European Commission

DG Health and Food Safety

OVERVIEW REPORT

Official controls on the production and harvesting of live bivalve molluscs for human consumption in the European Union

Health and Food Safety

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OVERVIEW REPORT ON OFFICIAL CONTROLS ON THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS FOR HUMAN CONSUMPTION IN THE EUROPEAN UNION

Executive summary

This report describes the main elements of the national control systems of the production and harvesting of live bivalve molluscs for human consumption in EU Member States, as well as the main challenges that they face. The Commission has gathered information from the 15 bivalve mollusc-producing Member States, through four audits and 11 replies to a questionnaire, complementing it with other publicly available official information.

Bivalve molluscs (mussels, clams, oysters or scallops) have been common in the human diet since ancient times. They are a source of protein, rich in vitamins and essential minerals and a good source of omega-3-fatty acids. In the EU, four Member States produce more than 80% of the production (France, Spain, Italy and Greece), mostly from aquaculture. Contrary to other aquaculture production systems, bivalve molluscs are produced without any human supplied additives or medicinal products.

Bivalve molluscs feed by filtering microscopic algae from surrounding water. During this filtering, they can accumulate microorganisms and chemical contaminants. Under certain circumstances, some algae species produce marine biotoxins, which accumulate in the tissues of bivalve molluscs and, above certain levels, can lead to illness in humans.

To reduce or mitigate the risk bivalve molluscs can pose to consumers, controls on production areas where bivalve molluscs are produced and harvested are essential. In EU legislation, these are the responsibility of the competent authorities, who are obliged to carry out comprehensive official controls.

This report concludes that the competent authorities in all producing Member States have developed, in different degrees, a system of official controls of bivalve molluscs. In this context, most of the Member States keep up-to-date lists of classified production areas. The classification of production areas is one of the key elements in the official control of bivalve molluscs. However, it appears particularly difficult for some Member States, despite the existence of a 'Community Guide' on microbiological classification and monitoring of production areas.

There are major differences between Member States in the development of sanitary surveys. These surveys are decisive for demonstrating the representativeness of sampling points and frequencies.

While in many of the Member States the monitoring of production areas for microbiological quality is in line with the relevant EU requirements, in others the situation differs from the requirements to varying degrees.

Monitoring of classified production areas for biotoxins is often not in line with EU requirements, mostly as regards the frequency and type of biotoxins tested. Additionally, the monitoring of production areas for toxin-producing plankton – which is a useful tool as an early warning system for the presence of biotoxins – varies widely among Member

States.

For the most part, Member States take measures when their monitoring results indicate a risk or a potential risk to health. However, weaknesses implementing appropriate monitoring sometimes reduce the timely detection of certain risks or delay the response to them.

In general, Member States follow the requirements of EU legislation for reopening production areas that were closed due to monitoring results. However, several do not consider relevant monitoring data during the review of classifications.

Finally, Member States have the means to communicate updated information to interested parties in a timely manner. However, recalling from the market bivalve molluscs that may pose a risk to consumers seems to be a problem, mostly due to the perishable nature of this product when it is placed on the market alive.

To conclude, although competent authorities in all producing Member States have developed official controls systems of bivalve molluscs, these systems do not always meet the objectives of EU legislation and, therefore, they are not always adequate to protect consumers' health.

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1. INTRODUCTION

Bivalve molluscs ([1]) (bivalves) are animals enclosed by a shell which has two hinged parts. They are filter feeders, gathering food through their gills. Some examples are mussels, clams, oysters or scallops.

Picture 1. Oyster freshly opened at the production area

EU legislation contains requirements for bivalves but also for other non-bivalve marine invertebrates such as echinoderms (*e.g.* sea urchins, sea cucumbers), marine gastropods (*e.g.* periwinkles, whelks) and tunicates (*e.g.* sea squirts). The scope of this overview report does not cover other non- bivalve marine invertebrates and only includes some information on production volumes or species.

Bivalves have been common in European people's diet since ancient times. They are a source of protein, rich in vitamins and essential minerals and a good source of omega-3-fatty acids. As with any other food, there are important food safety factors to consider during their production and processing.

Picture 2. Different types of bivalve molluscs and marine gastropods in a non-EU local market

([1]) Or filter-feeding lamellibranch molluscs, according to EU legislation.

Currently, most bivalve production comes from aquaculture (around 90% of global production). Bivalve molluscs may be cultivated on the seabed, in racks, trays, rafts, poles, long lines, etc. For this overview report, 15 Member States were considered to be actively engaged in producing or harvesting bivalves ([2]).

Aquaculture bivalves feed on marine phytoplankton that they filter directly from seawater without any human-supplied additives or medicinal products.

