

Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (Text with EEA relevance)

TITLE V

SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AND RELAYING AREAS

Article 51

Exclusion

This Title applies to live bivalve molluscs. It also applies to live echinoderms, live tunicates and live marine gastropods. This Title does not apply to live marine gastropods and live *Holothuroidea* that are not filter feeders.

Article 52

Classification of production and relaying areas for live bivalve molluscs

- 1 The competent authorities shall fix the location and boundaries of the production and relaying areas that they classify in accordance with Article 18(6) of Regulation (EU) 2017/625. They may, where appropriate, do so in cooperation with the food business operator.
- 2 The competent authorities shall classify production and relaying areas from which they authorise the harvesting of live bivalve molluscs as Class A, Class B and Class C areas according to the level of faecal contamination. They may, where appropriate, do so in cooperation with the food business operator.
- 3 In order to classify production and relaying areas, the competent authorities shall fix a review period for sampling data from each production and relaying area in order to determine compliance with the standards referred to in Articles 53, 54 and 55.

CHAPTER I

Specific requirements for the classification of production and relaying areas for live bivalve molluscs

Article 53

Requirements for Class A areas

- 1 The competent authorities may classify as Class A areas those from which live bivalve molluscs may be collected for direct human consumption.

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2 Live bivalve molluscs placed on the market from such areas shall meet the health standards for live bivalve molluscs set out in Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004.

3 Samples of live bivalve molluscs from Class A areas shall not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid.

4 The remaining 20 % of samples shall not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.

5 When evaluating the results for the fixed review period for maintenance of a Class A area, the competent authorities may, on the basis of a risk assessment based on an investigation, decide to disregard an anomalous result exceeding the level of 700 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 54

Requirements for Class B areas

1 The competent authorities may classify as Class B areas those from which live bivalve molluscs may be collected and placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in Article 53.

2 Live bivalve molluscs from Class B areas shall not exceed, in 90 % of the samples, 4 600 *E. coli* per 100 g of flesh and intravalvular liquid.

3 The remaining 10 % of samples shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 55

Requirements for Class C areas

1 The competent authorities may classify as Class C areas those from which live bivalve molluscs may be collected and placed on the market only after relaying over a long period so as to meet the health standards referred to in Article 53.

2 Live bivalve molluscs from Class C areas shall not exceed 46 000 *E. coli* per 100 g of flesh and intravalvular liquid.

Article 56

Sanitary survey requirements

1 Before classifying a production or relaying area, the competent authorities shall carry out a sanitary survey that includes:

- a an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
- b an examination of the quantities of organic pollutants released during the different periods of the year, according to the seasonal variations of human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;

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- c determination of the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area.

2 The competent authorities shall carry out a sanitary survey fulfilling the requirements set out in paragraph 1 in all classified production and relaying areas, unless carried out previously.

3 The competent authorities may be assisted by other official bodies or food business operators under conditions established by the competent authorities in relation to the performance of this survey.

Article 57

Monitoring programme

The competent authorities shall establish a monitoring programme for live bivalve mollusc production areas that is based on an examination of the sanitary survey referred to in Article 56. 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.

Article 58

The competent authorities shall establish a procedure to ensure that the sanitary survey referred to in Article 56 and the monitoring programme referred to in Article 57 are representative of the area considered.

CHAPTER II

Conditions for the monitoring of classified production and relaying areas for live bivalve molluscs

Article 59

Monitoring of classified production and relaying areas

The competent authorities shall periodically monitor production and relaying areas classified in accordance with Article 18(6) of Regulation (EU) 2017/625 in order to check:

- (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 classified production and relaying areas;
- (c) for the presence of toxin-producing plankton in production and relaying waters and marine biotoxins in live bivalve molluscs;
- (d) for the presence of chemical contaminants in live bivalve molluscs.

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Article 60

Recognised methods for the detection of marine biotoxins in live bivalve molluscs

1 The competent authorities shall use the analytical methods laid down in Annex V to check compliance with the limits laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and, where appropriate, to verify compliance by food business operators. Food business operators shall use these methods where appropriate.

2 In accordance with Article 4 of Directive 2010/63/EU, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used where possible, instead of a procedure as defined in Article 3(1) of that Directive.

3 In accordance with Article 4 of Directive 2010/63/EU, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

Article 61

Sampling plans

1 For the purposes of the checks provided for in points (b), (c) and (d) of Article 59, the competent authorities shall draw up sampling plans providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency shall ensure that the results of the analysis are representative of the classified production and relaying area concerned.

2 Sampling plans to check the microbiological quality of live bivalve molluscs shall take particular account of:

- a the likely variation in faecal contamination;
- b the parameters referred to in Article 56(1).

