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Review Paper

Zero-tolerance *Listeria* in EU: preparing for the stricter controls

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ABSTRACT

From July 1, 2026, significant amendments to Regulation (EC) No. 2073/2005 will come into effect, tightening microbiological criteria for food safety, particularly concerning *Listeria monocytogenes*. The revision, introduced through Regulation (EU) 2024/2895, responds to both a rise in listeriosis incidence across Europe between 2019 and 2023 and an identified legal loophole that allowed uneven enforcement among Member States. The updated framework extends responsibility across the entire food supply chain, holding all food business operators-from producers to retailers-accountable for compliance. Ready-to-eat foods must either demonstrate absence of *L. monocytogenes* in a 25 g sample or provide scientific evidence that levels of this pathogen remain below 100 CFU/g throughout the product's shelf life.

The rising burden of listeriosis, with EU-confirmed cases and fatalities increasing steadily, underscores the urgency of these measures. Vulnerable populations, particularly the elderly, remain at greatest risk, while the prevalence of *L. monocytogenes* in fish, fishery, and meat products highlights the need for strengthened controls. Key regulatory changes include stricter environmental monitoring, comprehensive shelf-life and challenge testing, and expanded obligations covering storage, distribution, and retail. Compliance will require enhanced HACCP programs, increased testing capacity, staff training, and systematic documentation, with substantial financial and operational implications for the food industry.

Adaptation strategies center on predictive microbiology and challenge testing, guided by ISO 20976-1:2019 and the EURL Lm Technical Guidance Document, ensuring reproducibility and scientific robustness. Ultimately, these reforms aim to reduce consumer exposure and improve food safety outcomes, albeit with anticipated costs, product reformulations, and market adjustments.

1. Introduction

On July 1, 2026, significant amendments to *Regulation (EC) No. 2073/2005* will be implemented, emphasizing microbiological criteria for food safety, particularly concerning *Listeria monocytogenes* (*Regulation (EU) 2024/2895*). The amendments can be attributed to (i) the rise in listeriosis incidence within the European Union during 2021 to 2022 and (ii) a legal loophole in Point 1.2 of Chapter 1 of Annex I to Regulation No. 2073/2005, as recognized by the European Court of Justice (CJEU) in

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2022 (*CJEU*, 2022), which could be interpreted differently across EU countries, so the CJEU allowed national authorities to enforce stricter measures than those laid down in respective EU legislation.

The constriction exerts a considerable influence on the comprehensive food supply chain, encompassing all stakeholders from producers to retailers. All food businesses operators (FBOs) within the chain will be held accountable for adhering to the established standards. This underscores the significance of conducting comprehensive shelf life and challenge tests, to ensure reliability and performance. In contrast to prior practices where the manufacturer held the primary responsibility, it is now imperative for all entities within the supply chain to demonstrate that their products comply with the established requirements for the entirety of their shelf life. The updated regulation stipulates that there must be either evidence demonstrating the absence of *L. monocytogenes* in a 25-gram sample of the product, or that any *L. monocytogenes* growth must be scientifically substantiated to remain below the threshold of 100 CFU/g. This indicates that food enterprises are required to enhance their procedural rigor while simultaneously improving their comprehension of the design and execution of microbiological testing methodologies.

2. *Listeria monocytogenes* –- a continual hazard and alarming statistics

L. monocytogenes is a Gram-positive pathogen associated with foodborne illnesses and is widely distributed in various environments. The organism's capacity to endure in a range of environments is attributed to several factors, including its robustness against different conditions found in food processing facilities, such as cold storage, as well as its ability to form biofilms (*Swaminathan and Gerner-Smidt*, 2007). Listeriosis has the potential to result in gastroenteritis or meningoencephalitis, with particularly severe outcomes observed in individuals with compromised immune systems (*Wiktorczyk-Kapischke et al*., 2023). It is also a continual challenge for the food industry, especially when it comes to ready-to-eat (RTE) foods that are consumed without further cooking.