Pictures 3 and 4. Oysters in trays and long lines

2. OBJECTIVES, SCOPE AND METHODOLOGY

The objective of this report is to provide an overview of the main elements of the national (food safety) control systems in EU Member States and the main challenges that they face. The scope focuses on the primary production of bivalve molluscs until harvesting.

For this report, the Commission gathered information from the 15 bivalve mollusc producing EU Member States, through four audits ([3]) and 11 replies to a questionnaire sent by the Commission ([4]). This was complemented with other publicly available official information (*e.g.* statistics from Member States and the Commission).

([2]) France, Spain, Italy, Greece, Netherlands, Denmark, Ireland, Germany, Portugal, Bulgaria, Croatia, Sweden, Belgium, Slovenia and Romania. The competent authorities of Cyrus and Malta confirmed that there is no bivalve mollusc production in their countries. Estonia, Finland, Latvia, Lithuania and Poland were not considered for this overview report as traditionally they have not been bivalve mollusc producers. The five inland Member States (Austria, Czechia, Hungary, Luxembourg and Slovakia) were also not considered.

([3]) Portugal - DG(SANTE) 2020-7119, Denmark - DG(SANTE) 2021-7253, Spain - DG(SANTE) 2021-7254 and Croatia - DG(SANTE) 2021-7255.

([4]) The quality of the information provided by two Member States did not allow conclusions to be reached for all the sections in this report. In the case of two other Member States, they had more than one official control system in place in different regions of their territory. In this case, the report considered the information related to the main producing regions.

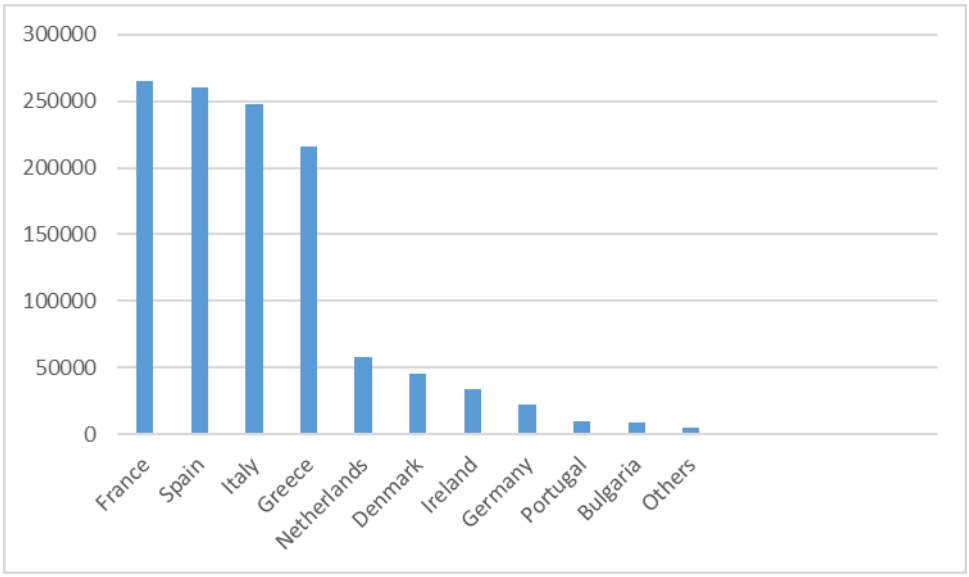
3. BACKGROUND

The previous series of Commission audits in EU Member States on the controls on bivalve molluscs for human consumption took place from 2011 to 2013 and covered eleven Member States ([5]).

Since then, the Official Controls Regulation ([6]) entered into force. However, the Implementing and Delegated Regulations adopted within this new official control framework do not introduce significant changes to the sector. The main legislation that currently applies therefore is Regulation (EU) 2017/625, Regulation (EU) No 853/2004, Regulation (EU) 2019/624 and Regulation (EU) 2019/627.

