# Commission Regulation (EU) 2019/229 of 7 February 2019 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for Listeria monocytogenes in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat) (Text with EEA relevance)

## COMMISSION REGULATION (EU) 2019/229

of 7 February 2019

amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards certain methods, the food safety criterion for *Listeria monocytogenes* in sprouted seeds, and the process hygiene criterion and food safety criterion for unpasteurised fruit and vegetable juices (ready-to-eat)

(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) and Article 12 thereof,

Whereas:

(1) Commission Regulation (EC) No 2073/2005[(2)] 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.

(2) The European Committee for Standardisation and the International Organisation for Standardisation recently revised a number of reference methods and a protocol to verify compliance with microbiological criteria. Regulation (EC) No 2073/2005 therefore needs to be updated accordingly. The update should concern in particular the requirements for the use of alternative methods in light of the revised reference standard protocol EN ISO 16140-2, the way results are reported in accordance with the new revised methods and the new references of certain methods for the detection of *Salmonella* (EN ISO 6579-1), of *Cronobacter* (EN ISO 22964) and of staphylococcal enterotoxin (EN ISO 19020), for the detection and the quantification of histamine (EN ISO 19343), for the enumeration of aerobic colony count (EN ISO 4833-1) and for the colony-count method for *Enterobacteriaceae* (EN ISO 21528).

(3) The micro-organism *Enterobacter sakazakii* was reclassified in 2007 and was named *Cronobacter* spp.

(4) The full names of the two *Salmonella* serotypes are '*Salmonella enterica* subsp. *enterica* serotype Typhimurium' and '*Salmonella enterica* subsp. *enterica* serotype Enteritidis'. In accordance with the recommendations of the World Health Organisation

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Collaborating Centre for Reference and Research on *Salmonella*[3], Regulation (EC) No 2073/2005 should refer to those serotypes in the same way.

(5) Regulation (EC) No 2073/2005 sets a food safety criterion for '*Listeria monocytogenes* in ready-to-eat foods unable to support the growth of *Listeria monocytogenes*, other than those intended for infants and for special medical purposes'. In accordance with an opinion of the European Food Safety Authority of 15 November 2011[4], sprouted seeds support the growth of *Listeria monocytogenes* and should therefore be covered by the criterion for ready-to-eat foods able to support the growth of *Listeria monocytogenes*, other than those intended for infants and for special medical purposes.

(6) Annex I to Regulation (EC) No 2073/2005 sets a food safety criterion for *Salmonella* and a process hygiene criterion for *E. coli* for unpasteurised fruit and vegetable juices (ready-to-eat). Given that alternative processes to pasteurisation exist, which achieve a similar bactericidal effect, the food safety criterion for *Salmonella* and a process hygiene criterion for *E. coli* for unpasteurised fruit and vegetable juices (ready-to-eat) should not apply to fruit and vegetable juices (ready-to-eat) that have been subject to bactericidal process with a similar effect to pasteurisation on *E. coli* and *Salmonella*.

(7) It is appropriate to transitionally allow current alternative methods to be further applied in order to give sufficient time to food business operators to adapt their methods, as some certificates of alternative methods based on the previous standard ISO 16140:2003 may still be valid until end of 2021.

(8) Regulation (EC) No 2073/2005 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*

**Amendments to Regulation (EC) No 2073/2005**

Regulation (EC) No 2073/2005 is amended as follows:

(1) in Article 2 the following points are inserted after point (m):

(n) "a broad range of foods", as referred to in EN ISO 16140-2, means food as defined by the first subparagraph of Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[5];

(o) "independent certification body" means a body which is independent from the organisation that manufactures or distributes the alternative method and which provides a written assurance, in the form of a certificate, testifying that the validated alternative method meets the requirements of EN ISO 16140-2;

(p) "production process assurance of the manufacturer" means a production process whose management system guarantees that the validated alternative method remains conform to the characteristics required by EN ISO 16140-2

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and ensures that mistakes and defects in the alternative method are prevented;;

(2) Article 5 is amended as follows:

(a) the third subparagraph of paragraph 2 is replaced by the following:

Food business operators manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below six months, which pose a *Cronobacter* spp. risk shall monitor the processing areas and equipment for Enterobacteriaceae as part of their sampling scheme.;

(b) the third and fourth subparagraphs of paragraph 5 are replaced by the following:

The use of alternative analytical methods is acceptable provided they are:

— validated against the specific reference method provided for in Annex I in accordance with the protocol set out in standard EN ISO 16140-2, and

— validated for the food category specified in the relevant microbiological criterion set in Annex I the compliance with which is verified by the food business operator, or validated for a broad range of food as referred to in EN ISO 16140-2.

Proprietary methods may be used as alternative analytical methods, provided they are:

— validated, in accordance with the protocol set out in standard EN ISO 16140-2, against the specific reference method provided for verifying compliance with the microbiological criteria laid down in Annex I, as provided for in the third subparagraph, and

— certified by an independent certification body.

The certification of the proprietary method referred to in the second indent of the fourth subparagraph shall:

— be subject, at least every 5 years, to reassessment through renewal procedures,

— show that the production process assurance of the manufacturer was evaluated, and

— include a summary of or a reference to the validation results of the proprietary method and a statement on the quality management of the production process of the method.

Food business operators may use other analytical methods than those validated or certified as provided for in the third, fourth and fifth subparagraphs, where such methods have been validated in accordance with internationally accepted protocols and their use has been authorised by the competent authority.;

(3) Annex I is amended in accordance with the Annex to this Regulation.

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*Article 2*

**Transitional provision**

Until 31 December 2021, food business operators may apply the alternative analytical methods referred to in Article 5 of Regulation (EC) No 2073/2005 applicable before being amended by Article 1 of this Regulation.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 February 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER