

Here to give the UK seafood sector
the support it needs to thrive.



Review of the application of the Official Control Regulations for shellfish production as they relate to microbial contamination

Report produced by Seafish for the Shellfish
Stakeholder Working Group

June 2021

The Shellfish Stakeholder Working Group (SSWG) is a forum for live bivalve mollusc producers, researchers, and regulators to convene to discuss problems and identify solutions to issues related to the application of the shellfish water classification regulations. The SSWG is chaired by the Shellfish Association of Great Britain and is facilitated by Seafish.

This report was prepared by Dr. Eunice Pinn (Marine Environment Regulation Advisor, Seafish). With additional support provided by Cristina Fernandez (Seafish), Dr. Shelagh Malham and Prof. Lewis Le Vay (Bangor University).

The report was peer reviewed by Food Standards Agency (FSA), The Centre for Environment, Fisheries and Aquaculture Science (CEFAS) and the New Zealand Food Safety Science and Research Centre.

Executive Summary

The Shellfish Stakeholder Working Group (SSWG) commissioned Seafish to undertake a review of the application of the Official Control Regulations that apply to live bivalve production in EU Member States, with a focus on the microbial requirements. This review does not consider the biotoxin and other Official Control Regulation requirements for the production of live bivalve molluscs.

At the end of the UK-EU transition period, all directly applicable EU law in force, including that enacted but not yet enforced, became part of the body of domestic law in Great Britain (England and Wales, and Scotland) on 31 December 2020. Under the terms of the Northern Ireland Protocol, the majority of EU food and feed hygiene and safety law (as listed in Annex 2 to the Protocol) continue to apply directly in Northern Ireland.

Water quality, in terms of the bacteria and viruses present, affects the incidence of microbial contamination (bacterial and viral) in shellfish. If shellfish are eaten raw or is only lightly cooked, some of these microbes can cause a variety of illnesses in humans, the most common of which are gastro-enteric illnesses. These microbial contaminants are primarily derived from two key sources: human sewage and land-based activities (e.g. wildlife and livestock agriculture), with the former being of greater concern in terms of human pathogens.

The EU Official Control Regulations manage these potential human health risks and are focused on a site classification regime that is based on levels of *Escherichia coli* (*E.coli*) contamination in shellfish flesh. The aim of this report was to review the application of these official controls across different EU Member States and to identify areas of deviation and flexibility that may exist.

EU Regulation 2017/625 requires that competent authorities classify production and relay areas for live bivalve molluscs, while EC Regulation 853/2004 notes that producers can collect bivalve shellfish for commercial sale only from classified areas. EC Regulation 2019/627 specifies the rules for the official controls on products of animal origin including live bivalves. This legislation requires all EU Member States to routinely monitor the level of faecal contamination in production and relaying areas, and to classify these production areas accordingly. The EU Good Practice Guidance provides additional advice on the interpretation and application of these Control Regulations for live bivalve production.

How a site is classified can affect business flexibility, operating costs, and even the ability to trade. As such 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. This is considered easier to achieve with a regulatory system that is responsive, adaptive and ultimately risk-based, i.e. one that incorporates a proactive approach to pollution management to reduce risk of harvesting contaminated bivalves when there are water quality issues, as well as one that can respond quickly and easily should the water quality circumstances improve. The purpose of the review was to consider if variations existed in how these regulations are applied in practice and if this could inform how the UK might adopt a more flexible, risk based approach to regulating bivalve production in line with public health requirements.

This review uses case studies focused on the key European bivalve mollusc producers: France, Netherlands, Ireland, Denmark, Italy, Spain, Portugal, Germany and Sweden. It also included Norway through its membership of the European Free Trade Association. Consideration was given to how the legislation and the EU Good Practice Guidance has been applied, including the handling of high and anomalous *E.coli* results by these countries, and the identification of situations where such results might be removed from the classification dataset.

Given the UK's changing status with respect to the EU, the review investigated how Third Countries exporting bivalve molluscs to the EU meet microbial contamination requirements. The review highlights that:

- there are differences across Member States, in how the EU requirements are met.
- there is a degree of variation in how the official controls are implemented and in what the EU will consider as equivalence when it comes to third country status.

Member States: The variation identified in the application of the legal requirements by Member States indicates that despite standard legislation and guidance, different approaches to regulating bivalve production are in operation. In some instances the variation is more restrictive than the UK (e.g. it takes 12 months to secure an initial site classification in France compared to potentially 3 months in the UK) but generally it is risk based in approach and more permissive. The variation includes how anomalous results are treated, the frequency of site sampling, use of different approved test methods, use of rolling classification systems and the ability for industry to collect samples.

Third Countries: The review found that while Third Country arrangements are different from the EU, they are considered to provide an equivalent level of public health protection. Areas of difference with the EU Official Control Regulations include:

- four categories of classification compared to the UK/EU model of three categories, with one of the four providing a mechanism for industry to operate microbially compromised sites;
- a more permissive regime for offshore sites (sites >5km from shore);
- more reliance on a wider suite of environmental indicators to inform site classification;
- the use of management plans that activate periodic closures when pollution is likely (e.g. in response to rainfall, river flow, salinity or sewage spills); and
- spatial exclusion of shellfish production close to wastewater discharges.

The effectiveness of the different shellfish monitoring programmes in protecting public health was not evaluated in this report. As a result, the impact of these areas of difference has not been quantified.

Table of Contents

Executive Summary	3
Chapter 1: Report Purpose and Objectives	10
Chapter 2: Introduction	11
2.1 Legislative framework	11
2.2 Methodology	13
Chapter 3: Comparison of classification of shellfish production sites by Member States using England and Wales as a baseline.....	16
3.1 Legislation	16
3.1.1 EU Guidance	16
3.2 Approach	18
3.3 UK	19
3.3.1 Initial site classification	19
3.3.2 Ongoing monitoring	19
3.3.3 Seasonal monitoring	20
3.3.4 Long term stable sites (only applicable in England & Wales)	20
3.3.5 Review of classifications	20
3.3.6 Variation relevant to Northern Ireland	21
3.3.7 Variation relevant to Scotland	21
3.4. France	22
3.4.1 Initial site classification	22
3.4.2 Ongoing monitoring	22
3.4.3 Seasonal sites	23
3.4.4 Long term stable sites	23
3.4.5 Review of classifications	23
3.4.6 Variation in relation to UK approach	23
3.5 Ireland	24
3.5.1 Initial site classification	24
3.5.2 Ongoing monitoring	24
3.5.3 Seasonal sites	24
3.5.4 Long term stable sites	24
3.5.5 Review of classifications	25
3.5.6 Variation in relation to UK approach	25
3.6 The Netherlands	25
3.6.1 Initial site classification	25
3.6.2 Ongoing monitoring	26
3.6.3 Seasonal sites	26
3.6.4 Long term stable sites	26
3.6.5 Review of classifications	26
3.6.6 Variation in relation to the UK approach	26
3.7 Spain	27
3.7.1 Initial site classification	27
3.7.2 Ongoing monitoring	27
3.7.3 Seasonal sites	28
3.7.4 Long term stable sites	28
3.7.5 Review of classifications	28
3.7.6 Variation in relation to the UK approach	28
3.8 Italy	28
3.8.1 Initial site classification	29

3.8.2 Ongoing monitoring.....	29
3.8.3 Seasonal sites	29
3.8.4 Long term stable sites.....	29
3.8.5 Review of classifications	29
3.8.6 Variation in relation to the UK approach.....	30
3.9 Portugal.....	30
3.9.1 Initial site classification.....	30
3.9.2 Ongoing monitoring.....	30
3.9.3 Seasonal sites	31
3.9.4 Long term stable sites.....	31
3.9.5 Review of classifications	31
3.9.6 Variation in relation to UK approach.....	31
3.10 Germany	31
3.10.1 Initial site classification.....	32
3.10.2 Ongoing monitoring.....	32
3.10.3 Seasonal sites	32
3.10.4 Long term stable sites.....	32
3.10.5 Review of classifications	32
3.10.6 Variation in relation to the UK approach.....	32
3.11 Sweden	32
3.11.1 Initial site classification.....	33
3.11.2 Ongoing monitoring.....	33
3.11.3 Seasonal sites	33
3.11.4 Long term stable sites.....	33
3.11.5 Review of classifications	34
3.11.6 Variation in relation to the UK approach.....	34
3.12 Denmark.....	34
3.12.1 Initial site classification.....	34
3.12.2 Ongoing monitoring.....	34
3.12.3 Seasonal sites	35
3.12.4 Long term stable sites.....	35
3.12.5 Review of classifications	35
3.12.6 Variation in relation to the UK approach.....	35
3.13 Norway	36
3.13.1 Initial Site classification	36
3.13.2 Ongoing monitoring.....	36
3.13.3 Seasonal classifications.....	37
3.13.4 Long term stable sites.....	37
3.13.5 Review of Classifications	37
3.13.6 Variation in relation to the UK approach.....	37
3.14 Member State Compliance with the Shellfish Control Regulations.....	37
3.15 Summary of variation in relation to UK implementation of the Shellfish Control Regulations	39
3.16 Assessment.....	40
3.16.1 Bivalve species	40
3.16.2 Time of year and location.....	40
3.16.3 Environmental indicators.....	40
3.16.4 Sample collection and analysis	41

Chapter 4: Handling of above threshold *E.coli* results and the determination of those considered anomalous 43

4.1 UK	45
4.1.1 Action taken on receipt of an above threshold result	45

4.1.1 Anomalous <i>E.coli</i> results.....	46
4.2 France.....	47
4.2.1 Action taken on receipt of an above threshold result.....	47
4.2.2 Anomalous <i>E.coli</i> results.....	48
4.2.3 Comparison with the UK approach.....	48
4.3 Ireland.....	48
4.3.1 Action taken on receipt of an above threshold result.....	48
4.3.2 Anomalous <i>E.coli</i> results.....	49
4.3.3 Comparison with the UK approach.....	49
4.4 Netherlands.....	50
4.4.1 Action taken on receipt of an above threshold result.....	50
4.4.2 Anomalous <i>E.coli</i> results.....	50
4.4.3 Comparison with the UK approach.....	50
4.5 Spain.....	50
4.5.1 Action taken on receipt of an above threshold result.....	50
4.5.2 Anomalous <i>E.coli</i> results.....	50
4.5.3 Comparison with the UK approach.....	51
4.6 Italy.....	51
4.6.1 Action taken on receipt of an above threshold result.....	51
4.6.2 Anomalous <i>E.coli</i> results.....	52
4.6.3 Comparison with the UK approach.....	52
4.7 Germany.....	52
4.7.1 Action taken on receipt of an above threshold result.....	52
4.7.2 Anomalous <i>E.coli</i> results.....	52
4.7.3 Comparison with the UK approach.....	52
4.8 Sweden.....	53
4.8.1 Action taken on receipt of an above threshold result.....	53
4.8.2 Anomalous <i>E.coli</i> results.....	53
4.8.3 Comparison with the UK approach.....	53
4.9 Denmark.....	54
4.9.1 Action taken on receipt of an above threshold result.....	54
4.9.2 Anomalous <i>E.coli</i> results.....	54
4.9.3 Comparison with the UK approach.....	54
4.10 Norway.....	55
4.10.1 Action taken on receipt of an above threshold result.....	55
4.10.2 Anomalous <i>E.coli</i> results.....	55
4.10.3 Comparison with the UK approach.....	55
4.11 Member State compliance with the Shellfish Control Regulations.....	55
4.12 Potential laboratory and transcription errors.....	56
4.13 Overview of the variation in how above threshold <i>E.coli</i> results are treated.....	57
4.13.1 The decision to temporarily close sites or reclassify.....	57
4.13.2 Resampling timeframe and number of samples required.....	57
4.13.3 Process for treating above threshold results in the classification record.....	58
4.13.4 Exclusion of extraordinarily high monitoring results.....	58
4.13.5 Rainfall and the disregarding of high <i>E.coli</i> results as anomalous.....	58
4.13.6 Activities taken into account when considering whether an above threshold result is anomalous.....	59
4.13.7 Summary.....	59
Chapter 5: Third Country equivalence and export to the EU	60
5.1 Canada.....	62
5.1.1 Initial site classification.....	62
5.1.2 Ongoing monitoring.....	64

5.1.3 Seasonal monitoring	64
5.1.4 Long term stable sites	64
5.1.5 Review of classification	64
5.1.6 Handling of above threshold microbial results	64
5.1.7 Variation in relation to the UK approach	65
5.1.8 Additional requirements for exports	67
5.2 New Zealand	67
5.2.1 Initial site classification	68
5.2.2 Ongoing monitoring	69
5.2.3 Seasonal monitoring	69
5.2.4 Long term stable sites	70
5.2.5 Review of classification	70
5.2.6 Handling of above threshold microbial results	70
5.2.7 Variation in relation to the UK approach	70
5.2.8 Additional requirements for exports	71
5.3 USA	71
5.3.1 Initial site classification	72
5.3.2 Ongoing monitoring	73
5.3.3 Seasonal monitoring	74
5.3.4 Long term stable sites	74
5.3.5 Review of classification	74
5.3.6 Handling of above threshold microbial results	74
5.3.7 Variation in relation to the UK approach	74
5.3.8 Additional requirements for exports	75
5.4 Third Country Equivalence with the EU Shellfish Control Regulations and UK implementation	76
5.5 Summary of the variation in relation to the UK Implementation	77
5.5.1 Nomenclature	77
5.5.2 Water quality testing	78
5.5.2 Type of test	78
5.5.3 Test thresholds	78
5.5.4 Variability in testing	79
5.5.4 Sanitary survey requirements	79
5.5.6 Frequency of sampling	79
5.5.7 Environmental indicators	79
5.5.8 Explicit recognition of offshore sites and development of a specific monitoring approach	80
5.5.9 End product testing and export	80
Chapter 6: Conclusions	81
6.1 Case for Review	81
6.2 Scope	82
6.3 Summary of findings: EU Member States	83
6.3.1 Site classification and monitoring	83
6.3.2 Handling of above threshold results	85
6.4 Summary of findings: Third Countries	87
6.5 Conclusion	88
6.5.1 Continued alignment with the EU system	89
6.5.2 Implementing a Third Country approach	90
Appendix 1: Summary of Audits relating to the microbial aspects of the Shellfish Control Regulations.	92

Appendix 2: Comparison of the production site classification monitoring implemented by different Member States.....	97
Appendix 3: Comparison of the current approaches adopted by Member States for handling high and anomalous <i>E.coli</i> results.....	99
Appendix 4: Summary of Third Country Audits and comparison to the EU Shellfish Control Regulations.	101
Appendix 5: Shellfish Stakeholders Working Group (SSWG) Member Organisations	102

Chapter 1: Report Purpose and Objectives

The Shellfish Stakeholder Working Group (SSWG)¹ identified the need for a comprehensive review of the application of the Official Control Regulations for bivalve production by different Member States and Third Countries importing bivalves into the European Union. SSWG commissioned Seafish to undertake the review.

The purpose of the review was to explore if variations exist in how the Official Control Regulations for shellfish production are applied in practice. This could inform how the UK might adopt a more flexible, risk based approach to regulating bivalve production in line with public health requirements. Given the UK's exit from the EU, the review also investigated how Third Countries exporting bivalve molluscs to the EU meet microbial contamination requirements. There were three key objectives to the review:

Objective 1: To compare how EU Regulations 2017/625 and 2019/627 (formerly applied through EU Regulation 854/2004) are implemented across different EU Member States relevant to the UK. This comprises a review of:

- the application of monitoring requirements for *E.coli* in shellfish and consideration of how the microbial test results are applied to determine classification of Class A, B and C waters using a series of case studies; and
- how unusually high single *E.coli* results are treated, including details of any protocols that exist to allow for such results to be discounted and under what circumstances. The review focused on this because site classification can be influenced by unusually high individual monitoring results.

Objective 2: To assess how Third Countries exporting bivalve molluscs to the EU demonstrate equivalency with the EU monitoring requirements.

Objective 3: To identify evidence of flexibility in how other Member States implement these requirements, which could in turn inform the potential for the UK to adopt a more flexible, risk-based approach to regulating bivalve production.

This review does not consider the biotoxin and other Official Control Regulation requirements for the production of live bivalve molluscs. Nor does the review consider the public health impact of the microbial monitoring programmes implemented by the case study countries, although the assumption is the approaches adopted meet public health requirements.

¹ SSWG brings together shellfish producers, regulators and researchers to work collaboratively to identify, discuss and find solutions to issues affecting UK shellfish production. The group is facilitated by Seafish and chaired by the Shellfish Association of Great Britain (SAGB). A list of members can be found in Appendix 5.

Chapter 2: Introduction

The classification and regulation of shellfish production sites is considered a public health matter. This is because water quality, in terms of the bacteria and viruses present, affects the incidence of microbial contamination (bacterial and viral) in shellfish. If shellfish is eaten raw or is only lightly cooked, some of these microbes can cause a variety of illnesses in humans, the most common of which are gastro-enteric illnesses such as norovirus and hepatitis infections. These microbial contaminants are derived from both human (i.e. sewage) and animal sources (e.g. wildlife and livestock agriculture), with the former being of greater concern in terms of human pathogens.

The variety of human pathogens of concern, means that *Escherichia coli* (*E.coli*) is used as a proxy or faecal indicator; *E.coli* levels in shellfish flesh are used to classify production sites and determine the required harvesting protocols.

Shellfish water quality is a complex issue which has been identified as a key constraint on the expansion of the UK farmed shellfish industry. When *E.coli* counts in shellfish exceed particular threshold levels, the classification of a site may be downgraded, introducing stricter post-harvesting controls, or the site may be temporarily closed until product quality levels recover sufficiently.

The current method² of assessing and managing the potential risks of shellfish contamination to consumer health is considered problematic by some stakeholders because:

1. Testing is retrospective. It can take several days from sampling to results being issued; hence product can already be placed on the market by the time a high *E.coli* result is recorded.
2. The testing system is not responsive, which means it can place restrictions on a business long after the risk period has passed.
3. Sampling occurs at fixed timeframes, usually monthly, which means the testing regime is not always able to accurately determine risk outside this period.
4. High variability in test results is not uncommon, which can lead to unnecessary restrictions due to anomalous results and increased business uncertainty.
5. The system is based on *E. coli* as an indicator while the primary human health concern from consumption of shellfish is viral infection (e.g. norovirus).
6. The system does not fully take account of other measures to address the potential risk, such as cooking.

2.1 Legislative framework

At the end of the UK-EU transition period 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) on 31 December 2020. Under the terms of the Northern Ireland

² The current method to assess microbial contamination in shellfish flesh is the Most Probable Number (MPN) test. This test uses *E.coli* as an indicator of pathogen presence to classify shellfish production areas.

Protocol³, 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.

Bivalve production in the EU is regulated via a complex suite of food safety and hygiene regulations known as 'Official Controls'. The key 'Official Controls' relevant to managing the risk of microbial contamination in farmed shellfish production include:

- EC Regulation 2017/625⁴ requires that Competent Authorities classify production and relay areas for live bivalve molluscs. This was previously applied through Regulation 882/2004⁵.
- EC Regulation 853/2004⁶ permits the commercial sale of bivalve shellfish from classified sites.
- EC Regulation 2019/627⁷ specifies the rules for the official controls on products of animal origin including live bivalves; targeting relay and production areas for bivalve molluscs and the end product. These requirements '*shall be without prejudice to food business operators' primary legal responsibility for ensuring food safety, as laid down in Regulation (EC) No 178/2002*'⁸. The requirements of Regulation 2019/627 were previously applied through Regulation 854/2004⁹.

These regulations are collectively referred to as the Shellfish Control Regulations. In summary, the regulation and control of shellfish quality requires production area monitoring in order to ensure:

'(a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

(b) the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;

(c) for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs; and

(d) for the presence of chemical contaminants in live bivalve molluscs.'

The Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production¹⁰ provides advice on the interpretation and

³

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised_Protocol_to_the_Withdrawal_Agreement.pdf

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R0625>

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0882&from=EN>. From December 2019 this regulation was repealed and the requirements continuing through EU Regulation 2017/625.

⁶ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:139:0055:0205:en:PDF>

⁷ Commission Implementing Regulation (EU) 2019/627 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0627&from=EN>

⁸ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20080325:EN:PDF>

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0854&from=EN>

¹⁰ EU 2018. Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004.

https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_guidance_community_guide_bivalve_mollusc_monitoring_en.pdf

application of these legal requirements. This guidance is updated at regular intervals, most recently in 2018. The EU Guidance is supported by a technical application document¹¹, which further encourages consistent application by Member States.

In 2018, the European Parliament noted that the sustainable growth of aquaculture needed to be based on business investment predictability and legal certainty¹². This included the need for close cooperation between the Commission and the Competent Authorities. The European Parliament also recognised the potential for aquaculture to contribute to food and nutrition security as a climate-smart and environmentally sustainable food production system.

The legal requirements for shellfish production enable Member States to implement a risk based approach, although anecdotal evidence indicates variation in the interpretation and application of these requirements. To inform the development of an adaptive risk-based approach for UK site classification monitoring and shellfish harvesting, this review explores where variation exists in how the Shellfish Control Regulations are applied in practice across different Member States. This includes consideration of how high and anomalous *E.coli* monitoring results are dealt with. Given the UK's changed status with respect to the EU, the review also investigated how Third Countries exporting bivalve molluscs to the EU meet equivalence in the microbial standards required. As a Third Country, exports of live bivalve molluscs from Great Britain will need to meet the EU requirements for imports of live bivalve molluscs into the EU. Northern Ireland continues to remain part of the EU single market.

2.2 Methodology

This review compared and contrasted the application of the Shellfish Control Regulations between the UK, selected Member States and Third Countries through a series of case studies. It also considers the EU Guidance on the application of these legal requirements.

Member State case studies were chosen primarily on the basis of their live bivalve production data (e.g. Spain and France), but with consideration also given to country case studies that were considered to have adopted a more explicit risk based approach (e.g. the Netherlands and Sweden) (Table 1). EU Implementing Regulation 2019/626 lists the Third Countries that are eligible to import live, chilled or frozen bivalves into the EU (Table 2). Third country case studies were chosen on the basis of current and historic exports of mussels and oysters into Europe. In addition, consideration was also given to recent trade agreements between the EU and Third Countries that specifically incorporated bivalves.

For each case study, any publicly available national legislation and/or guidance relating to bivalve production requirements were identified and translated, where necessary, using the Multilizer document translator package. 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 addition

¹¹ EU 2018. Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application. https://eur.cef.eu/media/14117/20181231gpg_issue-7-final.pdf

¹² European Parliament resolution of 12 June 2018 on towards a sustainable and competitive European aquaculture sector: current status and future challenges. http://www.europarl.europa.eu/doceo/document/TA-8-2018-0248_EN.html?redirect

to national legislation and/or guidance documents, any relevant audits of a country's implementation of the requirements were also identified and reviewed.

In some cases, the available information did not provide sufficient detail on how the Shellfish Control Regulations are 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.

The country case studies comprised France, Ireland, Netherlands, Italy, Spain, Denmark, Portugal, Germany, Sweden, Norway, New Zealand, USA and Canada.

Table 1: Overview of live bivalve production data for 2017 for the countries featured in the case studies¹³. (* Norway is a member of the European Free Trade Association¹⁴ (EFTA) and therefore implements the same Regulations as EU Member States; ** Countries explicitly implementing a risk based approach by species and/or location; † UK data is that presented in DG SANTE 2018-6568¹⁵).

Country	Mussels (t)	Pacific oyster (t)	Clams (t)	Cockles (t)	Native oyster (t)	Scallops (t)	Ranked Total production (t)
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

¹³ Data taken from EC, 2018. Overview report on a series of fact-finding missions carried out in 2018 on the implementation of the rules on bivalve mollusc aquaculture. DG(SANTE) 2018-6568.

¹⁴ [https://www.efta.int/about-efta/european-free-trade-association#:~:text=The%20European%20Free%20Trade%20Association%20\(EFTA\)%20is%20an%20intergovernmental%20organisation, trading%20partners%20around%20the%20globe.](https://www.efta.int/about-efta/european-free-trade-association#:~:text=The%20European%20Free%20Trade%20Association%20(EFTA)%20is%20an%20intergovernmental%20organisation, trading%20partners%20around%20the%20globe.)

¹⁵ Cefas data for 2017 indicates production was actually much greater: 16,200t mussels, 2,200t Pacific oyster, 21t clams, 5,200t cockles, 23t native oyster and 46t scallops.

Table 2: Third Countries **permitted** to export live bivalve molluscs to EU¹⁶

Country	Exports occurring	Notes
Australia	Scallops (<i>Amusium balloti</i> and <i>Pecten fumatus</i>), Pacific oyster and pipi (<i>Plebidonax deltooides</i>) to Belgium, France, Italy and Portugal.	Export is irregular and mainly frozen.
Canada	Live mussels (<i>Mytilus</i> spp.), Manila clams (<i>Tapes japonica</i> and <i>T. philippinarum</i>) and Atlantic oysters (<i>Crassostrea virginica</i>) to Belgium, Spain and the Netherlands.	No notifications or product recalls for exports to EU.
Chile	Frozen or processed mussels (<i>Mytilus chilensis</i>) only exported.	No live bivalves exported.
Greenland	Only exports frozen wild caught scallops to Denmark	No live bivalves exported.
New Zealand	Greenshell mussels (<i>Perna canaliculus</i>), Pacific oyster, scallops (<i>Pecten novaezelandiae</i>) and NZ littleneck clam (<i>Austrovenus stutchburyi</i>). Live bivalves are exported to Italy, Germany, Spain and UK.	Commitment of the producers to deliver safe bivalves and good collaboration with competent authorities noted during audit.
Tunisia	No bivalves exported.	No live bivalves exported.
Turkey	Cooked or frozen bivalves only exported. Species not identified.	No live bivalves exported.
Uruguay	No bivalves exported.	No live bivalves exported.
USA	Oysters and other bivalve molluscs to Spain and the Netherlands.	Audit noted a sophisticated system for the official controls for the production of live bivalve molluscs.

¹⁶ Information taken from DG SANTE audits of Third Countries: Australia DG(SANCO)/2007-7287; Canada DG(SANCO) 2009-8036; Chile DG(SANCO) 2013-6721; Greenland DG(SANCO)/ 2009-8042; New Zealand DG(SANCO)/ 2008-767; Tunisia DG(SANTE) 2019-6694; Turkey DG(SANTE) 2018-6508; Uruguay DG(SANTE) 2015-7471; USA DG(SANTE) 2015-7486.

Chapter 3: Comparison of classification of shellfish production sites by Member States using England and Wales as a baseline

The Shellfish Control Regulations outline the need for sanitary surveys and site classification prior to production commencing, and regular monitoring and testing during the production process.

3.1 Legislation

The Shellfish Control Regulations require live bivalve molluscs to only be harvested from approved production sites that have been identified and classified by the Competent Authority. The legislation sets out the criteria for classification of these sites including the microbial standards to be met. A classification determines whether the site can be used for harvesting and the level of post-harvesting treatment required to reduce microbiological contamination to meet the end product standard¹⁷ specified in the legislation, i.e. the threshold at which the bivalves are considered safe for human consumption (Table 3).

Shellfish site classification requires a sanitary survey to be undertaken, which includes an evaluation of the sources and types of faecal contamination in the vicinity of the harvesting area. Classifications are awarded on an annual basis, but may also be limited to the harvesting period if it only occurs during certain months of the year. In some cases, sites can be awarded two classifications, each related to the contamination risk of the relevant season.

