Interpretation of the European legal framework for the microbiological classification of bivalve mollusc production areas

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Highlights:

- Water quality can influence microbial contamination of bivalve molluscs.
- The European Union manages these health risks via the Official Control Regulations.
- Implementation of the requirements varies across Countries.
- It can be risk based and permissive, or much more restrictive.
- The approach taken affects business and the ability to trade.

Abstract

Water quality, in terms of the bacteria and viruses present, affects the incidence of microbial contamination in bivalve molluscs. The European Union Official Control Regulations manage these potential human health risks, requiring all Member States to routinely monitor the level of faecal contamination in production and relaying areas, and to classify these production areas accordingly. How a site is classified can affect business flexibility, operating costs, and even the ability to trade. The protection of public health is the primary remit of the national competent authorities implementing the regulations, while businesses are keen to achieve and maintain a classification indicative of good water quality, and to minimise the likelihood of a site being downgraded or closed. Equally, they do not want to make their customers sick. Balancing protection of public health and the viability of bivalve shellfish production is most easily achieved with a regulatory system that is responsive, adaptive and ultimately risk-based. Despite the standard legislation and supplementary guidance to ensure consistency of approach, interpretation and implementation varies across countries. Some take a risk based and more permissive approach, whilst others are much more restrictive. This indicates the ability of Member States to exert some independence within the overarching legal framework, reflecting regional variation in environmental conditions, historical approaches to shellfish hygiene controls as well as the range of relationships between producers and regulators.

Keywords: bivalve, aquaculture, classification, Official Control Regulations

1. Introduction

The classification and regulation of bivalve mollusc production sites is considered to be a public health matter [1-4]. This is because water quality, in terms of the bacteria and viruses present, affects the incidence of microbial contamination in bivalves. If the bivalves are eaten raw or only lightly cooked, some of these microbes can cause a variety of illnesses in humans [5,6], the most common of which are gastro-enteric illnesses (e.g. norovirus) and hepatitis infections [7-9]. These microbial contaminants are derived from human (i.e. sewage) and animal sources (e.g. wildlife and livestock agriculture), with the former being of considerably greater concern in terms of human pathogens.

For Member States of the European Union, EU Regulation 2017/625 [10] requires that Competent Authorities classify production and relay areas for live bivalve molluscs, while EC Regulation 853/2004 [11] notes that producers can collect bivalves for commercial sale only from classified areas. EC Regulation 2019/627 [12] specifies the rules for the official controls on products of animal origin including live bivalves. This legislation requires all Member States to routinely monitor the level of faecal contamination in production and relaying areas, and to classify these production areas accordingly. Collectively these regulations are, hereafter, referred to as the Shellfish Control

Regulations. They are additional to the legal requirements to ensure any food placed on the market is safe to eat (i.e. EU Regulation 178/2002 [13]). The Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production [14] (hereafter referred to as 'EU Guidance') provides advice on the interpretation and application of these legal requirements. This EU Guidance is also supported by a technical application document [15], which further encourages consistent application of the legislative requirements.

Countries that export bivalve molluscs into the EU must demonstrate that they provide an equivalent level of public health protection. In order to export bivalves to the EU, an equivalency agreement must be established between the EU and the exporting country (the Third Country). This includes an evaluation of the Third Country practices by the Health and Food Audits and Analysis Office of the European Commission, Directorate General for Health and Food Safety (DG SANTE). Similarly, the Third Country will audit EU practices. The evaluation includes the assessment of all relevant laws, decrees, regulations, requirements and procedures, as well as all aspects of bivalve cultivation from site classification through to end-product testing. Onsite evaluations and audits of the relevant Parties are also conducted as part of the process. A Third Country approach does not need to mirror the EU regulatory system, but it does need to ultimately deliver at least the same assurance in terms of human health.

2. Effect of the Shellfish Control Regulations on Industry

Water quality and the shellfish regulatory regime are complex issues, both of which have been identified as a key constraints on the expansion of industry [16-18]. How a site is classified can affect business flexibility, operating costs, and even the ability to trade. The variety of human pathogens and the lack of suitable tests, means that *Escherichia coli* (*E.coli*) is used as a proxy or faecal indicator. The levels of *E.coli* in shellfish flesh are used to classify production sites and determine the required harvesting protocols (Table 1). When *E.coli* counts in shellfish flesh exceed particular threshold levels, the site classification may be downgraded, introducing stricter post-harvesting controls, or the site may be temporarily closed until product quality levels recover sufficiently in order to protect public health.

The current method of assessing and managing the potential risks of shellfish contamination to consumer health can be problematic because:

- The system is based on *E. coli* as an indicator while the primary human health concern from consumption of bivalves is viral infection (e.g. norovirus). *E.coli* can be derived from a variety of sources including non-human and, therefore, high levels in shellfish may not always be indicative of human pathogens [19, 20]. Conversely, the rate of reduction of viruses in shellfish during post-harvest controls, such as depuration, is lower than that of the indicator *E.coli* [21]. This means contaminated bivalves can still reach the market even when they meet end product testing requirements.
- Testing is retrospective and intended for risk characterisation of production areas rather than time-sensitive controls. It can take four or five days from sampling to the results being issued; hence product may already have reached the market and been consumed before the producer is notified of an above threshold monitoring result.
- Sampling occurs at fixed timeframes, usually monthly or bimonthly, whilst the concentration of *E. coli* in bivalves can vary greatly over a few hours [15, 22]. This raises concerns about how accurately the monitoring regime determines the pathogen risk in reality.

- Producers have expressed concerns that high variability in *E. coli* test results is not uncommon, which can lead to unnecessary restrictions due to anomalous results and increased business uncertainty.
- The testing system is not responsive, which means it can place restrictions on a business long after any public health risk period has passed.

Although bivalve aquaculture production has continued to grow globally [23], it has stagnated in Europe [16, 18]. The regulatory system has been identified as one of the most important causes of this [24, 25]. To reverse the situation and to sustainably grow the industry, business predictability and legal certainty is required [18, 26]. The way in which the Shellfish Control Regulations are interpreted and applied, therefore, has a significant role to play in the industry's future. This is particularly important when bivalve production could contribute to environmentally sustainable food security, whilst also providing significant ecosystem services and benefits for humanity [27-32]. Despite the overarching legal and regulatory framework and unified guidance, it is apparent that application of the Shellfish Control Regulations may vary between individual countries. This review investigates the extent of this flexibility, comparing and contrasting how the regulations are applied in practice across nine European Union Member States, Norway and the UK, while retaining legal compliance.

