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[...] (2023) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**amending Regulation (EC) No 2073/2005 as regards *Listeria monocytogenes***

(Text with EEA relevance)

# COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Regulation (EC) No 2073/2005 as regards *Listeria monocytogenes***

(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<sup>1</sup>, and in particular Article 4(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 2073/2005<sup>2</sup> 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) In particular, Regulation (EC) No 2073/2005 lays down food safety criteria, which define the acceptability of a product, or a batch of foodstuff applicable to products placed on the market. That Regulation provides for food safety criteria for *Listeria monocytogenes*, which is a major foodborne pathogen posing serious risk to public health due to its high fatality rate. In its latest report on zoonoses<sup>3</sup>, the European Food Safety Authority (the ‘Authority’) observed that the number of cases of listeriosis in humans in the Union was 15.9 % higher in 2022 than in 2021 and the number of deaths from foodborne outbreaks and caused by *Listeria monocytogenes* in the Union in 2022 was one of the highest numbers ever reported to the Authority in the last ten years. In view of this upsurge of listeriosis cases in the Union, it is crucial that food safety criteria for *Listeria monocytogenes* can offer a high and consistent level of protection of consumers throughout the food chain.
- (3) The risk of contracting listeriosis through food is influenced by both the individual susceptibility of the consumer and the ability of the contaminated food to support the growth of *Listeria monocytogenes* to high levels. Infants and consumers with weakened immune defences because they are suffering diseases, disorders or medical conditions are highly susceptible to *Listeria monocytogenes* and cannot be exposed to food containing this pathogen at any concentration. For other consumers, it is scientifically recognised that only ingestion of food containing concentration of *Listeria monocytogenes* over the limit of 100 cfu/g is potentially injurious to health. Therefore, ready-to-eat foods, other than those intended for infants and for special medical purposes, which are able to support the growth of *Listeria monocytogenes* beyond the limit of 100 cfu/g throughout their shelf-life represent a sensitive food commodity group on which risk mitigation measures should be focused.

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<sup>1</sup> OJ L 139, 30.4.2004, p. 1., ELI: <http://data.europa.eu/eli/reg/2004/852/oj>.

<sup>2</sup> OJ L 338, 22.12.2005, p. 1., ELI: <http://data.europa.eu/eli/reg/2005/2073/oj>.

<sup>3</sup> <https://doi.org/10.2903/j.efsa.2023.8442>

- (4) Pursuant to Regulation (EC) No 2073/2005 the presence of *Listeria monocytogenes* is not to be detected in 25g of ready-to-eat foods able to support the growth of *Listeria monocytogenes*, other than those intended for infants and for special medical purposes, before they have left the immediate control of the producing food business operator where that food business operator is not able to demonstrate, to the satisfaction of the competent authority, that the level of *Listeria monocytogenes* will not exceed the limit of 100 cfu/g throughout the shelf-life of the foods concerned. However, Regulation (EC) No 2073/2005 does not provide for a criterion which applies to those foods once they have left the immediate control of the producing food business operator while it is still not possible to ensure that the limit of 100 cfu/g will not be exceeded throughout their shelf-life.
- (5) In order to guarantee the same level of public health protection from production to distribution for ready-to-eat foods other than those intended for infants and for special medical purposes that are able to support the growth of *Listeria monocytogenes*, the food safety criterion “*Listeria monocytogenes* not detected in 25 g” should apply to all situations where those foods are placed on the market during their shelf-life and for which the producing food business operator has not been able to demonstrate, to the satisfaction of the competent authority, that the level of *Listeria monocytogenes* will not exceed the limit of 100 cfu/g throughout their shelf-life.
- (6) To allow food business operators sufficient time to adapt their practices and procedures to the new requirement, this Regulation should not apply before 1 January 2026.
- (7) Regulation (EC) No 2073/2005 should therefore be amended accordingly.
- (8) 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*

Annex I to Regulation (EC) No 2073/2005 is amended in accordance with the Annex to this Regulation.

#### *Article 2*

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

It shall apply from 1 January 2026.

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

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*