A sampling plan must also be developed as part of the approvals process. This plan details the representative monitoring points (RMPs) which are the sampling points across the site. RMPs should incorporate the full extent of the shellfishery, as well as accounting for variations in tidal flows and the locations of local pollutant sources. Ongoing monitoring is required to determine whether the level of risk has changed or when short-term controls need to be applied or the classification status changed.

The legislation also outlines the decisions to be taken when the classification criteria are exceeded, including downgrading or temporary closure. Sites can be re-opened when the microbial thresholds for the classification are met.

3.1.1 EU Guidance

Following the identification of issues in relation to interpretation and consistency of application of the Shellfish Control Regulations, the Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production¹⁸ (hereafter

¹⁷ The end product standard required for shellfish includes a microbial threshold of <230 *E.coli*/100g flesh and intravalvular fluid.

¹⁸ EU 2018. Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004.

referred to as the EU Guidance) was published. The aim of this document is to encourage the consistent application of the legal requirements by Member States, whilst allowing some degree of flexibility. The objective of the EU Guidance is to enable Competent Authorities to implement scientifically based programmes for the protection of public health and promotion of intra-community trade within the EU.

The EU Guidance provides the key principles and practice on implementation of the legal requirements. For example, sanitary surveys should incorporate:

- A desk study characterising the shellfishery, land use in the wider catchment and known sources of pollution.
- A shoreline survey confirming the accuracy of the desk based study and the identification of any additional potential sources of pollution.
- A hydrodynamic study of the area assessing potential significant sources of faecal contamination in the proximity of the harvesting area.
- If the most appropriate locations for the RMPs are not obvious, a bacteriological study should be undertaken to confirm the best locations consisting of at least three samples taken from each site at intervals not closer together than fortnightly and tested for *E. coli*.
- An analysis of historical bacterial data if available and links to the contamination of shellfish.

The Guidance also provides a detailed description of the requirements for the sampling plan and ongoing monitoring, how samples should be collected and transported for analysis, the method of analysis (i.e. the Most Probable Number [MPN]¹⁹ technique specified in EN/ISO 16649-3), and interpretation of the monitoring results.

There is no requirement for sites to have pollution management plans. Instead, the EU Guidance notes that faecal pollution can be highly variable over short timeframes, particularly in areas subject to strong currents or marked rainfall influences. Pathogen occurrence also varies according to factors such as prevalence in the community and relative environmental

https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_guidance_community_guide_bivalve_mollusc_monitoring_en.pdf

¹⁹EU Implementing Regulation 2019/627 stipulates that *'The reference method for analysis of E. coli in live bivalve molluscs shall be the detection and 'most probable number' (MPN) technique specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140.* MPN estimates the population density of viable microorganisms in a test sample using the numbers of observed positive growth responses to a standard series of sample dilutions used to inoculate a set number of culture media tubes. The number of sample dilutions used is based on the size of the expected microbial population. Generally tenfold serial dilutions are used in a 3 or 5 tube MPN series. In England & Wales, an extra dilution series is added (i.e. 5x4 tube MPN) to allow enumeration of results up to >180,000 – the standard 5x3 tube MPN only enumerates up to >18,000 which is below the class C limit of 46,000. When a higher number of tubes are inoculated, the confidence in the MPN result is increased. As alternatives to the MPN, the impedance test and pour plate methods have also been approved. See Impedance method: EURL generic protocol - Enumeration of *Escherichia coli* in live bivalve molluscan shellfish by the direct impedance technique using Bactrac 4300 series analyser. Current issue. <https://cefaswebsitedev.cefastest.co.uk/media/taulrzt/c-users-ab19-documents-coe-seafood-safety-generic-protocol-enumeration-of-e-coli-in-bivalve-molluscs-using-impedance.pdf> and Colony count method: EURL generic protocol - Enumeration of *Escherichia coli* in bivalve molluscan shellfish by the colony count technique (based on ISO 16649-2). Current issue. <https://cefaswebsitedev.cefastest.co.uk/media/vdwl5v5/generic-protocol-enumeration-of-e-coli-in-bivalve-shellfish-using-pour-plate-tbx.pdf>

persistence. The EU Guidance therefore notes that a ‘single or small numbers of *E. coli* results will not give an indication of the general risk of contamination by the pathogens.’ Classification should therefore be based on a sufficient number of results obtained over time (see Table 3). Once established, this is recommended to be at least 24 sample results over a 3 year period. For sites with a stable classification, this can be reduced to 12 sample results over 3 years.

Table 3: The *E.coli* classification thresholds for shellfish beds

Class	<i>E.coli</i> concentration threshold	Post-harvest treatment required to reduce microbial contamination
A	80% of sample results must be less than or equal to 230 <i>E.coli</i> per 100g flesh; AND no results may exceed 700 <i>E.coli</i> 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 <i>E.coli</i> per 100g flesh; AND all samples must be less than 46000 <i>E.coli</i> 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: <ul style="list-style-type: none"> • 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 <i>E.coli</i> 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: <ul style="list-style-type: none"> • 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 <i>E.coli</i> per 100g flesh using a three dilution Most Probable Number (MPN) test	Shellfish from areas with consistently prohibited level results must not be subject to production or harvested.

3.2 Approach

The application of the Shellfish Control Regulations in each Member State 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, and
- The review process for site classification status.

Points of difference between Member States and the application of the regulations in the UK are also described. Where available, details of how implementation of the Shellfish Control Regulations was funded is also provided.

The EU Guidance also outlines the alert procedures that should be implemented when above threshold *E.coli* results are obtained, and how anomalous monitoring results should be handled. This is discussed further in Chapter 4.

3.3 UK

The UK has two Competent Authorities:

- The Food Standards Agency (FSA) covers England, Wales and Northern Ireland
- Food Standards Scotland (FSS) covers Scotland.

Each organisation has its own guidance²⁰ for implementing Shellfish Control Regulations. Whilst relatively similar, there are several key differences in the Scottish system which are outlined in section 3.3.7.

3.3.1 Initial site classification

Sanitary surveys are required for new shellfish production sites or relaying areas prior to classification. These surveys incorporate all the elements required by legislation. For example, the identification of RMPs takes into account the extent of the shellfishery, the position of local faecal pollution sources, tidal flows and other relevant factors. Sanitary survey sampling is undertaken, where possible, on as random a basis as possible with respect to likely influencing environmental factors e.g. tidal state, rainfall, wind etc. so as to avoid bias in the results.

A minimum of 10 classification samples, with samples obtained at least 1 week apart, are required from each RMP over a minimum period of 3 months, before a provisional classification is assigned²¹. Once awarded, commercial harvesting can begin, subject to other necessary licences and controls being in place²². Sample results returning prohibited levels (i.e. >46,000 *E.coli*/100g flesh) of microbiological contamination during initial monitoring towards provisional classification, may result in the site being designated as 'prohibited' and the classification application rejected at that time.

Once a provisional classification has been determined, the sampling frequency is reduced to monthly for the remainder of the year in order to obtain the full classification for the site.

3.3.2 Ongoing monitoring

Routine official control sampling is undertaken by the Local Authority on a monthly basis. Full monthly monitoring is expected for established sites, i.e. 12 samples from each RMP per year. Class A sites with less than 10 samples per year, and Class B and C sites with less than 8 samples, are likely to be declassified (i.e. commercial harvesting will be prohibited).

²⁰ FSA, 2020. Protocol for Classification of Shellfish Production Areas, England and Wales. <https://www.food.gov.uk/business-guidance/shellfish-classification>; FSANI, 2020. Protocol for the Classification of Shellfish production and relaying areas in Northern Ireland. <https://www.food.gov.uk/sites/default/files/media/document/ni-shellfish-classification-protocol-november-2020.pdf>; FSS, 2020. Protocol for Classification of Shellfish Production Areas. <https://www.foodstandards.gov.scot/downloads/Shellfish - Classification Protocol - Final - 17-08-2020.pdf>

²¹ In practice, however, this process can take up to 10 months.

²² Applications for bivalve production sites may also require a Marine Licence, a seabed lease, planning consent, and/or a water abstraction or discharge licence. Authorisation to operate as an Aquaculture production Business is also required. In addition to the microbial monitoring phytoplankton and biotoxin assessments will be required.

All testing is undertaken by accredited laboratories in accordance with the agreed EU reference method, i.e. the Most Probable Number test (MPN; ISO 16649-3:2015) using the 5 tube x 4 (or very occasionally 5) dilution method. Funding for shellfish site monitoring is provided by the competent authorities.

All samples are normally collected by the relevant Local Authority. Additional industry sampling may be used to supplement the official control sampling so long as the samples have been collected using the same protocols and analysed by Official Control laboratories. This cost for this extra sampling is borne by the producer. If there is a difference between the Official Control sample and that taken by the producer, the results of the Official Control sample takes precedence. The Guidance to Local Authorities²³, however, allows for industry assistance with sample collection under exceptional circumstances, and on a case by case basis to be agreed with FSA. To date there are very few production sites in England and Wales where such an arrangement has been agreed.

3.3.3 Seasonal monitoring

Seasonal classifications are used in the UK to provide mitigation for seasonal water quality issues. To obtain a seasonal classification, at least 3 years' worth of data showing a clear seasonal trend is required. Seasonal classifications must comprise at least 3 consecutive months and the data for each season must be significantly different. Each classified site can have only 2 separate seasons per year.

A buffer period before the start of the season is required (i.e. before production can start). This is one month for Class C to B or Class B to A areas, and two months for Class C to A. During the buffer period the monthly monitoring sample must show compliance with the higher/'better' classification prior to the 'better' season commencing.

3.3.4 Long term stable sites (only applicable in England & Wales)

When a Class B production site has 90% compliance over a 5-year period with no results >46,000 *E.coli*/100g, a long-term classification (B-LT) can be awarded. Whilst this does not change the monitoring requirements, it helps demonstrate that water quality is more stable in these areas and may enable the industry to promote a better quality product. There is no provision for a long-term stable classification for Class A or C sites, and this long term classification is not used in Scotland or Northern Ireland.

3.3.5 Review of classifications

Results of the classification monitoring programme are reviewed annually on the expectation that the samples are taken on a random basis with respect to as many of the influencing environmental factors as possible. This review is used to determine the classification for the coming year.

The previous three years of monitoring results from the production area (or all data if less than 3 years) are used to inform the classification award. As part of this determination, specific

²³ FSA and CEFAS, 2018. Protocol for the Collection of Shellfish under the Microbiological Classification Monitoring Programme (EU Regulation 854/2004). <https://www.cefaz.co.uk/media/0ryah05g/h-website-201807-cefas-classification-sampling-protocol-for-local-authorities-version-9-final-dj-passed.pdf>

consideration is given to the most recent year's results to determine whether there is any evidence of improving or deteriorating water quality over the past 12 months. This is particularly pertinent for marginal Class B sites where compliance can be an issue.

Within year reviews are also undertaken, using a rolling approach, if the monitoring data indicate that an upgrade or downgrade to the site classification may be required. These rolling reviews were introduced to help create better classification stability for the industry. The reviews are conducted by CEFAS on a monthly basis to ensure the site is conforming to its classification requirements, and downgrades implemented as soon the thresholds are no longer met through agreement with FSA. Site upgrades generally need to be requested by the producer.

3.3.6 Variation relevant to Northern Ireland

The long term stable Class B (B-LT) classification has not been implemented in Northern Ireland²⁴.

3.3.7 Variation relevant to Scotland

The application of the requirements of the Shellfish Control Regulations is generally similar in Scotland²⁵ although there are three areas of deviation.

The long term stable Class B (B-LT) classification has not been implemented in Scotland.

The use of industry to collect the official control samples is more explicitly recognised than elsewhere in the UK and industry are actively involved in official control sample collection. The Guidance to Sampling Officers²⁶ differentiates between verified samples, i.e. those collected by the authorised sampling officer for the Competent Authority, and those which are collected by industry on behalf of the authorised sampling officer. The industry collected official control samples fall into two categories:

- A 'verified from shore' (VFS) sample where the producer collects the sample from the agreed monitoring point under observation by an authorised sampling officer from the shore.
- An 'unverified' sample where the producer collects the sample from the agreed monitoring point but where the authorised sampling officer cannot observe this happening due to the remoteness of the monitoring point or distance from any vantage point.

There is, however, no difference in the consideration of the results from these two categories.

In addition, Scotland also enables the collection of supplementary samples by industry, the costs of which are borne by the industry. The collection of these supplementary samples usually occurs approximately two weeks after the Official Control samples are collected. The

²⁴ FSA, 2020. Protocol for the classification of shellfish areas, Northern Ireland.

<https://www.food.gov.uk/sites/default/files/media/document/ni-shellfish-classification-protocol-november-2020.pdf>

²⁵ FSS, 2020. Protocol for Classification of Shellfish Production Areas.

[https://www.foodstandards.gov.scot/downloads/Shellfish - Classification Protocol - Final - 17-08-2020.pdf](https://www.foodstandards.gov.scot/downloads/Shellfish_-_Classification_Protocol_-_Final_-_17-08-2020.pdf)

²⁶ CEFAS, SSQC, Fera & HMMH, 2020. Food Standards Scotland protocol for appointed sampling officers for the collection and transport of shellfish samples for the purpose of Official Control Monitoring of classified shellfish production areas in Scotland. <https://www.cefass.co.uk/media/kywbxnsoc7715-sampling-officer-shellfish-sampling-and-transport-protocol-scotland-final-version-6-accessible-021220-dj-pased.pdf>

results from this supplementary sampling is given equivalent status in the site classification record because the samples are not collected concurrently.

A different *E.coli* sample analysis methodology is also utilised. Rather than the 5 tube x 4 (or 5) dilution MPN test, Scotland uses a 5 tube x 3 dilution MPN method. The use of the 5 x 3 dilution MPN test means that samples can only be quantified up to 18,000 *E.coli*/100g. Consequently, for any result >18,000 *E.coli*/100g, a new official control sample must be collected as soon as possible for further dilution testing to determine whether the levels of *E. coli* present are over the statutory maximum (i.e. 46,000 *E.coli*/100g). In the interests of public health the Local Authority and harvester may agree to a voluntary closure for the site pending the results of further analysis. It is this second classification sample that contributes towards the site classification record rather than the initial sample collected. This approach means that unusually high above threshold results must be verified before they are incorporated into the classification record. The 5x3 MPN test provides sufficient analysis capability because 95% of bivalve production sites in Scotland are classed as A, seasonal A/B or B and therefore are generally expected to be <18,000 *E.coli*/100g threshold²⁷.

3.4. France

The classification of shellfish production sites in France is a state responsibility, overseen by Direction Générale de l'Alimentation du ministère de l'Agriculture et de l'Alimentation. The legal requirements are implemented through DGAL/SDSSA/2016-448²⁸ and supported by a guidance document²⁹.

3.4.1 Initial site classification

The designation of new production sites requires a sanitary survey that encompasses all the elements required by legislation. For example, the identification of sources of microbiological contamination of faecal origin, identification and monitoring of RMPs, and interpretation of the results to assess the quality of the area.

The initial classification is determined using at least 24 samples per sampling point collected over the minimum period of a year. Commercial harvesting can begin following initial classification.

3.4.2 Ongoing monitoring

Sampling is undertaken on a monthly basis for newly classified sites for a minimum period of three years.

Besides the MPN test recommended in the Shellfish Control Regulations, France also uses the impedance test (NF V 08-106) to enumerate *E.coli* in shellfish³⁰. The impedance method

²⁷ See FSS shellfish classification documents <https://www.foodstandards.gov.scot/business-and-industry/industry-specific-advice/shellfish>

²⁸ DGAL/SDSSA/2016-448 Réglementation sanitaire applicable aux zones de production de coquillages. 30/05/2016.

²⁹ IFREMER 2018. Procédure 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>

³⁰ Impedance method: EURL generic protocol - Enumeration of *Escherichia coli* in live bivalve molluscan shellfish by the direct impedance technique using Bactrac 4300 series analyser. Current issue.

is easier to perform than the MPN method, although interpretation of the results is potentially more difficult³¹. Results are also obtained much more quickly³², which allows for more rapid intervention to protect public health in the event of contaminated shellfish being detected.

The Local Authority is responsible for collecting samples and analysis is undertaken by accredited laboratories. Funding for the shellfish monitoring is provided by the Competent Authority.

3.4.3 Seasonal sites

Sampling is monthly at seasonal sites throughout the harvesting period.

3.4.4 Long term stable sites

After 3 years, the sampling frequency can be reduced from monthly to bi-monthly if the following conditions are met:

- *E.coli* results are stable and consistent;
- The classified site has not been the subject of any alerts over the past 3 years; and
- Biotxin and other quality assessments for the site are consistent with the requirements of the classification.

Bi-monthly monitoring reverts immediately to monthly sampling if these conditions are no longer being met.

3.4.5 Review of classifications

For sites sampled on a monthly basis, the classification assessment is carried out on an annual basis using a minimum number of 24 samples obtained over the last 3 calendar years. For sites monitored at bi-monthly frequency, the classification assessment is carried out annually using a minimum of 12 samples obtained over the last 3 calendar years.

For seasonal production areas where sampling frequency is adapted to periods of commercial exploitation, the annual classification assessment is based on minimum number of 24 samples collected over the previous 3 year period.

3.4.6 Variation in relation to UK approach

There are three key differences between the French implementation of the Shellfish Control Regulations microbial requirements and the approach applied in the UK:

- Use of the impedance test in addition to MPN test for assessing levels of *E.coli* in bivalves means sampling results are obtained more quickly which enables a more rapid intervention to protect public health if required;

<https://cefaswebsitedev.cefastest.co.uk/media/taulrzh/c-users-ab19-documents-coe-seafood-safety-generic-protocol-enumeration-of-e-coli-in-bivalve-molluscs-using-impedance.pdf>

³¹ IFREMER, 2014. Enumeration of *Escherichia coli* in live bivalve molluscan shellfish by the direct impedance technique using the BacTrac 4300 series analyser. <https://cefaswebsitedev.cefastest.co.uk/media/taulrzh/c-users-ab19-documents-coe-seafood-safety-generic-protocol-enumeration-of-e-coli-in-bivalve-molluscs-using-impedance.pdf>

³²Dupont, J., Dumont, F., Menanteau, C. and Pommepuy, M. (2004), Calibration of the impedance method for rapid quantitative estimation of *Escherichia coli* in live marine bivalve molluscs. *Journal of Applied Microbiology*, 96, 894-902.

- At least 12 months of sampling is required to determine the initial site classification prior to commercial harvesting in France. In contrast, a provisional classification can be awarded after 3 months of sampling in UK;
- A reduction in sampling frequency to bimonthly sampling for French production areas that have had a stable classification for 3 years. No such reduction in monitoring is provided for under the UK system; and
- Classifications are managed on an annual basis in France whilst in the UK within year downgrades and upgrades are possible through the rolling review process.

3.5 Ireland

The competent authority for shellfish production is the Food Safety Authority of Ireland. The implementation of the legal requirements for shellfish production are detailed in guidance³³, with additional interim guidance also provided for norovirus³⁴, although not legally enforceable.

3.5.1 Initial site classification

The designation of new production sites requires a sanitary survey that encompasses all the elements required by the legislation in order to determine a preliminary (provisional) classification. Preliminary (provisional) classification of an area requires at least 12 samples collected not closer together than fortnightly, at which point commercial harvesting can begin. Thereafter, sampling is undertaken on a monthly basis until three years of data have been obtained and the full classification can be determined.

3.5.2 Ongoing monitoring

The minimum sampling frequency for ongoing monitoring at classified production sites is monthly on a year-round basis.

All testing is undertaken by the accredited laboratories using the MPN test. Samples are collected by the local authorities, although industry may also provide samples. Agreements for the use of industry samples are drawn up on a local basis, using trained staff and some level of supervision by official samplers. Funding for the shellfish monitoring is provided by the Competent Authority.

3.5.3 Seasonal sites

Where there are clear seasonal patterns to commercial activity and where a site is closed for part of the year, monitoring can be reduced to just cover the harvesting period. Monitoring must start at least 1 month prior to the harvesting season for class A areas and two months prior to the season for class B areas, and continue throughout the season.

3.5.4 Long term stable sites

For sites that have three years of sampling data (minimum 30 samples), the sampling frequency can be reduced to bimonthly if the following criteria are met:

³³ SFPA, 2017. Code of Practice for the Microbiological Monitoring of Bivalve Mollusc Production Areas.

<https://www.sfpa.ie/LinkClick.aspx?fileticket=cgysNdPOXyo%3d&portalid=0&resourceView=1>

³⁴ SFPA. Interim Guidance on the Management of Norovirus in Oysters by Shellfish Producers.

https://www.sfpa.ie/LinkClick.aspx?fileticket=f_5x2T8giw%3d&portalid=0&resourceView=1

- Class A – where the site was subject to a sanitary survey which confirmed the location of the representative sampling point and that no result >230MPN *E.coli* /100g was detected in the previous three years.
- Class B - where the site was subject to a sanitary survey which confirmed the location of the representative sampling point and that no result >4600 MPN *E.coli*/100g was detected in the previous three years.

3.5.5 Review of classifications

Results from the monitoring programme are reviewed annually as part of the classification review process. This review takes account of the last 3 years' data, or all data if there is less than 3 years' worth available. The classifications are determined on the basis of demonstrating compliance with the criteria for the given class. The sanitary survey must be reviewed every 6 years.

3.5.6 Variation in relation to UK approach

There are three key differences between the Irish approach and that used in the UK:

- At least 6 months of samples are required before an interim site classification is awarded and commercial harvesting can begin, compared to the potential of 3 months in the UK;
- Sampling frequency is reduced to bimonthly sampling for production areas that have had a stable classification for 3 years. In contrast a long term stable classification is awarded after 5 years in the UK and there is no change in the monthly monitoring frequency;
- The option to use trained industry staff to collect samples is available. There is no such provision in the UK; and
- Classifications are managed on an annual basis in Ireland whilst in the UK within year downgrades and upgrades are possible through the rolling review process.

3.6 The Netherlands

The Dutch Competent Authority is Nederlandse Voedsel-en Warenautoriteit (NVWA) and the Shellfish Control Regulations are given effect through national legislation³⁵.

3.6.1 Initial site classification

The entire Dutch coastline is divided into designated shellfish production areas which are prescribed in regulation.

Each production area has 4 RMPs and at least 12 bacteriological samples from each RMP are required to determine the provisional classification. These samples must be collected over a minimum period of 6 months, with at least one week to a maximum of 3 months apart.

³⁵ Regeling van de Inspecteur-generaal van de Nederlandse Voedsel- en Warenautoriteit namens de Minister van Volksgezondheid, Welzijn en Sport van 13 februari 2014, NVWA/14/1430/AtC, houdende vaststelling van de beleidsregels bemonsteringsplannen sanitaire monitoring. <https://wetten.overheid.nl/BWBR0034873/2014-03-01>

3.6.2 Ongoing monitoring

For a classified production area less than three years old, monthly sampling is generally recommended. However, the frequency of microbial sampling can be increased for certain production area and bivalve species.

- For wild caught bivalves, fishermen undertake the control sampling. Because the relevant production areas can vary, sampling sites are selected in such a way that a geographical distribution in the production area can be ensured. 4 samples must be collected from the area for testing on a monthly basis.
- For cultured bivalves in the Wadden Sea, from July to October, *E.coli* samples are taken twice per month. From November to June sampling is reduced to monthly for all bivalves except oysters. This reflects a lower risk period, but also takes into account that oysters are usually eaten raw rather than cooked. The microbiological data of the National food safety monitoring program of the Wadden Sea demonstrates that microbiological loads are generally <230 *E.coli*/100g flesh³⁶, i.e. class A waters.
- For oysters from Grevelingenmeer, which has no specific tidal pattern, *E.coli* sampling is undertaken monthly from January to August, increasing to fortnightly from September to December in line with higher risk periods.

All testing is undertaken by the accredited laboratories using the MPN test or pour plate colony count technique³⁷, with samples collected by fisheries inspectors or the industry. Funding for the shellfish monitoring is provided by the Competent Authority.

3.6.3 Seasonal sites

No consideration is given to seasonal classification of sites.

3.6.4 Long term stable sites

The Dutch approach recommends that the sampling frequency for long term stable sites remains unchanged.

3.6.5 Review of classifications

The classification of each production area is determined annually using the data from the previous 3 years. If there have been significant changes in the potential sources of contamination, only the results collected after the noted change will be utilised.

3.6.6 Variation in relation to the UK approach

Four key differences between the approach adopted by the Netherlands and that used in the UK were identified:

- The Netherlands takes a risk-based approach, with increased sampling of oysters during the winter when the risk of norovirus contamination is higher. This increased sampling is not required for mussels. No such differentiation occurs in the UK, either for species or for periods of higher norovirus contamination.

³⁶ S.T. Glorius and M. Poelman, C. van Zweeden en A.C. van Gool, 2014. Interreg Safeguard – Food safety mapping of mussels and oysters (*Crassostrea gigas*) in the Dutch Wadden Sea. Report number C104/1

³⁷ Walker et al., 2018. *Escherichia coli* testing and enumeration in live bivalve shellfish - Present methods and future directions. Food Microbiology, 73, 29-38.

- In addition to the MPN test, the pour plate colony count technique for determining *E.coli* levels in bivalves is also used by the Netherlands. The UK uses the MPN methodology;
- Industry is permitted to collect some of the official control samples in the Netherlands. Whilst a similar approach is utilised in Scotland, elsewhere in the UK this only occurs in exceptional circumstances; and
- Classifications are managed on an annual basis in the Netherlands whilst in the UK within year downgrades and upgrades are possible through the rolling review process.

3.7 Spain

Spain has adopted a regional approach to the application of the Shellfish Control Regulations. As Galicia is the most important region, accounting for over 90% of Spain's mussel production, application of the shellfish control regulations in this region was used for the case study³⁸.

The following information was obtained via personal communication as the protocols are not publicly accessible. The outputs from European Commission's Directorate General for Health and Food Safety (DG SANTE) audit of the Spanish shellfish production were also used³⁹.

The competent authority responsible for site classification is Ministerio de Medio Ambiente, y Medio Rural y Marino.

3.7.1 Initial site classification

Sanitary surveys are undertaken as described by the Shellfish Control Regulations. In order to obtain a provisional classification, 10 samples collected on a monthly basis from each RMP is usually required. Sampling frequency can be reduced to fortnightly if rapid provisional classification is required so as to enable commercial harvesting.

Notably, the entire Galician coast was defined as a shellfish production area in 1993. The region is further subdivided into 7 sectors, each with between 6 and 44 RMPs⁴⁰. Any further subdivision of the existing subsectors will be treated as the identification of a new harvesting area and, therefore, require the designation of new RMPs.

3.7.2 Ongoing monitoring

In order to obtain a full classification, monthly sampling is required for three years. Closed areas can be monitored on bimonthly basis.

All testing is undertaken by accredited laboratories using the MPN test with samples collected by the designated authority. Funding for the shellfish monitoring is provided by the Competent Authority.

³⁸ 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>

³⁹ DG SANTE, 2011. 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) 2011-888.

⁴⁰ <http://www.intecmar.gal/Intecmar/Microbiologia.aspx>

3.7.3 Seasonal sites

Where harvesting is restricted to a particular season due to meteorological, demographic or other factors, monitoring is only undertaken during the harvesting period.

3.7.4 Long term stable sites

After 5 years of data collection, if a production area has a stable classification, i.e. the monitoring has not recorded any result outwith the recognised thresholds, monitoring can be reduced to bimonthly.

3.7.5 Review of classifications

The classification of each site is reviewed annually, using the last 3 years of data. There is no revision to the classification unless there are at least 24 sample results covering the 3 year period.

3.7.6 Variation in relation to the UK approach

Two key differences between the Spanish approach and that used in the UK were noted:

- The reduction in sampling frequency to bimonthly for production areas that have had a stable classification for 5 years. There is no equivalent reduction in sampling in the UK; and
- Classifications are managed on an annual basis in Spain whilst in the UK within year downgrades and upgrades are possible through the rolling review process.

3.8 Italy

Italy has also adopted a regional approach, with key producing areas developing their own guidance for the implementation of the Shellfish Control Regulations. The key mussel producing regions are in Tyrrhenean Sea (central Italy and Sardinia) and Gulf of Taranto (southern Italy)⁴¹. The Italian case study focused on the requirements for shellfish production in Lazio (central Italy)⁴² and Sardinia⁴³ as key production areas.

Responsibility for the official controls is assigned centrally to the Ministero della Salute. However, in practice the day to day responsibility for enforcement functions is divided between central, regional and local authorities.

41 Barnabé, G. & Doumenge, F., 2001. Mariculture of Mediterranean Species. In J.H. Steele (Ed) Encyclopedia of Ocean Sciences (Second Edition). Academic Press, Pages 532-536. FAO, 2019. The European market for mussels. <http://www.fao.org/in-action/globefish/fishery-information/resource-detail/en/c/338588/>

42 10/07/2018 - BOLLETTINO UFFICIALE DELLA REGIONE LAZIO - N. 56 - Supplemento n. 1. Regione Lazio DIREZIONE SALUTE ED INTEGRAZIONE SOCIO SANITARIA Atti dirigenziali di Gestione Determinazione 26 giugno 2018, n. G08133 Aggiornamento del piano regionale per il controllo sanitario della produzione primaria dei molluschi bivalvi vivi. Sostituzione dell'Allegato A alla determinazione regionale n. B4517 del 09.06.11. <http://www.izslt.it/wp-content/uploads/2018/07/Piano-molluschi.pdf>

43 Sardegna Salute, 2014. Piano regionale per la vigilanza ed il controllo sanitario della produzione e commercializzazione dei molluschi bivalvi e per il monitoraggio periodico delle zone di produzione e di stabulazione di molluschi bivalvi vivi (revisione 2014). <http://www.sardegna.salute.it/index.php?xsl=316&s=9&v=9&c=4695&na=1&n=10>

3.8.1 Initial site classification

The local Competent Authority determines the RMPs for the site, although for offshore areas (>5km from the coast) not subject to pollutant discharge points, RMPs can be chosen at random throughout the sampling period.

Typically a site undergoes twelve months of sampling prior to a classification being awarded. This can be reduced to six months in areas where there is additional environmental/health monitoring, and where the absence of any critical issues has been demonstrated.

At least 12 samples must be taken for each RMP for *E.coli*, over a period of at least 6 months with a time interval between two subsequent samples of no less than 2 weeks for classification. In cases where the provisional classification is awarded after six months, monitoring for *E.coli* should occur at least fortnightly for a further 6 months, until an entire year of data has been collected.

3.8.2 Ongoing monitoring

For mollusc production areas, *E.coli* sampling is required every two weeks from bivalve flesh and 3 months for water samples. The sampling for *E.coli* in bivalves may be reduced to monthly if (1) other types of environmental and/or health monitoring have indicated an absence of any critical issues (e.g. biotoxins) and (2) additional water sampling is undertaken in conjunction with adverse events (e.g. high precipitation, river flood events).

All testing is undertaken by accredited laboratories using the MPN test or the impedance test. The official control samples are collected by the fisheries inspectors, but may be collected by shellfish producers who have received appropriate training. The cost of classification sampling is borne by the industry.

3.8.3 Seasonal sites

For harvesting activities that take place only at certain times of the year, sampling can be confined to a more limited period. A seasonal classification must be based on at least 3 years of sampling data and must cover a minimum period of six months. Sampling should start two months prior to harvest beginning in class C areas and one month prior to harvest for class A and B areas.

3.8.4 Long term stable sites

After three years, sampling frequency can reduce from every two weeks to monthly. There is a minimum requirement for eight samples to be collected for each RMP per site every year. This requirement takes account of poor weather preventing sampling or unsuitable samples being collected.

3.8.5 Review of classifications

All classified areas are reviewed every three years to determine if a new classification is necessary; this review uses the monitoring data for the previous three year period.

If there have been changes in contamination levels that indicate a change in classification may be warranted, consideration must be given to undertaking a new sanitary survey and developing a new sampling plan.

3.8.6 Variation in relation to the UK approach

There are seven key differences between the Italian and the UK approach:

- Italy has adopted a risk-based approach to the site classification and monitoring that requires biweekly sampling of bivalve flesh and quarterly sampling of *E.coli* in water for the first three years. The biweekly sampling can be reduced to monthly where other types of environmental/health monitoring have indicated an absence of any critical issues. Sampling is increased during adverse events (e.g. high precipitation, river flood event). This is more regular monitoring than currently occurs under the UK system;
- Italy uses the impedance test in addition to MPN test for assessing levels of *E.coli* in bivalves. The sampling results are obtained more quickly which enables a more rapid intervention to protect public health if required;
- A minimum of 6 months sampling is required to determine the provisional site classification prior to commercial harvesting. In contrast, only 3 months of sampling is required in UK;
- A long term stable classification can be achieved after 3 years in Italy whilst it requires 5 years in the UK, although the reduction in monitoring that occurs after 3 years brings the Italian monitoring in line with the UK;
- Industry is permitted to collect the official control samples in Italy, provided staff have completed the required training. Whilst a similar approach is utilised in Scotland, elsewhere in the UK this only occurs in exceptional circumstances;
- Classifications are managed on a tri-annual basis in Italy whilst in the UK within year downgrades and upgrades are possible through the rolling review process; and
- The shellfish classification monitoring is funded by industry in Italy, in contrast to the Competent Authorities in the UK.

3.9 Portugal

The implementation of the Shellfish Control Regulations in Portugal was updated significantly following the results of a DG SANTE audit in 2013. The competent authority is the Ministério da Agricultura e do Mar.

3.9.1 Initial site classification

The 2013 audit indicated the absence of any regular monitoring of bivalve production areas. In response, Portuguese authorities implemented an action plan to rectify the situation⁴⁴. This required new sanitary surveys for all production areas, and the analysis of at least three *E.coli* samples from each RMP, collected at intervals of not less than 15 days apart.

The action plan does not consider the provisional classification of new sites.

3.9.2 Ongoing monitoring

From May to November, sampling occurs every two weeks. From December through to April, monthly sampling is undertaken.

⁴⁴ Instituto 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

All testing is undertaken by designated laboratories using the MPN test. The official control samples are provided by the industry using agreed protocols. Funding for the shellfish monitoring is provided by the Competent Authority.

3.9.3 Seasonal sites

There is no provision for seasonal site classification under the Portuguese system.

3.9.4 Long term stable sites

There is no provision for a long term stable site designation under the Portuguese system.

3.9.5 Review of classifications

Sites are reclassified every three years taking into account the results of monitoring undertaken during that period and any control actions that may have been implemented.

3.9.6 Variation in relation to UK approach

Three key differences were identified between the UK and Portuguese approach:

- Industry provides the official control samples in Portugal. Whilst industry can provide samples in Scotland, elsewhere in the UK this only occurs in exceptional circumstances;
- There is increased sampling during periods of increased risk of contamination (every two weeks, between May and November). There is no similar requirement in the UK; and
- Production sites are reclassified every 3 years in Portugal rather than annually as in the UK. Additionally, within year downgrades and upgrades are also possible in the UK through the rolling review process.

3.10 Germany

Germany has adopted a regional approach for providing guidance on the application of the Shellfish Control Regulations. The federal competent authority for shellfish production is Bundesministerium für Ernährung und Landwirtschaft.

Mussel farming along the German North Sea coast has a long-standing tradition in the States of Lower Saxony⁴⁵ and Schleswig-Holstein Wadden Sea Area⁴⁶, with the industry depending on a well-established extensive fishery-culture system⁴⁷. The German case study was therefore based on the requirements for shellfish production in these two regions.

⁴⁵ Niedersächsisches Ministerium für Ernährung und Landwirtschaft und Verbraucherschutz 2017. Niedersächsische Ausführungshinweise für die Überwachungsbehörden zur Durchführung der Muschelhygieneüberwachung.

⁴⁶ 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

⁴⁷ Buck et al., 2006. The development of mollusc farming in Germany: Past, present and future. World Aquaculture, January 2006.

3.10.1 Initial site classification

Sanitary surveys are undertaken as described by the Shellfish Control Regulations. In order to obtain a provisional classification, 12 samples must be collected over a six month period with at least one week between each sample collection. Following this, bi-weekly sampling is required for a further six months, with the full site classification determined after 12 months of sampling.

3.10.2 Ongoing monitoring

Monthly sampling is required, with at least 24 sample results collected over three years (i.e. at least 8 sample per year) to maintain the site classification.

All testing is undertaken by the Official Control laboratories using the MPN test. Official samples are collected by shellfish producers who have demonstrated appropriate expertise obtained through initial training and annual retraining by the competent local authority. The cost of classification sampling is borne by the industry.

3.10.3 Seasonal sites

Sampling of seasonal sites is initiated one month in advance of harvesting for class A and B production areas and two months in advance of harvesting for class C areas.

3.10.4 Long term stable sites

Once three years of data have been collected and monitoring indicates site stability, sampling can be reduced to bi-monthly.

3.10.5 Review of classifications

Reviews can be undertaken either annually or on a rolling basis, using data from the past three years.

Many of Germany's sites are seasonal, which means that at least 12 results from the past three years (i.e. at least four samples per year) are required in order to maintain classification.

3.10.6 Variation in relation to the UK approach

There are three key differences in approach between the German application of the Shellfish Control Regulations and the UK Approach.

- Sampling frequency is reduced from monthly to bimonthly for production areas that have had a stable classification for three years. A long term stable classification is awarded after five years in the UK but does not lead to any change in the monthly monitoring frequency; and
- Official samples are collected by shellfish producers in Germany provided they have completed the appropriate training. Whilst industry can provide official samples in Scotland, elsewhere in the UK this only occurs in exceptional circumstances; and
- The shellfish classification monitoring is funded by industry in Germany, in contrast to the Competent Authorities in the UK.

3.11 Sweden

The Competent Authority is Livsmedelsverket, the Swedish Food Agency. Sweden operates a risk based approach to live bivalve production that differentiates between shellfish that are

eaten raw and those that are cooked prior to consumption⁴⁸. This approach also takes into account the results of the sanitary survey, historic monitoring data including biotoxin results, and the environmental aspects, such as wind, rainfall and hydrographic conditions (e.g. salinity, currents) of the site⁴⁹.

3.11.1 Initial site classification

The requirements of the sanitary survey recognise the need for a good understanding of possible sources of contamination and the potential links to environmental conditions. The survey is expected to include consideration of the hydrodynamics and hydrology of the catchment as well as weather conditions that may impact harvesting. For example, years that have dry periods followed by heavy rainfall can impact the microbial status of the site. The contamination risks are analysed with respect to season, the occurrence of algal toxins and human pathogens at the location, the hydrodynamic situation and the species of bivalve being cultivated⁵⁰.

No specific microbial sampling requirements for provisional classifications are outlined for initial site classification purposes. The guidance instead states that the classification of production and relaying areas is expected to be undertaken in accordance with Annex II of Regulation (EC) No 854/2004 which requires the development of a sampling plan and identification of RMPs that are representative as possible for the area being considered and that variation in faecal contamination is taken into account.

3.11.2 Ongoing monitoring

Monthly *E.coli* sampling is required for mussel production areas and every two weeks for oyster and cockle production sites. Because oysters are usually eaten raw, they are monitored more frequently as a precautionary measure. The sampling frequency may be increased to weekly if biotoxin and other contaminant monitoring indicates that more frequent sampling is required.

All testing is undertaken by the OC laboratories using the MPN test. 20% of samples must be collected by official personnel, with the remaining 80% of samples collected by industry personnel who have received training. Following initial training, refresher training is required every two years to maintain competence. Funding for the shellfish monitoring is provided by the Competent Authority.

3.11.3 Seasonal sites

Monitoring is expected to be undertaken throughout the year in areas where harvesting is permitted. There is no provision for reduced monitoring of seasonal production sites.

3.11.4 Long term stable sites

For long term stable sites, the frequency of the *E.coli* monitoring may be varied on the basis of a risk assessment. This assessment takes account of the results of the sanitary survey,

⁴⁸ Livsmedelsverket. Sveriges kontrollprogram för tvåskaliga blötdjur enligt förordning (EG) nr 854/2004.

⁴⁹ Persson, M., Karlson, B., Zuberovic Muratovic, A., Simonsson, M., Bergkvist, P., Renborg, E. 2020. L 2020 nr 24: Kontrollprogrammet för tvåskaliga blötdjur, Årsrapport 2014-2019. Livsmedelsverkets rapportserie. Livsmedelsverket, Uppsala.

⁵⁰ Rehnstam-Holm, A.-S. & Hernroth, B., 2005. Shellfish and Public Health: A Swedish Perspective. Ambio, 34, 139–144.

historic data, biotoxin results for the production area as well as those for other sites in the locality, and the environmental aspects of the site (e.g. wind and water conditions).

3.11.5 Review of classifications

Site classification is reviewed on an annual basis utilising the last three years of data. Historically, Sweden used an ongoing or rolling analysis approach, with sites classified according to weekly monitoring results.

3.11.6 Variation in relation to the UK approach

Sweden has adopted a risk-based approach that differentiates between shellfish that are eaten cooked or raw and one that also considers environmental indicators of contamination. Two key differences to the UK approach were identified:

- Sampling frequency varies depending on the species; for oysters and cockles, the frequency is expected to be every two weeks and for mussels monthly. Sampling requirements are increased where an elevated risk of contamination has been indicated (e.g. due to local biotoxin results or environmental conditions). Adapting the monitoring regime based on (1) the species being farmed and the risk level associated with the species and (2) the contamination risk in relation to consumption (i.e. raw or cooked) is not an approach that has been adopted in the UK; and
- Industry is expected to collect up to 80% of the official control samples provided the appropriate training requirements have been met. Whilst industry can provide official samples in Scotland, elsewhere in the UK this only occurs in exceptional circumstances.

3.12 Denmark

The Competent Authority is Fødevarestyrelsen (Danish Veterinary and Food Administration) of the Miljø- og Fødevareministeriet (Ministry of Environment and Food), with the legal requirements for shellfish production implemented through national legislation⁵¹.

3.12.1 Initial site classification

For a provisional or temporary site classification, microbial samples are required every week for three weeks, followed by two samples taken at two week intervals. Samples are required from five RMPs within 1.5 nautical miles of the centre point of the classification area. Consequently, commercial harvesting can begin 6 weeks after the first samples are taken.

Producers that harvest wild mussels in the same temporary or permanent production area may establish a common plan for the microbial testing of mussels.

3.12.2 Ongoing monitoring

Sites are sampled on a weekly basis. Microbiological classification of a production area is valid for harvesting for one week, although this may be extended to two weeks over the period of Christmas and New Year.

⁵¹ Miljø- og Fødevareministeriet 2020. BEK nr 1793 af 02/12/2020. Bekendtgørelse om muslinger m.m. <https://www.retsinformation.dk/eli/lt/2020/1793>

All testing is undertaken by the OC laboratories using the MPN test, with all official control samples submitted by mollusc producers. Funding for the shellfish monitoring is provided by the industry.

3.12.3 Seasonal sites

There is no specific consideration given for seasonal or temporary sites, although the regulation notes that sampling should begin in the week prior to any commercial harvesting being initiated. The classification is removed if sampling ceases.

3.12.4 Long term stable sites

Following three years of monitoring, a production area can be permanently classified and the frequency of the tests reduced where the results of the monitoring of microbiological contaminants in the production area show that there are sufficient grounds for doing so. This permanent classification, however, only applies to a specific timeframe aligned with verification sampling.

A minimum of 24 monitoring results obtained over a three year period are required to apply for permanent status. For the most recent 12 month period, there should be at least the required number of samples must have been taken (i.e. 10 for class A and 8 for class B) with 95% of results within classification thresholds. The remaining 5% must be <4,600 *E.coli*/100g for class A and <46,000 *E.coli*/100g for class B sites. For class C sites, 8 results are required over the last year, with 90% within classification thresholds.

Verification of the permanent microbiological classification of a production area is valid for harvest in class A areas for 4 weeks, class B for 13 weeks and class C for 26 weeks. Prior to the verification period expiring, a within threshold sample must be obtained or the permanent classification will be revoked. There is no indication that further monitoring in addition to these verification samples is required.

3.12.5 Review of classifications

The Danish Veterinary and Food Administration reclassify the permanent once a year, and do not reclassify areas on the basis of abnormal microbiological results. However, site classifications are reviewed on an ongoing weekly basis with a flexible approach adopted where the monitoring results obtained determine the site classification for the coming week. For example, if the sample indicates an A classification, the site will be classed A until the next weekly test. If the result is B, then the site will be classed as such until the subsequent test. To work effectively, this requires a very rapid monitoring system with close cooperation between the regulators and industry, and with relatively stable site classifications.

3.12.6 Variation in relation to the UK approach

Six key differences in Denmark's implementation of the Shellfish Control Regulations were identified compared to the UK approach.

- A provisional site classification can be obtained in Denmark after six weeks of microbial sampling, compared to a possible 12 weeks in UK;
- Ongoing site monitoring occurs on a weekly basis in Denmark compared to monthly in the UK;

- The Danish classification system requires an effective and rapid monitoring system, with close cooperation between the regulators and industry, and relatively stable site classifications. Site classification is awarded on a rolling basis in line with the weekly monitoring results. In comparison it is awarded annually in the UK, although within year downgrades and upgrades are also possible through the rolling review process;
- After three years of monitoring, a permanent classification status can be awarded which means reduced monitoring is required to verify the classification (every 4 weeks for Class A, 13 weeks for Class B and 26 weeks for Class C). The permanent classification, however, only applies to a specific timeframe aligned with verification sampling. A long term stable classification is awarded in England and Wales after five years, but does not lead to any change in the monthly monitoring frequency;
- All Official Control samples are collected by shellfish producers in Denmark. Whilst industry can provide official samples in Scotland, elsewhere in the UK this only occurs in exceptional circumstances; and
- The shellfish classification monitoring is funded by industry in Denmark, in contrast to the Competent Authorities in the UK.

3.13 Norway

As a member of the European Free Trade Association, Norway also adheres to the EU Shellfish Control Regulations. Norway is currently the only country that exports live bivalves to Europe in bulk⁵²; primarily mussels cultivated in Trøndelag and on the Helgeland coast.

The competent authority for shellfish production is Mattilsynet.

3.13.1 Initial Site classification

An initial temporary classification can be made following the analysis of three samples collected at 14 day intervals. Harvesting can begin thereafter with the requirement for weekly sampling. If a monitoring sample is not submitted or analysed, the temporary classification will be revoked.

Alternatively, a permanent classification can be awarded following at least 12 shellfish samples collected at monthly intervals over the period of a year.

3.13.2 Ongoing monitoring

Active production areas are sampled on a monthly basis, with at least six samples required each year to maintain the classification. In addition, a licence to harvest is also required. Such licenses are generally valid for two weeks from the date when the last sample was taken.

All testing is undertaken by the OC laboratories using the MPN test. Samples are collected by the competent authority and by shellfish producers. The Competent Authority funds a maximum of 12 samples per site per annum. The industry pays for any additional sampling.

⁵² <https://fishingnews.co.uk/news/eu-mussel-exports-threat/>

3.13.3 Seasonal classifications

If harvesting is limited to certain times of the year then the sampling regime can be confined to the same period. Seasonal sites can only open for harvesting after three microbial samples have been collected at 14 day intervals.

Seasonal classifications can also be assigned to sites where there are clear and predictable changes in the classification linked with season e.g. a site could be classified as an A site for part of the year and as a B site for the remainder, reflecting site conditions. Sampling occurs on a monthly basis throughout the year.

3.13.4 Long term stable sites

Any decision to reduce sampling frequency must be based on a risk assessment that ensures the site is not exposed to pollution (e.g. offshore waters) and must also incorporate at least one year of *E.coli* monitoring results. A minimum of four monitoring samples are required per year.

3.13.5 Review of Classifications

Classification reviews are undertaken annually.

3.13.6 Variation in relation to the UK approach

Three key differences in Norway's implementation of the Shellfish Control Regulations were identified compared to the UK approach:

- A provisional or temporary classification can be obtained in Norway in 4 weeks following the collection of three samples. This compares to the requirement for 10 samples to be collected over at least three months in UK;
- Although monthly sampling is expected, only six samples are required per year for a site to maintain its classification compared to 10 samples for class A and 8 for classes B and C in the UK; and
- For long-term stable sites, a minimum of four samples are required per year to maintain the classification. In the UK the standard monitoring approach of 10 samples for class A and 8 for classes B and C applies to long-term sites in England and Wales.

3.14 Member State Compliance with the Shellfish Control Regulations

The case studies above clearly indicate that the approach taken to implementing the requirements of the Shellfish Control Regulations varies between different Member States. As a result, it was important to assess if this variation is considered acceptable by DG SANTE. Consequently, the most recent audits of Member State compliance with the regulations were also reviewed.

DG SANTE uses the EU Good Practice Guidance as an example of the expectation for legislative implementation when auditing Member States and Third Countries. The EU Guidance, endorsed by the Standing Committee of the Food Chain and Animal Health, provides the key principles that should be followed in implementing an official control

monitoring programme⁵³. Between 2011 and 2013, DG SANTE's Food and Veterinary Office audited the application of the Shellfish Control Regulations across all Member States. The EFTA Surveillance Authority undertook a similar audit of Norway's approach in 2015⁵⁴. These audits comprise a desk based review of the relevant legislation, guidance and reports provided by the Competent Authority, complemented by on-site visits and discussions to assess the practical application of the Shellfish Control Regulations. Details of the individual audit findings can be found in Appendix 1.

All Member States had classified production areas for the harvesting of live bivalve molluscs using the three categories (i.e. A, B and C) according to the level of faecal contamination established in EU legislation. Most Member States used national or regional laws and guidelines to document procedures for monitoring classified production.

Notably for this review, the majority of Member States' legislation and guidance material currently in use was updated or introduced following these audits. This means that it is not possible to categorically state that the approaches currently in use would satisfy an 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 (Galician region) for microbial monitoring whereas, as noted above, significant shortcomings were identified with the approach taken by Portugal.

With regard to the consideration of initial site designation, the audits identified some issues with the level of detail to be incorporated in sanitary surveys. This included RMP locations not necessarily being representative of the production area for almost all Member States and Norway. The audits did not identify any issues with the sampling frequency and timeframe used by Member States to provisionally classify sites.

Issues with the ongoing monitoring of classified sites were noted in relation to sampling not always being undertaken at the RMP (Ireland, Sweden, UK), the frequency of monitoring or sample size collected not complying with the legal requirements (Portugal, Germany, France, Denmark) and the lack of monitoring of prohibited areas (Germany, Netherlands). The lack of training for personnel collecting the official control samples (Norway) and issues with the test methodology and/or accreditation of laboratories undertaking the analysis (France, Portugal, Denmark) were also identified.

The audits did not identify any issues associated with the monitoring of seasonal sites. With regard to monitoring of long term stable sites, concerns were raised regarding Denmark's approach. No issues were identified specifically relating to the review of classifications.

Although the audit results are historic, some of the current approaches across different Member States would have been in place at the time of the audit.

⁵³ EC 2015. Overview report on audits in member states in order to evaluate the official control systems in place for production and placing on the market of bivalve molluscs. DG(SANCO)/2014-7270 – OR Final.

⁵⁴ <https://www.eftasurv.int/internal-market/food-safety/food-safety-missions/mission-norway-20-24-april-2015-live-bivalve>

3.15 Summary of variation in relation to UK implementation of the Shellfish Control Regulations

The variation identified in the application of the legal requirements by Member States indicates that despite standard legislation and guidance, different approaches to regulating bivalve production are in operation across different member states. In some instances the variation is more restrictive than the UK (e.g. it takes 12 months to secure an initial site classification in France compared to potentially three months in the UK) but generally it is risk based in approach and more permissive. A detailed comparison can be found in Appendix 2 and the areas of variability can be summarised as:

- Variation in the length of time required for a provisional classification to be awarded: varying from three months in the UK, six months (Ireland, Germany, Italy and the Netherlands), 10 months (Spain) to 12 months (France). Norway and Denmark had the shortest time frames for provisional classification, four and six weeks respectively.
- 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 production sites that have demonstrated long term stability, a reduction in sampling frequency is introduced by some Member States, e.g. France, Ireland, Spain, and Germany move from monthly to using bimonthly sampling whilst Denmark moves from weekly to bimonthly sampling and Italy from sampling every two weeks to monthly. In contrast, no change in sampling frequency is introduced in UK, Netherlands or Portugal. For sites with more than 3 years of data, the EU Guidance indicates that monitoring can be reduced to a bi-monthly 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 a minimum of 12 results over a 3 year period.
- Reviews of site classification were undertaken annually (e.g. UK, France, Netherlands, Spain, Germany, Sweden and Norway), every three years (e.g. Italy and Portugal) or on a rolling basis (e.g. Denmark). Notably, the Scottish system includes a facility for appealing the classification decisions, which is not available elsewhere in the UK.
- Denmark applies a flexible rolling classification system using weekly monitoring results to determine the site classification for that week if it deviates from the awarded classification. For example, if the sample indicates an A classification, the site will be classed A until the next weekly test. If the result is B, then the site will be classed as such until the subsequent test. To work effectively, this requires a rapid monitoring system with close cooperation between the regulators and industry, and relatively stable site classifications to begin with. In addition to the annual reviews, England and Wales uses a rolling classification system to upgrade and downgrade sites within the review period. Noting that downgrades are automatic if the monitoring results record that a site is outwith its classification, but that an upgrade, if the monitoring results are more favourable, 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 occurs in exceptional circumstances. In the UK, there is also the facility for industry to provide supplementary monitoring samples; although in England and Wales these samples are not accorded the same status as the official control samples.

- The MPN test (ISO 16649-3:2015) is used by the case study countries (including the UK) to determine *E.coli* levels in shellfish flesh. In addition to the MPN test, 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).

It may be assumed that the observed differences in application represent levels of flexibility that are considered acceptable by DG SANTE. However, further work will be required to corroborate this.

3.16 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 site location and/or time of year. 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).

3.16.1 Bivalve species

Explicit recognition of the potential risk associated with consumption of different shellfish species has been adopted by some Member States. 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.

3.16.2 Time of year and location

The risk of enteric-transmitted pathogens, for which *E.coli* is used as an indicator, is much greater in winter or when a local population is increased during holiday periods. Some Member States 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.

3.16.3 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 use of environmental indicators (e.g. 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. Such an approach is not currently applied in the UK.

3.16.4 Sample collection and analysis

With the exception of France and Spain; all other Member States featured in this review permit industry to collect official samples. Whilst industry can provide official samples in Scotland, elsewhere in the UK this only occurs in exceptional circumstances.

The MPN test method is used extensively. It is 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 and the pour plate method (Table 4).

Table 4: Comparison of the MPN, impedance and pour plate test methodologies.

