Food Safety Information Notice 03-2026 Guidance on Changes to *Listeria monocytogenes* Criteria for Ready-to-Eat Seafood Products from 1st of July 2026

AN t-ÚDARÁS UM CHOSAINT IASCAIGH MHARA | SEA-FISHERIES PROTECTION AUTHORITY

The Sea-Fisheries Protection Authority has issued a Food Safety Information Notice entitled "**Guidance on Changes to *Listeria monocytogenes* Criteria for Ready-to-Eat Seafood Products from 1st July 2026**".

At a glance

- **Legal change:** entry 1.2 of Annex I, Chapter 1 of Regulation (EC) No 2073/2005 is amended by Commission Regulation (EU) 2024/2895.
- **Applicable from:** 1st July 2026.
- **Applies to:** Category 1.2 RTE foods able to support the growth of *Listeria monocytogenes* (other than those for infants and special medical purposes).
- **Criterion applies from 1 July 2026:** 100 cfu/g (*footnote 5*) or 'not detected in 25 g' (*footnote 7*), depending on whether the producing food business operator (FBO) has demonstrated, to the satisfaction of the competent authority, that *Listeria monocytogenes* will not exceed 100 cfu/g throughout shelf-life.
- **Non-compliance:** 'detected in 25 g' without satisfactory evidence to show that *Listeria monocytogenes* will not exceed 100 cfu/g throughout shelf-life will be designated as unsatisfactory. In the case of an unsatisfactory result the FBO must take the actions set down in Article 7 of Regulation (EC) No 2073/2005, as amended.

Legislative Basis / Relevant Documentation

- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs
- Commission Regulation (EU) 2024/2895 amending Regulation (EC) 2073/2005 regarding *Listeria monocytogenes* in ready-to-eat foods
- Regulation (EC) no 178/2002 (General Food Law)
- Regulation (EC) 852/2004 on the hygiene of foodstuffs
- European Commission: GUIDANCE DOCUMENT on *Listeria monocytogenes* monitoring and shelf-life studies for ready-to-eat foods under Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
- FSAI Guidance Note No. 27: Guidance on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs
- FSAI Guidance Note No. 45: Guidance on Environmental Monitoring of Listeria monocytogenes in Ready-to-Eat Food Production Areas

Glossary of Terms

Terms/ Acronyms	Description
cfu/g	Colony forming units per gram
FBO	Food Business Operator
FSMS	Food Safety Management System

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g	gram
HACCP	Hazard Analysis and Critical Control Point
RTE	Ready-to-eat
SFPA	Sea Fisheries Protection Authority
SFPO	Sea-Fisheries Protection Officer
Listeria monocytogenes	A pathogenic bacterium capable of causing serious foodborne illness called listeriosis

Introduction

The purpose of this document is to provide information regarding changes to microbiological criteria for *Listeria monocytogenes* in certain ready-to-eat foods from 1st of July 2026.

Listeria monocytogenes is a foodborne pathogen capable of causing severe illness, particularly in vulnerable consumers including older persons, pregnant women and immunocompromised individuals. It is a pathogen which is widely present in the environment and can be very difficult to control if it gets into a food factory.

Ready-to-eat (RTE) seafood products such as cold smoked salmon, smoked trout, and RTE cooked prawns may present an increased risk where the product supports the growth of *Listeria monocytogenes* during shelf life.

Listeria monocytogenes is of particular concern because:

- It can survive and grow at refrigeration temperatures
- It may persist in food production environments; and
- It is frequently associated with post-process contamination of RTE foods

The legislation for *Listeria monocytogenes* – the microbiological criteria – is set out in Chapter 1 of Regulation (EC) No 2073 of 2005. It has three different microbiological criteria for *Listeria monocytogenes.* The category of relevance to this change in the legislation is **Category 1.2.** Within this category there are two subcategories with a limit of 100 cfu/g or not detected in 25 g.

Why is the legislation changing?

The legislation is changing to close a regulatory gap and further protect public health. Commission Regulation (EU) 2024/2895 amends Regulation (EC) No 2073/2005 regarding microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods.