3.1. Production of bivalve molluscs in the EU

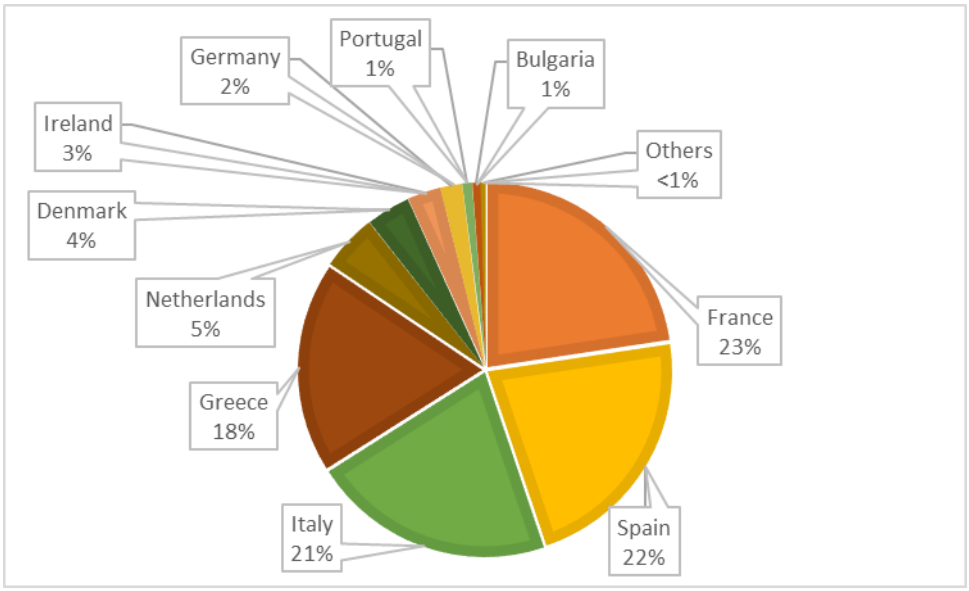
The following two graphs summarize the information gathered for this report from the 15 Member States producing or harvesting bivalves concerning a) production volumes and b) percentage of EU production by Member State.



Graph 1. Volume of production in Member States (in tonnes). Others include, in decreasing order, Croatia, Sweden, Belgium, Slovenia and Romania

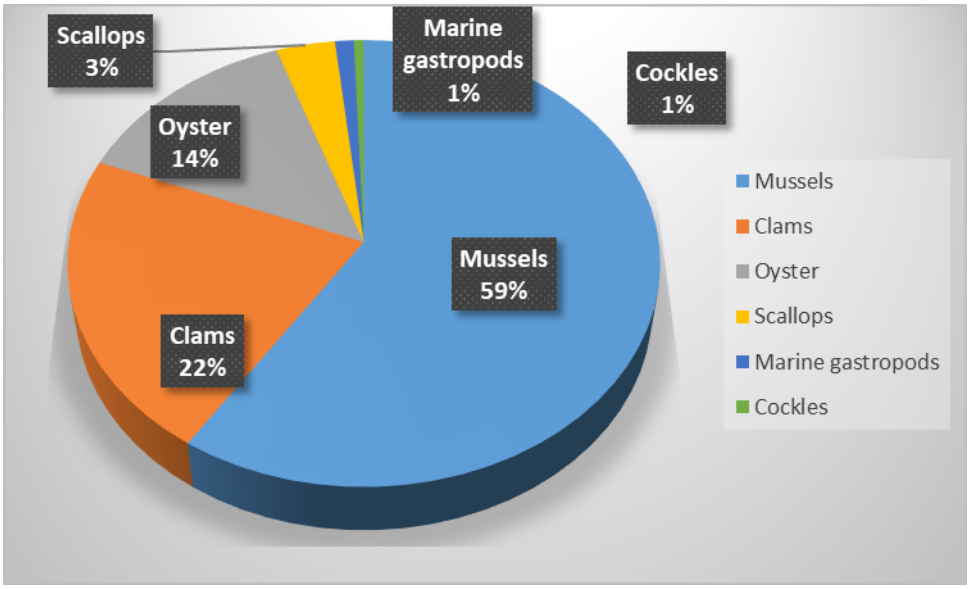
([5]) Reports on individual audits as well as the corresponding overview report are available at: https://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=68

([6]) Regulation (EU) 2017/625 of the European Parliament and the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation).



Graph 2. Member State percentage of total EU production. 'Others' include, in decreasing order, Croatia, Sweden, Belgium, Slovenia and Romania.

The main species produced in the EU are mussels, clams, oysters and scallops. This is followed by a much smaller production of marine gastropods, cockles, razor clams and echinoderms (mostly sea urchins).



Graph 3. Contribution of different products to total EU production, according to information provided by Member States**.**

According to Eurostat, mussels, oysters and clams were three of the seven major species in aquaculture production in the EU in 2019.

In Europe, mussels are the most farmed bivalves in aquaculture. They are produced mainly in Spain, primarily in farms in the Northeast Atlantic cost (Mediterranean mussels- *Mytilus galloprovinciallis*) and, in much smaller volumes, in Italy. A different type of mussels (Blue mussels- *M. edulis*) are produced in the

Netherlands, France and Ireland. Spain, Italy, France and Ireland mostly use rack-like structures and long lines, while most Dutch production is collected from the seabed.

Pictures 5 and 6. Mussels in racks and on long lines

According to the United Nations' Food and Agricultural Organisation (FAO), the European market for mussels is estimated to be just under 600 000 tonnes in equivalent live animal weight, of which 500 000 tonnes is of domestic origin with the balance of 100 000 tonnes imported from outside the EU.

