

Shellfish classification

How production areas are classified, the method of treatment and how to apply for classification.

The classification of a production area determines the treatment required before Live Bivalve Molluscs (shellfish) may be marketed for human consumption.

Shellfish production and relay areas are classified according to the levels of E. coli detected in shellfish flesh.

Permitted levels of E. coli

Levels of E. coli are measured per 100g flesh.

In all cases, the health standards are set out in:

- Annex III of retained EU law Regulation (EC) 853/2004
- Articles 53, 54 and 55 of retained EU law Regulation (EU) 2019/627

The end product microbiological criteria specified in the retained EU law Regulation (EC) 2073/2005 must also be met.

The production area will be classified as A, B or C, with A as the least and C as the most contaminated. The level of treatment required to remove contamination from the LBMs after harvesting depends on this classification. If contamination levels are consistently so high that a class C cannot be achieved then harvesting from the area may be prohibited.

The standards that must be achieved and the level of treatment required for each classification are:

Class A

- minimum of 10 samples required per year
- 80% of sample results must be less than or equal to 230 E. coli/100g
- no results may exceed 700 E. coli/100g

Shellfish can be harvested for direct human consumption if the end product standard requirements are met.

Class B

- minimum of 8 samples required per year
- 90% of sample results must be less than or equal to 4600 E. coli/100g
- No sample result may exceed 46000 E. coli/100g

Shellfish can be supplied for human consumption after one of three processes. The options are:

- purification in an approved establishment
- relaying for at least one month in a classified Class A relaying area
- an EC approved heat treatment process

For class B beds in England and Wales, there is a long term classification (LTC) system. This is in place to show greater stability in the classifications which are based on compliance over

five years instead of the standard three years.

Class C

- minimum of 8 samples required per year
- All sample results must be less than or equal to 46000 *E. coli*/100g

Shellfish can only be sold for human consumption after completing one of three possible processes.

These processes are:

- relaying for at least two months in an approved class B relaying area followed by treatment in an approved purification centre
- relaying for at least two months in an approved class A relaying area
- after an EC approved heat treatment process

Prohibited areas

Shellfish from areas with consistently prohibited level results (greater than 46000 *E. coli*/100g) must not be subject to production or be harvested.

Shellfish purification

Shellfish can be purified (depurated) by holding them in purpose built tanks of clean or artificial seawater. The shellfish are placed in water for the time necessary to reduce contamination to make them fit for human consumption. The water conditions encourage the shellfish to filter out contaminants such as *E. coli*.

Dispatch centres are any on-shore or off-shore area that processes shellfish fit for human consumption.

All purification and dispatch establishments must be approved by your local authority. You must meet the specific requirements for purification and dispatch centres in Annex III of retained EU law Regulation (EC) 853/2004.

IMPORTANT

EU references in FSA guidance documents

The FSA is updating all EU references, to accurately reflect the law now in force, in all new or amended guidance published since the Transition Period ended at the end of 2020. In some circumstance it may not always be practicable for us to have all EU references updated at the point we publish new or amended guidance.

Other than in Northern Ireland, any references to EU Regulations in this guidance should be read as meaning retained EU law. You can access retained EU law via HM Government's [EU Exit Web Archive](#). This should be read alongside any EU Exit legislation that was made to ensure retained EU law operates correctly in a UK context. EU Exit legislation is on [legislation.gov.uk](#). In Northern Ireland, EU law will continue to apply in respect to the majority of food and feed hygiene and safety law, as listed in the [Northern Ireland Protocol](#), and retained EU law will not apply to Northern Ireland in these circumstances.

For further information on purification and approval please refer to our [Purification Guide](#) and [approval aide memoire](#).

Application process

Potential classification and filling out the form

If you are interested in principle to harvest/fish or relay shellfish in England, Wales and Northern Ireland, you must first apply for classification of the production area. The production or relay area application form should be completed by the applicant (the harvester) in conjunction with the local authority.

Please complete and submit this form electronically, along with a suitable map and any other relevant supporting information, and refrain from completing by hand. Hard or scanned copies will not be accepted.