	MPN	Impedance	Pour plate
Limit of detection (LoD)	18 <i>E.coli</i> /100g	140 <i>E.coli</i> /100g	200 <i>E.coli</i> /100g
Time	2-3 days	5-10 hours	1 day
Cost per sample analysis	£4-5	£2-3	£2
Other considerations	<p>Relatively simple to perform.</p> <p>Recognised globally for shellfish testing.</p> <p>LoD means it can be used for end-product testing as well as monitoring.</p>	<p>Although test is simple to perform, interpretation of the results can be more difficult.</p> <p>Initial set up costs are extremely high (estimated at £50k).</p>	<p>Simplest of all three tests to perform.</p> <p>Limited range of detection values means method is more appropriate for clean environments. Upper threshold for detection is 18,000 <i>E.coli</i>/100g</p>

In addition to MPN tests, France and Italy use the impedance test 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, although interpretation of the results is perceived as being more difficult⁵⁵. The impedance method allows for more rapid intervention to ensure public health protection in case of shellfish contamination⁵⁶.

Similarly, the Netherlands also uses the pour plate colony count technique (ISO 16649-2) as well as the MPN test in their official Control monitoring. The pour plate method is useful where high *E.coli* levels might be expected⁵⁷. In samples with high microbial load, the MPN determinations are less precise and often higher than those obtained by pour plate colony count techniques⁵⁸. 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 issue; 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 address 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.

⁵⁵ IFREMER, 2014. Enumeration of *Escherichia coli* in live bivalve molluscan shellfish by the direct impedance technique using the BacTrac 4300 series analyser. <https://cefaswebsitedev.cefastest.co.uk/media/taulrzth/c-users-ab19-documents-coe-seafood-safety-generic-protocol-enumeration-of-e-coli-in-bivalve-molluscs-using-impedance.pdf>

⁵⁶ Dupont, J & Dumont, F & Menanteau, C & Pommepuy, M., 2004. Calibration of the impedance method for rapid quantitative estimation of *Escherichia coli* in live marine bivalve molluscs. *Journal of Applied Microbiology*, 96, 894-902.

⁵⁷ EU 2018. Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application. https://euricefas.org/media/14117/20181231gpg_issue-7-final.pdf. CEFAS, 2014. Enumeration of *Escherichia coli* in bivalve molluscan shellfish by the colony-count technique (based on ISO 16649-2)

<https://cefaswebsitedev.cefastest.co.uk/media/vdwl5v5/generic-protocol-enumeration-of-e-coli-in-bivalve-shellfish-using-pour-plate-tbx.pdf>, and Jacobs-Reistma W. F., van Overbeek W., Franz E. and Pol-Hofstad I. E., 2010, Expert lab report on the MicroVal ISO 16140:2003 validation of the TBX pour plate method (ISO 16649-2) for enumeration of *Escherichia coli* in bivalve molluscs, Rikilt Report 2010. 507. USDF, 2014. Laboratory Guidebook: Most Probable Number Procedure and Tables. QD-F-Micro-0004.07. <https://www.fsis.usda.gov/wps/wcm/connect/8872ec11-d6a3-4fcf-86df-4d87e57780f5/MLG-Appendix-2.pdf?MOD=AJPERES>

⁵⁸ Volteera et al., 1980. Bacteriological monitoring of pollution in shellfish: methodological evaluation. *Water, Air and Soil Pollution*, 13, 399-410; and Bonadonna, L., Volterra, L. 1989. Comparative recovery rates of MPN and Pour Plate methods for the enumeration of faecal streptococci in shellfish. *Water, Air and Soil Pollution*, 45, 243-251; and Chandrapati, S. & Williams, M.G., 2014. Total viable counts: Most Probable Number (MPN). In C.A. Batt & M.L. Tortorello (Eds) *Encyclopedia of Food Microbiology* (Second Edition), Academic Press, Pp. 621-624.

Chapter 4: Handling of above threshold *E.coli* results and the determination of those considered anomalous

The Shellfish Control Regulations state that *'Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the harvesting of live bivalve molluscs. However, the competent authority may [also] reclassify a production area as being of Class B or C if it meets the relevant criteria set out in Part A and presents no other risk to human health....The competent authority may re-open a closed production area only if the health standards for molluscs once again comply with Community legislation'*.

For the purposes of this chapter, the term 'above threshold' refers to any official control sampling result that is above the site classification thresholds (i.e. >230 *E.coli*/100g for Class A, >4600 *E.coli*/100g for Class B and >46,000 *E.coli*/100g for Class C). An anomalous result is defined as an above threshold result but one that is unusually high for the site, does not reoccur; the cause of which may or may not be explainable. The EU Guidance identifies an anomalous result as *'results that are markedly higher or lower than those previously seen in an area may potentially be considered anomalous'* and *'results falling more than 3 standard deviations from the mean for a longer term (e.g. 3 years) log transformed dataset would be unusual.'*

In the event of *E.coli* results that exceed the site classification criteria, i.e. an above threshold result, the EU Guidance makes further recommendations on additional short-term controls. This includes implementing an alert process when above threshold *E.coli* results are obtained.

The investigative actions taken, however, depend on the magnitude of the result and on the classification status of the area. When results are obtained that are within the compliance tolerance of the classified area (i.e. Class A results of >230 and ≤ 700 *E. coli*/100g and Class B results >4600 and ≤ 46,000 *E. coli*/100g), the results should be checked against previous monitoring records (i.e. the sampling information that is used to review the classification, typically the last three years' worth of data). If the assessment indicates potential or actual non-compliance with classification, the site should be reclassified or an investigation instigated to determine whether the classification is still appropriate.

The EU Guidance indicates that if the classification threshold is exceeded (i.e. Class A >700 *E. coli*/100g, Class B >4,600 *E.coli*/100g or C >46,000 *E. coli*/100g) then an alert procedure should be instigated immediately. This procedure requires that:

- A risk assessment is conducted to determine the need for short-term controls (e.g. temporary closure or downgrading of the site) to protect public health;
- Instigation of pollution event investigations;
- Immediate follow up investigative sampling and, depending on the results, further sampling at a minimum of weekly frequency to determine whether a contamination event persists;

- An investigation to determine if the sample result may be anomalous (i.e. a result that should be removed from the classification record);
- A review of the classification status of the area informed by the above investigations;
- Consideration of short-term controls to protect public health. If the site is classified as B or C and the threshold is breached then the site must be closed. There is some scope for Class A waters to be reclassified as a Class B site, provided the result is within the Class B threshold; and
- Notification of relevant official and industry bodies at the national, regional and local level.

The EU Guidance explicitly details when above threshold results may be considered anomalous and therefore be excluded from the classification data set:

- When the sampling protocols have not been followed correctly.
- When there has been sewage treatment failure that has since been rectified, and the risk of reoccurrence is low.
- Failure of an animal slurry storage facility or other animal waste disposal practices that has been rectified or reoccurrence is low.
- A rainfall event with a return period of five years or greater (i.e. rainfall of an intensity or duration which occurs once every five years or longer) has occurred and where the authority responsible for the monitoring programme deems that this has, or may have, significantly impacted on the microbiological status of the harvesting area. If the return period analysis is not available, an equivalent assessment can be determined using the rainfall on either of the two days prior to sampling. If this exceeds the 99.9th percentile of a long-term (preferably 10 years and a minimum of five years) daily rainfall data set then it can be considered equivalent to the 1 in 5 year rainfall event.

All anomalous result exclusions must be fully documented and justified, although there is no requirement to make this information publicly available.

How very high and unusual above threshold results, i.e. those considered anomalous, are handled is an important issue for the UK aquaculture sector. In July 2015 there was a series of exceptionally high above threshold *E.coli* results recorded by the control monitoring programme for England and Wales, with the number, magnitude and geographical spread of the results being unprecedented. Forty of the samples collected generated *E.coli* results considerably higher than any previously observed for the relevant harvesting site.

These exceptionally high results were recorded from the Bristol Channel across the south west and southern coasts to Hampshire and the Isle of Wight over a two-week period. As a result, sites were closed temporarily to shellfish harvesting. Investigative samples taken one to two weeks after the initial above threshold results were within expected ranges for the relevant site classification. The unprecedented *E.coli* results were considered anomalous and removed from the classification record. This decision was justified on the basis of the magnitude of the initial sample results and the Environment Agency confirming that there were no notable *E.coli* detections in the bathing water monitoring during the same timeframe.

This chapter reviews how different Member States approach the handling of above threshold and anomalous *E.coli* results. Case studies are presented from France, Ireland, Netherlands,

Spain, Italy, Germany, Sweden, Denmark and Norway using the information provided in the national legislation and/or guidance previously referenced. The approach adopted in each case study considers the action taken if there is an above threshold result and whether discounting occurs and on what basis. Comparisons are also made with the UK approach.

4.1 UK

When an above threshold result is obtained, a Local Action Group (LAG) is formed. This comprises FSA or FSS as the competent authority, Cefas as the co-ordinator of the monitoring programme, the Local Authority responsible for shellfish classification sampling and other stakeholders such as the Environment Agency (assistance with identifying pollution incidents), Health Protection Units (advice on infection control measures) and trade bodies (assist in notifying harvesters and food business operators). The role of the LAG is to implement the Local Action Plan⁵⁹, determine the need for management measures, investigate the cause of above threshold result and determine whether it can be considered anomalous.

4.1.1 Action taken on receipt of an above threshold result

E.coli monitoring data is analysed continuously throughout the year and, if above threshold results are recorded, the production area may be temporarily closed, or changes to the classification notified if harvesting is to continue.

The UK has implemented an approach for handling above threshold *E.coli* results that mirrors the EU Guidance. Where *E.coli* results are above the classification threshold, notifications are issued and the action taken depends on the site classification and the magnitude of the result⁶⁰:

- **Investigation state** – issued following a result above the classification thresholds for Class A (>230 *E.coli*/100g) and Class B (4600 *E.coli*/100g) sites. An investigation of the potential cause will be initiated but temporary closure/restrictions are generally not applied.
- **Trigger state** – issued following results for Class A > 700 *E.coli*/100g, Class B >18,000 *E. coli*/100g and Class C >46,000 *E. coli*/100g). Temporary closure of the area should be considered. Where high results continue for 3 months or more, reclassification is probable.

To re-open a temporarily closed production site, two consecutive satisfactory samples must be taken at least seven days apart. In England, Wales and Northern Ireland, these samples are for investigation purposes only and are not retained on the classification record.

⁵⁹ Each LAG must develop an effective local action plan (LAP) to implement 'Investigation' and 'Action' states when high *E.coli* results, biotoxin or pollution events occur. LAPs must cover all classified beds and RMPs. The effectiveness of a LAP relies on it being tailored to specific local needs. The LAP must detail the investigation process during the Investigation and Action states, allocate roles to LAG members to assist in investigating high results, outline the data collection process and how information will be shared to members, determine when and how information should be given to Cefas for analysis and advice, include criteria and agreed templates for lifting control measures, time scale for reporting results and ending of Investigation and Action states and cover actions to be taken following a biotoxin or pollution event.

⁶⁰ FSA 2020 Protocol for the Classification of Shellfish Harvesting Areas – England and Wales.

<https://www.food.gov.uk/business-guidance/shellfish-classification> FSANI, 2020. Protocol for the Classification of Shellfish production and relaying areas in Northern Ireland. <https://www.food.gov.uk/sites/default/files/media/document/ni-shellfish-classification-protocol-november-2020.pdf>

However the initial above threshold result is included on the site's classification record. Where the LAG determines that the results remain valid and that the classification thresholds have been exceeded, then a downgrade may be appropriate. The final decision on any downgrade is made by the Competent Authority on advice from the LAG.

In Scotland, further sampling is undertaken if high results are recorded because of the difference between the 5 x 3 tube MPN test method which can only quantify values up to 18,000 *E.coli*/100g, and the 5 x 4 (or 5) tube MPN test method used elsewhere in the UK. This verification sample is retained in the classification record. In the interests of public health, a voluntary closure may be agreed pending the results of the verification sample. Slightly different thresholds are also used in Scotland⁶¹.

- **Investigative State:** Class A 231 to 1000 *E.coli*/100g and Class B 4601 to 9100 *E.coli*/100g. An investigation of the potential cause will be initiated but temporary closure/restrictions are generally not applied.
- **Incident State:** Class A ≥ 1001 *E.coli*/100g, Class B sites $\geq 9,101$ *E.coli*/100g and Class C $\geq 18,000$ *E.coli*/100g. Closure of the area should be considered whilst extra dilution test is being carried out for results $> 18,000$ *E.coli*/100g. Where high results continue for 3 months or more, reclassification will be considered.

The 1000 *E.coli*/100g threshold used in Scotland for class A exceeds the current EU upper threshold of 700 *E.coli*/100g.

4.1.1 Anomalous *E.coli* results

Following a closure, an above threshold *E.coli* result may be considered anomalous and, after an investigation can be discounted provided the criteria outlined in the EU Guidance are strictly met. These investigations are desk-based and rely on the knowledge of the LAG.

In England and Wales, results that can be attributed to an unusual or "one-off event" that is unlikely to recur may be excluded from the classification record by the FSA. The FSA guidance for England and Wales provides the following examples of such events:

- Failure of a sewage treatment works where it is deemed that the resulting discharges will have markedly impacted on the shellfish bed(s);
- A 1 in 5 year (or longer) return period rainfall event occurring within 48 hours of the sample being taken. This timeframe may be extended depending on the nature of the event and local circumstances⁶²; and
- Where the sampling has not complied with the standard sampling protocol, i.e. exclusion of results for samples that have exceeded the 48-hour limit between sampling and testing.

The 48-hour limit on the 1 in 5 year rainfall event is not specified in the EU Guidance and is an additional requirement applied in the UK. There may be some flexibility in the application of the requirement but there is no detail in the UK guidance on when that might occur. This

⁶¹ FSS, 2020. Protocol for Classification of Shellfish Production Areas.

https://www.foodstandards.gov.scot/downloads/Shellfish_-_Classification_Protocol_-_Final_-_17-08-2020.pdf

⁶² FSA, 2020. Guidance for Local Action Groups (LAGs) on handling high *E.coli* results, biotoxin results and pollution events - classification and monitoring of live bivalve molluscs. <https://www.food.gov.uk/sites/default/files/media/document/local-action-groups-guidance-lbm.pdf>

possible implications of this are that it is less likely that an above threshold result will be considered anomalous. Although this window maybe extended on the basis of local circumstances, it is an additional interpretation applied in the UK which may act as a further constraint on when an above threshold result might be deemed anomalous. The Northern Ireland guidance indicates that results may be discounted in accordance with the criteria laid down in the EU Guidance, i.e. without the additional 48 hour limit provision. In contrast, the Scottish guidance does not consider criteria for discounting high *E.coli* monitoring results. Because Scotland uses the 5x3 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 cannot be considered an anomaly and is retained on the classification record.

The investigations undertaken on receipt of an above threshold result in the UK are desk based. There is no routine site investigation to identify whether the elevated results relate to a specific change in the production area. The investigations rely on the knowledge and understanding of LAG members (e.g. water companies are required to report the failure of a sewage treatment works to the Environment Agency) and therefore the accuracy of reporting if a pollution event occurs.

4.2 France

4.2.1 Action taken on receipt of an above threshold result

France has instigated an alert system similar to that outlined in the EU guidance. Where an above threshold monitoring result is obtained that is outwith the requirements for the site classification (e.g. >700 *E.coli*/100g for a class A area) the site will be temporarily closed and resampled within 48 hours.

The action taken thereafter depends on the result of the resample. For Class A sites:

- if the resample is <230 *E.coli*/100g no further action is taken and the temporary closure is lifted,
- if the resample is between 230 and 700 *E.coli*/100g weekly sampling is instigated until one sample <230 *E.coli*/100g is recorded. At this point the temporary closure will be lifted,
- if >700 *E.coli*/100g the weekly sampling is instigated until two samples are obtained <230 *E.coli*/100g.

Class B sites:

- if the resample is <4,600 *E.coli*/100g no further action is taken and the temporary closure is lifted,
- if the resample is >4,600 *E.coli*/100g weekly sampling is instigated until two samples are obtained <4,600 *E.coli*/100g at which point the temporary closure will be lifted.

Class C sites:

- if the resample is <46,000 *E.coli*/100g then no further action is taken and the temporary closure is lifted,

- if the resample is >46,000 *E.coli*/100g weekly, sampling continues until two samples are obtained <46,000 *E.coli*/100g, at which point the temporary closure will be lifted.

4.2.2 Anomalous *E.coli* results

The reasons for removing anomalous *E.coli* results from the classification record are outlined in the French legislation and largely accord with those in the EU guidance. Exceptional rainfall events must be interpreted in light of any observed link between rainfall and microbial contamination at the site.

In addition to the legislation, for the 1 in 5 year rainfall events, the French guidance indicates that this occurrence can be cumulative in the preceding two days. If rainfall has been systematically associated with high *E.coli* results, then the result must be retained. However, the French system allows for "aberrant" results to be disregarded; these are results that are considered outliers on the site record and where there is no identifiable cause for the unusual result⁶³.

4.2.3 Comparison with the UK approach

Three key differences were identified in the French approach to handling above threshold *E.coli* results compared to the UK approach:

- France has adopted a rapid 48 hour resampling approach on receipt of an above threshold *E.coli* monitoring result in order to verify the result. This is combined with quick resumption of harvesting provided the verification resample is within the classification. In the UK, two consecutive samples taken at least seven days apart are required prior to resumption of harvesting
- France automatically closes sites when above threshold monitoring results are obtained. If the above threshold results continue, weekly sampling is instigated until two consecutive within threshold results are obtained. The closure can then be lifted. There does not appear to be any consideration given to within year reclassification of the site. In contrast, in the UK an above threshold monitoring result will be assessed through the rolling review and may lead to within year reclassification.
- A single *E.coli* result that is an outlier from that expected for the site and where no obvious cause has been identified, is considered 'aberrant' and can be disregarded. There is no such provision in the UK, although in 2015 anomalous results across the entire south coast region were eventually disregarded following an inconclusive investigation into their cause.

4.3 Ireland

4.3.1 Action taken on receipt of an above threshold result

When an *E.coli* result is obtained that is above the threshold for the site classification, the site will be temporarily downgraded and additional treatment, i.e. purification in an approved purification centre or heat treatment by an approved process, will be required for any bivalves

⁶³ DGAL/SDSSA/2016-448 Réglementation sanitaire applicable aux zones de production de coquillages. 30/05/2016.

already harvested. Further harvesting operations are expected to cease as soon as the producer is made aware of the above threshold result. The Irish guidance provides no information on when harvesting can subsequently resume.

Ireland has introduced alert levels corresponding to 700 *E.coli*/100g for class A sites, 18,000 *E.coli*/100g for class B and 46,000 *E.coli*/100g for class C. The validity of any monitoring result exceeding these thresholds is checked with the laboratory in the first instance. If the sample is invalid (e.g. due to long transit time, incorrect temperature on arrival, incorrect practice in the laboratory), the site is resampled. If the result is considered valid, an investigation is initiated to identify the cause.

The Irish guidance does not indicate that the frequency of monitoring should be increased following an above threshold *E.coli* monitoring result. Nor does the guidance indicate the number of samples required within threshold in order to re-open a temporarily closed site to harvesting.

4.3.2 Anomalous *E.coli* results

The criteria adopted by Ireland for identifying and disregarding anomalous *E.coli* results are those outlined in the EU guidance, with the inclusion of additional events that may influence the microbial quality of the shellfish. These include changes in agricultural practices such as slurry spreading⁶⁴ and other activities such as harbour dredging⁶⁵.

4.3.3 Comparison with the UK approach

Three key differences were identified in the Irish approach to handling above threshold *E.coli* results compared to the UK approach:

- No specific information is provided in the Irish guidance on how temporarily closed sites can be reopened. In the UK, two consecutive samples taken at least seven days apart are required prior to the resumption of harvesting;
- Disregarding results in relation to a 1 in 5 year rainfall event is not constrained to occurrence in the preceding 48 hour period prior to sampling, which is usually the case in the UK. This allows greater flexibility when deciding whether a result can be disregarded from the classification record.
- The inclusion of additional events, such as slurry spreading or harbour dredging, potentially widens the scope of activities that could be considered as part of the investigation into high *E.coli* results, and whether a high result can be discounted. The UK guidance to LAG does not explicitly include such activities for consideration.

⁶⁴ In Ireland, slurry cannot be spread on land from 15 October to January 12 / 15th / 31st (depending on which part of the country a farm is located). All land spreading activity is conditional on weather and ground conditions being suitable. Livestock manures or any chemical fertilisers should not be applied to land when it is waterlogged, flooded or likely to flood, frozen or if heavy rain is forecasted within 48 hours. <https://www.gov.ie/en/publication/b87ad-nitrates-directive/#the-slurry-spreading-calendar>

S.I. No. 65/2018 - European Union (Good Agricultural Practice for Protection of Waters) (Amendment) Regulations 2018 requires each farm to prepare an annual fertiliser plan that must detail the expected application of manure and other fertilisers and be made available by 1 March. At least 50% of slurry produced on the holding shall be applied by 15 June.

⁶⁵ All maintenance and capital harbour or port dredging requires statutory permissions. These are a Foreshore Consent (granted by the Department of Housing, Planning and Local Government) and a Dumping at Sea Permit (granted by Environmental Protection Agency).

4.4 Netherlands

4.4.1 Action taken on receipt of an above threshold result

Although the Dutch regulation does not outline an alert system, it does note the need to adhere to the Shellfish Control Regulation requirements. The Dutch regulation indicates that when an *E.coli* sample result exceeds the classification threshold the site should be temporarily closed or downgraded. The site should then be resampled the following week, and if the result is within classification thresholds, no further action will be taken. If the resample is above the threshold, resampling will be maintained on a weekly basis for three weeks. Thereafter downgrading may be considered if results remain above classification thresholds.

4.4.2 Anomalous *E.coli* results

The Dutch legislation provides little information on when above threshold sample results may be considered anomalous and discounted from the classification record. In line with the EU guidance, potential issues that could affect the results such as issues with sampling and weather conditions (e.g. rainfall) are noted, but no specific detail is provided.

4.4.3 Comparison with the UK approach

Three key differences were identified between the Dutch and UK approaches to handling above threshold *E.coli* monitoring results.

- The Netherlands has not implemented an alert system as described in the EU Guidance. Compared to the UK approach, this reduces the potential for an early warning of a possible deterioration in site conditions.
- The Dutch system requires a weekly resampling approach on receipt of a high *E.coli* monitoring result. Harvesting can resume when a sample result is within the classification threshold. This means that sites are typically able to reopen more quickly compared to the UK. The UK system requires two consecutive samples within the threshold, and these samples must be taken at least seven days apart before harvesting can resume.
- In the Netherlands, the consideration of an unusual weather event as being the cause of the above threshold is not constrained to the preceding 48 hour period. This allows greater flexibility when deciding whether a result is anomalous and if it can be disregarded from the classification record. In the UK such considerations are generally constrained to 48 hours preceding the sample which is more restrictive.

4.5 Spain

4.5.1 Action taken on receipt of an above threshold result

Where an *E.coli* result exceeds the classification threshold, sampling will be increased to weekly until sample results return to normal. In these cases, a temporary change to the classification may be implemented, depending on the classification and the monitoring result obtained. Alternatively, the site may be temporarily closed.

4.5.2 Anomalous *E.coli* results

Spain has implemented the criteria for disregarding above threshold *E.coli* results as outlined in the EU guidance. The rainfall criterion, however, explicitly focuses on exceedance of the 99.9 percentile of daily rainfall data over a 10 year period (rather than the 1 in 5 year rainfall

event calculation). The EU technical guidance indicates that the daily rainfall percentile approach should be constrained to the 48 hours period prior to the high *E.coli* result. This 48 hour time constraint is, however, not mentioned in the Spanish guidance.

Additionally, the Spanish guidance notes that if the time interval between two samples is less than 15 days, then one of the sample results will be disregarded. The guidance, however, provides no further detail on which result to retain.

4.5.3 Comparison with the UK approach

There are three key differences that were identified between the Spanish and UK approaches to handling above threshold *E.coli* monitoring results.

- Spain has adopted a weekly resampling approach on receipt of an above threshold *E.coli* monitoring result combined with resumption of harvesting once the sample is within the classification threshold. Sites are therefore potentially able to reopen more quickly than in the UK where two consecutive samples are required at least seven days apart before the site can reopen.
- Spain uses 10 years' of rainfall data to assess exceedance thresholds rather than the 1 in 5 year rainfall event. These two approaches are deemed equivalent if the former is constrained to consideration of the rainfall exceedance thresholds to 48 hours. There is no indication, however, that the Spanish constrain consideration of rainfall events to the preceding 48 hours. This potentially allows greater flexibility when deciding whether a result can be disregarded from the classification record, e.g. if a heavy rainfall event 3 days prior to receipt of an above threshold result could be used to justify it as anomalous.
- Where two control samples are collected less than 15 days apart, one of the results will be removed from the classification record in Spain. There is no equivalent formal process applied in the UK, although the option to discount results is available under certain circumstances in Scotland.

4.6 Italy

4.6.1 Action taken on receipt of an above threshold result

If an *E.coli* result exceeds the classification limit the production area is either temporarily closed or reclassified if the microbiological criteria for the lower class is met. Reclassification requires that the appropriate post-harvest measures (e.g. cooking, depuration or relaying) are taken prior to the bivalves being made available for human consumption. For grade C sites, if a single sample exceeds the microbiological limits for class C (i.e. 46,000 *E.coli*/100g), the area will be declassified.

Italy has not adopted an alert system as suggested in the EU guidance. If a control sample exceeds the classification threshold, a repeat sample is collected within one week. If this verification sample indicates the site is within classification then no further action is taken. If the repeat sample is not within the required threshold then measures remain in place and the sampling continues until at least two consecutive results below the classification threshold are collected, separated by at least seven days.

4.6.2 Anomalous *E.coli* results

The Italian guidance indicates that results can be disregarded (i.e. those identified as anomalous) if a subsequent investigation into the cause considers this is warranted. However, the guidance does not provide any specific detail on the criteria that can be used to disregard results.

4.6.3 Comparison with the UK approach

Two key differences have been identified in how Italy handles above threshold *E.coli* results compared to the UK:

- Italy has not implemented an alert system as specified in the EU Guidance, which the UK has. This likely limits the opportunity for an early warning of a possible deterioration in site conditions.
- Italy has adopted a weekly resampling approach when above threshold results are detected, with only one sample within classification required for any measures to be lifted. Sites are therefore potentially able to reopen more quickly following a high *E.coli* monitoring result. In contrast the UK requires two consecutive samples, taken at least seven days apart prior to resumption of harvesting.

4.7 Germany

4.7.1 Action taken on receipt of an above threshold result

German guidance specifies that if an *E.coli* result exceeds the relevant limits for a site's classification, then the production area will either be temporarily closed, or reclassified if microbiological criteria for the lower class are met. When an area is closed, the Competent Authority may reopen it if *E.coli* sampling indicates the conditions for bivalve molluscs are within the classification requirements.

At least two successive samples below the threshold are required to restore the classification. These additional samples may be undertaken at weekly intervals on request and are utilised as part of the classification record.

If a number of above threshold microbiological samples are recorded consecutively, an intensive sampling programme will be implemented. The nature of this programme will depend on the type, duration and intensity of the possible sources of contamination, but will require a higher sampling frequency as well as an increase in the number of samples taken within the vicinity of the production area.