In the European Union, the data show a statistically significant upward trend in *L. monocytogenes* infections from 2019 to 2023, with this pathogen ranking fifth among the most frequently reported foodborne infections. According to a 2022 report by the European Food Safety Authority (EFSA), cases of listeriosis increased by 15.9% compared to 2021 and the number of deaths was one of the highest in the last 10 years. In 2023, there was a documented increase of 5.8% in the listeriosis notification rate relative to 2022, culminating in a total of 2,952 confirmed invasive human cases identified from a pool of 5,691 foodborne outbreak cases and leading to 335 fatalities (*EFSA*, 2024). In 2024, 179 cases of listeriosis were reported in England and Wales, and incidence rates of listeriosis were highest in people aged 80 years and over (*UKHSA*, 2025). Death was reported for 28 cases, of whom 9 were known to have listeriosis recorded as a cause of death on the death certificate.

These data indicate a notable escalation and underscore the critical necessity for enhanced food safety protocols. The EFSA reports indicated a higher prevalence of *L. monocytogenes* in specific categories of RTE foods, specifically fish, fishery products, and meat products. The data appear to have been a crucial factor in instigating the recent legislative modifications designed to improve control measures.

The recent increase in listeriosis cases throughout Europe presents a multifaceted problem with numerous contributing elements grouped into these four major categories:

- Alterations in consumer behavior: The increasing prevalence of RTE foods, although advantageous in terms of convenience, elevates the likelihood of exposure due to possible mishandling and storage complications.
- Complex supply chains: The phenomenon of globalization has resulted in the development of intricate supply chains, thereby complicating the process of tracing ingredients and identifying sources of contamination.
- Persistence and adaptability: *L. monocytogenes* exhibits remarkable resistance, demonstrating the ability to survive in diverse environments, including those at refrigeration temperatures. Additionally, it possesses the capability to form biofilms on surfaces, which poses significant challenges to effective control measures.
- Poor awareness and knowledge issues: Insufficient awareness regarding safe food handling practices, especially within vulnerable populations, may facilitate the transmission of foodborne pathogens. The role of education is fundamental in the context of prevention strategies.

3. Key changes in upcoming regulatory framework

Key changes which will be introduced from 2026 include stricter criteria and extension of FBO responsibility. The initial regulation concentrated on the management of *Listeria* during the production phase. The amendment broadens this responsibility to encompass all phases of the food chain, thereby guaranteeing a uniform level of protection across the entirety of the product's shelf life. The amendment establishes more stringent criteria, mandating that *L. monocytogenes* must be absent in RTE foods available on the market, unless the producer can provide evidence that the levels will consistently remain below the established safety threshold for the duration of the product's shelf life. In more straightforward language: Should a producer be unable to demonstrate that their RTE food will maintain a *L. monocytogenes* level below 100 CFU/g for its entire shelf life, it is imperative that *L. monocytogenes* is entirely absent (i.e., not detected in 25 g).

The recent regulatory update necessitates prompt consideration of each FBO's environmental monitoring program. Although the reference methods EN ISO 11290-1 (*ISO*, xxxx) and EN ISO 11290-2 (*ISO*, xxxx) have not undergone alterations, it is imperative that the frequency and scope of testing be considerably increased. Current environmental monitoring protocols are presumably centered around critical control points and surfaces that come into direct contact with food. The newly established regulation (*European Commission*, 2024) mandates thorough monitoring of both food contact and adjacent non-food contact surfaces, ensuring that assessments are conducted with adequate frequency to identify persistent contamination prior to its escalation into a systemic issue. Documentation will serve as a critical resource for ensuring compliance. All products that can facilitate the proliferation of *L. monocytogenes* must undergo comprehensive shelf-life investigations, which encompass physico-chemical assessments, predictive modeling, and frequently, challenge testing. The HACCP and/or quality assurance teams will be required to conduct thorough trend analyses that document continuous control measures and to maintain detailed records of corrective actions for each positive finding. This is not solely a matter of fulfilling regulatory obligations; it involves constructing a robust food safety framework capable of enduring regulatory examination.

The regulation further expands each FBO's obligations beyond the confines of their respective facilities. The interconnected nature of storage, distribution, and retail operations necessitates adherence to compliance obligations. It is essential to acknowledge that temperature abuse or cross-contamination occurring during transport and display can undermine even the most stringent production controls. The supplier agreements and customer specifications will certainly require revision to accurately represent the delineated shared responsibilities, but also to address considerable expenses associated with compliance.

There has been a lot of negative perception in the food industry sector ever since the EU established the zero-tolerance policy for *L. monocytogenes* in late 2024. Even during the vote on the Regulation, unanimity was not attained, because 25 member states voted in favor of the modification, Finland abstained, and Belgium voted against. The primary obstacle lies in the necessity for rigorous scientific validation. Manufacturers will be required to provide scientific evidence that products consistently exhibit a "not detected in 25g" status for *L. monocytogenes* over the food's shelf-life, or that *L. monocytogenes* will not surpass the 100 CFU/g threshold if asserting this exception. This has been understood by certain national authorities as necessitating challenge testing, wherein products are inoculated with *L. monocytogenes* and observed throughout their shelf-life. Conversely, other authorities adopt a more pragmatic stance, permitting FBOs to utilize existing historical data on prevalence of *L. monocytogenes* at the end of product shelf-life. Also, a significant number of researchers express skepticism regarding shelf-life testing, arguing that the artificial conditions of laboratory environments fail to accurately replicate real-world scenarios. Next, regular microbiological testing could result in a considerable increase in the financial costs involved due to the need for increased environmental monitoring. Considerable modifications to FBOs' HACCP plans will be needed, such as elimination of potential harborage points, the implementation of enhanced hygienic zoning with stricter separation between raw food and RTE food areas, an increase in testing capacity, staff training focused on improved procedures, and the establishment of data management systems for trend analysis. The modifications in regulatory frameworks are anticipated to improve consumer safeguards against listeriosis, especially among susceptible groups where mortality rates could escalate to 30%. Manufacturers must

anticipate market repercussions, which could include potential price escalations as compliance expenditures are integrated, the likelihood of product discontinuation for items that may no longer be economically feasible, and reduced shelf-lives as reformulation strategies are enacted.

4. Adaptation to the new legislation

In order to comply with this new legislation by July 1, 2026, FBOs can demonstrate that their RTE products do not exceed the 100 CFU/g threshold by means of various tools. Among these options, challenge tests and predictive microbiology are most frequently used. Predictive microbiology involves use of mathematical models that forecast bacterial behavior depending on variables such as pH level, water activity, salt content, inhibitory components, adjuvants, background microbiota and temperature. On the other hand, challenge tests involve the deliberate contamination of a product to assess the proliferation of *L. monocytogenes* over a designated timeframe and inside a particular RTE product. It is important to highlight that these two tools are not mutually substitutable, but rather complementary, since the application of predictive microbiology modeling enables the forecasting of bacterial behavior in various environments, eliminating the need for laboratory experimentation, while a bacterial challenge test is essential for acquiring precise data concerning bacterial activity in a specific product under defined storage conditions.

The implementation of shelf-life and challenge tests aimed at evaluating the growth of *L. monocytogenes* has been detailed in international standard ISO 20976-1:2019 (*ISO*, 2019). The EU reference laboratory for *L. monocytogenes* (Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail, France) has systematically documented various protocols for challenge and durability tests for *L. monocytogenes* in a technical guidance document (TGD) (*EURL Lm*, 2021). The TGD is especially critical in enhancing the reliability and reproducibility of microbiological testing, thereby ensuring that results are both consistent and of high quality. It anticipates use of selected *L. monocytogenes* strains that are pertinent to the specific product type, and pre-testing a minimum of three distinct production batches in advance of the challenge test. Furthermore, it stipulates analysis of no fewer than five samples from each batch for parameters such as water activity (aW), pH, and salt concentration to address variability both within individual batches and across different batches. The TGD also incorporates simulation scenarios of temperature variations in production, distribution, and consumer storage.

For the purposes of pre-analysis or research and development by the FBO, challenge testing, as well as predictive modeling, can be conducted at the FBO's own laboratory, provided it exists. However, for regulatory self-inspections, these tests must be conducted in accredited laboratories that have been recognized by local authorities for the purpose of performing challenge tests and which possess the requisite expertise, infrastructure and knowledge potential to conduct these intricate tests. This aspect is important not only for the reliability of the results but also for compliance with legal frameworks and regulatory standards.

5. Conclusion

The forthcoming amendments to Regulation (EC) No. 2073/2005 represent a decisive shift towards strengthening consumer protection against *L. monocytogenes*. By extending accountability across the entire food supply chain, Regulation 2024/2895 (*European Commission*, 2024) compels all stakeholders to adopt more rigorous monitoring, testing, and documentation practices. While compliance will entail significant financial and operational challenges, it also fosters the development of more robust and scientifically validated food safety systems. Ultimately, these measures are expected to reduce listeriosis incidence, safeguard vulnerable populations, and enhance trust in the European food market.

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