regard to potential upgrade for all classifications will be reviewed.

- Upgrade criteria Class B – A - Mandatory requirement: 80% of results must be less than or equal to 230, with no results >700 over the most recent 3 year period (at least 24 samples). Where known discharge improvements have taken place then this period may be reduced.
- Upgrade criteria Class C –B - Mandatory requirement: 90% of results must be less than or equal to 4,600 over the most recent 12 month period (at least 8 samples) with no result over 46,000 within that period. To give a reasonable level of confidence that a water quality improvement has actually occurred and that an upgrade is therefore justified the EU Good Practice Guide recommends that there should ideally be at least 24 results over a minimum period of 3 years showing 90% (or better) compliance. Where known discharge improvements have taken place then this period may be reduced with increased monitoring frequency.
- Prohibited areas (possible upgrade to C) - Mandatory requirement: All results must be less than or equal to 46,000 over the most recent 24 month period with at least 16 samples. Where known discharge improvements have taken place then this period may be reduced.

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