EU to extend criteria for Listeria monocytogenes in ready-to-eat food to the whole food chain – WTO SPS consultation

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EU to extend criteria for Listeria monocytogenes in ready-to-eat food to cover the whole food chain

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

Draft Annex

Update

The European Commission has informed the World Trade Organization Sanitary and Phytosanitary (WTO SPS) Committee that it proposes to extend a food safety criterion for *Listeria monocytogenes* in ready-to-eat food – "*Listeria monocytogenes* not detected in 25 g" – that is currently applicable to food at the production stage (G/SPS/N/EU/764).

Impacted products

Ready-to-eat foods

What is changing?

Under Regulation 2073/2005, ready-to-eat foods placed on the EU market (other than foods for infants and for special medical purposes) must not contain *L. monocytogenes* above 100 cfu/g. Food businesses are responsible for putting in place procedures based on hazard analysis and critical control points (HACCP) principles and good hygiene practices that ensure this limit can be met. This includes conducting studies that investigate and demonstrate compliance with microbiological criteria. If a food business cannot demonstrate that ready-to-eat food will remain below the limit of 100 cfu/g throughout its shelf-life, they must demonstrate that no *L. monocytogenes* is present in 25 g of the product at the production stage (before the food has left their immediate control). The limit of zero presence of *L. monocytogenes* does not currently apply to these foods once they are placed on the market.

Under the proposed Regulation, this will change and the criterion "*Listeria monocytogenes* not detected in 25 g" will apply throughout the **entire shelf-life** of the product.

This means that where levels of *L. monocytogenes* above zero are found during the shelf-life of ready-to-eat foods placed on the market, foods will not be compliant, unless the food producer can demonstrate that the food will remain below the limit of 100 cfu/g throughout its shelf-life.

Why?

The number of cases of listeriosis in humans in the EU was 15.9% higher in 2022 than in 2021 (EFSA and ECDC 2023). In 2022, annual deaths from foodborne outbreaks of *L. monocytogenes* in the EU were among the highest reported over the past 10 years. In view of this upsurge, it is considered crucial that the food safety criteria for *L. monocytogenes* are tightened to offer a consistently high level of consumer protection throughout the shelf-life of ready-to-eat foods.

Timeline

Expected date of application: **1 January 2026**.

What are the major implications for exporting countries?

This proposal has been the subject of an EU "Have your say" consultation. Responses were received from sectors including fruit and vegetables (European Sprouted Seeds Association (ESSA) & Freshfel Europe), fish (EU Fish Processors and Traders Association, AIPCE-CEP), meat products (Liaison Centre for the Meat Processing Industry in the EU, CLITRAVI), dairy products (European Dairy Association), and the retail sector (EuroCommerce).

Comments raised, which may also be relevant to suppliers from non-EU countries, include the following.

- Contamination can occur at very low levels that are not necessarily a risk to public health, which would make a zero limit in 25 g very difficult to meet for some categories of ready-to-eat foodstuffs
- Rapidly securing the necessary demonstration of compliance with the 100 cfu/g limit may be difficult in practice. This could potentially lead to products being unnecessarily withdrawn from the market, and would contribute to food waste.
- There is a lack of guidelines on how tests should be performed to demonstrate meeting the 100 cfu/g criterion.

- A change in regulation that moves the focus away from the production stage towards controls of final products could shift resources away from good manufacturing practice and good health practice that are essential to managing L. monocytogenes.
- Using single laboratory results does not provide an accurate picture of how pathogens behave and the associated risks, and disregards the importance of continuous good hygiene practices and routine monitoring.
- Testing costs are high, and laboratory testing capacity is limited.
- There will be potential increases in food waste if food is withdrawn on the basis of isolated test results that do not take into account the entire manufacturing environment.
- More guidance for better enforcement of existing rules would be preferable.

Recommended Actions

Producers of ready-to-eat foods for export to the EU should assess their current practices for control of *L. monocytogenes*. Companies that export ready-to-eat foods to the EU must be able to demonstrate that foods in which *L. monocytogenes* can grow will not exceed the 100 cfu/g limit for this pathogen throughout the product's shelf-life. Sectors particularly likely to be affected include salads, sprouts, cheese, cooked meats, smoked fish, and desserts.

Background

Under the umbrella of the EU's General Food Law (Regulation 178/2002), Regulation 852/2004 lays down general rules for food business operators on the hygiene of all foods. It is necessary to ensure food safety throughout the food chain. Primary responsibility for food safety rests with the food business operator.

Regulation 2073/2005 lays down food safety criteria for products placed on the European market. It lays down the microbiological criteria for foodborne pathogens, including *L. monocytogenes*, that pose a serious risk to public health. This proposal concerns "ready-to-eat" foods, defined as "food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern" (Art. 2).

These Regulations are mentioned in the public health attestation that non-EU country authorities must sign to guarantee that only food produced in compliance with the EU legislation is exported to the EU.

Food containing a concentration of *L. monocytogenes* over the limit of 100 cfu/g is potentially injurious to health.

The 100 cfu/g limit **does not apply to food for infants and consumers with weakened immune defences**, who must not be exposed to any concentration of this pathogen.

Resources

EFSA and ECDC (2023) The European Union One Health 2022 Zoonoses Report. EFSA Journal, 21(12): e8442. European Food Safety Authority and European Centre for Disease Prevention and Control.

European Commission: Have your say > *Listeria monocytogenes* in ready-to-eat foods – update of safety criteria > Feedback

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Regulation (EC) No 852/2004 on the hygiene of foodstuffs

Sources

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

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