4.7.2 Anomalous *E.coli* results

The German guidance does not consider criteria for discounting anomalous *E.coli* monitoring results. It does, however, note the need to meet the current recommendations outlined in the EU Guidance.

4.7.3 Comparison with the UK approach

Two key differences have been identified in how Germany handles above threshold *E.coli* results compared to the UK:

- Germany has not implemented an alert system, as described in the EU Guidance. This could reduce the potential for an early warning of a possible deterioration in a site's condition. The UK has such an alert system in place.
- Germany implements a monthly sampling regime, similar to the UK approach. However, under the German system, if an above threshold result is obtained, the producers can request that sampling frequency is increased to weekly. This provides a more responsive approach and means that any management measures applied to the site can potentially be lifted more quickly than would happen in the UK.

4.8 Sweden

4.8.1 Action taken on receipt of an above threshold result

Under the Swedish system if the threshold requirements for *E.coli* in shellfish are exceeded then the site is closed. If the site has been closed for less than 3 months, it may be reopened following two consecutive samples, taken at least one week apart, that meet the classification threshold. For a site that has been closed for three months or more, the classification requirements must be met in at least three consecutive samples, each taken at least one week apart.

For class A sites where the result lies between 230 and 700 *E.coli*/100g, operators are requested to check that all batches harvested from the area meet the health requirements before sale for human consumption. When there are repeat occurrences of results between 230 and 700 *E.coli*/100g, the site may be downgraded.

4.8.2 Anomalous *E.coli* results

When the thresholds for a site's classification are exceeded, an investigation is always implemented. The Swedish guidance however does not detail how *E.coli* monitoring results are deemed anomalous and can, therefore, be discounted.

4.8.3 Comparison with the UK approach

There are two key differences in how Sweden deals with above threshold *E.coli* results compared to the UK:

- Sites are automatically closed if an above threshold result is obtained and reclassification is only considered following multiple occurrences of above threshold monitoring results. In the UK, sites may be reclassified rather than closed, with reclassification based on a single above threshold result rather than multiple occurrences. This UK approach to reclassification will have a greater negative impact on business operations.
- For sites closed for less than three months, two samples within threshold are required for the site to reopen. For sites closed for more the three months, at least three samples are required. The length of temporary closure of a site in the UK does not alter the sample requirements for reopening (i.e. two consecutive samples taken 7 days apart). Sites in the UK can therefore open more quickly after lengthy closures, but are likely to have been downgraded.

4.9 Denmark

4.9.1 Action taken on receipt of an above threshold result

Denmark combines the classification award with a rolling monitoring approach using weekly sampling to monitor the site. If an above threshold result is obtained, the site will be temporarily downgraded for that week. This then determines the post-harvest requirements for cooking, relaying or depuration prior to the bivalves being made available for consumption.

If sampling results indicate that the >46,000 *E.coli*/100g threshold has been exceeded, then the production area will be temporarily closed. The site can only reopen following classification results from three samples in the first week and one sample over the following two weeks (i.e. it will take a minimum of three weeks for a site to reopen).

For permanently classified long term stable sites that exceed their classification threshold, a period of intensive sampling is required (this is similar to the sampling regime for a temporary classification). The permanent classification may be revoked if the conditions are no longer being met on a regular basis.

4.9.2 Anomalous *E.coli* results

The Danish regulation does not specify how above threshold *E.coli* monitoring results are assessed to be anomalous and if they can be discounted.

4.9.3 Comparison with the UK approach

Since Denmark uses a temporary classification system, comprising weekly sampling and a rolling classification process, the approach is quite different to that utilised in the UK. Three key differences were identified:

- The Danish approach of weekly monitoring to determine the operating classification of a site, which then determines the harvesting protocol, is very different to the UK (monthly monitoring with an annual determination of site classification). Sites are managed on a real time basis in Denmark, which provides greater business certainty.
- The 'real time' approach means sites are only closed when a result >46,000 *E.coli*/100g is obtained. Intensive sampling is then required over a 3 week period before the site can reopen. In contrast, in the UK has a more restrictive approach where sites may be closed and/or downgraded as a result of a single above threshold result. Any result >46,000 *E.coli*/100g will result in the site being closed. This may be permanent where a second sample is recorded if >46,000 *E.coli*/100g is recorded.
- The intensive sampling implemented in Denmark requires multiple samples to be taken in the first week. This provides a better sense of the extent of risk that needs to be managed. Multiple samples enables an assessment of the veracity of the result as well as the variability in the *E.coli* levels in shellfish across the site. There is no requirement for multiple samples in the UK.

4.10 Norway

4.10.1 Action taken on receipt of an above threshold result

The Norwegian approach requires that a site is temporarily closed to harvesting if the threshold for *E.coli* is exceeded. Further sampling takes place within 14 days and the site can reopen if this sample is within the classification threshold.

Where above threshold results occur on a regular seasonal basis, reclassification will be considered.

4.10.2 Anomalous *E.coli* results

The Norwegian guidance notes that individual monitoring results are not necessarily representative of a site's condition. Above threshold results can be deemed anomalous and disregarded following an investigation, with the guidance noting that rainfall is the main cause of such incidents. However, no further detail is provided on how rainfall thresholds are used in justifying that an above threshold result is anomalous and therefore can be disregarded.

4.10.3 Comparison with the UK approach

Four key differences were identified between the Norwegian and UK approaches to handling high *E.coli* monitoring results:

- Unlike the UK, Norway has not implemented the alert system as described in the EU Guidance. This reduces the potential for an early warning of possible deterioration in a site's condition.
- Sites with above threshold results will only be reclassified within year after multiple occurrences of such results. This is potentially more permissive than the UK, where site reclassification can occur on the basis of a single above threshold result rather than multiple occurrences.
- Norway resamples sites within 14 days of receipt of a high *E.coli* monitoring result. If this verification result is within threshold for the classification, harvesting can resume. Sites are therefore able to reopen more quickly following a high *E.coli* monitoring result. In comparison, the UK requires two consecutive samples taken at least seven days apart before harvesting can be resumed.
- Rainfall is noted as a key reason for above threshold results and the guidance implies that such results can be considered anomalous. However, there is no specific detail in the Norwegian guidance on the attributes of such a rainfall event, although they do not appear to be constrained to a 1 in 5 year rainfall event or to occurrence within the 48 hour period prior to sampling which is the norm in the UK.

4.11 Member State compliance with the Shellfish Control Regulations

The case studies above indicate that the approaches taken by Member States to the handling of above threshold *E.coli* monitoring results vary. As in the previous chapter, the most recent audits of Member State compliance with the regulations were reviewed to assess if this variation is considered acceptable by DG SANTE.

Between 2011 and 2013, DG SANTE's Food and Veterinary Office undertook evaluation audits of the official controls systems in place for production of bivalve molluscs⁶⁶. The EFTA Surveillance Authority undertook a similar audit of Norway's official controls systems for the production of bivalve molluscs in 2015⁶⁷. Details of the individual audits can be found in Appendix 1. Notably for this review, the majority of Member States' legislation and guidance material currently in use was updated or introduced following these audits. This means that it is not possible to categorically state that the approaches currently in use would satisfy an 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.

In summary, few problems were identified with the way in which Member States handled above threshold results. The main issue was 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. Specific issues uncovered by these historic audits include:

- sites not being closed (or temporarily downgraded if appropriate) prior to resampling occurring (France, Ireland, Italy, and Norway); or
- investigations into above threshold results were not always completed (UK).

No issues were identified with the approaches adopted by Spain (Galician region), Germany, Denmark, Sweden or the Netherlands.

4.12 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 and UK 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 include:

- poor hygiene practices leading to samples becoming contaminated.
- Transcription errors include 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.

⁶⁶ EC 2015. Overview report on audits in member states in order to evaluate the official control systems in place for production and placing on the market of bivalve molluscs. DG(SANCO)/2014-7270 – OR Final.

⁶⁷ <https://www.eftasurv.int/internal-market/food-safety/food-safety-missions/mission-norway-20-24-april-2015-live-bivalve>

4.13 Overview of the variation in how above threshold *E.coli* results are treated

A variety of approaches for handling above threshold *E.coli* monitoring results have been identified. A detailed comparison is provided in Appendix 3, which can be summarised as:

4.13.1 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. Similar to the UK, both of these options have been adopted in Spain, Italy and Germany. 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 classification 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 and Italy do not undertake within year re-classifications. These approaches to within year reclassification are more permissive than the UK where a site can be downgraded in response to a single above threshold monitoring result.

4.13.2 Resampling timeframe and number of samples required

The Shellfish Control Regulations stipulate that to reopen a temporarily closed site, the required health standards (i.e. the microbial classification criteria) must be met. EU Guidance recommends that at least weekly sampling is implemented for investigative monitoring 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 in the UK would enable a more rapid reassessment of a site's classification status and allow harvesting to resume more quickly than currently happens.

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, Germany, Sweden, Denmark and the UK require two samples within classification thresholds before restrictions are lifted. France also requires two samples, although these are both collected within four days of the initial high result. The timeframe employed for resampling can have a significant effect on how quickly a site can reopen.

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.

4.13.3 Process for treating above threshold results in the classification record

Within England, Wales and Northern Ireland an above threshold sample result will automatically be added to a site's classification record. In contrast, EU Member States, Norway and Scotland only add the result to the record once it has been confirmed via a subsequent sample. It is the result of this validation sample that is added to the classification record. This retest 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 can reopen. Not automatically applying an above threshold result until it has been confirmed can have a positive influence on the overall classification assessment as it can contribute to a lower threshold level against which the site is monitored.

4.13.4 Exclusion of extraordinarily high monitoring results

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*'. There is only one example of a similar approach being taken in the UK. This occurred when unprecedented high results were noted over the entire south and south west region in 2015. There is no provision or indeed precedence for this approach to be applied to an individual site in the UK.

4.13.5 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. The accumulation and clearance of *E.coli* from bivalves varies not only between species but also between sites in relation to a variety of environmental factors (e.g. soil type and permeability, recent rainfall history)⁶⁸. More specifically, 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 (including the UK) 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 indicates these two approaches should be equivalent when the daily rainfall calculation is constrained to the 48 hours period prior to the high *E.coli* result.

⁶⁸ Campos et al., 2017. Determining the zone of impact of norovirus contamination in shellfish production areas through microbial monitoring and hydrographic analysis. *Water Research*, 124, 556-563; Malham et al., 2017. Review of current evidence to inform selection of environmental predictors for Active Management Systems in classified shellfish harvesting areas. FSA project FS103001; and de Souza, R., Younger, A., Alves, M. & Campos, C. (2019). The influence of the number of *Escherichia coli* results on the classification status and assessment of microbiological risk of shellfish production areas. *Food Control*, 103, 86-90.

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 constrains 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 Member States have greater flexibility in deciding whether a result can be disregarded from the classification record. The UK and France are potentially retaining high results on the record that would have been discounted by other Member States. Further, research indicates that the cumulative rainfall of the preceding seven days is more closely correlated to the levels of *E.coli* in bivalves⁶⁹.

4.13.6 Activities taken into account when considering whether an above threshold result is anomalous

As part of the guidance on 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. Explicit inclusion of such activities in national guidance helps to highlight the need for these risks to be managed, and for investigations to consider these factors. 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 and other fertilisers. These plans can then be taken into account during any investigation of an above threshold classification result and help determine if it is anomalous.

While the UK has a specific code of conduct that farmers must adhere to when applying slurry to fields, in order to minimise runoff and pollution, there is no requirement to register when this activity is taking place. As a result, such activity is generally not taken into account as part of any consideration of an above threshold monitoring result. The application of slurry to fields rarely results in a major pollution incident, e.g. one that leads to fish kills, so is not always easily detected as a potential issue. Currently, only major pollution incidents are investigated by the Environment Agency. Minor pollution incidents may, however, have a negative impact on bivalves leading to elevated or above threshold *E.coli* levels which can incorrectly be retained on the classification record and may result in a site downgrade.

4.13.7 Summary

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 in the UK. The case studies outlined above suggest that alternative approaches are available in how the Shellfish Control Regulations are applied with respect to uncharacteristically high *E.coli* results (i.e. those which are '*more than 3 standard deviations from the mean for a longer term (e.g. 3 years) log transformed dataset*').

⁶⁹ Campos, et al., 2011. Rainfall and river flows are predictors for β -glucuronidase positive *Escherichia coli* accumulation in mussels and Pacific oysters from the Dart Estuary (England). *Journal of Water Health*, 9(2), 368–381; Derolez et al., 2012. Impact of weather conditions on *Escherichia coli* accumulation in oysters of the Thau lagoon (the Mediterranean, France). *Journal of Applied Microbiology*, 114 (2), 516–525; Campos et al., 2017. Risk factors for norovirus contamination of shellfish water catchments in England and Wales. *International Journal of Food Microbiology*, 241, 318–324.

Chapter 5: Third Country equivalence and export to the EU

The EU is one of the world's largest importers of seafood, including aquaculture products. On behalf of all EU Member States, the European Commission negotiates the import rules for seafood and fishery products, with rules harmonised across all EU Member States⁷⁰.

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 the same assurances in terms of human health.

DG SANTE establishes the import conditions for fishery products including bivalve molluscs. Imports must meet the following conditions:

- Come from an approved non-EU country;
- Be accompanied by appropriate signed health certification;
- Come from an EU-approved fishery product establishment, premises or approved bivalve mollusc production or growing area, which must be recorded on the EU health certificate;
- Bivalve molluscs can only be commercially harvested from approved production areas to ensure they meet the toxin and microbiological criteria requirements. Notably, product coming from Third Countries must meet Class A standards, i.e. the microbial content must be <230 *E.coli*/100g;
- Must enter the EU through an officially designated Border Control Post (BCP) where veterinary/hygiene checks are carried out by an Official Fish Inspector; and
- All consignments must be pre-notified to the BCP prior to arrival.

Annex 1 of EU Implementing Regulation 2019/626⁷¹ lists the Third Countries authorised to export live, raw, frozen or processed molluscs into the European Union for human consumption. Of the 17 countries listed, only nine are permitted to export live bivalve molluscs and, of these, only four actually do (Table 5).

Third Country case studies were chosen on the basis of current and historic exports of mussels and oysters into Europe. In addition, consideration was also given to recent trade agreements between the EU and Third Countries that specifically incorporate bivalves. The case studies

⁷⁰ EC. EU import conditions for seafood and other fishery products.

https://ec.europa.eu/food/sites/food/files/safety/docs/ia_trade_import-cond-fish_en.pdf

⁷¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0626&from=EN>

utilised to assess the requirements of Third Country equivalence were Canada, New Zealand and USA.

The shellfish monitoring programmes in each Third Country case study were assessed on:

- The process for initial site classification;
- The ongoing monitoring once a site is 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
- How high or anomalous microbial results are considered as part of the classification record.

Points of difference between the systems detailed in the Third Country case studies and the application of the Shellfish Control Regulations in the UK are also described.

Table 5: Third Countries permitted to export live bivalve molluscs to EU⁷²

Country	Exports occurring	Notes
Australia	Scallops (<i>Amusium balloti</i> and <i>Pecten fumatus</i>), Pacific oyster and pipi (<i>Plebidonax deltooides</i>) to Belgium, France, Italy and Portugal.	Export is irregular. 8 sites included in the EU approved growing areas, all equating to class A.
Canada	Live mussels (<i>Mytilus</i> spp.), Manila clams (<i>Tapes japonica</i> and <i>T. philippinarum</i>) and Atlantic oysters (<i>Crassostrea virginica</i>) to Belgium, Spain and the Netherlands.	740 sites included in the EU approved growing areas, all equating to class A.
Chile	Frozen or processed mussels (<i>Mytilus chilensis</i>).	No live bivalves exported. 57 sites included in the EU approved growing areas equating to class A and 92 to class B.
Greenland	Frozen wild caught scallops to Denmark	No live bivalves exported. No sites currently approved for export.
New Zealand	Greenshell mussels (<i>Perna canaliculus</i>), Pacific oyster, scallops (<i>Pecten novaezelandiae</i>) and NZ littleneck clam (<i>Austrovenus stutchburyi</i>).	71 sites included in the EU approved growing areas equating to class A and 4 to class B. Bivalves from class B sites must be purified prior to export.
Tunisia	No bivalves exported.	No live bivalves exported. 5 sites included in the EU approved growing areas equating to class A and 1 to class B.
Turkey	Cooked or frozen bivalves. Species not identified.	No live bivalves exported. 2 sites included in the EU approved growing areas equating to class A, 11 to class B and 5 to class C.
Uruguay	No bivalves exported.	No live bivalves exported. No sites currently approved for export.
USA	Oysters and other bivalve molluscs to Spain and the Netherlands.	175 sites included in the EU approved growing areas, all equating to class A.

⁷² Information taken from DG SANTE audits of Third Countries: Australia DG(SANCO)/2007-7287; Canada DG(SANCO) 2009-8036; Chile DG(SANCO) 2013-6721; Greenland DG(SANCO)/ 2009-8042; New Zealand DG(SANCO)/ 2008-767; Tunisia DG(SANTE) 2019-6694; Turkey DG(SANTE) 2018-6508; Uruguay DG(SANTE) 2015-7471; USA DG(SANTE) 2015-7486.

5.1 Canada

The Canadian Shellfish Sanitation Program (CSSP)⁷³ is led by the Canadian Food Inspection Agency (CFIA) in collaboration with Environment and Climate Change Canada (ECCC) and Fisheries and Oceans Canada (DFO) to ensure that:

- bivalve molluscs are harvested from growing areas meeting approved federal water quality criteria;
- potential pollution sources in these areas are identified and appropriately managed; and
- all shellfish sold commercially is harvested, transported, and processed in an approved manner.

ECCC monitors the bacteriological water quality in shellfish production areas, identifies and evaluates sanitary pollution sources, and recommends the classification assigned to shellfish harvest areas. CFIA monitors the processing of edible shellfish for compliance with federal standards and DFO open and close shellfish beds on the recommendation of either ECCC or CFIA.

The Canadian shellfish classification system is based on the regular sampling of faecal coliforms in water rather than on *E.coli* in shellfish flesh⁷⁴. This approach is considered equivalent to the European Official Control Regulations requirements⁷⁵.

5.1.1 Initial site classification

A comprehensive sanitary survey of any new production site is initially required. This includes consideration of any environmental factors which could affect the water quality. The number and location of sample sites selected must enable effective evaluation of all point and non-point sources of sanitary pollution. A minimum of 15 water samples are required from each sample location to determine water quality of the site⁷⁶.

Sites are classified as Approved, Conditionally Approved, Restricted, Conditionally Restricted or Prohibited. Bivalves harvested from growing areas classified as Restricted, or Conditionally Restricted will require relaying or further processing prior to human consumption. Bivalves harvested from Conditionally Approved sites may be harvested for human consumption or require relaying/further processing depending on the conditions imposed.

Site classification assessments are based on the following:

- **Approved:** the median or geometric mean faecal coliform of the water does not exceed 14/100mL, and not more than 10% of the samples exceed a faecal coliform of 43/100mL. Evidence of potential pollution sources such as sewage overflows, direct

⁷³ CFIA, 2019. Canadian Shellfish Sanitation Program. <https://www.inspection.gc.ca/food-safety-for-industry/food-specific-requirements-and-guidance/fish/canadian-shellfish-sanitation-program/eng/1527251566006/1527251566942>

⁷⁴ Faecal coliforms are a specific subgroup of total coliform bacterial group. Collectively, these are relatively harmless microbes that live in the intestines of humans and other vertebrate animals aiding food digestion of food. The most common member of the faecal coliform subgroup is *E.coli*.

⁷⁵ Equivalence is evaluated by an examination of the sanitary and phytosanitary measures in use in each Party, which includes all relevant laws, decrees, regulations, requirements and procedures, including end-product criteria, processes and production methods, testing, inspection, and certification and approval procedures. In addition, equivalence is also evaluated by how each party implements their measures, often determined through onsite evaluations and audits.

⁷⁶ CSSP does not set out the timeframe for the collection of these samples.

sewage discharges, septic tank seepage is sufficient to exclude the growing waters from the Approved classification. This is considered equivalent to the EU standard of Class A. Notably, it is unlikely that any sites meeting these Canadian criteria exist in the UK due to the presence of sewage discharges such as Combined Sewer Overflows (CSOs).

- **Conditionally Approved:** These sites meet the Approved criteria for a predictable period although the site is subject to intermittent pollution caused, for example, by releases and/or discharges from wastewater systems, seasonal increases in the local population, boating activity and non-point source pollution such as rainfall events. The microbial water quality must meet the Approved status when harvesting and precautions must be taken to ensure that bivalves are not marketed when the site fails to meet the required classification standard. This designation is considered equivalent to the EU standard of Class A if product is harvested when the water quality meets the Approved status, potentially mirroring borderline A/B site in the UK.
- **Restricted:** Bivalves can only be harvested under license and must be treated prior to consumption, e.g. through depuration, natural relaying, container relaying or canning. The median or geometric mean faecal coliform of water must not exceed 88/100mL, and not more than 10% of the samples shall exceed 260/100mL. This designation is considered equivalent to the EU standard of Class B.
- **Conditionally Restricted:** The site meets the Restricted classification criteria for a predictable period, i.e. median or geometric mean faecal coliform of water must not exceed 88/100mL, and no more than 10% of the samples can exceed 260/100mL. This designation is considered equivalent to the EU standard of Class B or borderline B/C.
- **Prohibited:** No harvesting of bivalves other than for seed, spat, bait or scientific purposes. An area will be defined as Prohibited where it:
 - is within a minimum 300-metre radius of points of continuous or intermittent discharge from a sanitary sewer system;
 - is around points of continuous sanitary discharge which does not achieve adequate viral reduction through a combination of wastewater treatment and dilution in the production site;
 - is within a minimum 300-metre radius of industrial outfalls;
 - is within a minimum 125-metre radius of marinas or wharves;
 - may not be possible to adequately depurate or naturally purify the bivalves due to the degree of contamination in the growing waters (i.e., waters having excessive concentrations of fecal material or other contaminants).
- Offshore areas for harvesting may also be listed. Such locations are beyond 5km of land and are considered to be well removed from pollution sources and other sanitary concerns with a very low risk of becoming contaminated with faecal coliform bacteria. The sanitary quality of such areas used for direct shellfish harvesting may be more appropriately assessed by evaluating actual and potential pollution sources in the area, coupled with occasional bacteriological testing of the shellfish.

5.1.2 Ongoing monitoring

For Approved and Conditionally Approved areas, a minimum of five water quality samples for faecal coliform are required per year for non-remote areas. This is reduced to two samples per year for remote areas⁷⁷. For Conditionally Restricted areas, five samples per month are required during harvesting.

Canada uses the MPN test to determine the faecal coliform levels in water samples⁷⁸. All samples are collected by the relevant federal or provincial agencies overseeing implementation of the CSSP. All laboratories performing CSSP testing must be accredited to the international standard ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" by a recognized Canadian accrediting body.

5.1.3 Seasonal monitoring

Canada does not specifically designate seasonal sites, although production areas classified as conditionally approved or conditionally restricted may operate on a seasonal basis. Such production areas require a management plan which details the times and/or conditions under which harvesting can occur.

5.1.4 Long term stable sites

There is no provision for a long term stable site designation under the Canadian system.

5.1.5 Review of classification

The site classification is reviewed annually to ensure there have been no changes in the status of the water quality. In addition, every third year, a re-assessment survey is required which may include a complete re-evaluation of the classification if there has been a significant change in water quality and/or potential pollution sources in the area.

5.1.6 Handling of above threshold microbial results

The CSSP notes that it is imperative that shellfish areas affected by contamination are closed immediately until the shellfish can self-cleanse and are again safe for human consumption.

Where microbiological levels in water exceed CSSP requirements for the classification, the site will be temporarily closed. In order to re-open, the water quality requirements for the classification must be met as well as shellfish microbial criteria:

- Approved and Conditionally Approved sites: ≤ 230 faecal coliform/100g. Five bivalve samples are required for the test, with only 1 permitted to exceed 230 *E.coli*/100g and must be < 330 *E.coli*/100g. This recognises the variability of *E.coli* levels in bivalves across a site as well as taking account of variability in the test itself. With respect to Conditionally Approved sites with wastewater discharge or sewage systems, the samples for testing must not be collected until at least 7 days after the event has ceased.

⁷⁷ It is unlikely that any locations in the UK would qualify as remote.

⁷⁸ HPB Methods for the Microbiological Analysis of Foods (2002). Enumeration of Coliforms, Faecal Coliforms and of *E.coli* in Foods using the MPN Method. MFHPB-19. <https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/compendium-methods/methods-microbiological-analysis-foods-compendium-analytical-methods.html>

- Restricted or Conditionally Restricted sites: ≤ 2300 faecal coliform/100g. If bivalves are relayed for 14 days, no testing is required.

If samples are not collected, the sites remain closed for 21 days to mitigate the risk of contamination⁷⁹.

A Temporary Requirement for Quality Management Program (QMP) Controls may also be introduced. For example, in 2017 biweekly sampling of oyster flesh was introduced in British Columbia to address an outbreak of norovirus⁸⁰. The production areas were required to demonstrate that the *E.coli* levels in the oysters were $<230/100g$ in order to continue harvesting. These additional control measures remained in place for approximately 2 months⁸¹.

The CSSP includes a facility to proactively close production areas in relation to significant weather events where, for example, rainfall levels are likely to cause overflows of sewage treatment systems and/or pollution resulting from land surface runoff. The Meteorological Service of Canada issues rainfall warnings when heavy or prolonged rainfall is likely to cause local or widespread flooding or flash floods. ECCC monitors both these rainfall warnings and the actual reported rainfall measurements, and will make recommendations to close a production area based only on actual reported rainfall; i.e. the predicted rainfall does not influence closure of an area. However, mollusc producers are encouraged to monitor rainfall warnings in order to prepare for any potential closures through an adjustment of their harvesting plans.

There are no set criteria for triggering a rainfall-based closure. Instead, rainfall events will be assessed on a case-by-case basis taking into account both the volume of rainfall and the time frame of occurrence (e.g. 110mm of rain falling over 72 hours may not have the same impact as 90mm of rain falling over an 18-hour period) as well as the time of year (e.g. moderate rainfall may have a greater impact when it follows a prolonged dry period than heavy rain during the predominantly wet season). Additionally, it is recognised that heavy rainfall may pose different risks at different times (e.g. an agricultural area where manure or slurry has been spread in the spring will pose a higher risk than the same field in the winter). Rainfall closures remain in effect for a minimum of seven days. In order to reopen a site, the water quality requirements for the classification must be met and shellfish samples must meet the microbial criteria outlined above or the site will remain closed for 21 days.

5.1.7 Variation in relation to the UK approach

There are six key differences between the Canadian and UK approaches:

- The Canadian classification system uses faecal coliform thresholds to determine the water quality of production sites. Shellfish flesh tests are undertaken when a site has

⁷⁹ If the closure results from a norovirus outbreak, it will remain in effect for a minimum of 30 days and can only reopen when testing does not detect norovirus (5 samples). If no testing is undertaken, the site must remain closed for at least 60 days.

⁸⁰ <https://www.inspection.gc.ca/food-safety-for-industry/archived-food-guidance/fish-and-seafood/communiques/notice-to-industry-2017-03-07/eng/1488818068203/1488818068743>

⁸¹ <https://www.inspection.gc.ca/food-safety-for-industry/archived-food-guidance/fish-and-seafood/communiques/notice-to-industry-2017-05-11/eng/1494436545513/1494436546152>

been temporarily closed. In contrast, the UK measures *E.coli* levels in bivalve flesh for regular site monitoring.