3. Materials and Methods

National case studies were chosen primarily on the basis of the scale of live bivalve production (e.g. Spain and France), but with consideration also given to those countries that were thought to have adopted a more explicit risk based approach (e.g. the Netherlands and Sweden) (Table 2). Norway was included as a member of the European Free Trade Association (EFTA), providing an example of a non-EU country implementing the Shellfish Control Regulations. The UK was included as a case study as, until 31 January 2020, it was an EU Member State. At the end of the UK-EU transition period on 31 December 2020 all directly applicable EU law in force, including that enacted but not yet in force, became part of the body of domestic law in Great Britain (England and Wales, and Scotland). Under the terms of the Northern Ireland Protocol [33] the majority of EU food and feed hygiene and safety law (as listed in Annex 2 to the Protocol) continued to apply directly in Northern Ireland. As a result, the UK continues to apply the Shellfish Control Regulations but has the potential to alter its application of the requirements in the future.

For each of the case studies, the import of bivlaves molluscs from within the EU and from elsewhere was also considered (Table 3). The UK, Denmark, Ireland and Sweden all import a greater proportion of bivalves from within the EU, whilst the remaining Countries import considerably more bivalves from outwith the EU. There were also significant differences in sufficiency of production between Countries. Production levels in Denmark and Ireland equate to more than 66% of market supply (defined as total production plus total imports), whilst production in Portugal, German and the Netherlands equate to less than 10% (Table 3).

For each country, any publicly available national legislation and/or guidance relating to bivalve production requirements were identified (see appendix 1) and translated, where necessary, using Multilizer Document Translator (© Rex Partners Oy). A sample of these translations were checked for accuracy by native or second language-speakers. If no publicly available information could be identified, approaches were made to industry experts for the relevant documents. In some cases, the available information did not provide sufficient detail on how the Shellfish Control Regulations were being implemented. Where this was the case, every effort was made to establish the approach being used through informal communication with operators in those countries.

In addition to national legislation and/or guidance documents, any relevant EU audits of a country's implementation of the requirements were also identified and reviewed. DG SANTE uses the EU Guidance [14] as an example of the expectation for legislative implementation when auditing Member States. Between 2011 and 2013, DG SANTE's Food and Veterinary Office audited the application of the Shellfish Control Regulations across all Members States (including the UK). The EFTA Surveillance Authority undertook a similar audit of Norway's approach in 2015. More recently (2020-2021), DG SANTE has undertaken new audits in Portugal, Spain, and Denmark.

The application of the Shellfish Control Regulations in each Country was assessed on:

- The process of initial site classification,
- The ongoing monitoring once a site was classified,
- How seasonal sites are treated in the classification process,
- If provisions are made for long-term stable sites,
- The review process for site classification status, and
- Handling of above threshold results and the action taken.

4. Practical application of the EU Official Controls for shellfish production

Variation was identified in the application of the European legal requirements (Table 4). This indicates that, despite standard legislation and guidance, different approaches to regulating bivalve production are in operation across different countries. Whilst some approaches are reasonably consistent (Table 5), there are differences which can be summarised as:

- Variation in the length of time required for a provisional classification to be awarded: varying from 4 to 6 weeks (Norway and Denmark), three months (UK), six months (Ireland, Germany, Italy and the Netherlands), 10 months (Spain) to 12 months (France).
- Ongoing monitoring of production areas occurs on a weekly basis (Denmark), every two weeks (e.g. Italy, Netherlands [varies by location, species and time of year], Sweden [for oysters and cockles] and Portugal [May to November]) or monthly (e.g. UK, Ireland, France, Spain, Germany, Netherlands [varies by location, species and time of year], Sweden [for mussels], Portugal [December to April] and Norway).
- For sites with more than 3 years of data, the EU Guidance indicates that monitoring can be reduced to a bimonthly frequency. The guidance also notes that for stable sites, the Competent Authority may reduce the minimum number of samples required for the classification review to 12 results over a 3 year period. For production sites that have demonstrated long term stability, a reduction in sampling frequency is introduced by some countries. France, Ireland, Spain, and Germany move from monthly to bimonthly sampling whilst Denmark moves from weekly to monthly or bimonthly sampling depending on the classification and Italy from sampling every two weeks to monthly. In contrast, no reduction in sampling frequency is introduced in UK, Netherlands or Portugal for stable sites.
- Reviews of site classification are undertaken annually (e.g. UK, France, Netherlands, Spain, Germany, Sweden, Portugal and Norway), every three years (e.g. Italy) or on a rolling basis (e.g. Denmark). Besides the annual review, England, Wales and Northern Ireland also utilise a rolling classification system to upgrade and downgrade sites within the review period whilst Scotland does not. Through this rolling assessment, downgrades are automatic if the monitoring results record that a site is outwith its classification whilst upgrades must be requested by the producer.
- All monitoring samples are collected by designated officials in France and Spain. In Portugal, Germany and Denmark all official monitoring samples, and in Sweden up to 80% of samples,

are collected by shellfish producers. In Ireland, the Netherlands, Italy, and Norway, the industry can be used to collect samples where local agreements and training have been arranged. Whilst industry can provide official samples in Scotland, elsewhere in the UK this only occurred in exceptional circumstances until very recently. In September 2022, the Food Standards Agency changed their approach and permitted the delegation of sampling to industry representatives.

- The MPN test (ISO 16649-3:2015) is used by all countries to determine *E.coli* levels in shellfish flesh. In addition to this, France and Italy also use the impedance test (NF V 08-106:2010) and the Netherlands uses the pour plate colony count method (ISO 16649-2).

Notably, the majority of countries' legislation and guidance material currently in use was updated or introduced following DG SANTE audits undertaken between 2011 and 2013, whilst the response to the more recent audits has not yet been put in place. This means that it is not possible to categorically state that the approaches currently in use would satisfy a new audit. However, on the basis of the recommendations made in the audits, it is possible to identify approaches that were deemed acceptable and where no change was required. For example, no issues were identified with the Spanish approach adopted in the Galician region for microbial monitoring whereas significant shortcomings were initially identified with the approach taken by Portugal which have subsequently been addressed.