Oysters are produced mainly in France and, in much smaller volumes, in Ireland. Clams are grown mostly in Italy.

3.2. Risks associated with consumption of bivalves and their management

Microbiological risks

Consumption of raw or insufficiently cooked bivalve molluscs can result in illness due to the presence of harmful microorganisms such as *Escherichia coli*, *Salmonella,* marine vibrios (including *Vibrio parahaemolyticus* and *V. vulnificus*), norovirus or hepatitis A virus.

These microorganisms, which are normally associated with human and/or animal faecal contamination, can end up in sea waters. Bivalve molluscs can accumulate them when filtering water during feeding. These microorganisms, which are harmless to shellfish, are proven causes of human illness.

EU legislation addresses this microbiological risk by requiring compulsory classification of the production areas where bivalve molluscs are harvested. Production areas must be classified depending on their microbial contamination status, using *E. coli* as an indicator of the presence of faecal contamination. Depending on the level of contamination of the area, the legislation requires subsequent post-harvest treatment for the product to reduce its contamination. In severe cases there may even be a ban on harvesting.

Marine biotoxins

Bivalve molluscs feed by filtering microscopic algae (phytoplankton) from the surrounding water. Certain phytoplankton species produce marine biotoxins. These phytoplankton species can be naturally present in marine waters. Under certain conditions, for example, a combination of warm temperatures, sunlight, and nutrient-rich waters, these phytoplankton can reproduce rapidly, commonly referred to as "algal blooms".

Marine biotoxins accumulate in the tissues of bivalve molluscs during the feeding process and, above certain concentrations, they can lead to illness in humans. Heat treatment does not eliminate biotoxins. Algal blooms increase the likelihood of biotoxin production and thus the potential for molluscs to accumulate the toxins and cause illnesses in humans when consumed.

EU legislation currently regulates three distinct groups of biotoxins:

- paralytic shellfish poison (PSP) toxin, which produces symptoms of poisoning ranging from a tingling sensation or numbness around the lips to gradually more severe symptoms. In the most extreme cases, PSP toxin can paralyse the body's respiratory muscles and cause death;
- amnesic shellfish poison (ASP) toxin, which produce symptoms such as nausea, vomiting and diarrhoea, muscle weakness, and disorientation. More severe cases can produce brain damage;
- lipophilic toxins (for example, diarrheic shellfish poison toxin), which can cause diarrhoea, nausea, vomiting, headache, abdominal cramps and chills.

Chemical contaminants

Due to their feeding mechanism, bivalves can accumulate environmental pollutants such as dioxins, polychlorinated biphenyls, heavy metals (particularly lead, mercury and cadmium) and polycyclic aromatic hydrocarbons from the surrounding waters, which can result in different adverse health effects.

4. MAIN ELEMENTS OF OFFICIAL CONTROLS ON PRODUCTION AREAS PERFORMED BY COMPETENT AUTHORITIES

In the EU, responsibility for controlling production areas lies with the competent authorities in each Member State. EU legislation establishes the conditions for classifying and monitoring these areas for the microbiological quality of bivalve molluscs, toxin-producing plankton in water, and marine biotoxins and chemical contaminants in bivalve molluscs. This process of monitoring allows competent authorities to identify an increased risk of shellfish becoming contaminated and thus, is one of the main ways to protect the health of consumers of bivalve molluscs.

Competent authorities must draw up monitoring programmes, with plans to sample at regular intervals (or on a case-by-case basis if harvesting periods are irregular). The correct geographical distribution of the sampling points and the sampling frequency must

ensure that the results of the analysis are representative of the classified production and relaying area ([7]) concerned.

There are specific requirements for official controls on live bivalve molluscs, including decisions to be taken on receipt of monitoring results, for example the application of short-term control measures in the areas concerned or the re-classification of the area.

4.1. Location and boundaries of production areas

Official controls on bivalve molluscs start with the competent authorities fixing the location and boundaries of the production areas.

State of play

All Member States producing bivalve molluscs, except one, keep up-to-date lists of the classified production areas in their countries, that are publicly available (e.g. published in state or regional official journals, or on the competent authority websites).

In most cases, information on their location and boundaries is also publicly available. In some cases, information on the classification of production areas per bivalve species is also provided. The ready availability of these data in the public domain allows operators, harvesters and the general public to have up to date information on the location of production areas and their current classification status.

Relaying areas (areas used exclusively for the natural purification of live bivalve molluscs) are not common in EU waters, with very few Member States having any designated.

Based on the results of the Commission audits and the information provided by the Member States in response to the questionnaire, there was no evidence of particular shortcomings with the establishment of production areas and their boundaries.