- The Canadian system uses four classification types (Approved, Conditionally Approved, Restricted, or Conditionally Restricted) compared to the three used by the UK (Class, A, B or C) to identify sites where shellfish can be harvested. Shellfish from Approved and Conditionally Approved sites can go direct for human consumption similar to Class A production areas in the UK. The Conditionally Approved classification also appears to provide for equivalent A/B borderline sites in the UK.
- The Canadian system allows for the use of a median measure of the water quality standard⁸². Mathematically, the median is defined as the middle value in a sorted, ascending or descending list of values. In addition, only 10% of monitoring values may exceed the classification threshold, with no upper limit being stipulated. The median statistic combined with no upper threshold on the maximum allowable value provides a more permissive classification, particularly when there are occasional above threshold monitoring values⁸³.
- The Canadian system explicitly recognises offshore production sites as being >5km from the shore and assumes such locations will have high water quality. For such sites, the shellfish rather than the water quality is tested. Although the UK has one offshore site, situated between three and six miles (equivalent to 4.8 and 9.6km) from the coast, there is no defined or agreed approach for the designation and monitoring of such production sites. Within 1nm of the land, shellfish protected water areas⁸⁴ can be designated in the UK in order to protect and/or improve water quality for shellfish. Such designations are not applicable to waters beyond 1nm of the land, meaning there is a reduced level of protection for offshore production sites from pollution.
- Fewer samples are required to maintain the classification in Canada compared to UK (five and ten, respectively, for Class A equivalent sites).
- The Canadian system employs a proactive approach to site management and harvesting, using environmental triggers such as rainfall events to automatically close sites to reduce the risk of harvesting contaminated shellfish. If triggered, the production area remains closed for a minimum of seven days and only reopens once the water returns to classification standards. Additional monitoring for *E.coli* in shellfish may also be required prior to reopening. Such a proactive management approach is not utilised in the UK.

⁸² The geometric mean can also be used should the producer choose to do so.

⁸³ For example, using 2018 bathing water data collected near a UK class A mussel production site, the median calculation qualifies the site as conditionally approved. Using the geometric mean, however, the site would fail. The data consist of 20 points: MPN of 10 on 14 occasions, 27 on 3 occasions, plus an MPN recoding of 36, 100 and 560. The median value for the data set is 10 with 90% compliance (only 2 samples exceed 43MPN/100ml) which means the site is within thresholds. The geometric mean is 17MPN/100ml, i.e. >14MPN/100ml, and therefore the site is outwith the threshold using that statistic.

⁸⁴ Shellfish Water Protected Areas were originally designated through Council Directive 79/923/EEC on the quality required of shellfish waters, which was updated through EU Directive 2006/113/EC. These requirements have since been repealed through the Water Framework Directive (2000/60/EC). The Shellfish Protected Water Areas are now incorporated with river basin management plans.

5.1.8 Additional requirements for exports

Where bivalves are processed, treated, preserved, graded, packaged or labelled in Canada and sent or conveyed from one province to another or exported, the activities must be undertaken by a licenced operator.

Establishments exporting to the EU must appear on the appropriate list administered by DG SANTE, and all live products must come from an approved harvest area. It is up to the individual producers to apply for inclusion on this list. There are 740 Canadian sites listed which are all considered to have an equivalent status to class A. The harvest area must be indicated on the EU health certificate exactly as it appears on the list. Exporting organisations (i.e. the licenced operator) must have an export certification control plan (ECCP) to demonstrate with confidence that the products are acceptable to the EU market and will reach it successfully. A key part of the ECCP is the Preventive Control Plan (PCP). This is a written document that demonstrates how risks to food and food animals are identified and controlled.

As part of the PCP, licenced operators may also depurate bivalves. Depuration is expected to occur for a minimum of 44 hours, with daily verification that the water used has <2 total coliforms/100mL. The end product targets expected are:

- Oyster (*Crassostrea virginica*, *C.gigas*), Blue mussel (*Mytilus edulis*) and hard clam (*Mercenaria mercenaria*, *Protothaca staminea*, *Venerupis philippinarum*, *Nuttallia obscurata*): geometric mean 20 faecal coliforms/100g, upper 10% value 70 faecal coliforms/100g.
- Soft clam (*Mya arenaria*): geometric mean 50 faecal coliforms/100g, upper 10% value 130 faecal coliforms/100g.

5.2 New Zealand

The New Zealand shellfish classification and monitoring programme is implemented via the Animal Products (Regulated Control Scheme – Bivalve Molluscan Shellfish) Regulations 2006⁸⁵. The purpose of these regulations is to identify, monitor, evaluate and manage the risks associated with the commercial growing, harvesting, sorting and transporting of bivalves for human consumption. The monitoring programme adopts a flexible adaptive approach to management, taking the effect of known environmental triggers into account.

The Ministry for Primary Industries (MPI) is responsible for implementing the Regulatory requirements for bivalve production, with sites classified by the MPI Director-General or an Animal Product Officer (APO).

Establishments exporting to the EU must be in compliance with the New Zealand regulatory requirements and the product must meet Class A standards (i.e.<230 MPN/100g)⁸⁶. The New Zealand regime is focused on testing *E.coli* levels in both water and bivalve flesh, and has

⁸⁵ Animal Products (Regulated Control Scheme—Bivalve Molluscan Shellfish) Regulations 2006.

⁸⁶ http://www.legislation.govt.nz/regulation/public/2006/0038/latest/DLM369353.html?search=ts_regulation_bivalve_resel&sr=1

⁸⁶ <https://www.mpi.govt.nz/exporting/food/seafood/steps-to-exporting/>

been deemed equivalent to the EU requirements for site classification and monitoring purposes.

5.2.1 Initial site classification

The minimum sanitary survey requirements for bivalve production sites are rigorous. These surveys must be undertaken by an APO and must incorporate factors such as:

- the distance between each direct and indirect pollution source and the production site;
- the evaluation of all lake drains, ditches, streams, rivers and other watercourses in the catchment for potential effects on the production site;
- a house-to-house survey of septic tanks;
- the numbers, seasonality and location of resident and migratory wildlife and domestic animals;
- agricultural practices including the use of fertilisers, agrichemicals and animal waste treatment systems;
- the location of unfenced access to watercourses and the production sites;
- amount of rainfall and runoff over the last five-ten years including seasonal variation, frequency of significant rainfall events and the heaviest rainfalls in the last five years;
- volume and seasonality of river discharges;
- effects of ocean currents on production sites in bays, harbours and inlets; and
- a discussion of how actual and potential pollution sources may be influenced by environmental factors such as tides, rainfall and wind and the impact upon the water quality of the production site.

Following the sanitary survey, sites can be classified in one of six ways which determine the harvesting conditions and any treatment the bivalves require before human consumption⁸⁷: remote approved, approved, conditionally approved, restricted, conditionally restricted or limited. The commercial harvest of bivalves is prohibited from unclassified areas, although spat may be harvested for the purpose of relaying for on growing for a minimum of six months before harvest for human consumption.

- **Remote Approved** sites have no human habitation in the catchment, nor are they impacted by actual or potential pollution sources. The faecal coliform median of the water samples must not exceed 14/100ml, and the 90th percentile must not exceed 43/100ml; the *E.coli* median in shellfish must not exceed 230/100g and the 90th percentile must not exceed 700/100g. In order to determine the median values at least 15 samples are required⁸⁸. This is considered equivalent to the EU standard of Class A, although it is unlikely that sites in the UK would meet a remote classification status.
- **Approved** sites are suitable for harvesting bivalves for human consumption without the need for relay, depuration or post-harvest treatment. The area may be impacted

⁸⁷ Ministry for Primary Industries, 2018. Regulated Control Scheme - Bivalve Molluscan Shellfish for Human Consumption. <https://www.mpi.govt.nz/dmsdocument/30282/direct>

⁸⁸ The Regulation does not set out how frequently these samples should be collected, although there is a general expectation is that it will be biweekly or monthly during the period of the sanitary survey (C. Macleod pers comm).

by randomly occurring, intermittent events but is not impacted by discharges from sewage treatment facilities or combined sewerage overflows. The faecal coliform median of the water samples must not exceed 14/100ml and the 90th percentile must not exceed 43/100ml; the *E.coli* median in shellfish must not exceed 230/100g and the 90th percentile must not exceed 700/100g. In order to determine the median values at least 30 samples are required. This is considered equivalent to the EU standard of Class A, although it is unlikely that any sites in the UK would qualify as approved.

- **Restricted** sites may be subject to a limited degree of pollution, so harvested bivalves require relaying, depuration or post-harvest treatment. If the pollution is associated with sewage treatment facilities or combined sewerage overflows, the area may be classified as restricted only if the bivalves are subject to relay or other processing (and not merely to depuration). The faecal coliform median of the water samples must not exceed 88/100ml and the 90th percentile must not exceed 260/100ml; the *E.coli* median of the shellfish must not exceed 4,600/100g and the 90th percentile must not exceed 14,100/100g. In order to determine the median values at least 30 samples are required. This is considered equivalent to the EU standard of Class B.
- **Conditionally Approved** or **Conditionally Restricted** sites meet the criteria for classification as Approved or Restricted (as described above) during the harvesting period. The factors determining that period are known, predictable and not so complex as to prevent a reasonable management approach. The majority of UK sites would qualify as conditionally approved (i.e. Class A or borderline A/B) or conditionally restricted (Class B or borderline B/C).
- Bivalves can only be harvested from a Limited site when the final product is adductor muscle and/or roe.
- Prohibited zones include areas around major point source discharges, such as a sewage outfall with a minimum radius of 500m.

5.2.2 Ongoing monitoring

At least 5 water samples are required per year to maintain the site classification in Approved and Restricted areas. For Conditional areas, at least five shellfish samples are required in addition to the water samples, although for many locations monthly sampling will be required as part of the monitoring plan. In Remote Approved areas, the classification monitoring may be reduced to two water and two bivalve samples.

New Zealand uses a five-tube, three-dilution MPN test. Monitoring samples are collected either by the APO or by industry (where appropriate training has been undertaken). The samples must be analysed by a recognised laboratory as defined by the Animal Products Act 1999.

5.2.3 Seasonal monitoring

New Zealand does not specifically designate seasonal sites, although production areas classified as Conditionally Approved or Conditionally Restricted may operate on a seasonal basis. Such sites require a Conditional Area Management Plan, which determines when harvesting can occur and when the site will be closed in relation to, for example, specific environmental triggers such as rainfall or bird migrations.

5.2.4 Long term stable sites

There is no provision for a long term stable site designation under the New Zealand system.

5.2.5 Review of classification

A review of the site classification is undertaken annually using the last three years of data.

A sanitary survey of a growing area must also be conducted by an APO at least every 12 years following the initial sanitary survey, unless the Director-General grants an extension (which may be of no more than one year).

5.2.6 Handling of above threshold microbial results

Where microbiological levels in the water or shellfish exceed the classification requirements, the site will be temporarily closed. The APO for a site must be informed of any microbial monitoring result >14 MPN/100ml in seawater or >230 *E.coli*/100g in shellfish flesh within 1 hour of the analysis being performed. The APO may reopen the site as soon as the classification conditions for water quality and shellfish are met. However, where raw untreated sewage pollution is the cause of an emergency closure, the site must remain closed for at least 28 days.

Through the 'Conditional' classification, New Zealand uses a proactive approach to site management, closing production areas in response to particular environmental triggers that may influence water quality and lead to bivalve contamination. Examples of such triggers include seasonal bird migrations or rainfall events where a particular volume of rain is recorded within a defined timeframe.

The site management plan provides an estimated duration of such events and the time necessary to reduce the faecal coliform levels (in water and bivalves) to levels in line with those established by the sanitary survey. This may be explicitly defined as, for example, a specific number of days following a rainfall trigger event such as 50mm falling in 24 hour period.

5.2.7 Variation in relation to the UK approach

There are six key differences between the New Zealand and the UK approaches:

- The New Zealand monitoring system utilises a combination of water quality testing and bivalve testing whilst in the UK only shellfish testing is undertaken.
- The New Zealand system uses 5 classification types (Remote Approved, Approved, Restricted, Conditionally Approved, Conditionally Restricted and Limited) compared to the three used by the UK (Class, A, B or C). Shellfish from Remote Approved, Approved and Conditionally Approved sites can go direct for human consumption similar to Class A production areas in the UK. The Conditionally Approved classification also appears to provide for equivalent A/B borderline sites in the UK. Restricted and Conditionally Restricted sites are similar to Class B sites in the UK.
- Use of the median statistic rather than the geometric mean of the data, combined with there being no upper limit on the maximum water quality value allowed, provides a more permissive classification, particularly when there are occasional above threshold monitoring values at a site.

- Fewer samples are required to maintain the classification in New Zealand compared to UK (5 and 10, respectively, for Class A equivalent sites). However, many Conditionally Approved sites use monthly monitoring for both shellfish and water quality.
- The New Zealand system utilises a proactive approach to shellfish site management, with environmental triggers such as rainfall thresholds to reduce the risk of harvesting contaminated shellfish. If triggered, the production area remains closed for a specified period which is agreed as part of the management plan for the site. Such an approach is not utilized in the UK.

5.2.8 Additional requirements for exports

In order to export live bivalve molluscs to the EU, the shellfish must meet Class A standards (i.e. <230/100g flesh). The EU has listed 71 sites as being equivalent to Class A and a further 4 as Class B. New Zealand's export requirements note that bivalve molluscan shellfish are a high-risk product and must be sourced from the listed growing areas and processed for export in risk management programme (RMP) premises. Land-based wet storage and depuration of bivalve molluscs is considered to be primary processing and are approved as RMP premises. Depurated bivalves can be exported.

Given the importance of the export trade to New Zealand producers, businesses often undertake additional quality testing at their premises prior to export, so as to mitigate the risk of product being rejected at the border. Oyster producers typically monitor *E.coli* levels for every harvest. Greenshell mussel producers also end product test, with any sample >30 *E.coli*/100g being investigated.

If the producer is exporting live or raw product, they will have these results stipulated on their product. There is a strong relationship between processors and the Regulators in New Zealand, with both keeping the other informed of unusual microbial results, even if these do not actually exceed the threshold for classification.

5.3 USA

Until a decade ago, the USA was a key exporter of oysters to the EU. In 2010, however, the original equivalency agreement expired and trade ceased. This was in part due to concerns from the USA regarding public health issues associated with EU shellfish production sites that were in the vicinity of sewage treatment plants⁸⁹. Following the completion of separate equivalence assessments by both America and the EU, which included on-site audits to verify the other's systems, a finding of equivalence for the food safety control measures for molluscs was recommended. In 2018, an agreement was put in place for USA exports to resume from the States of Massachusetts and Washington⁹⁰ and, in 2020, a reciprocal arrangement was

⁸⁹ Blank, C., 2018. US EU propose resuming shellfish trade. <https://www.seafoodsource.com/news/supply-trade/us-eu-propose-resuming-shellfish-trade>

⁹⁰ Commission Implementing Decision (EU) 2018/1668. This was replaced by Commission Implementing Regulation (EU) 2019/626 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0626&from=en>

agreed with the Netherlands and Spain⁹¹. It is expected that in the coming years the equivalency determination will be expanded to include other US states and EU Member States.

The USA's shellfish monitoring programme is implemented via the National Shellfish Sanitation Program (NSSP⁹²). This programme establishes the minimum requirements necessary to protect consumer public health by assuring that shellfish are derived from safe sources and have not been contaminated during cultivation, harvesting, processing, shipping, or handling.

The programme has four components:

- To classify and monitor bivalve production sites based on potential pollution sources, water quality, and other factors that indicate suitability for harvest;
- To facilitate inspections to ensure the use of proper sanitary measures and adequate post harvest bacteriological control;
- To patrol closed or prohibited waters in order to deter illegal harvesting; and
- To conduct the laboratory testing and analysis of shellfish and water samples.

The US Food and Drug Administration (FDA), supported by the Interstate Shellfish Sanitation Conference (ISSC⁹³), is responsible for shellfish monitoring at the national level. These responsibilities are delegated to individual States, local shellfish control authorities or their designated agents to implement and enforce locally.

The American shellfish classification system is based on the regular sampling of total or faecal coliforms in water rather than on *E.coli* in shellfish flesh.

5.3.1 Initial site classification

A sanitary survey is required to evaluate the actual and potential pollution sources which may have a bearing on water quality of the production site. It is also required to survey the microbiological water quality, and evaluate the effect of any meteorological, hydrodynamic, and geographic characteristics that may affect the growing area. A minimum of 30 water quality samples are required in order to classify an area. This can be reduced to fifteen samples for remote locations where there are no pollution sources.

A production site can be classified using either a total coliform or a faecal coliform standard. Where laboratory findings demonstrate that the coliforms recovered from the site are not of direct faecal origin and do not indicate a public health hazard, the monitoring authority is not obliged to utilise a total coliform test. For the purposes of this review, only the faecal coliform thresholds are presented.

⁹¹ Food and Drug Administration Equivalence Determination Regarding Implementation by Spain and the Netherlands of the European Union System of Food Safety Control Measures for Raw Bivalve Molluscan Shellfish With Additional Controls <https://www.govinfo.gov/content/pkg/FR-2020-09-24/pdf/2020-20755.pdf>

⁹² FDA (2019) US National Shellfish Sanitation program (NSSP). Food and Drug Administration, U.S. Department of Health and Human Services, Washington, D.C. <https://www.fda.gov/food/federalstate-food-programs/national-shellfish-sanitation-program-nssp>

⁹³ The ISSC is a voluntary national organization of Federal and State regulatory officials and the shellfish industry that is engaged in the sanitary control of shellfish.

Following the sanitary survey, sites are classified as Approved, Conditionally Approved, Restricted, Conditionally Restricted or Prohibited. Bivalves harvested from growing areas classified as Restricted or Conditionally Restricted require relaying or canning.

- **Remote** Status (i.e. those where no human habitation or pollution sources affect the site) and **Approved** Status affected by point and non-point sources of pollution or adverse pollution events: faecal coliform median or geometric mean of the water samples must not exceed 14/100ml and the 90th percentile must not exceed 43/100ml for a five-tube decimal dilution test or 49/100ml for a three-tube decimal dilution test. In order to determine the median, geometric mean and 90th percentile values at least 15 samples for remote sites and 30 samples for Approved sites are required⁹⁴. This is considered equivalent to the EU standard of Class A, although it is unclear if any sites in the UK would meet a remote classification status.
- Offshore state waters greater than three nautical miles from shore will be classified as Approved.
- **Restricted** Status: faecal coliform median or geometric mean of the water samples must not exceed 88/100ml, and the 90th percentile must not exceed 260/100ml for a five-tube decimal dilution test or 300/100ml for a three-tube decimal dilution test. In order to determine the median, geometric mean and 90th percentile values at least 30 samples are required. This is considered equivalent to the EU standard of Class B.
- Sites classified as **Conditionally Approved** or **Conditionally Restricted**, require a management plan that is linked to predictable changes in microbiological water quality. Specifically, changes in the microbiological water quality are explicitly correlated with environmental conditions or other factors affecting the distribution of pollutants into the growing area. When open, these sites must meet the water quality microbial requirements for the Approved or Restricted classification, as appropriate. The majority of UK sites would potentially qualify as Conditionally Approved (i.e. Class A or borderline A/B) or Conditionally Restricted (Class B or borderline B/C).

5.3.2 Ongoing monitoring

Remote Approved sites require two water quality monitoring samples per year. At least six water samples are required per year to maintain the site classification in Approved and Restricted sites. For Conditional sites, monthly sampling is required where a waste water discharge system or combined sewer overflow is identified as a potential pollution source. If a monthly sample cannot be collected due to environmental constraints, collection of an additional water sample in the following month is considered acceptable.

The five-tube decimal dilution, three-tube decimal dilution and twelve tube single dilution versions of the MPN test are all permitted, with the threshold requirements varying in relation to the specific version of the test utilised. In addition, water samples may be analysed using the membrane-Thermotolerant *E.coli* (MF mTEC) test. All samples are collected by the designated officials.

⁹⁴ The NSSP does not set out how frequently these samples should be collected.

Experience with the microbiological analyses of shellfish and shellfish growing waters has indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. Therefore all laboratory analyses must be performed by a laboratory that meets the FDA Shellfish Laboratory Evaluation Officer (LEO) or FDA certified State Shellfish LEO requirements.

5.3.3 Seasonal monitoring

Remote production sites (i.e. those with no human habitation or pollution sources affecting the site) that have an Approved status may operate seasonally. The closure period must be clearly defined and at least one sample is required upon reopening the area.

Production sites classified as Conditionally Approved or Conditionally Restricted operate on a seasonal basis. The factors determining the harvesting conditions must be known and predictable, so as to enable a reasonable approach to management.

5.3.4 Long term stable sites

There is no provision for a long term stable site designation under NSSP.

5.3.5 Review of classification

A review of the site classification is undertaken annually using the last three years of data.

The sanitary survey is reviewed annually and re-evaluated on a triennial basis to ensure that the data are current and water quality conditions have remained unchanged. A new sanitary survey is required every twelve years.

5.3.6 Handling of above threshold microbial results

Where microbiological levels in the water or bivalves exceed the classification requirements, the site will be temporarily closed. Sites may reopen as soon as the classification conditions for water quality are met. However, where raw untreated sewage pollution is the cause of an emergency closure, the site must remain closed for at least 21 days. All samples are retained in the classification record.

A site management plan may be based on the effects of non-point sources of pollution such as rainfall events or storm water runoff. Such a plan will detail the criteria that must be met for the production area to remain open. Failure to meet these criteria will automatically place the area into a closed status. This management plan is based on the information gathered during the sanitary survey.

Sites that attract sufficient birds and/or mammals such that their waste poses a risk to human health are required to have an operational plan. Such a plan details the mitigation or deterrent measures to be used to minimise the potential pollution from birds and/or mammals.

5.3.7 Variation in relation to the UK approach

There are seven key differences between the USA and UK approaches:

- The American system uses four classification types (Approved, Conditionally Approved, Restricted, or Conditionally Restricted) compared to the three used by the UK (Class, A, B or C). Shellfish from Approved and Conditionally Approved sites can go direct for human consumption similar to Class A production areas in the UK. The

option of a Conditionally Approved status provides for sites that would likely fluctuate between Class A and B under the EU system.

- The American system explicitly recognises offshore production areas as being >3nm from the shore and classifies such sites as approved due to the expected high water quality. Although the UK has one offshore site, situated between three and six miles from the coast, there is no defined or agreed approach for the designation and monitoring of such production sites. Within 1nm of the land, shellfish protected water areas⁹⁵ can be designated in the UK in order to ensure and/or improve water quality for shellfish. Such designations are not applicable to waters beyond 1nm of the land, meaning there is a reduced level of regulatory protection for offshore production sites from pollution.
- The American system uses total or faecal coliform thresholds to measure water quality at bivalve production sites. No shellfish flesh testing is undertaken as part of the site classification monitoring. This is in contrast to the UK which measures *E.coli* levels in the shellfish.
- Use of the median statistic rather than the geometric mean of the data, combined with there being no upper limit on the maximum water quality value allowed, provides a more permissive classification, particularly when there are occasional above threshold monitoring values at a site.
- The USA uses a variety of tests (i.e. the five-tube decimal dilution, three-tube decimal dilution and twelve tube single dilution versions of the MPN test and the MF mTEC test) for determining the microbial water quality, each with their own thresholds for classification. England and Wales use the 5 tube x 4(or 5) dilution MPN test and Scotland uses the 5 tube x 3 dilution test.
- Fewer samples are required to maintain the classification in USA compared to UK (6 and 10, respectively, for Class A equivalent sites). However, Conditionally Approved sites use monthly monitoring, particularly where the presence of waste water discharges and combined sewer overflows may affect water quality. This is similar to UK requirements for Class A sites.
- The American system utilises a proactive approach for shellfish site management that takes account of environmental triggers (e.g. rainfall or the presence of birds and mammals) that may affect water quality. Such an approach is not utilized in the UK.

5.3.8 Additional requirements for exports

All shellfish products intended for export to the EU must be harvested by U.S. establishments that appear on the EU shellfish export list. Currently there are 175 sites listed, all within the States of Washington and Massachusetts, which may ship to Spain or the Netherlands. These listed sites are all considered to have an equivalent status to class A. Any establishment that processes bivalves for export to the EU must also be listed on the EU shellfish export list. All

⁹⁵ Shellfish Water Protected Areas were originally designated through Council Directive 79/923/EEC on the quality required of shellfish waters, which was updated through EU Directive 2006/113/EC. These requirements have since been repealed through the Water Framework Directive (2000/60/EC). The Shellfish Protected Water Areas are now incorporated with river basin management plans.

shipments must be accompanied by an export certificate issued by the National Oceanic and Atmospheric Administration (NOAA).

Dealers, i.e. persons certified to pack, ship or process shellfish (including depuration), are expected to monitor conditions and practices with sufficient frequency to ensure that the legal minimum requirements are met. All depuration lots must be treated for a minimum of 44 hours. The depuration water must be continuously treated with a disinfection system that produces seawater with no detectable coliform organisms and does not leave any unacceptable residue in the bivalves. For export purposes, dealers must ensure that bivalves are only obtained from a licensed harvester and come from Approved or Conditionally Approved areas with an open status.

5.4 Third Country Equivalence with the EU Shellfish Control Regulations and UK implementation

The case studies outlined above indicate that Canada, New Zealand and the USA all operate similar site classification systems. These are based on the regular sampling of total or faecal coliforms in water. New Zealand also incorporates the regular monitoring of *E.coli* in bivalve flesh, whilst Canada only requires shellfish testing in order to reopen sites following temporary closure. Although different in focus, the site monitoring regimes adopted by the three Third Country case studies has been deemed equivalent to the EU legislative requirements. Table 4 provides a comparative summary of the different approaches.

DG SANTE undertook audits of Canada in 2009, New Zealand in 2008 and USA in 2015 (Appendix 4). For all three case studies, these audits noted the control systems were substantially different from that prescribed by EU legislation, e.g. microbiological monitoring based on water rather than bivalve flesh testing. This approach was, however, deemed to provide an equivalent level of public health protection. The Third Country case study audits did not identify any issues with the sampling frequency and timeframe used to classify and subsequently monitor production sites. Two issues were identified:

- Canada was required to demonstrate that the test used to determine faecal coliforms in water was validated against the EU reference methods; and
- USA was required to introduce measures to ensure that the exact origin of exported bivalves could be identified.

The audit found no issues with the approach New Zealand has adopted for the official control measures of bivalve production sites.

The differences identified in these Third Country case studies provide examples of flexibility that the UK might consider adopting as part of a risk-based approach to site monitoring.

Table 6: Comparison of microbial testing for site classification implemented by the Third Country case studies with the EU requirements and UK implementation.