4.1 Risk Based Approach to Site Assessment

The Netherlands, Sweden, Portugal and Italy have each adopted explicit risk-based approaches for site monitoring and classification. These approaches take account of the bivalve species being farmed, the time of year and/or site location. Additionally, Sweden and Italy have adopted approaches that utilise other environmental indicators that take an increase in the risk of pathogen contamination into account (e.g. rainfall data, tidal data, salinity).

4.1.1 Bivalve species

Explicit recognition of the potential risk associated with consumption of different shellfish species has been adopted by some Countries. For example, the monitoring adopted by Sweden differentiates between shellfish that are eaten raw and those that are cooked prior to consumption, with increased frequency of monitoring required for oysters and cockles compared to mussels. Similarly, the Netherlands requires increased frequency of monitoring for oyster production compared to mussels.

4.1.2 Time of year and location

The risk of enteric-transmitted pathogens is much greater in winter or when a local human population is increased during holiday periods. Some Countries have taken these seasonal differences into account. For example, Portugal requires an increased frequency of monitoring between May and November when the risk of contamination is higher compared to the remainder of the year. In the Netherlands, there is increased frequency of monitoring between July and October compared to the remainder of the year for cultured bivalves in the Wadden Sea whilst for oysters from Grevelingenmeer, there is increased sampling between September and December.

4.1.3 Use of Environmental Indicators

In Sweden, the frequency of *E.coli* monitoring may be varied on the basis of a risk assessment. This assessment takes account of the results of the sanitary survey, historic monitoring data for the production area and the environmental aspects of the site (e.g. wind and water conditions). In Italy, sampling frequency can be reduced if other types of environmental/health monitoring has indicated an absence of critical issues. Typically additional sampling is undertaken in conjunction with adverse events (e.g. high precipitation, river flood events).

The accumulation and clearance of *E.coli* from bivalves varies between species and sites in relation to a variety of environmental factors (e.g. soil type and permeability, recent rainfall history) [35-41]. The use of environmental indicators such as specific rainfall or tidal conditions to help monitor periods of potentially increased shellfish contamination should contribute to a more flexible and adaptive approach for shellfish monitoring and harvesting. Such an approach has the positive advantage of reducing the risk of harvesting contaminated bivalves and, therefore, has public health benefits.

4.1.4 Sample collection and analysis

With the exception of France and Spain; all other Member States permit or require the industry to collect the official control samples. Whilst industry can provide official samples in Scotland, elsewhere in the UK this was only permitted from September 2022. For France and Spain, all of the monitoring samples are collected by designated officials.

The MPN test method is used extensively. It is considered to be well characterised and standardised, and is therefore widely acceptable for use in shellfish programmes and meets global market access requirements. While the Shellfish Control Regulations specify the reference method for analysis of *E.coli* as the MPN technique (EN/ISO 16649-3), the regulations do allow for the use of other tests that meet the requirements of EN ISO 16140. Two other tests have been approved for use: the impedance test (NF V 08-106:2010) and the pour plate method (ISO 16649-2).

In addition to MPN test methods, France and Italy also use impedance to measure *E.coli* levels in bivalves. The impedance method has the advantage of reducing the analysis time with results being obtained within 5-10 hours [42], allowing for more rapid intervention to ensure public health protection in case of shellfish contamination [43].

The Netherlands uses the pour plate colony count technique in addition to the MPN test. The pour plate method is useful where high *E.coli* levels might be expected [15, 44, 45]. In samples with high microbial load, the MPN determinations are less precise and often higher than those obtained by pour plate colony count techniques [46-50]. In addition, pour plate colony count techniques are less time-consuming and less labour-intensive than MPN, which is particularly relevant when public health intervention might be required.

Although there is a degree of variety with any microbial test, there are acknowledged issues with the reliability and variability of the MPN test. The ISO standard (EN/ISO 16649-3) also acknowledges this; i.e. if a sample is subdivided and analysed, the results from the subsamples may be different. Having more than one test option available increases flexibility and can help addresses issues of variability when *E.coli* levels are close to the boundary between classifications, where this variability could affect the classification of the production site.

4.2 Handling of above threshold monitoring results

The approaches taken when above threshold *E.coli* monitoring results were obtained varied between Countries (Table 6). DG SANTE audits, however, identified very few problems with the way in which different Countries handled such results. The main issues were to ensure that decisions taken after monitoring align with the requirements and, that if the health standards are not met, then the affected bivalves are not placed on the market for human consumption.

4.2.1 The decision to temporarily close sites or reclassify

On receipt of an above threshold *E.coli* monitoring result, the Shellfish Control Regulations require that the Competent Authority temporarily close sites in order to prevent bivalves from reaching the market. However, Competent Authorities may allow producers to continue to operate at a lower classification if those requirements are met. Both of these options have been adopted in Spain, Italy, Germany and UK. In contrast, Denmark and Ireland will reclassify sites whilst France, Sweden and Norway automatically close sites on receipt of an above threshold result until it has been verified. This latter approach may appear to be a stricter application of the requirements, but if the high result is not confirmed, the sites can return to harvesting more rapidly.

There are also differences in the process used for when classifications are altered in response to above threshold results. Sweden and Norway only consider within year reclassification following multiple occurrence of above threshold results whilst France, Spain, Portugal, Netherlands and Italy do not undertake within year re-classifications. Nor are they undertaken in Scotland, whilst in the remainder of the UK a site can be downgraded in response to a single above threshold monitoring result. Such results also remain on the record for 3 years, continuing to affect the site's classification long after any public health issue has passed. In most Member States, the annual review of the last 3 years of data uses a risk based approach when considering single isolated monitoring results, meaning such a result does not affect site classification.

4.2.2 Reopening timeframe and number of samples required

The Shellfish Control Regulations stipulate that to reopen a temporarily closed site, the required health standards must be met. EU Guidance recommends that at least weekly sampling is implemented for investigative monitoring purposes to determine whether the contamination event persists. Timeframes implemented by Member States ranged from 48 hours (France), one week (Denmark, Germany, Italy, Spain, Sweden, and the Netherlands) to two weeks (Norway and UK). Increasing the frequency of investigative monitoring enables a more rapid reassessment of a site's classification status and allows harvesting to resume more quickly. In contrast, where investigative sampling has a longer timeframe, reopening of a site can be significantly delayed.

France, Netherlands, Spain, Italy and Norway remove any temporary control measures if the first repeat sample is within classification thresholds, and no further action is required. These repeat samples are used to verify the initial above threshold result or confirm that the site is within classification. In contrast, France, Germany, Sweden, Denmark and the UK require two samples within classification thresholds before restrictions are lifted. The timeframe employed for this resampling has a significant effect on how quickly a site can reopen. For example, in the UK there is a requirement for at least 2 samples collected at weekly intervals, although the guidance to Local Authorities suggests a separation period of two weeks or longer may be appropriate. The speed at which such sampling is undertaken can have a significant impact on how quickly a site can resume operation.

Denmark provides the only example of a requirement for multiple samples to be collected and analysed following an above threshold *E.coli* monitoring result. This enables an assessment of the veracity of the result as well as the variability in the *E.coli* levels in shellfish across the site. Such an approach likely delivers greater business and regulator certainty in the accuracy of the monitoring result.

4.2.3 Validation sampling

As noted in section 3.2.1, the Competent Authority must temporarily close or downgrade a site when sampling indicates that health standards have been exceeded. The UK, Spain, Italty and Germany make use of both options. France, Sweden and Norway close sites when an above threshold result is obtained whilst Ireland, Netherlands and Denmark will temporarily downgrade a site.

The subsequent handling of these above threshold results and whether they are retained on the classification can have a significant effect on the future operation of the site, particularly Class A sites. For example, in England, Wales and Northern Ireland, an above threshold result will lead to an automatic downgrade and will be retained on the classification record unless the Competent Authority is satisfied that there is sufficient justification to remove it. Thereafter it is a lengthy process to demonstrate that the original classification should be reinstated. It is only after the above threshold result is no longer part of the most recent 3 years of sampling data that the site can be returned to its original grade. In the interim, the site may be awarded a seasonal classification on the basis of this single result. This approach has business implications that extend well beyond a single monitoring result.

In contrast, on receipt of an above threshold result France, Netherlands and Norway require a validation sample. This validation sample could confirm the above threshold result and the need for additional management measures. Alternatively, it could indicate that the site is back within the classification threshold and that harvesting can resume. Not automatically applying an above threshold result to the classification record until it has been confirmed will have a positive influence on the overall classification assessment and is also beneficial for businesses. Because above threshold results are validated and appropriate measures introduced when required, it is unlikely that such approaches would have a detrimental effect on public health.

4.2.4 Rainfall and the disregarding of high *E.coli* results as anomalous

EU guidance specifically identifies rainfall as one of the environmental factors linked to high *E.coli* levels in bivalve molluscs. Additionally, the EU Guidance notes that the occurrence of a rainfall event with the intensity and duration that is only likely to occur once every five years or longer can be used to justify the removal of a high *E.coli* monitoring result from the classification record. Where rainfall return period analysis is not available, then the assessment can be based on the daily rainfall on either of the two days prior to sampling where this exceeds the 99.9th percentile of a long-term dataset (preferably 10 years).

Of the case studies that noted possible reasons for disregarding results, the majority cite the 1 in 5 year rainfall event, whilst Spain uses the percentile approach on 10 years of daily rainfall data. It is unclear how these different approaches may influence the decisions taken to retain or disregard an individual monitoring result. However, the EU technical guidance [15] indicates these two approaches should be equivalent when the latter daily rainfall calculation is constrained to the 48 hours period prior to the high *E.coli* result.

The UK and France appear to be the only countries which combine both requirements; i.e. use the 1 in 5 year rainfall event and constrain the consideration of these rainfall events to the 48 hour period preceding the sample collection. This is more restrictive, and the intimation is that other Countries have greater flexibility in deciding whether a result can be disregarded from the classification record due to a rainfall event. Further, research indicates that the cumulative rainfall of the preceding seven days is more closely correlated to the levels of *E.coli* in bivalves [51-53]. By only considering rainfall events in the preceding 48 hours, business could be negatively impacted by an above threshold result caused by rainfall which is not recognised as such and retained on the classification record. Where such results are retained, they will continue to impact the business for the next 3 years during the annual reviews.

4.2.5 Factors taken into account when considering whether an above threshold result is anomalous

As part of the guidance on identifying anomalous results, Ireland includes additional activities, such as slurry spreading or harbour dredging, in the list of activities that can influence levels of microbial contamination in bivalves [54]. Explicit inclusion of such activities in national guidance helps to highlight the need for these risks to be managed, and for investigations into above threshold results to consider a broader range of influencing factors than is outlined in the EU Guidance. In Ireland, this is further aided by the requirements for farmers to produce an annual fertiliser plan that must detail the expected timing and application of manure to the fields. There are also specifications about when and where slurry can be spread (or not) on the fields. Taking such information into account during any investigation of an above threshold classification result is clearly beneficial in helping to determine whether it is anomalous.

Whilst investigations of above threshold results do take place in the UK, the links to potential pollution events is not so easily made. If there is a notified pollution incident that has been investigated by the Environment Agency, then the subsequent report will be included in any above threshold result investigation. However, pollution incidents often only get notified (and therefore investigated) if there is an obvious, visible impact e.g. fish dying or numerous public complaints. Small pollution incidents without obvious water quality impacts are not always recorded and, even if they are recorded, such events are rarely investigated. These small pollution incidents could impact shellfish test results but are not taken into account during the investigation. This leads to above threshold results being retained on the classification record and, therefore, potentially impacting the business for the next 3 years.

In complete contrast, the French guidance allows for high *E.coli* results, i.e. those where there is no clear cause for the anomalous reading, to be considered 'aberrant' and disregarded. Notably, these are results that are '*more than 3 standard deviations from the mean for a longer term (e.g. 3 years) log transformed dataset*'. For the 2020/21 annual review of site classifications, the UK has introduced a similar criterion allowing for results more than 3 standard deviations of the log transformed dataset to be discounted during the annual review [55]. However, where such results are identified they are still being retained on the classification record rather than being removed for public health related concerns.

