

Commission Regulation (EU) 2015/2285 of 8 December 2015 amending Annex II to Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption as regards certain requirements for live bivalve molluscs, echinoderms, tunicates and marine gastropods and Annex I to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (Text with EEA relevance)

Article 1

Regulation (EC) No 854/2004 is amended as follows:

- (1) in Chapter II of Annex II before Part A:
 - (a) the sentences: ‘The reference method for analysis of *E. coli* is the detection and Most Probable Number (MPN) technique specified in EN/ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140’ are added;
 - (b) the sentences of paragraphs (4) and (5) Part A ‘the reference method for this analysis is the five-tube, three-dilutions Most Probable Number (MPN) test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140’ are deleted;
- (2) paragraph 2 of Part A of Chapter II is replaced by the following:
 2. The competent authority must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator. In order to classify production areas, the competent authority must define a review period for sampling data from each production and relaying area in order to determine compliance with the standards referred to in this paragraph and in paragraphs 3, 4 and 5.
- (3) paragraph 3 of Part A of Chapter II is replaced by the following:
 3. The competent authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs placed on the market from these areas must meet the health standards laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No 853/2004.

Samples of live bivalve molluscs from these areas must not exceed, in 80 % of samples collected during the review period, 230 *E. coli* per 100 g of flesh and intravalvular liquid. The remaining 20 % of samples must not exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.

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

Changes to legislation:

There are currently no known outstanding effects for the Commission Regulation (EU) 2015/2285, Article 1.