Please note that the classification of a shellfish harvesting area does not confer the right to harvest shellfish.

You may need permissions from other bodies before proceeding. It is the responsibility of the applicant to obtain these permissions, as required, and for the local authority to check everything is in place, including their ability to sample for ongoing monitoring, before the application is submitted to the FSA.

[View Bivalve mollusc production or relaying area application form as Word](#) (86.83 KB)

Northern Ireland

[View Application form for classification of a shellfish production area in Northern Ireland as Word](#) (101.63 KB)

After you've sent the form

Once we receive your application, it is verified by us and we will ask for further information or clarification if needed. Once we are satisfied, we will send it to our contractor to undertake a sanitary survey if it's necessary.

A sanitary survey is an assessment of the pollution sources affecting the shellfish harvesting area, to determine appropriate sampling points and a sampling plan for potential classification.

Ten official control samples, taken by the local authority in England and Wales and a range of sampling bodies in Northern Ireland, at least a week apart are required for a provisional classification. After a full year of official control sampling, an annual classification may be granted.

A minimum of 16 weeks from the date of application submission is required before any shellfish harvesting could commence, pending approval of classification.

Further information on the classification process is available in the classification protocol.

Sanitary survey reports

Between April 2017 and March 2020 an interim arrangement was in place for the assessment of new production areas to determine provisional representative monitoring points (RMPs). An RMP is one monitoring point within a shellfish production area, which can represent a number of sites within that production area.

From April 2020, we commission sanitary surveys which consider additional information for production areas.

[Sanitary Survey Reviews April 2020 - present](#)

[Classification zone assessments April 2020 - present](#)

[RMP assessments April 2017 - March 2020](#)

[Sanitary Survey and RMP assessment reports 2007 - 2017](#)

Classification protocol

When a shellfish bed has been closed indefinitely additional samples may be required before a bed may be re-opened. The classification process may have to start again if it is closed for a number of years or if has been declassified.

You can apply for potential classification in England and Wales using our application form.

[View Protocol for classification of shellfish production areas in England and Wales](#)

There is more information on the classification protocols for Northern Ireland.

You can apply for classification in Northern Ireland using our application form.

Northern Ireland

[View Protocol for the Classification of Shellfish production and relaying areas in Northern Ireland as PDF](#)

(239.41 KB)

Dealing with high results

Local action groups exist in England and Wales.

A local action group is led by your local authority and can include local industry groups, fishermen or shellfish gatherers and other stakeholders who can contribute to the investigation, e.g. the Environment Agency or Natural Resources Wales and Water Companies.

This group deal with high results and consider whether to:

- close the bed
- notify harvesters
- take action to protect public health
- liaise with FSA food incidents when necessary

For further information please refer to our Local action group guidance.

[View Local action groups guidance as PDF](#) (285.83 KB)

Action plans

Local action plans are decided using local factors and conditions. The amount of detail in the plan will depend on:

- the number and size of shellfish beds under the responsibility of the local food authority
- any special local conditions
- the number of stakeholders involved

Action states

Action states apply to all classes of shellfish beds. It will be in place after your results have been found to be above the permitted level.

A bed may be temporarily downgraded or closed as part of short term control measures during an action state.

To re-open the bed at its previous classification, two consecutive satisfactory samples taken at least seven days apart.

We start investigating into classification results that are, for example, above the threshold for the classification awarded.

Information from DAERA, NIEA and harvesters will be asked for to try to establish the cause of the higher result and determine future action.

Any areas with results above the permitted level will be closed for harvesting.

Current classification lists

England and Wales

[View Shellfish classifications England and Wales 2020-2021 as PDF](#) (420.21 KB)

Northern Ireland

[View Shellfish Harvesting Classifications Northern Ireland 2021 as PDF](#) (142.67 KB)

Classification monitoring results

[England and Wales classification monitoring results](#)

[Northern Ireland classification monitoring results](#)

[Classification monitoring results from previous years on the National Archives website](#)

[Microbiological sampling schedules for Northern Ireland](#)