The handling of above threshold *E.coli* sampling results, their retention on the site classification record, and a more restrictive approach to determining if such results could be deemed anomalous is perceived by the industry to have caused significant issues for shellfish producers. The implications of this are that results that could be considered anomalous by one Country (and therefore discounted) are retained on site record in others, leading to a reduced site classification. This could place the shellfish producers affected by such an approach at a commercial disadvantage.

4.3 Potential laboratory and transcription errors

One aspect of the handling of high and anomalous *E.coli* results that is notably missing from all the case studies, as well as the EU guidance, is consideration of laboratory and transcription errors. Whilst there are strict requirements in the legislation with regard to Competent Authorities designating laboratories able to undertake the analysis of monitoring samples and requirements for audits to ensure adequate performance and staff training, mistakes can still be made.

Laboratory errors can include, for example:

- Occasional poor hygiene practices leading to samples becoming contaminated, and
- Transcription errors such as the monitoring results from one site being assigned to a different production site in the near vicinity or a completely incorrect listing of the sample location.

Such errors could clearly create issues within the site classification record if, for example, an above threshold *E.coli* result is attributed to the wrong production site or if an above threshold result due to lab contamination is retained on the classification record. It may be that where Countries have an appeal process or, alternatively, a rapid validation or resampling of an above threshold that such errors are quickly uncovered and discounted.

5. Summary

This review focused on the practices across nine EU Member States, Norway and the UK. Despite standard legislation and supplementary guidance to ensure consistency of approach, interpretation of the legislative requirements and implementation varies. From the DG SANTE audits, however, it can be concluded that this degree of flexibility is largely considered acceptable. When countries must incorporate the rules into domestic legislation there is, almost inevitably, some variation in how the supporting guidance is interpreted. This occurs even within a country, for example, in the UK Food Standards Scotland applys a different interpretation to aspects of the guidance than does the Food Standards Agency for England, Wales and Northern Ireland. This reflects, to some extent, regional differences in prevailing water quality conditions.

5.1 Shellfish Official Control implementation to support industry

Five key issues with the current method of assessing and managing the potential risks of shellfish contamination to consumer health were identified in section 2. Whilst this review did not set out to resolve these, some of the practices identified provide examples of more supportive approaches that can benefit industry whilst still maintaining high standards of hygiene and public health.

- **The system is based on *E. coli* as an indicator while the primary human health concern from consumption of bivalves is viral infection (e.g. norovirus).**

Currently the Shellfish Control Regulations do not require the monitoring of viral contaminants such as norovirus. Whilst *E.coli* levels provide a general indication of water quality and potential sewage contamination, *E.coli* in shellfish is not always an effective indicator of human pathogens. As a result, there have been instances where shellfish from production sites with the highest level of water quality have been linked to food safety incidents. In particular, the prevalence of norovirus in shellfish is a growing area of concern for the EU [56] and FAO [57].

While it is possible to detect the presence of norovirus in shellfish, the standard tests cannot determine whether the virus particles are viable and therefore infectious. Despite this, the EU is considering the introduction of mandatory norovirus testing for shellfish. The initial thresholds and level of testing proposed, however, have raised significant concerns for the future viability of the industry [58, 59]. The Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) occurred 28 November to 2 December 2022 and discussed a revision of the guidelines on norovirus in live bivalve molluscs [57]. If agreed, the first step in this revision would be a review of the current scientific evidence including an assessment of potential test methods and the utility of viral or other indicators of contamination associated with norovirus.

- **Testing is retrospective and intended for risk characterisation of production areas rather than time-sensitive controls. It can take four or five days from sampling to the results being issued; hence product may already have reached the market and been consumed before the producer is notified of an above threshold monitoring result.**

The classification system characterises water quality of shellfish production areas, assessed by the monthly sampling over the three preceding years. As such, official control sampling is not intended for, nor well suited to, real-time management of consigments of harvested shellfish entering the supply chain for human consumption.

Whilst producers undertake end product testing to ensure the bivalves are safe to supply to market, more responsive Official Control sampling would be beneficial for business. The choice of the test method can have a significant influence on the response times between a sample being collected and the result being reported to the producer. Where an above threshold result is identified and commiunicated rapidly to the producer, they may be in a position ot prevent harvest from occurring rather than having to destroy harvested product or recall product already supplied to the market.

- **Sampling occurs at fixed timeframes, usually monthly or bimonthly, whilst the concentration of *E. coli* in bivalves can vary greatly over a few hours [15, 22]. This raises concerns about how accurately the monitoring regime determines the pathogen risk in reality.**

The accumulation and clearance of *E.coli* from bivalves varies between species and sites in relation to a variety of environmental factors and over the period of a few hours [35-41]. In contrast, the classification is based on 12 samples collected over the year, which can be reduced to 6 samples for well established sites, with the last 3 years of data used to assign the classification. There is a disparity between the legal requirements and the realities of shellfish production in a varible environment.

Risk based approaches adopted by some Countries utilise much more frequent sampling depending upon the season or species and/or take environmental factors (e.g. rainfall, slurry spreading) into account which can impact the levels of *E.coli* levels in shellfish without necessarily leading to the increased presence of pathogens. Such appreches can help alleviate this issue whilst still maintaining effective hygiene and health standards.

- **Producers have expressed concerns that high variability in *E. coli* test results is not uncommon, which can lead to unnecessary restrictions due to anomalous results and increased business uncertainty**.

Although MPN is the most common test method utilised globally, the high variability of test results is well known [46-50]. The approved pour plate test method is considered more useful where high *E.coli* levels might be expected [15, 44, 45]. Consequently, the use of alternative methods to MPN may prove advantageous in some locations, reducing the number of closures and the need for resampling whilst still maintaining good hygiene and health standards.

Additionally, the way in which above threshold results are considered will also impact business operations. A risk based approach that effectively accounts for above threshold results and can justify their removal from the classification record when appropriate may provide much greater business certainty.