4.2. Sanitary surveys in production areas

EU legislation requires competent authorities to carry out a sanitary survey before classifying a production or a relaying area. In those production areas that were classified before this provision came into force, this is also a requirement unless it has been previously carried out.

A sanitary survey is an evaluation of the sources of faecal contamination (human and animal) in or near a harvesting area, together with an assessment of the potential impact of these sources of contamination on the microbiological status of the area. Correctly implemented sanitary surveys provide assurances that the

([7]) Relaying areas means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs (Regulation (EC) No 853/2004).

number of samples taken during official controls as well as their geographical distribution and the sampling frequencies are representative for the production areas that they cover. Based on the results of the sanitary surveys, competent authorities must establish a monitoring programme for those areas.

Performing sanitary surveys can be complex and burdensome. Nevertheless, they are a key element on which to base a consistent microbiological monitoring programme.

State of play

Over half of the Member States covered by this report carried out sanitary surveys in most or all of their production areas. The remaining Member States either have not carried them out in the majority or in any of their production areas.

Some Member States have made major efforts to fulfil this requirement and have conducted well-structured comprehensive surveys. However, the situation in other Member States is less positive, with (at best) poor quality surveys having been conducted or (at worst) no surveys at all. Common shortcomings in terms of survey quality relate to failing to demonstrate the representativeness of the sampling sites, or failing to include recommendations on sampling frequencies, or the species and points to be sampled. Overall, there is significant room for improvement in Member States' performance in this area.

4.3. Classification of production areas

EU legislation ([8]) requires that competent authorities classify the areas from which they authorise the harvesting of live bivalve molluscs as Class A, B or C production areas. It establishes the criteria for the different classes, meaning that all producers in all Member States should operate under the same conditions (although this requirement does not apply to scallops harvested offshore). Classification determines the post-harvest treatment that bivalve molluscs must be subjected to, helping to ensure the safety of the product.

The table below summarises the conditions for classifying the areas.

([8]) Regulation (EU) 2019/627.

Class	Microbiological standard	Post-harvest treatment required
A	80% of samples must not exceed 230 *E. coli* most probable number ([9])(MPN) per 100 g of flesh and intravalvular liquid. The remaining 20% of samples must not exceed 700 *E. coli* MPN.	None, they can directly go for human consumption.
B	90% of samples must not exceed 4 600 *E. coli* per 100 g of flesh and intravalvular liquid. The remaining 10% of samples must not exceed 46 000 *E. coli* MPN.	Purification ([10]), relaying ([11]) or heat treatment by an approved method.
C	Samples must not exceed 46 000 *E. coli* MPN per 100 g of flesh and intravalvular liquid.	Relaying over a long period or heat treatment by an approved method.

The competent authorities also have to set a review period for sampling data from each area, which establishes clear basis for classifications to determine compliance with the classification criteria. During the review, often carried out on annual basis, the data considered should be from a relatively large number of samples spread over a length of time and environmental conditions to allow a proper assessment of the status of the areas. This provides assurances that production areas remain correctly classified (even with seasonal variations) throughout the whole year.

State of play

Many Member States consider, fully or partly, the recommendations contained in the Community Guide ([12]), when classifying their production areas.

In some cases, review periods and dataset assessments have resulted in inadequate classification of production areas. Examples include setting of short review periods, which did not allow a proper assessment of the status of the areas. In other cases, the review disregarded monitoring results that exceeded the criteria, without the Member State having conducted conclusive investigations to justify the decision. Some Member States also failed to comply with EU legislation, carrying out weekly classification and/or the classification of production areas based on the results of operators' own checks, but not following the necessary requirements established in EU legislation for the use of this type of non-official results. Collectively these shortcomings undermine the provision of

([9]) The EU reference method is the MPN technique specified in EN/ISO 16649-3.

([10]) In a "purification centre" with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption.

([11]) In a "relaying area" used exclusively for the natural purification of live bivalve molluscs.

([12]) "Community guide to the principles of good practice for the microbiological classification and monitoring of bivalve mollusc production and relaying areas with regard to Implementing Regulation 2019/627", available at: https://www.aesan.gob.es/en/CRLMB/docs/docs/procedimientos/Micro_Control_Guide_DEC_2021.pdf.

the necessary public health assurances.

Continuous compliance with the parameters required to ensure correct classification of production areas is one of the key elements in the official controls on bivalve molluscs. Regrettably, adherence to this appears particularly difficult for some Member States.

4.4. Monitoring of microbiological quality

EU legislation requires monitoring programmes for microbiological quality to be based on the information gathered via the sanitary surveys, thus supporting their decisions on the species to be sampled, the location and geographical distribution of sampling points, and the frequency and distribution of sampling over time.