3 Sampling plans to check for the presence of toxin-producing plankton in the water in classified production and relaying areas and for marine biotoxins in live bivalve molluscs shall take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling shall comprise:

- a periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in live bivalve mollusc flesh shall be followed by intensive sampling;
- b periodic toxicity tests using live bivalve molluscs from the affected area most susceptible to contamination.

4 The sampling frequency for toxin analysis in live bivalve molluscs shall be weekly during harvesting periods, except when:

- a the sampling frequency may be reduced in specific classified relaying or production areas, or for specific types of live bivalve mollusc, if a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic episodes;
- b the sampling frequency shall be increased where such an assessment suggests that weekly sampling would not be sufficient.

5 The risk assessment referred to in paragraph 4 shall be reviewed periodically in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

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6 Where knowledge of toxin accumulation rates is available for a group of species growing in the same classified production or relaying area, the species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. Where toxin levels in the indicator species are above the regulatory limits, the harvesting of the other species may be allowed only if further analysis of the other species shows toxin levels below the limits.

7 With regard to the monitoring of plankton, the samples shall be representative of the water column in the classified production or relaying area and provide information on the presence of toxic species and on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency for live bivalve molluscs shall be increased or precautionary closures of the areas established until results of toxin analysis are obtained.

8 Sampling plans to check for the presence of chemical contaminants shall enable the detection of any overshooting of the levels laid down in Regulation (EC) No 1881/2006.

CHAPTER III

Management of classified production and relaying areas after monitoring

Article 62

Decisions following monitoring

1 Where the results of the monitoring provided for in Article 59 indicate that the health standards for live bivalve molluscs are not met or that there may otherwise be a risk to human health, the competent authorities shall close the classified production or relaying area concerned, preventing the harvesting of live bivalve molluscs. However, they may reclassify a production or relaying area as being of Class B or C if it meets the relevant criteria set out in Articles 54 and 55 and presents no other risk to human health.

2 Where the results of microbiological monitoring show that the health standards for live bivalve molluscs referred to in Article 53 not met, competent authorities may, on the basis of a risk assessment, and only on a temporary and non-recurring basis, permit continued harvesting without closure or reclassification subject to the following conditions:

- a the classified production area concerned and all approved establishments receiving live bivalve molluscs from it are under the official control of the same competent authorities;
- b the live bivalve molluscs concerned are subjected to appropriate restrictive measures such as purification, relaying or processing.

3 The accompanying registration document, as referred to in Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, shall include all the information concerning the application of paragraph 2.

4 The competent authorities shall establish the conditions under which paragraph 2 can be availed of in order to ensure, for the production area concerned, maintenance of the compliance with the criteria established in Article 53.

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Article 63

Re-opening of production areas

1 The competent authorities may re-open a closed production or relaying area only if the health standards for live bivalve molluscs comply once again with the relevant requirements of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and present no other risk to human health.

2 Where the competent authorities have closed a production or relaying area because of the presence of plankton or levels of toxins in live bivalve molluscs that exceed the regulatory limit for marine biotoxins laid down in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, they may re-open it only if at least two consecutive analytical results separated by at least 48 hours are below the regulatory limit.

3 When deciding whether to re-open a production or relaying area, the competent authorities may take account of information on phytoplankton trends.

4 Where there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authorities may decide to re-open an area with results below the regulatory limit in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 obtained from a single sampling.

Article 64

Control system

1 The competent authorities shall set up a control system to ensure that products of animal origin harmful to human health are not placed on the market. The control system shall comprise laboratory tests to verify food business operators' compliance with the requirements for the end product, including live bivalve molluscs and any products derived from them, at all stages of production, processing and distribution.

2 This control system shall verify, where applicable, that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

Article 65

Decision by the competent authorities

1 The competent authorities shall act promptly where a production area must be closed or reclassified, or may be re-opened, or where live bivalve molluscs are subject to the application of measures as referred to in Article 62(2).

2 When deciding on the classification, reclassification, opening or closure of production areas in accordance with Articles 52, 62 and 63, competent authorities may take into account the results of checks carried out by food business operators or organisations representing food business operators, only if the laboratory carrying out the analysis is designated by the competent authorities, and the sampling and analysis are performed in accordance with a protocol agreed upon jointly by the competent authorities and food business operators or organisation concerned.

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CHAPTER IV

Other requirements

Article 66

Recording and exchange of information

The competent authorities shall:

- (a) establish and keep up to date a list of classified production and relaying areas, with details of their location, and boundaries, as well as the Class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of Article 52. This list shall be communicated to interested parties affected by this Regulation, such as producers, gatherers and operators of purification centres and dispatch centres;
- (b) immediately inform the interested parties such as producers, gatherers and operators of purification centres and dispatch centres, of any change to the location, boundaries or Class of a production area, of its temporary or final closure, or of the application of measures as referred to in Article 60(2).

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