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 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.

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.

Status: Point in time view as at 15/03/2019. 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)

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.;
- 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.

Status: Point in time view as at 15/03/2019. 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)

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.

Status:

Point in time view as at 15/03/2019.

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.