The sampling plan is the basis of the microbiological monitoring programme for production areas. EU legislation requires that sampling plans use *E. coli* as an indicator of faecal contamination, taking particular account of the likely variation in the faecal contamination and of the parameters contained in sanitary surveys. The results from the monitoring programme are used for reviewing the classification of the production areas.

State of play

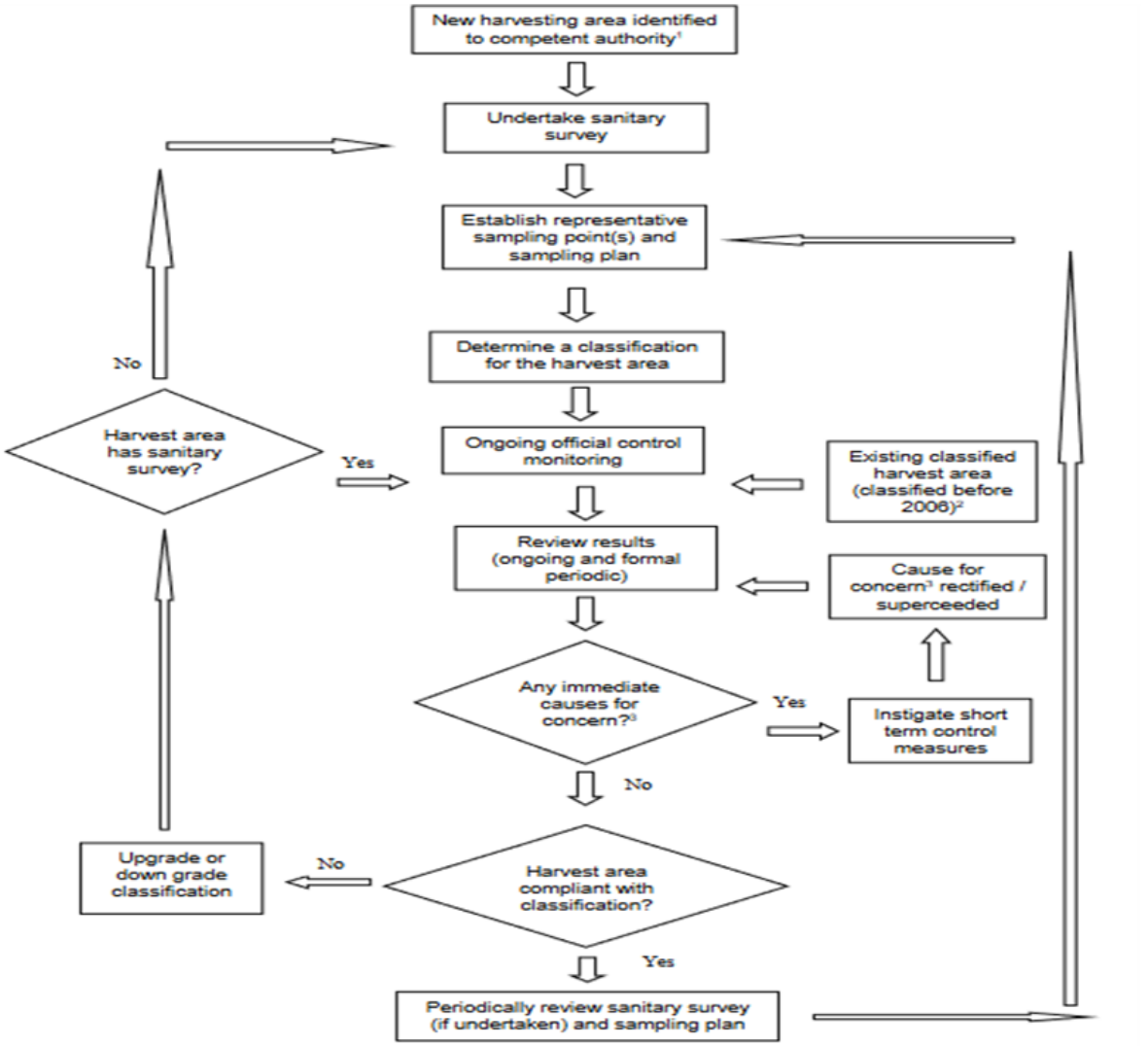
All Member States monitor production areas for microbiological quality. Most Member States meet the relevant EU requirements and follow the Community Guide recommendations for the sampling plan. When sanitary surveys are available, the sampling points recommended in them are usually those from which samples are taken for the monitoring plan.

In most cases either official staff or trained and officially supervised harvesters take the samples.

The main shortcomings identified on the basis of the evidence gathered include the fact that some Member States only monitor production areas during harvesting periods, thereby deviating from EU requirements. In some Member States there was insufficient information available that would justify the selection of the sampling points as being representative of the area concerned.