- **The testing system is not responsive, which means it can place restrictions on a business long after any public health risk period has passed.**

There is a significant difference between the legilslative requirements for dealing with above threshold results and the approach outlined in the EU guidance, with the latter being much more restrictive and impactful on business operation. Following the legislative requirements, which require a single repeat sample within classification thresholds to remove any temporary control measures, is more beneficial for businesses as they can resume normal operation more quickly.

The subsequent handling of these above threshold results and their retention on the classification record will also significantly effect on the future operation of the site. Unless an above threshold result can justifiably be disregarded, it will continue to influence the site's classification grade for the next 3 years; seasonal downgrades can be on the basis of a single result. Such an approach has business implications that extend well beyond any potential public health risk.

6. Conclusions

Protection of public health is the primary remit of the national Competent Authorities implementing the Shellfish Control Regulations, while businesses are keen to achieve and maintain a classification indicative of good water quality, and to minimise the likelihood of a site being downgraded or closed. Equally, they do not want to make their customers sick. Balancing protection of public health and the viability of bivalve shellfish production is most easily achieved with a regulatory system that is responsive, adaptive and ultimately risk-based. The implementation of Shellfish Control Regulations varies across countries; with some taking a risk based and more permissive approach, whilst others are much more restrictive. This indicates the ability of Member States to exert some independence within the overarching regulatory framework, reflecting regional variation in environmental conditions, historical approaches to shellfish hygiene controls as well as the differences in the relationships between producers and regulators.

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Appendix 1: List of national legislation, guidance and other sources describing implementation of the Shellfish Control Regulations.

Denmark

- Miljø- og Fødevareministeriet 2020. BEK nr 1793 af 02/12/2020. Bekendtgørelse om muslinger m.m. https://www.retsinformation.dk/eli/lta/2020/1793
- Final report of an audit carried out in Denmark from 12 to 19 November 2012 in order to evaluate the control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2012-6516.
- Final report of an audit of Denmark from 28 April to 12 May 2021 in order to evaluate the control system in place for live bivalve molluscs. DG (SANTE) 2021-7253.

France

- DGAL/SDSSA/2016-448 Réglementation sanitaire applicable aux zones de production de coquillages. 30/05/2016.
- DGAL/SDSSA/2019-866 Plan de surveillance de la contamination des coquillages par Escherichia coli au stade de la distribution - 2020.
- IFREMER 2018. Procedure nationale de la surveillance sanitaire microbiologique des zones de production de coquillages prescriptions du res eau de surveillance microbiologique des zones de production (remi). https://archimer.ifremer.fr/doc/00461/57260/59303.pdf
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- Final report of an audit performed in France from 12 to 23 September 2011 in order to evaluate the control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2011-8882.

Germany

- Niedersächsisches Ministerium für Ernährung und Landwirtschaft und Verbraucherschutz 2017. Niedersächsische Ausführungshinweise für die Überwachungsbehörden zur Durchführung der Muschelhygieneüberwachung.
- Ministerium für Energie wende, Landwirtschaft Umwelt und ländliche Räume, Programm zur Bewirtschaftung der Muschelressourcen im Nationalpark "Schleswig-Holsteinisches Wattenmeer" gemäß § 40 Landesfischereigesetz (LFischG) vom 31. März 2017. https://www.schleswig-holstein.de/DE/Fachinhalte/F/fischerei/Downloads/Muschelprogramm.pdf;jsessionid=1FB1C17169FE39AF6C32892E8380C978.delivery2-master?__blob=publicationFile&v=1
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Ireland

- Sea Fisheries Protection Authority (SEPA), 2020. Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas. https://www.sfpa.ie/LinkClick.aspx?fileticket=tTkrzmemDFU%3d&portalid=0&resourceView=1

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- S.I. No. 65/2018 - European Union (Good Agricultural Practice for Protection of Waters) (Amendment) Regulations
- Final report of an audit carried out in Ireland from 09 to 20 May 2011 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2011-6007.
- Final report of an audit carried out in Ireland from 21 to 30 October 2013 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs (follow-up). DG (SANCO) 2013-6674.

Italy

- Determinazione del responsabile del servizio prevenzione collettiva e sanità pubblica 11 agosto 2020, N. 13959. Procedure e modalità operative concernenti il sistema di classificazione e monitoraggio nelle zone di produzione e raccolta dei molluschi. n.304 del 02.09.2020. https://bur.regione.emilia-romagna.it/dettaglio-inserzione?i=a4d2d4219a624c2cbee48e008d201378
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- Final report of an audit carried out in Italy from 16 to 26 October 2012 in order to evaluate the control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2012-6542.

Netherlands

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- Final report of an audit carried out in the Netherlands from 17 to 27 April 2012 in order to evaluate the control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2012-6468.

Norway

- Tilsyn med produksjonsområder, høsting og omsetning av muslinger, pigghuder, kappedyr og sjøsnegler. ePhorte saksnr: 2011/6553-2. Sist endret: 06.10.2016.
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Portugal

- Instito Português do Mar e da Atmosfera. 2013. PLANO DE AÇÃO. SISTEMA NACIONAL DE MONITORIZAÇÃO DE MOLUSCOS BIVALVES INSTITUTO PORTUGUÊS DO MAR E DA ATMOSFERA, I.P. http://www.ipma.pt/bin/docs/institucionais/p.accao_snmb_2013.pdf
- Final report of an audit carried out in Portugal from 18 to 27 September 2013 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2013-6667.
- Final report of an audit of Portugal carried out from 09 November 2020 to 20 November 2020 in order to evaluate the control system in place for live bivalve molluscs. DG (SANTE) 2020-7119.

Spain

- Decreto 399/96, de 31 de octubre por el que se regulan los programas de control sanitario de moluscos bivalvos vivos. https://www.sergas.es/gal/NormativaConvenios/NormativaSanitaria/archivos/18111996225103361.htm
- Final report of an audit carried out in Spain from 10 to 21 October 2011 in order to evaluate the food safety control systems in place governing the production and placing on the market of bivalve molluscs. DG (SANCO) 2011-8881.
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Sweden

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Table 1: The *E.coli* classification thresholds for shellfish beds under the EU Shellfish Control Regulations

Class	***E.coli* concentration threshold**	**Post-harvest treatment required to reduce microbial contamination**
A	80% of sample results must be less than or equal to 230 *E.coli* per 100g flesh; AND no results may exceed 700 *E.coli* per 100g flesh using a five-tube, three dilution Most Probable Number (MPN) test	Shellfish can be harvested for direct human consumption.
B	90% of samples must be ≤4600 *E.coli* per 100g flesh; AND all samples must be less than 46000 *E.coli* per 100g flesh using a five-tube, three dilution Most Probable Number (MPN) test	Shellfish can be supplied for human consumption after one of three processes: • purification in an approved establishment • relaying for at least one month in a classified Class A relaying area • an EC approved heat treatment process
C	≤46000 *E.coli* per 100g flesh using a five-tube using a three dilution Most Probable Number (MPN) test	Shellfish can only be sold for human consumption after completing one of three possible processes: • 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	>46000 *E.coli* per 100g flesh using a three dilution Most Probable Number (MPN) test	Shellfish from areas with consistently prohibited level results must not be harvested.

Table 2: Overview of live bivalve production data for 2017 for the countries featured in the case studies (adapted from European Union [34]). **Countries explicitly implementing a risk based approach by species and/or location).

Country	**Bivalve Production (t)**						**Ranked Total production (t)**
	Mussels	**Pacific oyster**	**Clams**	**Cockles**	**Native oyster**	**Scallops**	
Spain	229,000	914	9,600	2,250		448	242,212
France	77,360	80,000	1,418	987	1,307		161,072
Italy**	64,200	53	33,000				97,253
Denmark	41,000		184	6,000	83		47,267
Netherlands**	38,400	2,500		1,212	110		42,222
Ireland	14,000	7,500	90		985	35	22,610
UK	4,060	992	11	2,500	35	5	7,603
Germany	6,700						6,700
Portugal**	688	741	3,339	449			5,217
Norway	2,328				5	23	2,356
Sweden**	1,726						1,726
Ranked Total production (t)	507,205	92,700	47,651	13,398	2,685	792	664,431

Table 3: Comparison of national bivalve production with bivalve imports in 2017. (Trade data obtained from Eurostat).

Country	National bivalve producti on (t)	Main species produced (>75% by weight)	Bivalve imports from EU Member States (t)	Bivalve imports from outside EU (t)	Main species imported (>75% by weight)	Production as a percentage of market supply
Denmark	47,267	mussels	15,798	2,804	scallops	71.8
Ireland	22,610	mussels, Pacific oyster	7,859	3,367	oysters, scallops	66.8
Spain	242,212	mussels	83,759	343,271	clams/cockle s, scallops	36.2
France	161,072	Pacific oysters, mussels	168,950	536,049	mussels, scallops	18.6
UK	7,603	mussels, cockles	19,025	18,722	mussels, scallops, clams/cockle s	16.8
Italy	97,253	mussels, clams	84,895	475,635	mussels, oysters	14.8
Sweden	1,726	mussels	8,340	7,241	mussels, oysters, scallops	10.0
Netherlands	42,222	mussels	108,224	286,266	mussels	9.7
Portugal	5,217	clams, Pacific oyster	10,239	59,467	mussels	7.0
Germany	6,700	mussels	28,905	92,718	mussels, scallops	5.2

Table 4: Comparison of the production site classification monitoring legislative requirements, guidance and implementation by different Countries.

Country	**Provisional classification sampling**	**Monitoring of classified areas**	**Monitoring in long term stable production sites**	**Classification reviews**
EU Implementing Regulation 2019/627	The number of samples, geographical distribution of sampling points and sampling frequency for the programme shall ensure that the results of the analysis are representative of the area in question. Competent authorities shall periodically monitor classified production sites to ensure they meet the required health standards.			Competent authorities should fix a review period in order to determine compliance with the health standards.
EU Good Practice Guidance (Technical Application)	At least 12 samples over 6 month period with a minimum interval of not less than one week. If remote, 6 samples over a 3 month period. Thereafter fortnightly sampling for remainder of year.	Monthly on a year-round basis. Sampling frequency may be bimonthly for areas that conform to the definition of remote.	Bimonthly. If results indicate an issue then monthly sampling should be reinstated.	Annually, taking into account the last 3 years' data, or all data if less than 3 years' worth. Alternatively, on a rolling basis as each new result is received taking into account the last 3 years' data.
England/ Wales/ Northern Ireland	10 samples over a minimum of 3 months, with samples obtained at least 1 week apart.	Monthly. Monitoring data is analysed continuously and can result in changes to classification.	Monthly sampling. Class B production areas with a stable compliance over a 5-year period can be awarded a long-term classification (B-LT).	3 years of data and the most recent complete year's results if change in water quality noted.
Scotland	A minimum of 10 samples taken at least a week apart, followed by	10 monthly samples for A sites and 8 for B and C sites.	No change in monitoring requirements.	3 years of data, reviewed annually to determine site classification for the coming year.

Country	Provisional classification sampling	Monitoring of classified areas	Monitoring in long term stable production sites	Classification reviews
	monthly sampling for remainder of year.	No changes to classification throughout the year.		
France	24 samples over a year.	Monthly.	Bimonthly as long as the results are within classification thresholds and the site has not been subject to any alerts over the previous 3 years.	Annual, based on 24 (monthly) or 12 (bimonthly) data obtained over the last 3 calendar years.
Ireland	12 samples, not closer together than fortnightly.	At least monthly on a year-round basis.	If 30 samples over three years, monitoring may be reduced to bimonthly. Results must be within thresholds.	Annual. Results not used to open and close production areas on a week-to-week basis.
Netherlands	12 samples over 6 months, obtained at least 1 week apart.	Fortnightly or monthly depending on the time of year, location and species.	No change in monitoring requirements.	Annual using 3 years of data.
Spain	Monthly.	Monthly.	After 5 years, bimonthly sampling.	Annual using 3 years of data.
Italy	12 samples over 6 months, with samples obtained no less than 2 weeks apart.	Taking a risk based approach, fortnightly sampling may be reduced to monthly but additional sampling in conjunction with adverse events will be required.	After 3 years, bimonthly sampling can be initiated, although a minimum of 8 samples per year are required.	Every three years.
Portugal	Bi-weekly for first 3 years.	Monthly, increases to	Monthly	Every 3 years until 2013. Thereafter,

Country	Provisional classification sampling	Monitoring of classified areas	Monitoring in long term stable production sites	Classification reviews
		fortnightly if indication of biotoxins presence.		annual reviews introduced.
Germany	12 samples over at least 6 months.	Monthly, with a minimum of 8 per year once established.	After 3 years, bimonthly, with a minimum of 12 samples in 3 years.	Annual or rolling assessment.
Sweden	No information found.	Monthly for mussels and bi-weekly for oysters.	Potential to vary monitoring frequency on the basis of historical data and environmental factors.	Ongoing through year.
Denmark	One week before the first harvest, and weekly thereafter.	One week before the first harvest, and weekly thereafter.	After 4 years, minimum requirements every 4 weeks in class A, 13 weeks in class B and 26 weeks in class C.	Ongoing through year on a weekly basis.
Norway	3 samples at 14 day intervals.	Monthly, with a minimum of 6 per year once established.	No change in monitoring requirements.	Annual.