From the 1st of July, FBOs may continue to use the "not detected in 25 g" criterion by testing finished product at the end of manufacturing to assess compliance with the Category 1.2 criteria. However, the key change is that this same criterion will also apply in products placed on the market during their shelf-life (for example at wholesale/retail) after 1st of July unless the FBO can provide robust evidence that *Listeria monocytogenes* growth in the product will not exceed 100 cfu/g throughout shelf-life of the food under reasonably foreseeable conditions of distribution, storage and use as written in footnotes 5 and 7 and Article 3 of Regulation (EC) No 2073/2005.

FBOs are responsible for ensuring that food placed on the market is safe in accordance with general food law (Regulation 178/2002). Seafood FBOs producing relevant RTE products should review their Food Safety Management Systems in advance of 1st of July 2026

It is very important that FBOs understand the risk profile of the RTE food being produced. For example, understanding its physicochemical characteristics, such as the pH and water activity (a_w) of the food, understanding the process, understanding whether the type of food being produced has been linked to listeriosis outbreaks in the past.

What can Food Businesses do to ensure compliance?

The basics to keep *Listeria monocytogenes* risk under control are very important, such as

- Solid pre-requisite programme and HACCP-based procedures
- Implementing a robust supplier control programme, good staff training and retraining as necessary, good hygiene and monitoring programmes, and cold chain maintenance.
- Implementing *Listeria monocytogenes* environmental monitoring programme, and a risk-based microbiological sampling and testing programme which includes end-product testing

What should Food Businesses do if Listeria monocytogenes is found in product or the environment?

If *Listeria monocytogenes* is found in product or in the environment – that the corrective actions documented under the FSMS are followed, which must include a root cause analysis to determine the point source of contamination.

FSAI Guidance Note 45 “Guidance on Environmental Monitoring of *L. monocytogenes* in Ready-to-Eat Food Business Operations” details suggested corrective actions for the *Listeria monocytogenes* monitoring programme that would be triggered if *Listeria monocytogenes* is detected such as:

- Manage potential risk to the RTE food
- Ensure that the FSMS is functioning and fit for purpose
- Ensure hygiene programme is adequate
- Evaluate role of barrier and vector in the contamination event
- Determine the Root Cause of the contamination event
- Evaluate the long-term implications of the contamination event

In addition, FSAI Guidance Note 27 “Guidance Note on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs” gives guidance on acting on unsatisfactory results

Environmental Monitoring

Environmental monitoring is a critical component of *Listeria monocytogenes* control in ready-to-eat seafood production environments. Environmental monitoring must be carried out by FBOs producing RTE food.

FBOs should ensure that environmental monitoring programmes are:

- Risk based;
- Documented;
- Routinely reviewed;
- Capable of identifying contamination trends and harbourage sites.

Particular attention should be given to:

- High care areas;
- Slicing equipment;
- Smoking machine;
- Drains;
- Vacuum packing equipment;
- Boot washers;
- Areas where post-process contamination may occur

Shelf-life studies

An FBO can only use the microbiological criterion limit of ≤100 cfu/g to assess compliance with the requirements of Category 1.2 in products placed on the market during their shelf-life, when the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life.

In Annex II of Regulation (EC) No 2073/2005 there are five different types of shelf-life studies listed. Some of these studies are compulsory and some can be done in addition if the FBO wishes to do so:

Compulsory for all FBOs:

- Characterising the product being produced (pH, water activity (a_w), salt, preservatives etc.) and building up a risk profile of the product.
- Reviewing scientific literature and research data and understanding risk profile of the product (if *Listeria monocytogenes* is likely to grow, similar products on the market involved in listeriosis)

Additional studies which an FBO can undertake (non-compulsory):

- Predictive microbiology study for the product using an appropriate tool
- Challenge testing:
  In the case of a Challenge test, the product is deliberately inoculated with a strain relevant to the product. The product is held at different temperature profiles to reflect reasonably foreseeable conditions of distribution, storage and use. The growth of *Listeria monocytogenes* is monitored throughout the shelf-life assigned to the product to see if it will grow beyond 100 cfu/g.
  The laboratories which do challenge testing are very specialised. Currently there are not any laboratories in the Republic of Ireland doing such tests. There are some commercial labs in Britain and mainland Europe.
- Durability studies:
  These can be done when there is a naturally occurring contamination of *Listeria monocytogenes* in the product. The product is stored under reasonably foreseeable conditions of distribution, storage and use, and the growth is monitored throughout the shelf-life. It is important for FBOs to work with a laboratory that is competent in carrying out these studies.