Lastly, several Member States use indicator species to monitor the microbiological quality of some production areas. However, the selection of such species sometimes lacked adequate supporting data.

The graph below ([13]) gives an overview of the previous headings 4.1 to 4.4, with the key stages of the classification of the production areas, taking into account the outcome of the sanitary surveys and ongoing monitoring for microbiological quality.



(1) By food business operator or other interested party.

(2) According to paragraph 2 of article 56 to Implementing Regulation (EU) 2019/627, the competent authorities shall carry out a sanitary survey fulfilling the requirements set out in paragraph 1 of the same article in all classified production areas, unless carried out previously.

(3) Human health incidents, pollution events, anomalous result.

4.5. Monitoring of toxin-producing phytoplankton

EU legislation requires that monitoring programmes include periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution.

([13]) From the Community guide to the principles of good practice for the microbiological classification and monitoring of bivalve mollusc production and relaying areas with regard to Implementing Regulation 2019/627.

The monitoring of plankton can help as an early warning of the potential occurrence of biotoxins in bivalve molluscs, and supports the management of the monitoring plan for biotoxins (*e.g.* increasing the frequency of sampling for biotoxins, preventive closures of production areas).

In 2019, the "EU Working Group on Toxin-producing Phytoplankton Monitoring in Bivalve Mollusc Harvesting Areas", within the EU Reference Laboratory (EURL) for Marine Biotoxins, finalised a "Guide to Good Practice: Technical Application on Monitoring of Toxin-producing Phytoplankton in Bivalve Mollusc Harvesting Areas" ([14]).

State of play

Member States monitor toxin-producing plankton, but the implementation of this monitoring varies widely among Member States regarding both:

- *the selection of sampling points, with production areas having more than one sampling point, or an external sampling point, or the sampling point being the same for plankton and for biotoxins (therefore of little use as early warning); and*
- *the sampling frequency, going from weekly to fortnightly, monthly or even less frequent.*

The main objective is to have a sound basis to select representative sampling points and to determine the appropriate sampling frequencies. Only then can the presence and concentration of toxin-producing plankton be detected early enough to predict the likely increase in the concentration of biotoxins in bivalve molluscs which would be harmful to consumers and which would require mitigating measures to be taken to prevent human poisoning.

The guidance from the EURL should help the competent authorities to improve their controls on this issue and achieve the objectives of the legislation.

4.6. Monitoring of marine biotoxins

The sampling plans for monitoring marine biotoxins should include periodic toxicity tests using live bivalve molluscs taken from a point that is representative of the production area. In general, the sampling frequency for toxin analysis in live bivalve molluscs is weekly during harvesting periods, but it can be higher for example if toxic episodes approach, or lower if a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. In principle, all species of bivalve molluscs harvested in a production area have to be sampled,

([14]) available at https://www.aesan.gob.es/en/CRLMB/docs/docs/procedimientos/Phyto_Monitoring_Guide_DEC_2021.pdf

but EU legislation allows the possibility of using the species with the highest rate of contamination as an indicator, when there is a solid scientific basis for it.

At the time of drafting this report, the EURL for Marine Biotoxins is preparing a guide to the monitoring of biotoxins in bivalve mollusc harvesting areas.

State of play:

Monitoring classified production areas for the presence of biotoxins in bivalves presents challenges for Member States. All of them but one monitor biotoxins, although in many cases this monitoring is not in line with EU requirements. While in most cases all of the production areas are monitored when they are open for harvesting, the frequency varies widely between Member States and this also depends on the type of biotoxin to be tested. The inherent limitation of the questionnaire did not allow us to ascertain whether there was robust scientific evidence supporting such a divergence in sampling frequency.

Some Member States use indicator species when monitoring production areas for biotoxins, but it is unclear if this strategy is scientifically valid or that the most appropriate indicator species have been selected.

The forthcoming guidance from the EURL should help competent authorities to better achieve the objectives of legislation.

4.7. Monitoring of chemical contaminants

According to EU requirements sampling plans should be able to detect chemical contaminants which exceed the permitted maximum levels ([15]), including dioxins, polychlorinated biphenyls, heavy metals and polycyclic aromatic hydrocarbons.

State of play

Member States monitor chemical contaminants in bivalves either directly in samples drawn from the production areas or as part of wider programmes of food monitoring. In most cases they monitor for heavy metals (cadmium, lead and mercury) but not always for other required chemical contaminants.

5. MANAGEMENT OF CLASSIFIED PRODUCTION AND RELAYING AREAS AFTER MONITORING

5.1. Closure or reclassification decisions

According to EU requirements competent authorities must promptly close a production area, preventing the harvesting of live bivalve molluscs, if the results of

([15]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

the monitoring indicate that the health standards for live bivalve molluscs are not met or that there may be a risk to human health if the bivalves are consumed.

