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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(1)], and in particular Article 4(4) thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[(2)], and in particular the introductory phrase and point 13 of Article 18 thereof,

Whereas:

(1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It provides that Member States are to ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex II thereto.

(2) Paragraph 2 of Chapter II Part A of Annex II to Regulation (EC) No 854/2004 provides that 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.

(3) In order to classify production areas the competent authority should define a review period for sampling data from each production and relaying area in order to determine compliance with the standards specified in that Regulation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2015/2285. (See end of Document for details)*

(4) Paragraph 3 of Chapter II Part A of Annex II to Regulation (EC) No 854/2004 states that the competent authority may classify as Class A, areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from those areas are required to meet the health standards laid down in Annex III, Section VII, Chapter V of Regulation (EC) No 853/2004 of the European Parliament and of the Council[(3)].

(5) Commission Regulation (EC) No 2073/2005[(4)] lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators in respect of the general and specific hygiene requirements referred to in Article 4 of Regulation (EC) No 852/2004. More particularly, it lays down a food safety criterion for *Escherichia coli* on live bivalve molluscs and live echinoderms, tunicates and gastropods.

(6) The Codex Alimentarius criterion for *E. coli* for products placed on the market differs from the criterion contained in European Union legislation. The Codex Alimentarius criterion is a three-class plan (n = 5, c = 1, m = 230 and M = 700 *E. coli* MPN/100 g of flesh and intravalvular liquid), while the European Union criterion is a two-class plan (n = 1, c = 0, M = 230 *E. coli* MPN/100 g of flesh and intravalvular liquid). This divergence has implications for international trade. The Codex Alimentarius criterion, based on international standards, should also be reflected in the rules on the classification of Class A production areas laid down in Annex II to Regulation (EC) No 854/2004.

(7) The Codex Alimentarius three-class plan approach is more likely to detect non-compliant batches particularly as contamination levels approach the regulatory limit. The Codex Alimentarius approach for end-product testing is considered scientifically more precise and it offers on average broadly equivalent health protection.

(8) Regulation (EC) No 2073/2005 and Regulation (EC) No 854/2004 should be aligned to the Codex Alimentarius as regards this criterion and should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

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

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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.

Article 2

In Annex I to Regulation (EC) No 2073/2005, Chapter 1 is amended as follows:

(1) in the table on food safety criteria, row 1.25 is replaced by the following:

1.25 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods	*E. coli* ([15])	5 ([16])	1	230 MPN/100 g of flesh and intravalvular liquid	700 MPN/100 g of flesh and intravalvular liquid	EN/ISO 16649-3	Products placed on the market during their shelf-life

(2) footnote 16 is replaced by the following:

([16]) each sample unit comprises a minimum number of individual animals according to EN/ISO 6887-3.

(3) (a) in the notes on the interpretation of the test results, the entry 'the limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.'