Table 5: Summary of the key similarities and differences when implementing the Shellfish Control Regulations across 9 case studies countries.

Areas of consistent interpretation of the legal requirements	**Key areas of deviation in interpretation of the legal requirements**
• Almost all use the reference test method (MPN), although some countries (e.g. Netherlands) use one of the approved alternative methods	• Implementation of a risk based approach to monitoring
• Almost all use a monthly frequency for monitoring of production areas for first 3 years of designation	• Length of time required for a provisional classification to be awarded
	• Variation in monitoring frequency for long term production areas
	• Frequency at which classification reviews are undertaken
	• Use of industry representatives to collect official control monitoring samples
	• Handling of above threshold results and retention on the record; including number and frequency of repeat or verification samples, and the timeframe for lifting temporary restrictions

Table 6: Comparison of the approaches for handling high and anomalous *E.coli* monitoring results (NB: The national legislation and guidance available was rarely explicit on how high and anomalous results are identified and disregarded).

Country	**Guidance for handling high and anomalous *E.coli* results**
EU Implementing Regulation 2019/627	Class A areas: on the basis of a risk assessment an anomalous result exceeding the level of 700 E. coli per 100 g of flesh and intravalvular liquid maybe disregarded. Class B areas: 90 % of the samples <4 600 E. coli per 100 g of flesh and intravalvular liquid with remaining 10 % of samples <46 000 E. coli per 100 g of flesh and intravalvular liquid. Class C areas: all samples <46 000 E. coli per 100 g of flesh and intravalvular liquid.
EU Guidance and Technical Application	Although the regulation only considers anomalous results in the context of Class A areas, it is considered good practice to also apply the same criteria to Class B and Class C areas. Results that are markedly higher or lower than those previously seen in an area may potentially be considered anomalous (e.g. more than 3 standard deviations from the mean for a 3 year log transformed dataset). A minimum of 48 hours is required for resampling, with at least weekly sampling is recommended for investigative monitoring.
England/ Wales/ Northern Ireland	Investigative sampling is undertaken for any above threshold results. Two consecutive satisfactory samples must be taken at least seven days apart. Advice to Local Authorities, however, indicates that these samples are likely to be taken at a two week interval. These samples are for investigation purposes only and are not retained on the classification record.
Scotland	Because Scotland uses the 3 tube MPN test, there is a requirement to resample any result >18,000 MPN/100g. FSS have indicated that if this repeat sample does not reflect the initial one, the first is considered an anomaly and removed from the classification record. If the high result is repeated, then it is not an anomaly and is retained.
France	Class A: If sample >230 *E.coli*/100g flesh, repeat sampling is undertaken with 48 hours. If <230 *E.coli*/100g, no further action taken. If the sample is >230 but <700 *E.coli*/100g flesh, weekly sampling instigated until 2 consecutive results <230 *E.coli*/100g flesh are obtained, usually one week apart. However, if the resample is within classification, the second sample can be taken 48 hours later. Class B and C: If sample exceeds threshold, repeat sampling within 48 hours. If within threshold no further action taken. If exceeds threshold, weekly sampling instigated until 2 consecutive within classification results are obtained. Following a within classification sample, the second sample can be taken 48 hours later.

Country	Guidance for handling high and anomalous *E.coli* results
	An ‘aberrant’ result corresponding to a single sample that is outwith the general background noise of the area without any real cause being identified will be disregarded.
Ireland	Alerts triggered: A class - >700 *E. coli*/100g flesh, B class - >18,000 *E. coli*/100g flesh and C class - >46,000 *E. coli*/100g flesh. In managing any such situation, the overriding concern will be consumer protection. Consideration will also be given to the sustainable long-term development of the shellfish industry when decisions are made. If a high result of a one-off pollution event that will not recur, the high result should be recorded but not used in the classification data and repeat sample should be taken.
Netherlands	If outwith classification thresholds, resampled within one week and if result meets classification, no further action. Resampling will be maintained on a weekly basis for three weeks prior to downgrading or closure being considered.
Spain	Where an *E.coli* result exceeds the classification threshold, sampling will be increased to weekly until sample results return to normality. Where additional sampling has been undertaken in a weekly basis, samples that exceed the classification threshold will not be considered for classification if the time interval between two samples is less than 15 days (the required minimum time for the microbiological monitoring in a production area).
Italy	If sample exceed classification threshold, a repeat sample is taken within one week. No further action will be taken if resample with within classification. An abnormal result that exceeds the level of 700 *E.coli* per 100 g flesh may be disregarded on the basis of a risk assessment as Class A allows a 20% tolerance in the sampling results.
Germany	If class A thresholds exceeded, the site will be closed or downgraded to B. If class B or C, *E.coli* sampling will be undertaken at weekly intervals on request. At least two successive studies below the thresholds are required to return the classification. This additional sampling may be carried out as an officially regulated sample.
Denmark	Downgrading or reclassification does not occur on the basis of abnormal results in an otherwise stable area. If the results of the analysis of one or more samples show that the threshold for a C classification has been exceeded the production area will be closed. Any closures will be maintained until three samples have been taken for one week, followed by one sample taken for each of the following 2 weeks, meeting thresholds for temporary A, B or C classification.
Norway	Sites temporarily closed. A resample is required within 14 days. If this is within the classification threshold, harvesting can resume.