

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**

#### *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.

##### *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.

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*Changes to legislation:* There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/627. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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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.

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.

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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.

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**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Signature words omitted by [S.I. 2020/1631 reg. 16\(26\)](#)
- Annex 5 Ch. 3 Pt. A words substituted by [S.I. 2020/1631 reg. 16\(28\)\(a\)](#)
- Annex 2 para. 1 substituted by [S.I. 2020/1631 reg. 16\(27\)\(a\)](#)
- Annex 2 para. 3 words substituted by [S.I. 2020/1631 reg. 16\(27\)\(b\)](#)
- Annex 6 Ch. 1 Pt. D words omitted by [S.I. 2020/1631 reg. 16\(29\)\(a\)\(i\)\(aa\)](#)
- Annex 6 Ch. 1 Pt. D words omitted by [S.I. 2020/1631 reg. 16\(29\)\(a\)\(i\)\(bb\)](#)
- Annex 6 Ch. 1 Pt. D words substituted by [S.I. 2020/1631 reg. 16\(29\)\(a\)\(ii\)](#)
- Annex 6 Ch. 2 Pt. A word substituted by [S.I. 2020/1631 reg. 16\(29\)\(b\)\(ii\)](#)
- Annex 6 Ch. 2 Pt. A para. 1(d) word substituted by [S.I. 2020/1631 reg. 16\(29\)\(b\)\(i\)\(bb\)](#)
- Annex 6 Ch. 2 Pt. A para. 1(d) words substituted by [S.I. 2020/1631 reg. 16\(29\)\(b\)\(i\)\(aa\)](#)
- Art. 1(c) word omitted by [S.I. 2020/1631 reg. 16\(2\)](#)
- Art. 2(49)-(51) inserted by [S.I. 2020/1631 reg. 16\(3\)](#)
- Art. 3(3)(b) word omitted by [S.I. 2020/1631 reg. 16\(4\)\(a\)](#)
- Art. 3(3)(b) words substituted by [S.I. 2020/1631 reg. 16\(4\)\(b\)](#)
- Art. 3(3)(b) words substituted by [S.I. 2020/1631 reg. 16\(4\)\(c\)](#)
- Art. 14(1)(b)(ii) words omitted by [S.I. 2020/1631 reg. 16\(8\)\(a\)](#)
- Art. 14(1)(b)(ii) words substituted by [S.I. 2020/1631 reg. 16\(8\)\(b\)](#)
- Art. 18(1)(b) words substituted by [S.I. 2020/1631 reg. 16\(9\)\(a\)](#)
- Art. 18(2)(a) words substituted by [S.I. 2020/1631 reg. 16\(9\)\(b\)](#)
- Art. 30(1)(c) words inserted by [S.I. 2020/1631 reg. 16\(11\)](#)
- Art. 35(1)(c) omitted by [S.I. 2020/1631 reg. 16\(13\)](#)
- Art. 37(1)(c) word omitted by [S.I. 2020/1631 reg. 16\(15\)\(a\)](#)
- Art. 37(1)(c) words omitted by [S.I. 2020/1631 reg. 16\(15\)\(b\)](#)
- Art. 45(e) word omitted by [S.I. 2020/1631 reg. 16\(19\)\(a\)\(i\)](#)
- Art. 45(e) words inserted by [S.I. 2020/1631 reg. 16\(19\)\(a\)\(ii\)](#)
- Art. 45(i) words substituted by [S.I. 2020/1631 reg. 16\(19\)\(b\)](#)
- Art. 45(j) words inserted by [S.I. 2020/1631 reg. 16\(19\)\(c\)\(ii\)](#)
- Art. 45(j) words omitted by [S.I. 2020/1631 reg. 16\(19\)\(c\)\(i\)](#)
- Art. 45(n) words substituted by [S.I. 2020/1631 reg. 16\(19\)\(d\)](#)
- Art. 71(b) word omitted by [S.I. 2020/1631 reg. 16\(24\)\(b\)](#)
- Art. 71(b) words substituted by [S.I. 2020/1631 reg. 16\(24\)\(a\)](#)