For microbiological monitoring, and depending on the results, the authorities can reclassify the production area or permit harvesting without closure, under specific conditions. Such actions should prevent potentially unsafe product from entering the food distribution chain and allow the prompt recall of unsafe product that has already been placed on the market.

State of play

In principle, all Member States take measures when their monitoring results indicate a risk or a potential risk for human health. However, the weaknesses in appropriately implementing the various monitoring programmes (referred to earlier in this report) sometimes result in certain risks not being identified in a timely manner or contribute to delays in the competent authorities' response to them, weakening the effectiveness of the control system. In some cases, Member States incorrectly took measures in relation to the part of the production area where they identified the risk, whereas the measures should have been applied to the whole area inside the set boundaries, as required by the EU rules.

5.2. Re-opening of production areas

Competent authorities shall only re-open a closed production area if the health standards for live bivalve molluscs comply with the relevant requirements and present no other risk to human health. According to EU legislation, for closure, re-classification and re-opening decisions the authorities can take into account – under specific conditions – the results of checks carried out by food business operators or organisations representing food business operators. A correct and prompt re-opening of closed areas ensures the safety of the product while reducing the negative trade impact on producers.

State of play:

In general, Member States follow the requirements of EU legislation for reopening production areas that were closed due to the risk of biotoxins. Similarly, measures taken seem to be mostly adequate in those Member States that preventively close production areas based on their monitoring results for toxin-producing plankton.

However, in the case of those production areas closed or downgraded for failing to meet microbiological criteria, several Member States reopened or restored the original classification and, when reviewing the classification, disregarded results that exceeded the criteria without a conclusive investigation justifying the decision.

In general, market recall of bivalve molluscs that may pose a risk to consumers is a challenge, partly due to the perishable nature of this commodity when placed on the

market alive.

6. RECORDING AND EXCHANGING INFORMATION

EU legislation requires competent authorities to immediately inform stakeholders (such as producers, gatherers and operators of purification centres and dispatch centres) and the general public of any change to the location, boundaries or classification of an area, of its temporary or final closure, or of the application of any other preventive measures. This ensures that operators know at all times precisely in which areas they can harvest, and what if any treatment should be applied to their product.

Promptly updating available information in Member States helps to avoid mistakes due to delays and to prevent uncontrolled harvesting from areas that could be a threat to public health.

State of play

All Member States except one have the means to communicate with interested parties and this seems to provide updated information in a timely manner.

7. MAIN ELEMENTS IN THE OFFICIAL CONTROLS ON SCALLOPS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Regulation (EU) 2017/625 allows for the derogation of classification of production areas for scallops, and Regulation (EU) 2019/624 establishes the conditions for it. The competent authorities can use this derogation when official controls to verify compliance with the health standards of scallops as well as other specific requirements are carried out in fish auctions, dispatch centres and processing establishments.

There are three Member States producing scallops in the EU: France, which produces considerable volumes, followed by Ireland and Belgium in much smaller amounts ([16]). Other Member States, such Spain, also produce them in small or very small quantities. Most of the scallops are harvested outside classified production areas.

State of play

Official controls on scallops vary very widely between Member States. Some regularly sample all harvesting grounds; others only randomly sample some of them. In some, all samples are collected by officials; in others, most of the samples are taken by operators as part of their own checks.

([16]) According to the information gathered for this report, 35 000 tonnes France, 2 500 tonnes Ireland, 700 tonnes Belgium.

8. OVERALL CONCLUSION

Although competent authorities in all producing Member States have developed official controls systems of bivalve molluscs, these systems do not always meet the objectives of EU legislation and, therefore, they might not be adequate to protect consumers' health.

9. ACTIONS FROM THE COMMISSION

In addition to following up the actions proposed by the competent authorities to address the recommendations made during the audits carried out in four Member States, the Commission intends to carry out a few more audits to other bivalve mollusc producing EU Member States.

The Commission and the Member States have regular dedicated meetings to discuss and, when necessary, revise the bivalve molluscs legislation, in order to adapt and update the rules to the exigencies of the Member States in a sector that is rapidly evolving. The current discussions taking place with the Member States experts focus, for instance, on improving the traceability of shellfish destined to purification or exchanged between Member States, and on the possible revision of the determination of biotoxins content in shellfish.

In this context, dedicated meetings will take place to reflect how best to address the findings of this report, possibly via a roadmap for revising legal requirements in line with current experience and needs.

Finally, the EURL for Marine Biotoxins is working to finalise a guide on monitoring biotoxins in bivalve mollusc harvesting areas.

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