(For both challenge and durability studies, the European Union Reference Laboratory for *Listeria monocytogenes* has a technical guidance document which specifies the laboratory protocol. This protocol will be used by competent authorities when assessing evidence produced by FBOs that *Listeria monocytogenes* will not grow beyond 100 cfu/g.)

EURL Lm Technical Guidance Document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to Listeria monocytogenes

Where sufficient evidence is not available, the criterion: "Not detected in 25g" will be applied throughout shelf life.

FBO obligations from 1st July 2026

FBOs producing Category 1.2 RTE fishery products

- The FBO must determine whether the product can support the growth of *Listeria monocytogenes* (by determining the physicochemical characteristics of the products like pH, a_w, temperature profile across shelf-life, packaging and intended use). The basis for this determination must be documented in the FBO's Food Safety Management System (FSMS).
- If an FBO intends to demonstrate compliance with the ≤ 100 cfu/g criterion, they must hold and maintain sufficient documented shelf-life evidence that is specific to each relevant product to satisfy the competent authority that *Listeria monocytogenes* will not exceed 100 cfu/gram throughout shelf-life, under reasonably foreseeable conditions of distribution, storage and use. The FBO must submit this evidence to the SFPA for review. SFPA will notify the FBO whether the evidence is sufficient and acceptable for applying the ≤ 100 cfu/g criterion going forward.
- Where evidence has not been accepted by the SFPA, the 'not detected in 25 g' applies throughout shelf-life on the market.
- The FSMS, HACCP plan, verification sampling and environmental monitoring programmes, must reflect the applicable criterion.

FBOs placing Category 1.2 RTE products on the market that they have not produced

- The FBO must hold documented evidence from the producing FBO identifying the applicable criterion and the supporting shelf-life basis.
- Storage and distribution conditions must be consistent with the shelf-life basis declared by the producing FBO.

Official Controls by the SFPA

The SFPA will continue to carry out official controls in RTE seafood producing establishments on a risk basis. When taking a sample of product for official control analysis (microbiological), the SFPA will continue, as it currently does, to apply the 'not detected in 25 g' criterion limit. The enumeration method and assessment of compliance against the ≤100 cfu/g criterion limit will only be used if the FBO has a shelf-life study approved by the SFPA.

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Non-compliance

Where *Listeria monocytogenes* is detected in a Category 1.2 RTE product for which scientific evidence has not been provided to the satisfaction of the SFPA, the result is designated as unsatisfactory. FBO must take corrective action under the FSMS and, as appropriate, the product may be subject to withdrawal or recall from the market.

Scientific evidence cannot be generated retrospectively during a live food incident.[1]

Where contamination is identified in product not yet at retail level, further processing may be permitted in accordance with Article 7.2 of Regulation (EC) No 2073/2005 to eliminate the hazard, where the further processing does not pose a risk to public or animal health and is authorised by the competent authority.

Corrective actions should be implemented as documented under the FSMS when non-compliant results are identified.

Summary key messages

- On the 1st of July 2026, the microbiological criteria legislation (EC) No Regulation 2073/2005) is changing with respect to Category 1.2 RTE foods able to support the growth of *Listeria monocytogenes.*
- The main change is that the more stringent *Listeria monocytogenes* criterion (not detected in 25 g) will apply after manufacture (at wholesale and retail) unless the FBO has documented scientific evidence to show that *Listeria monocytogenes* will not grow beyond 100 cfu/g throughout the shelf life. Such studies will require approval by the SFPA and be documented in the FBO's FSMS.
- All food businesses are responsible for producing safe food (under General Food Law).
- It is very important for food businesses to get the basics right to address *Listeria monocytogenes* risk (good supplier control, good hygiene programme, cold chain maintenance, good staff training, environmental monitoring for *Listeria monocytogenes* etc.)
- FBOs must act immediately if *Listeria monocytogenes* is detected in product and or the environment by taking appropriate corrective actions, as documented under the FSMS. Actions can vary depending on whether *Listeria monocytogenes* was detected in food product or the environment. You must notify your inspector immediately if any food placed on the market is deemed unsafe.

Contact Details

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[1] FBOs can work to gather & submit the evidence at any time but not during a live food incident.