	Third Country case studies	EU Shellfish Control Regulations and UK implementation
Harvest for human consumption	Approved/Conditionally Approved	Class A
Water quality	Faecal coliform median or geometric mean <14/100ml and 90 percentile must not exceed 43/100ml. Minimum of 5 or 6 samples required per year.	No microbial requirements.
Shellfish quality	Canada: following a closure, 5 samples required, only 1 permitted to exceed 230 faecal coliform per 100g and must be <330 faecal coliform per 100g. New Zealand: minimum of 5 samples per year <230 <i>E.coli</i> /100g with 10% permitted to exceed 700 <i>E.coli</i> /100g. USA: No shellfish testing required.	Geometric mean ≤230 <i>E.coli</i> /100g. 80% of sample results must be less than or equal to 230 <i>E.coli</i> /100g and no results may exceed 700 <i>E.coli</i> /100g. Minimum of 10 samples required per year.
Harvest for relay, depuration or further processing	Restricted/Conditionally Restricted	Class B
Water quality	Faecal coliform median or geometric mean <88/100ml and 90 th percentile must not exceed 260/100ml. Minimum of 5 or 6 samples required per year.	No microbial requirements.
Shellfish quality	Canada: following a closure, 5 samples required ≤2300 faecal coliform/100g. If bivalves are relayed for 14 days, no testing is required. New Zealand: minimum of 5 samples per year. Median must not exceed 4,600/100g and the 90 th percentile must not exceed 14,100/100g. USA: No shellfish testing required.	90% of samples must be ≤4600 <i>E.coli</i> /100g, and all samples must be less than 46,000 <i>E.coli</i> /100g. Minimum of 8 samples required per year.

5.5 Summary of the variation in relation to the UK Implementation

Ten areas of variation between the Third Country case studies and the UK implementation of the shellfish control measures were identified. It may be assumed that these differences in application represent levels of flexibility that were considered acceptable by DG SANTE through the audits that have been undertaken.

5.5.1 Nomenclature

All three Third Country case studies use systems that have four classification types (Approved, Conditionally Approved, Restricted, or Conditionally Restricted) compared to the three used by the UK (Class, A, B or C) to identify sites where shellfish can be harvested. Shellfish from

Approved and Conditionally Approved sites can go direct for human consumption similar to Class A production areas in the UK. The Conditionally Approved classification also appears to provide for equivalent A/B borderline sites in the UK. The Restricted and Conditionally Restricted appear to be equivalent to Class B or borderline B/C sites.

5.5.2 Water quality testing

DG SANTE considers the approach taken by all three Third Country case studies to test water quality rather than shellfish flesh as being equivalent to EU Shellfish Control Regulation requirements. Notably New Zealand uses both water and shellfish flesh testing for its monitoring whilst Canada uses additional testing of shellfish flesh to reopen a temporarily closed site. The USA does not ordinarily undertake shellfish flesh tests.

The concentration of faecal coliforms, including *E.coli*, in water is correlated with the levels found in bivalves, with a bioaccumulation factor between 3 and 15 depending on the season and bivalve species⁹⁶. The option of moving to a monitoring regime focused on the assessment of *E.coli* levels in water instead of/as well as in shellfish for the purposes of site classification is already being used in some Italian production regions (e.g. Sardinia). This approach would align well with existing water monitoring assessments (such as the Environment Agency's bathing waters assessments)⁹⁷

5.5.2 Type of test

The USA permits the use of a variety of different MPN tests, each with their own stipulated classification thresholds. Several of these align with the MPN test approved under EU legislation. New Zealand and Canada both use the EU legislation approved MPN test.

5.5.3 Test thresholds

The classification thresholds utilised by the Third Country case studies all allow for the use of a median measure of the water quality standard⁹⁸. Mathematically, the median is defined as the middle value in a sorted, ascending or descending list of values. In addition, only 10% of monitoring values may exceed the classification threshold, with no upper limit being stipulated. The median statistic combined with no upper threshold on the maximum allowable value provides a more permissive approach to classification, when compared to the EU Shellfish Control Regulations, particularly when there are occasional above threshold monitoring values⁹⁹.

⁹⁶ Burkhardt & Calci, 2000. Selective accumulation may account for shellfish-associated viral illness. *Applied and Environmental Microbiology*, pp. 1375-1378; Mok et al., 2016. Bacteriological quality evaluation of seawater and oysters from the Hansan-Geojaman area in Korea, 2011–2013: impact of inland pollution sources. *SpringerPlus* 5 1412 DOI 10.1186/s40064-016-3049-9; Kim et al., 2017. Comparison of bioaccumulation and elimination of *Escherichia coli* and male-specific bacteriophages by ascidians and bivalves. *Environ Sci Pollut Res*, 24, 28268–28276;

⁹⁷ Between May and September (inclusive), weekly water quality assessments are undertaken which include measurements of *E.coli* and intestinal Enterococci. Based on the effects of rain, tide and wind on bathing water quality, the Environment Agency then make daily pollution risk forecasts. Annual ratings are used to classify each bathing water site as excellent, good, sufficient or poor based on measurements taken over a period of up to four years

⁹⁸ The geometric mean can also be used should the producer chose to do so.

⁹⁹ For example, using 2018 bathing water data collected near a UK class A mussel production site, the median calculation qualifies the site as conditionally approved. Using the geometric mean, however, the site would fail. The data consist of 20 points: MPN of 10 on 14 occasions, 27 on 3 occasions, plus an MPN recoding of 36, 100 and 560. The median value for the data set is 10 with 90% compliance (only 2 samples exceed 43MPN/100m) which means the site is within thresholds. The geometric mean is 17MPN/100ml, i.e. >14MPN/100ml, and therefore the site outwith the threshold using that statistic.

5.5.4 Variability in testing

Canada utilises shellfish testing in order to reopen a site after temporary closure. These tests require 5 bivalve samples, one of which is permitted to exceed 230 *E.coli*/100g and must be <330 *E.coli*/100g. This approach recognises the variability of *E.coli* levels in individual bivalves and across a site, as well as taking account of variability in the test itself. This enables an assessment of the veracity of the result and potentially provides greater business certainty.

5.5.4 Sanitary survey requirements

The sanitary survey requirements of the Third Country case studies are more detailed than those stipulated by the EU Shellfish Control Regulations. Those of New Zealand are the most stringent of the three case studies. For example, house to house surveys of septic tanks, consideration of agricultural practices including the use of fertilisers, agrichemicals and animal waste treatment systems, the location of unfenced access to watercourses and the production sites, the amount of rainfall and runoff over the last 5-10 years (including seasonal variation, frequency of significant rainfall events and the heaviest rainfalls in the last 5 years), as well as knowledge of the volume and seasonality of river discharges are all required components. This detail enables implementation of a proactive and adaptive approach to site monitoring and management. This level of detail is much greater than that currently required for the UK sanitary surveys but could, if adopted, enable a more flexible and proactive approach to site classification in the future.

5.5.6 Frequency of sampling

Once a production site has been established, all three Third Country case studies reduce the sampling frequency to bimonthly, with 5-6 samples required per year. However, in New Zealand and USA, monthly sampling is required for production sites that may be influenced by waste water treatment and CSOs, i.e. those classified as Conditionally Approved. These sites are equivalent to Class A or borderline A/B sites occurring in the UK where monthly monitoring is expected.

5.5.7 Environmental indicators

These case studies all adopt a proactive approach to site monitoring and management through the use of various environmental indicators. Where sites may be exposed to contamination from sewage and waste water systems including CSOs, management plans are required. These plans detail the environmental indicators of contamination and the actions that need to be taken if triggered, i.e. it details the times and/or conditions under which harvesting can occur. Environmental indicators are often determined during the detailed sanitary survey for the site and may include factors such as rainfall events, storm water runoff and agricultural activity in the catchment.

The management plan provides an estimated duration/magnitude of the event and the expected closure time necessary to reduce the contamination in water and bivalves to the classification thresholds. This may be explicitly defined as, for example, a specific number of days following a rainfall trigger of a particular magnitude or the application of slurry to fields in the catchment. Reopening of a site may also require shellfish flesh testing in addition to the standard water quality requirements.

Development of a risk based management approach for shellfish production which incorporates environmental triggers into the harvesting and monitoring regimes provides a more flexible and adaptive system of management. It would also increase public health protection by limiting harvesting to periods where the risk of contamination was low.

5.5.8 Explicit recognition of offshore sites and development of a specific monitoring approach

Of the three case studies, Canada and USA explicitly recognise offshore production sites as being those greater than 5km or 3nm, respectively, from the shore. In reality, these distances are similar. New Zealand also takes offshore production into account through their 'remote' designation. Such offshore/remote sites are expected to have good water quality and not to be impacted by pollution in the same way that those close to the shore are likely to be. The sanitary survey of these offshore/remote sites, however, is used to confirm whether the location is impacted by pollution, e.g. from large river systems which may affect microbial water quality.

The monitoring of these offshore sites may be different to those closer to the shore with, for example, a focus on less frequent consideration of shellfish flesh rather than water quality. There is no such provision for the treatment of offshore sites under the EU Shellfish Control Regulations and it is likely to be one of the barriers to the further expansion of offshore bivalve production¹⁰⁰.

5.5.9 End product testing and export

In order to successfully export product to the EU, additional shellfish flesh testing is also required for Third Countries at the point of export. This End Product Testing can take place after purification. This increases the likelihood that product is able to meet the Class A export requirement (<230 *E.coli*/100g¹⁰¹), meaning the product is safe for human consumption and will pass any testing imposed by border controls. In New Zealand, the aim is to reduce any microbial contamination to <30 *E.coli*/100g for mussels and oysters, whilst in Canada a target of 20 faecal coliforms/100g is used.

¹⁰⁰ Anon, 2016. Plan Stratégique National: Développement des aquacultures durables 2020. https://ec.europa.eu/fisheries/cfp/aquaculture/multiannual-national-plans_en; Anon, 2016. Summary of the 27 Multiannual National Aquaculture Plans. European Commission. https://ec.europa.eu/fisheries/cfp/aquaculture/multiannual-national-plans_en and Barillé et al., 2020. Biological, socio-economic, and administrative opportunities and challenges to moving aquaculture offshore for small French oyster-farming companies. Aquaculture, 521, 735045. Anon, 2016. Summary of the 27 Multiannual National Aquaculture Plans. European Commission. https://ec.europa.eu/fisheries/cfp/aquaculture/multiannual-national-plans_en and Barillé et al., 2020. Biological, socio-economic, and administrative opportunities and challenges to moving aquaculture offshore for small French oyster-farming companies. Aquaculture, 521, 735045.

¹⁰¹ EU Regulation 2073/2005 on microbiological criteria for foodstuffs.

Chapter 6: Conclusions

Water quality, in terms of the bacteria and viruses present, affects the incidence of microbial contamination (bacterial and viral) in shellfish. If shellfish is eaten raw or is only lightly cooked, some of these microbes can cause gastro-enteric illness in humans. These microbial contaminants are primarily derived from two key sources: human sewage and land-based activities (e.g. wildlife and livestock agriculture). The EU Shellfish Control Regulations manage these potential human health risks. This is achieved by regularly testing production areas (using *E.coli* as a proxy) and:

- classifying sites based on water quality (Class A to Class C sites);
- implementing a monitoring programme and response system when unusual results are detected (which can lead to a site being closed and its classification being downgraded); and
- requiring additional measures (such as depuration or heat treatment) before product from Class B or Class C sites can be sold to the public so as to reduce health risks.

6.1 Case for Review

This review of the Official Control Regulations was undertaken at the request of the SSWG to explore how measures in place to regulate the potential human health risks associated with bivalve production are implemented across different EU Member States¹⁰². Specifically this was in response to industry and local authority representatives on the SSWG keen to:

- Identify options to reduce downgrades and closures of shellfish production areas. A site's classification can affect business flexibility, operating costs, and even the ability to trade so operators are keen to achieve and maintain a high classification.
- Better understand how EU Member States deal with anomalous results. This has been a longstanding concern for SSWG members and was indeed the primary motivation for establishment of the SSWG given the impact that outlier results can have on site classification.
- Understand the impact of a regulatory system that is responsive, adaptive and ultimately risk-based on site classification and if such an approach would be compliant with the interpretation and application of EU regulations.

The assumption is that consistency should apply in how EU regulatory controls are implemented by each Member State. In the case of the EU's Shellfish Control Regulations guidance for Member States has been produced to enable this to happen. However despite the ambition for consistency, it was unclear if this occurs in practice. So while Member States must incorporate the rules in domestic legislation there is, almost inevitably, some variation in how the supporting guidance is interpreted. This occurs even within the UK where Food Standards Scotland applies a different interpretation to aspects of the guidance than the Food Standards Agency in England, Wales and Northern Ireland does. Scotland uses a different sample analysis methodology and has a process for shellfish operators to appeal site

¹⁰² This research project commenced when the UK was still a member of the EU and was required to implement EU Official Control Regulations. Since 1 January 2021 the UK is considered a Third Country for trading purposes.

classifications. The existence of such variation in the UK highlighted the potential for similar variability across EU Member States.

This was the driver for this research; to identify how the rules are being applied, if variability existed, if this variability could deliver 'quick win' changes to how the UK implements the regulations, and whether evidence of this variability could indicate the potential for the UK to adopt a more flexible, risk-based approach to regulating bivalve production.

Further the UKs changing relationship with the EU has meant that now that the EU Exit transition period has passed the UK can review how it wishes to satisfy EU requirements to minimise the risk that shellfish pose to human health. Options include retaining the status quo and continuing to fully adopt the existing EU regime or, and in line with the UKs ability to achieve regulatory autonomy, establish a bespoke regime that is then assessed for equivalence with the EU. This is not binary, and any decision to shift from the status quo would likely be evolutionary.

As such the review also considers how Third Countries meet the requirements to export live bivalve molluscs to the EU for human consumption. Core to this is the EU agreeing equivalence with Third Country regulatory regimes and limiting exports so that only product harvested from Class A waters or equivalent can be exported live to the EU, i.e. provided consignments comply with the 230 *E coli*/100g product standard.

Any change in approach must still meet public health requirements. While the different approaches across Member States and Third Countries have been assessed, the public health impacts of the variations observed have not been considered. The assumption has been that if these variations meet the EU regulatory requirements, or are deemed to have equivalence then the public health risk is in turn mitigated sufficiently.

6.2 Scope

This review compared and contrasted the application of the Shellfish Control Regulations between the UK, selected Member States and Third Countries through a series of case studies. The key findings of this research are summarised below. This has been challenging to research; hampered by language barriers, a lack of accessible official documentation, and anecdotal evidence that suggests that practices on the ground can in reality deviate even further from legislation and guidance. This can be seen in the UK where a provisional site classification can typically take up to 10 months even though the domestic rules suggest it can be done in three months. It was beyond the scope of this review to assess how local interpretation and actual practice might deviate from those guidelines. The reason for this was twofold; (1) reflecting the challenges involved in sourcing this information, and (2) because any changes to the UK application of regulations would need to withstand scrutiny by the EU so clear regulatory alignment is key¹⁰³.

¹⁰³ Subsequent discussions are progressing with industry representatives in Ireland, France and the Netherlands to explore this point further.

This final chapter condenses the findings of the review. It summarises the points of distinction and variability in how Member States apply the classification requirements, how they monitor sites and how they treat anomalous results. Using a similar framework the review has also explored how Third Countries satisfy the EUs import requirements.

The paper does not make recommendations. Rather its remit is to identify areas of variability that could point to the UK adopting a different approach and how such flexibility might benefit businesses while ensuring potential human health risk are managed. It does propose areas where further research and investigation could be beneficial to assess the implications and feasibility of applying such an approach in the UK. .

6.3 Summary of findings: EU Member States

The review focused on the practices across 9 EU Member States, Norway and the UK¹⁰⁴. The variation identified in the application of the legal requirements by Member States indicates that despite standard legislation and guidance, different approaches to regulating bivalve production are in operation. In some instances the variation is more restrictive than the UK (e.g. it takes 12 months to secure an initial site classification in France compared to potentially 3 months in the UK) but generally it is risk based in approach and more permissive.

6.3.1 Site classification and monitoring

Areas of variation in how the classification system is implemented can be summarised as:

- Fixed monthly **sampling** in the UK contrasts with more frequent sampling in other Member States, e.g. weekly in Denmark or every two weeks in the Netherlands. More frequent sampling comes at a cost and will tend to result in greater likelihood of identification of periods of poor water quality. However, this may have contrasting outcomes depending on how results are applied. Where there are fixed (e.g. annual) periodic reviews of area classifications, frequent sampling may contribute both to more frequent downgrades and to the area maintaining a lower classification, with less prospect of upgrading at future reviews. In contrast, where frequent sampling is used to inform rolling review of area classifications (as in Denmark – see below), high quality sites that experience periods of poor water quality are less likely to be constrained by a more restrictive classification and may have extended periods operating at a higher classification (e.g. A vs B). There are also clear public health benefits as harvesting could be aligned to lower risk periods.
- Sites with **long-term stability** can have reduced sampling frequency e.g. France and Ireland move to bimonthly after three years. This provides for greater levels of business certainty, particularly for Class A sites.
- While official samples are primarily collected in the UK by designated officials, some Member States **permit industry to routinely collect official samples** provided the necessary training has been provided and appropriate monitoring is in place. Such an arrangement provides for a more cost effective sampling regime and makes more regular sampling feasible, which in turn supports a more responsive management

¹⁰⁴ Norway is a member of the European Free Trade Association and therefore applies the EU Shellfish Control Regulations.

regime. It also means samples can continue to be collected even if designated officials are not available, as has been the case during 2020 because of Covid-19 restrictions.

- The EU permits **alternative sampling test methods**. Most countries use the Most Probable Number (MPN) methodology to measure *E. coli* levels in shellfish samples. UK industry concern about the MPN method has been around the variability of results, the potential for unexplained high results and the time taken to obtain results (more than 48 hours). A degree of variation is inherent in any test methodology. CEFAS has assessed that the MPN method is most reliable where low contamination is expected (i.e. shellfish from A class waters and post-depuration) but can generate more variable results where there are high levels of *E. coli* contamination. Two other methods have been validated by the EU which are used by EU Member States; some laboratories in France and Italy use the **impedance** method, while the **pour plate** method has been validated and used in the Netherlands. The impedance method can provide more rapid return of results (*circa* 12h) offering potential benefits in allowing more rapid handling of decisions around high values and closer to real-time testing of batches of product before despatch. Interim results from current work under the DASSHH¹⁰⁵ project indicate that pour plate methods may provide more consistent results where there are high levels of *E. coli* contamination, e.g. in shellfish from B/C class waters. This could be important where *E. coli* levels are close to the boundary between classifications and MPN test variability may affect the classification of the production site. The pour plate method has a lower detection level threshold of around 200 *E. coli*/100g, making it less suitable for monitoring A class areas.
- Denmark implements a **rolling classification system** which means that site classifications are reviewed on an ongoing weekly basis. The monitoring results obtained determine the site classification for the coming week. For example, if the sample indicates an A classification, the site will be classed A until the next weekly test. If the result is B, then the site will be classed as such until the subsequent test. To work effectively, this requires a rapid monitoring system with close cooperation between the regulators and industry, and with relatively stable site classifications. However the benefit of this more frequent sampling could enable those sites that fluctuate between Class A and Class B to tailor operations to times when they are known to be at the higher classification while ensuring a high level of public health assurance. The option to use rapid-turnaround impedance testing may also make this option more responsive and feasible. While the UK also implements a rolling classification system, it is not at the same frequency as the Danish system. This means that changes in classification are less responsive and do not allow for advance planning harvesting activity in response to the most recent monitoring results.

¹⁰⁵ The Developing an Assurance Scheme for Shellfish and Human Health (DASSHH) Project seeks to develop an innovative risk-based approach to enable the production of high-quality shellfish that fully meets consumer safety and regulatory requirements, while recognising the variable water quality environment in which most UK aquaculture production occurs. The project is being managed by Seafish on behalf of SSWG and have been contracted to Bangor University. Project outputs are expected December 2021.

- Certain Member States, (e.g. Sweden, Netherlands, Portugal and Italy) have implemented explicit risk based approaches which adjust site monitoring requirements to reflect the:
 - species being farmed, with more stringent measures applying to species that are eaten raw (oysters) versus those cooked before consumption (mussels);
 - environmental aspects of the site (e.g. tides, prevailing wind direction); and
 - time of year, which can see additional testing when the risk is likely to be greater, often in winter.

These approaches may also use other types of environmental and health monitoring indicators as a proxy to assess existence/absence of critical issues. Generally such an approach leads to increased monitoring during higher risk periods.

6.3.2 Handling of above threshold results

E.coli sample results above a site's classification thresholds can lead to the site being closed or a temporary classification downgrade being implemented. This review has highlighted that there is variation in how unusual results (i.e. results that are above threshold and uncharacteristic of a site) are handled and in how these results are deemed anomalous. This is important because where anomalous results can be discounted and removed from a site's classification record, there is no long term impact from having returned an outlier result. Evidence of variation across Member States can be summarised as:

- The Shellfish Control Regulations require that when sampling indicates that health standards are exceeded the site must be temporarily closed pending further investigation. The regulations also specify that the site may be **temporarily downgraded to a lower classification**, but this is not a requirement and Member States interpret this differently. In the UK, in addition to the site being closed, if the above threshold result is at a certain level it can lead to an automatic downgrade and the result is retained on the classification record unless the FSA is satisfied that there is sufficient justification to remove it. Although the regulations specify a temporary downgrade it can be a lengthy process to demonstrate that the original classification should be reinstated. This can create business implications that extend beyond a temporary dip in *E.coli* monitoring results. In contrast, some Member States take a different approach. For example, France only responds with a site closure while Sweden and Norway will consider downgrading but only after repeated occurrences of an above threshold result.
- When a site produces an 'above threshold' *E.coli* monitoring result, there is a requirement to implement more **rapid investigative sampling** to confirm the result and to understand what may be causing it. Every Member State featured in this review does this more quickly than the UK. This ranges from 48 hours in France to within one week in Italy, Spain, Ireland and the Netherlands. In contrast, the UK takes up to two weeks for an investigative sample to be taken, which can delay the assessment of the site and its ability to reopen for production.
- Reopening a site requires **two consecutive acceptable samples** taken at least seven days apart. However if other environmental test results are available, and if these are

within threshold, then only one 'within threshold' sample is required. Spain, Italy, Norway and the Netherlands all take this approach. France will consider other environmental test results but still require two samples within classification thresholds. These are, however, taken at 48 hour intervals (i.e. harvesting can resume within four days). In contrast, the UK minimum sampling period is seven days apart with guidance to Local Authorities suggesting a separation of up to two weeks. The speed of sampling can have an impact on how quickly a site can resume operation.

- High rainfall can lead to above threshold *E.coli* levels and the Shellfish Control Regulations contain a provision for high results during **intense rainfall events** to be considered anomalous. However, the UK is one of only two countries that, as standard, considers the impact of high rainfall on a sample result only if the rainfall event occurred in the 48 hours prior to the sample being taken. This is despite research indicating that the cumulative rainfall of the preceding seven days is more closely correlated to the levels of *E.coli* in bivalves. The implications of this are that results that could be considered anomalous by another Member State (and therefore discounted) are retained on a UK site record which could mean that the site is reclassified to a lower classification. This could put UK shellfish producers at a commercial disadvantage.
- The process for treating **above threshold results relative to the classification record** is also a point of variation. Within England, Wales and Northern Ireland an 'above threshold' sample result is automatically added to a site's classification record. In contrast EU member states, Norway and Scotland only add the result to the record once it has been confirmed via a subsequent sample. It is this second sample result that is added to record; the result can either confirm the above threshold result or it can indicate that the site is back within the classification threshold and therefore can reopen. Not automatically applying the higher result until it has been confirmed can have a positive influence on the overall classification assessment as it can contribute to a lower threshold level against which the site is monitored.
- The review has highlighted that some Member States adopt different approaches to how they **respond to anomalous results**. The scope of what might lead to an anomalous result includes weather events (as outlined above) or failure of sewage treatment works and slurry etc., provided the cause of the failure has been rectified or is not likely to occur again. The review identified that some Member States are more explicit in taking account of these factors. For example, Ireland formally acknowledges that these other activities (e.g. spreading slurry) can influence results and takes this into account before deciding if an above threshold result is added to a sites classification record or if it can be discounted. In the UK if there is a notified pollution incident that has been investigated then the subsequent report will be included in any investigation where an above threshold result is recorded. However, pollution incidents often only get notified (and therefore investigated) if there is an obvious, visible impact e.g. fish dying, numerous public complaints. So while these pollution incidents can impact shellfish test results, they may not always be officially recorded and therefore their influence on test results is also unknown. The UK also does not have an equivalent requirement for slurry application plans, as required in Ireland. While there is a UK code

of conduct which indicates that slurry should not be applied during rainfall periods, there is no way of recording what occurs in practice and the potential impact this may have on test results. In France, there is scope for “aberrant” high results to be excluded from the classification record, even if they cannot be explained by a clear cause or source.

- The review did not identify any Member State that has a formal process in place to address **laboratory or transcription errors**, even though there is evidence that such errors occur. It may be that some Member States have an informal appeals process (as in Scotland) or, the ability for rapid sampling and testing that occurs in other Member States ensures such errors are quickly uncovered and discounted.

6.4 Summary of findings: Third Countries

Given the UK's changing relationship with the EU the review also considered how Third Countries satisfy EU requirements for shellfish exports. There are currently nine Third Countries permitted to export live bivalve molluscs to the EU but only three of these are exporting with any degree of regularity; Canada, New Zealand and the US¹⁰⁶. The review found that while Third Country arrangements are different from the EU, they are deemed to provide an equivalent level of public health protection. The variation can be summarised as:

- A more **flexible classification system**. All three Third Countries have four classification levels, compared to three in the EU. This includes an equivalent classification to the EU's Class A (“Approved” sites) but there is also provision for a Conditionally Approved site, which recognises that some sites fluctuate between what the EU system would consider a Class A or Class B categorisation. Conditionally Approved sites can operate as Approved sites, except for periods when environmental indicators (such as rainfall, seasonal human population changes) predict increased risk of poor water quality, when harvesting may be restricted, or depuration required. This approach provides public health assurance because product can only be harvested when water quality is at optimal levels. However, it also permits greater business flexibility as shellfish operators would not be restricted to the requirements of a lower classification, particularly once water quality has improved. Initial comparisons indicate that some shellfish production areas in the UK that are on the A/B boundary could be compliant with, for example, Conditionally Approved status
- All three Third Country systems are based primarily on **testing E.coli levels in water** rather than in shellfish flesh, with the initial classification requiring establishment of predictive relationships between environmental factors and water quality. However, New Zealand also undertakes regular testing of shellfish flesh whilst Canada requires it to reopen areas after closures. The classification thresholds can be based on median values rather than means, and allow for 10% exceedance of maximum values. This provides a less stringent approach which allows for some variability in shellfish test results (see MPN testing above).
- Recognition that **offshore sites** (>3 miles from shore) are likely to be at lower risk from contamination which is reflected in the measures applied to regulate production. Under

¹⁰⁶ Since 2018 only two US states Massachusetts and Washington are permitted to export to the EU.

the Canadian system, offshore sites have no formal controls; rather there is regular testing of shellfish flesh to make sure it meets public health standards. Similarly, under the US system all offshore sites are classed as 'Approved' (i.e. equivalent to Class A). The NZ system also recognises that the contamination risk is reduced at offshore sites but does consider the impact that large river systems can have on the microbiological profile of offshore sites. The UK currently has only one offshore site which is managed in the same way as every other site. The potential to adopt a risk based approach to the management of offshore sites could also open up further development opportunities for the farmed shellfish sector.

- All three countries use **environmental indicators or triggers** to inform how best to manage public health risks. For example, proactive closure of production areas occurs when there are significant weather events where, for example, rainfall levels are likely to cause overflows of sewage treatment systems and/or pollution resulting from land surface runoff¹⁰⁷. In Canada, mollusc producers are encouraged to monitor rainfall warnings in order to prepare for any potential closures through an adjustment of their harvesting plans. The Third Country approaches also take account of whether the presence of birds and mammals may affect water quality.
- In contrast to the approach adopted in the UK, all three case studies apply more rigorous **spatial exclusion** requirements for shellfish production close to waste water discharges. For example under the Canadian system an area is defined as Prohibited if it is located within a minimum 300-metre radius of points of continuous or intermittent discharge from a sanitary sewer system.
- Approval to export to the EU, once equivalence has been secured, also requires shellfish production sites and processing facilities to be **listed as approved establishments**. Third Countries can revise their national list of approved establishments for the EU on an annual basis. At the Third Country national level, it is up to individual producers and processors to apply for inclusion on the EU approved lists, which requires the establishments to demonstrate they are meeting the necessary production and export conditions. This suggests there may be scope to implement a specific/bespoke approach to those operators seeking to export live bivalve molluscs to the EU.

6.5 Conclusion

This review has established that variation exists in the approach applied by EU Member States and that a bespoke approach that permits a degree of flexibility can still achieve equivalence with EU requirements. While further analysis is required this review does highlight areas for potential change within the UK system. These areas are described below in terms of (1) the

¹⁰⁷ The EMFF funded 'Developing an Assurance Scheme for Shellfish and Human Health' (DASSHH) project being lead by Seafish and contracted to University of Bangor and CEH aims to provide a better understanding of the potential for using environmental triggers in shellfish site management. <https://www.seafish.org/trade-and-regulation/regulation-in-aquaculture/developing-an-assurance-scheme-for-shellfish-and-human-health/>

UK remaining fully aligned with the EU, and (2) adopting a bespoke system and in turn achieving equivalence.

While this report does not make explicit recommendations on changes that should be made in how the UK implements shellfish classification requirements it does identify proposals for further review that could deliver a more equitable system (one that meets public health requirements while minimising regulatory burden) and recommends they are progressed by the SSWG.

As noted previously, the SSWG has also commissioned research to:

- Improve our understanding of the sources of microbial contamination and how uptake by shellfish varies with a range of potentially predictive environmental factors.
- Assess the risk implications associated with microbial contamination and determine if there are post-harvest measures that can be used to remedy or mitigate this risk so that product is safe for consumption.
- Develop a site orientated risk based management system.

It is likely that the findings of this research will also be relevant to some of the proposals listed below.

6.5.1 Continued alignment with the EU system

Although the UK has now left the EU and is operating as a Third Country, there are practical reasons for it to still adhere to the EU system that was in place prior to 1 January 2021. Establishing a new classification system is time consuming, and while this review is not solely focused on export trade it has become a priority focus at time of writing. Notwithstanding the current issues, timeframes to establish a new system and to secure equivalence with the EU could have a long-term implications on future trade arrangements.

The proposals below are already in place across EU Member States so would be expected to meet EU regulatory requirements. They also could provide greater flexibility, via a more responsive management regime, for borderline sites (those sites that can on occasion fluctuate between Class A/B) which is relevant given the current trading constraints.

- **Proposal 1:** Assess the impact of the application of different *E.coli* testing methods on classifications.
- **Proposal 2:** Permit the use of industry samples and for these samples to be considered as part of the official sample record, provided the appropriate standards are followed and the required training has been completed.
- **Proposal 3:** Amend domestic guidance such that if an above threshold result is detected the site should be closed, pending investigation rather than also applying a temporary downgrade to the sites classification.
- **Proposal 4:** Revise the investigative sampling process (approach and timeframe) to minimise the closure period and in line with 2 above, use industry samples as part of the investigative process.

- **Proposal 5:** Review the relationship between 'above threshold' sampling results and the classification record.
- **Proposal 6:** Consider the role that other environmental indicators might play in decisions to reopen a site.
- **Proposal 7:** Implement improved processes for establishing why an 'above threshold' result has been recorded. This would include increased investigations into what factors might be driving the high results (e.g. pollution events) and causal factors.
- **Proposal 8:** Establish criteria and a formal process for the assessment and determination of when above threshold results can be considered anomalous, and how they should be treated.
- **Proposal 9:** Consider aligning official sampling with actual harvesting periods to enable a regime where harvesting occurs during low/lower risk periods.
- **Proposal 10:** Extend the duration of a seasonal classification period based on real time sampling.
- **Proposal 11:** Consider options to shorten the rolling classification period (36 months to 12 months), provided sufficient samples are collected.
- **Proposal 12:** Adopt a risk-based approach that reflects the variable risk associated with different species; an approach based on how species are handled prior to consumption (e.g. oysters are eaten raw versus mussels which are usually cooked).

6.5.2 Implementing a Third Country approach

The review of Third Country arrangements has also identified approaches that could be better suited for the UK situation.

- **Proposal 13:** Explore options to consider a more flexible approach to the regulation of offshore aquaculture sites.
- **Proposal 14:** Use End Product Testing as an additional risk assurance tool, particularly for exported product.
- **Proposal 15:** Adopt a classification system that provides explicitly for sites that have a borderline status (e.g. conditionally approved) alongside a robust monitoring and sampling regime.

It is clear from this review that shellfish water classification is a complex issue, one that requires careful balancing of the public health risks alongside the need for increased transparency and business certainty. The EU Official Control Regulations and the supporting guidance provide a framework that should enable this to happen.

In 2018, the European Parliament noted that the sustainable growth of aquaculture needed to be based on business investment predictability and legal certainty. While the requirement to produce food that is safe is paramount, there is also a requirement to ensure there is a tailored and proportionate approach to regulating businesses such that any restrictions (such as

closure or additional costs of production) are appropriate and reflect the likelihood of risk, so that the costs of regulation are no more than they need to be.

While the UK is no longer part of the EU, the decision to remain aligned with the EU regulatory system would suggest that there is a shared desire to provide an environment that permits the sustainable growth of aquaculture. The case studies presented in this report also suggest that it is possible to strike the right balance and to deliver a modern, risk-based, proportionate, robust and resilient food safety system that enables shellfish production.

Appendix 1: Summary of Audits relating to the microbial aspects of the Shellfish Control Regulations.

Country (audit number)	Audit findings	Audit Recommendations
France (DG (SANCO) 2011-8882)	<ul style="list-style-type: none"> The monitoring of microbiological quality of the production areas is consistent with EU legislation. The use of a threshold (1 000 <i>E. coli</i>/100 g) for <i>E. coli</i> counts in Class A areas exceeds the threshold defined in EU rules (230 <i>E. coli</i>/100 g); If the results of regular monitoring are a Class A area between 230 and 1 000 <i>E. coli</i>/100 g of IFL, no management measures are taken by the CA to ensure full compliance with regulatory health standards applicable to LBM placed on the market. If the second result after a Level 1 alert indicates that there is no contamination, no management measures are taken by the CA to ensure that regulatory requirements applicable to purification systems are fully met during the time elapsing between the first and the second result. In the event of a Level 2 alert, when it is decided to close a production area, no preventive measures are taken by the CA in FBO that use water taken from Class B areas to cleanse their LBM to ensure that regulatory requirements applicable to the purification systems are fully respected while the area is closed. 	<ul style="list-style-type: none"> The CA should ensure that the microbiological criteria for classification of production areas are brought into line with those prescribed in the Regulations. The CA should ensure that the criteria for classification of live bivalve mollusc production areas comply fully with the Regulations. The CA should ensure that live bivalve molluscs from production areas classified as Class A and placed on the market meet the microbial health standards required. The CA should ensure that laboratories involved in official controls of live bivalve molluscs respect the number of individuals per sample for counting <i>E.coli</i> using the EU reference method.
Ireland (DG (SANCO) 2011-6007 and 2013-6674)	<ul style="list-style-type: none"> The monitoring of microbiological quality of the production areas is consistent with EU legislation; Requirements for sanitary surveys and sampling programmes for newly classified areas are met but some issues with sanitary surveys are not conducted where classification status or boundaries of existing areas is subject to change. The procedures implemented for preliminary and seasonal classification of production areas are in line with the guidance. The current geographical distribution of the sampling points for microbiological monitoring of classified production areas cannot ensure that the results of the analyses are as representative as possible for the areas considered. Although changes have been made in order to reduce the tolerance level for <i>E. coli</i> for classification of A areas, the standard applied is not yet in line with the regulations (i.e. 230 <i>E. coli</i>/100 g). Some non-compliance with regard to closure of Class A sites due to high <i>E.coli</i> 	<ul style="list-style-type: none"> CAs should ensure compliance with the health standards when classifying and maintaining the classification of class A production areas. CAs should ensure that the requirements for sanitary surveys are taken into account during reclassification of areas and that the geographical distribution of the sampling points gives assurance that the results of the analysis are as representative as possible. CAs should ensure that samples for monitoring of classified production areas are taken at the designated samplings points CAs should ensure that the live bivalve mollusc health standards for microbiological contamination are met and that if exceeded the molluscs are not placed on the market.

Country (audit number)	Audit findings	Audit Recommendations
	<p>results. Sites were not closed until a high result is confirmed. This means adequate management of live bivalve molluscs produced in these Class A production areas following results above the prescribed limit was not undertaken.</p> <ul style="list-style-type: none"> • Classification of production areas can be undermined where some laboratories carrying out official analyses do not use the EU reference method (ISO TS 16649-3). 	
Netherlands (DG (SANCO) 2012-6468)	<ul style="list-style-type: none"> • The monitoring of microbiological quality of the production areas is consistent with EU legislation; • No monitoring of the classified production areas from which harvesting has been forbidden or subjected to special conditions is undertaken. 	<ul style="list-style-type: none"> • The CA should ensure the monitoring of classified areas from which harvesting has been forbidden or subjected to special conditions, to ensure that products harmful to human health are not placed on the market.
Spain (DG (SANCO) 2011-8881 and 2015-7659)	<ul style="list-style-type: none"> • Official controls are carried out on a risk basis, with appropriate frequency and in accordance with documented procedures. • The control system implemented in Galicia, which produces 96% of the national production of bivalve molluscs, is in compliance with EU legislation. • In Galicia, decisions after monitoring are taken in accordance with EU legislation. 	<ul style="list-style-type: none"> • There were no recommendations made in relation to the microbial shellfish monitoring requirements for the Galician region.
Italy (DG (SANCO) 2012-6542)	<ul style="list-style-type: none"> • The requirements for sanitary surveys and sampling programmes for newly classified production areas or reclassification of production areas are not met. • The frequency of monitoring of the microbiological quality of live bivalve molluscs is not always carried out according to that established in the regional guidelines. • In the classification of some production areas in the light of the results obtained during monitoring for faecal contamination are not properly carried out. • The geographical distribution of sampling points and the sampling methods used for the monitoring of microbiological quality of live bivalve molluscs do not ensure that results of the analyses are representative of the areas concerned. • The requirements of EU legislation for classification of class A production areas regarding health standards for microbiological contamination are not respected. • When non-compliances were related to the presence of <i>E. coli</i> exceeding class A or B thresholds production areas are not closed. 	<ul style="list-style-type: none"> • CA should ensure that official controls of live bivalve molluscs are properly implemented by the regional CAs in all Italian regions. • CAs should ensure that the requirements regarding sanitary surveys are taken into account in newly classified areas and when necessary for reclassification of areas. • CAs should ensure that, when classifying a production area, the geographical distribution of the sampling points and the sampling frequency ensure that the results of the analysis are as representative as possible for the area concerned. • CAs should ensure that the live bivalve mollusc health standards for microbiological contamination are met and that if exceeded the molluscs are not placed on the market.
Portugal (DG (SANCO) 2013-6667 and 2020-7119)	<ul style="list-style-type: none"> • Coordination between all the CAs involved in official controls of bivalve molluscs could be improved. • Location and boundaries of classified production areas are not adequately fixed 	<ul style="list-style-type: none"> • Ensure efficient and effective coordination between all the competent authorities involved in the official controls of bivalve molluscs. • Comply with the requirements regarding the boundaries of classified

Country (audit number)	Audit findings	Audit Recommendations
	<ul style="list-style-type: none"> Requirements of EU legislation for classification of production areas regarding health standards for microbiological contamination are not respected Not all classified production areas are regularly monitored for microbiological quality. The current sampling frequency and geographical distribution of the sampling points for monitoring of classified production areas cannot ensure that the results of the analyses are as representative as possible for the areas. Monitoring of classified production areas for microbiological contamination can be undermined as the official laboratory carrying out official analyses for 43% of the classified production areas is not accredited. The likely variation in faecal contamination in different species of molluscs and parameters related to pollution were not taken into account for the monitoring of microbiological quality. The placing of bivalve molluscs on the market that are a tangible risk for public health demonstrates an ineffective system for monitoring classified production areas and/or for taking adequate decisions after this monitoring. Decisions after monitoring where the results of sampling showed that the health standards for molluscs were exceeded are not taken when microbiological contamination exceeds the relevant criteria. <p>From 2020</p> <ul style="list-style-type: none"> The classification of production areas is consistent with the EU classification requirements and supported by recommendations from sanitary surveys. The provisional classification based on a reduced number of results may overestimate the microbiological quality of mollusc. The procedure does not foresee the closure or reclassification of production areas when health standards for live bivalve molluscs are not met. A downgrade in classification when results are exceeded is reverted following two good results within the expected limits. The procedure for sampling of classified production areas by non-official staff must be formalised to ensure that samples taken in the context of official monitoring are reliable. The results of microbiological analysis using non-accredited testing methods are 	<p>production areas, and compliance with the health standards.</p> <ul style="list-style-type: none"> Comply with requirements regarding the monitoring of all classified production areas and the geographical distribution of sampling points and the sampling frequencies. Ensure that sampling plans to check the microbiological quality of live bivalve molluscs take particular account of the likely variation in faecal contamination. Ensure that molluscs are continuously purified for a period sufficient to achieve compliance with microbiological criteria and that molluscs from class "C" production areas are relayed over a long period or undergo treatment to eliminate pathogenic micro-organisms. Ensure that decisions after monitoring are taken as required and that the decisions taken are in line with the requirements. Ensure that only laboratories that are accredited in accordance with specified European standards are designated to carry out the analyses of samples taken during official controls. <p>From 2020:</p> <ul style="list-style-type: none"> Ensure that the classification of production areas, the monitoring of production areas for microbiological quality and the decisions taken are carried out as required. To ensure that the training and supervision of non-official samplers when sampling classified production areas for monitoring. To ensure that analytical method used for classification and for microbiological monitoring of production areas provides reliable analytical results.

Country (audit number)	Audit findings	Audit Recommendations
	<p>not reliable and thus they generate the risk of misclassification of the areas. This only effects 2 of the 39 classified production areas.</p> <ul style="list-style-type: none"> The CA does not close or reclassify the production area when certain regulatory limits for microbiological quality are exceeded; reverts the classification downgrade without an evaluation of the results for the review period; excludes unexpected results without conclusive investigation. This may result in the placing on the market of bivalve molluscs that exceed the health standards. 	
Germany (DG (SANCO) 2013-6668)	<ul style="list-style-type: none"> For Schleswig-Holstein, the geographical distribution of sampling points and the frequency do not ensure that the results of the analyses are as representative as possible for the area. No such issues were identified for Lower Saxony. Appropriate decisions are taken to prevent the harvesting of bivalve molluscs when monitoring sample results show that maximum limits for <i>E.coli</i> have been exceeded. Bivalve molluscs are placed on the market in line with EU requirements. Both Lower Saxony and Schleswig-Holstein have well organised and documented systems for official control of live bivalve molluscs, including the classification and monitoring of production areas, laboratory testing and decisions after monitoring. 	<ul style="list-style-type: none"> Ensure that classification of production areas are conducted as required and that the sampling programme established for the classification of bivalve mollusc production areas guarantees that the geographical distribution of the sampling points and the frequency ensure that the results of the analyses are as representative as possible for the area considered. Ensure that the microbiological monitoring of production areas is carried out as required. Ensure that monitoring of classified production areas from which harvesting of bivalve molluscs is forbidden or subjected harvesting to special conditions, is carried out.
Sweden (DG(SANCO) 2012-6545)	<ul style="list-style-type: none"> Official controls are carried out on a risk basis, with an appropriate frequency and in accordance with documented procedures. The system in place for classifying production areas, based on the microbiological quality of live bivalve molluscs, does not take into account all EU requirements. Monitoring of the microbiological quality of live bivalve molluscs when production areas are open for harvest, is in line with EU requirements. 	<ul style="list-style-type: none"> Ensure that sanitary surveys are conducted in newly classified areas. Ensure that the sampling programme established for the classification of live bivalve production areas guarantee that the geographical distribution of the sampling. Points and the frequency ensure that the results of the analyses are as representative as possible for the area. Ensure that decisions after monitoring of microbiological quality of live bivalve molluscs adhere to the regulations.
Denmark (DG (SANCO) 2012-6516)	<ul style="list-style-type: none"> Production areas are classified/reclassified without sanitary surveys. Decisions are made based on inadequate monitoring data from sampling points that are not fixed and the compliance criteria used for classes A and C do not comply with EU requirements. No monitoring (i.e. testing) is undertaken in areas which are not open for harvesting. 	<ul style="list-style-type: none"> Ensure that sanitary surveys are conducted in classified areas. Ensure that the sampling programme established for the classification of live bivalve mollusc production areas guarantees that the geographical distribution of the sampling points and that the frequency guarantees that the results of the analyses are as representative as possible for the area.

Country (audit number)	Audit findings	Audit Recommendations
	<ul style="list-style-type: none"> The microbiological monitoring cannot be considered as meeting EU requirements in that the sampling plan is not based on the outcome of a sanitary survey for areas where the classification has changed or where a class A zone is opened within an class B area. Monitoring is not conducted at fixed sampling points and the frequency of monitoring is also not in compliance with EU requirements. Decisions after monitoring were found to be taken quickly and were well documented and in line with national and EU legislation. 	<ul style="list-style-type: none"> Ensure that when taking into account the results of sampling undertaken by a food business operator or its representative (with a view to classifying, opening or closing an area), the sampling and analysis have taken place in accordance with the protocol agreed between the CA and the food business operator. Ensure that only laboratories that are accredited in accordance with specified European standards are designated to carry out the analyses of samples taken during official controls.
UK (DG (SANCO) 2012-6469	<ul style="list-style-type: none"> The UK has official control systems for bivalve molluscs and their production and placing on the market which respects the requirements. The evaluation of the microbiological quality of live bivalve molluscs production areas is compliant with EU legislation. The monitoring of production areas is carried out at regular intervals. Some issues were identified with the classification of class B production areas and the geographical distribution of sampling points. Decisions after monitoring are largely compliant with EU legislation. However, the information flow is not always recorded and in a few cases the follow-up of investigation states was not completed. The additional monitoring requirements for bivalve molluscs, namely end-product testing, are not fully carried out and thus cannot be considered compliant with EU requirement. Food business operator's own-checks to decide on classification, opening or closure of production areas are not used in the UK. 	<ul style="list-style-type: none"> CAs should ensure that, when classifying a production area, the geographical distribution of the sampling points ensures that the results of the analysis are as representative as possible for the area concerned. CAs should ensure that for Class B sites, live bivalve molluscs must not exceed, in 90 % of the samples, 4,600 <i>E.coli</i> per 100 g flesh and that the remaining 10 % of samples must not exceed 46,000 <i>E.coli</i> per 100 g flesh. CAs should ensure that decisions taken after monitoring follow the requirements. Where alternative risk management measures are implemented by the CAs, ensure that bivalve molluscs are not placed on the market if they do not meet the required health standards.
Norway (EFTA Surveillance Authority assessment, April 2015; case no: 76409; Document no: 762088)	<ul style="list-style-type: none"> Limited progress since 2009 in implementing the legal requirements for harvesting and placing on the market of live bivalve molluscs. Harvesting areas have not been classified in accordance with legal requirements and sanitary surveys are not done or not done according to requirements. Monitoring cannot be considered as fully in compliant and appropriate decisions after monitoring are not always ensured. 	<ul style="list-style-type: none"> Ensure that production areas are classified in line with requirements. Ensure that the sampling frequency and geographical distribution of sampling points in classified production areas complies. Ensure that staff in charge of official controls receive appropriate training. Ensure that the decisions taken after monitoring, related to microbiological quality and biotoxins in live bivalve molluscs are legally compliant.

Appendix 2: Comparison of the production site classification monitoring implemented by different Member States

Country	Provisional classification sampling	Monitoring of classified areas	Monitoring in long term stable production sites	Classification reviews
EU Implementing Regulation 2019/627	<p>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.</p> <p>Competent authorities shall periodically monitor classified production sites to ensure they meet the required health standards.</p>			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 instituted.	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 monthly sampling for remainder of year.	10 monthly samples for A sites and 8 for B and C sites. No changes to classification throughout the year.	No change in monitoring requirements.	3 years of data, reviewed annually to determine site classification for the coming 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 (bi-monthly) 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	After 3 years, bimonthly sampling can be initiated, although a minimum of 8 samples per year are required.	Every three years.

Country	Provisional classification sampling	Monitoring of classified areas	Monitoring in long term stable production sites	Classification reviews
		monthly but additional sampling in conjunction with adverse events will be required.		
Portugal	Bi-weekly for first 3 years.	Monthly, increases to fortnightly if indication of biotoxins presence.	Monthly	Every 3 years.
Germany	12 samples over at least 6 months.	Monthly, with a minimum of 8 per year once established.	After 3 years, bi-monthly, 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, every 4 weeks in class A, 13 weeks in class B and 26 weeks in class C.	Ongoing through year on a weekly basis. For permanent sites, rolling assessments occur every 4 weeks in class A, 13 weeks in class B and 26 weeks in class C.
Norway	3 samples at 14 day intervals.	Monthly, with a minimum of 6 per year once established.	No change in monitoring requirements.	Annual.

Appendix 3: Comparison of the current approaches adopted by Member States for handling high and anomalous *E.coli* results.

The following table outlines the approaches adopted by different Member States when a high and anomalous *E.coli* monitoring sample is recorded. The national legislation and guidance available, however, is rarely explicit on how high and anomalous results are identified and disregarded.

Country	High and anomalous <i>E.coli</i> results
EU Implementing Regulation 2019/627	<p><u>Class A areas:</u> on the basis of a risk assessment an anomalous result exceeding the level of 700 <i>E. coli</i> per 100 g of flesh and intravalvular liquid maybe disregarded.</p> <p><u>Class B areas:</u> 90 % of the samples <4 600 <i>E. coli</i> per 100 g of flesh and intravalvular liquid with remaining 10 % of samples <46 000 <i>E. coli</i> per 100 g of flesh and intravalvular liquid.</p> <p><u>Class C areas:</u> all samples <46 000 <i>E. coli</i> per 100 g of flesh and intravalvular liquid.</p>
EU Good Practice Guidance (including Technical Application document)	<p>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.</p> <p>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).</p> <p>A minimum of 48 hours is required for resampling, with at least weekly sampling is recommended for investigative monitoring.</p>
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 cannot be considered an anomaly and is retained.
France	<p><u>Class A:</u> If sample >230 <i>E.coli</i>/100g flesh, repeat sampling is undertaken with 48 hours. If <230 <i>E.coli</i>/100g, no further action taken. If the sample is >230 but <700 <i>E.coli</i>/100g flesh, weekly sampling instigated until 2 consecutive results <230 <i>E.coli</i>/100g flesh are obtained, usually one week apart. However, if the resample is within classification, the second sample can be taken 48 hours later.</p> <p><u>Class B and C:</u> 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.</p> <p>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.</p>
Ireland	<p>Alerts triggered: A class - >700 <i>E. coli</i>/100g flesh, B class - >18,000 <i>E. coli</i>/100g flesh and C class - >46,000 <i>E. coli</i>/100g flesh.</p> <p>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.</p>
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.

Country	High and anomalous <i>E.coli</i> results
Spain	<p>Where an <i>E.coli</i> result exceeds the classification threshold, sampling will be increased to weekly until sample results return to normality.</p> <p>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).</p>
Italy	<p>If sample exceed classification threshold, a repeat sample is taken within one week. No further action will be taken if resample with within classification.</p> <p>An abnormal result that exceeds the level of 700 <i>E.coli</i> 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.</p>
Germany	<p>If class A thresholds exceeded, the site will be closed or downgraded to B. If class B or C, <i>E.coli</i> 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.</p>
Denmark	<p>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.</p> <p>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.</p>
Norway	<p>Sites temporarily closed. A resample is required within 14 days. If this is within the classification threshold, harvesting can resume.</p>

Appendix 4: Summary of Third Country Audits and comparison to the EU Shellfish Control Regulations.

Country (audit number)	Audit findings	Audit Recommendations
Canada (DG SANCO 2009-8036)	<ul style="list-style-type: none"> The official control system covers the whole bivalve production chain and is adequately implemented in accordance with the established procedures. The system differs from Community requirements with regard to site classification and monitoring (water quality vs shellfish meat testing). The detection methods for <i>E.coli</i> are not in accordance with (or validated against) the Community reference methods. 	<ul style="list-style-type: none"> Although Canada uses a 5x3 version of the MPN test it is not the same as the ISO standard test used by EU. The microbial detection methods used should be in accordance with (or validated against) the Community reference detection methods to guarantee that bivalves meet the microbiological standards.
New Zealand (DG SANCO 2008-767 and 9237/2003)	<ul style="list-style-type: none"> The official controls system for bivalve molluscs is well structured and documented, providing equivalent guarantees to those required by the relevant Community legislation. The supervision of the production areas is well organised and the laboratories performing the official tests provide reliable results. The commitment of the producers to deliver safe bivalves is very high and collaboration of the CA very strong. 	<ul style="list-style-type: none"> There were no recommendations made in relation to the shellfish site classification and microbial monitoring requirements.
USA (DG SANTE 2015-7486)	<ul style="list-style-type: none"> The USA has a sophisticated and well documented system for the official controls of live bivalve molluscs. This control system is substantially different from that prescribed by EU legislation, e.g. microbiological monitoring is based on water testing. The relative lack of faecal pollution associated illnesses suggests the system is adequately protective of public health. NSSP is well implemented and the FDA can guarantee that bivalve molluscs are harvested only when it is permitted. 	<ul style="list-style-type: none"> CA to ensure that a system of identification of bivalve batches harvested from the production areas is developed and implemented to provide full guarantees with regard to the exact origin and that only bivalve molluscs from approved areas are exported to EU. CA should ensure that all laboratories involved in official testing participate regularly in relevant proficiency tests.

Appendix 5: Shellfish Stakeholders Working Group (SSWG) Member Organisations

Shellfish Association of Great Britain (chair)
Seafish (secretariat)
Food Standards Agency
Environment Agency
Centre for Environment, Fisheries and Aquaculture Science (CEFAS)
Agri-Food and Biosciences Institute (AFBI-NI)
Cornwall Port Health
Teignbridge Local Authority
Bournemouth Christchurch and Poole Council Port Health
Isle of Anglesey County Council
Bangor Mussel Producers Ltd
Rock Shellfish Ltd
Offshore Shellfish Ltd
Othniel Oysters Ltd
Bangor University
Centre for Ecology and Hydrology (CEH)

For more information please contact:

Eunice Pinn
Marine Environment Regulation Advisor

E: eunice.pinn@seafish.co.uk

Seafish
18 Logie Mill
Logie Green Road
Edinburgh
EH7 4HS

www.seafish.org

Here to give the UK seafood sector
the support it needs to thrive.

The Seafish logo features the word "seafish" in a white, lowercase, sans-serif font. Above the letters "i" and "s" is a stylized graphic of a fish, composed of several small, white, diamond-shaped elements arranged to form the outline of a fish's head and body.

seafish