

A new legal approach for microbiological criterion for *L. monocytogenes* in RTE foods

AGNIESZKA JACKOWSKA-TRACZ, PAWEŁ PNIEWSKI, MICHAŁ TRACZ

Department of Food Hygiene and Public Health Protection, Institute of Veterinary Medicine,
Warsaw University of Life Sciences – SGGW, Nowoursynowska 159 bldg. 24, 02-776 Warsaw, Poland

Received 06.07.2026

Accepted 26.08.2026

Jackowska-Tracz A., Pniewski P., Tracz M.

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Summary

Commission Regulation (EU) 2024/2895 amends the practical application of criterion 1.2 of Annex I to Commission Regulation (EC) No 2073/2005 for ready-to-eat foods that support the growth of *Listeria monocytogenes*. The amendment does not modify the microbiological limits themselves, yet clarifies the regulatory consequence of insufficient evidence. The limit of 100 CFU/g may be applied only where the FBO demonstrates, to the satisfaction of the competent authority, that this level will not be exceeded throughout the entire shelf life. In the absence of such a demonstration, the stricter criterion „not detected in 25 g” also applies to products already on the market during their shelf life.

This clarification is particularly relevant for RTE foods, including meat, fishery and dairy products, which remain important areas of official veterinary control. The revised interpretation of criterion 1.2 reinforces an evidence-based approach to food safety management: the selected microbiological criterion should be supported by product-specific data and integrated with product classification, shelf-life justification, environmental monitoring, validation of control measures and verification of HACCP-based procedures. From the perspective of official control, the key issue is not only which limit has been selected, but whether the documentation allows an informed assessment of why that limit is appropriate for the product concerned. Regulation (EU) 2024/2895, therefore, makes the evidence supporting the selected *L. monocytogenes* criterion a central element of compliance for FBOs and competent authorities supervising foods of animal origin.

Keywords: *Listeria monocytogenes*, RTE food, growth potential, microbiological criteria, criterion 1.2, Regulation (EU) 2024/2895, HACCP, official veterinary control

Regulation (EC) No 2073/2005 distinguishes three categories of ready-to-eat foods in relation to *Listeria monocytogenes*: foods intended for infants and foods for special medical purposes (food category 1.1), ready-to-eat (RTE) foods able to support the growth of *L. monocytogenes* (food category 1.2), and ready-to-eat foods unable to support its growth (food category 1.3). These categories reflect a risk-based gradation: from products intended for the most vulnerable consumers, where the potential health consequences are greatest, through products in which the likelihood of pathogen growth during shelf life is increased, to products whose intrinsic or extrinsic characteristics do not support such growth.

For RTE foods able to support the growth of *L. monocytogenes*, other than foods intended for infants and foods for special medical purposes, criterion 1.2 provides two alternative regulatory reference points: the quantitative limit of 100 CFU/g and the qualita-

tive criterion „not detected in 25 g”. The application of the 100 CFU/g limit is not automatic. It depends on whether the food business operator (FBO) can demonstrate to the competent authority’s satisfaction that this level will not be exceeded throughout the product’s shelf life.

Comparative analyses of regulatory systems show that approaches to *L. monocytogenes* in RTE foods vary between jurisdictions. Against this background, the EU model is not a simple zero-tolerance system, but a risk-based and evidence-based framework in which the 100 CFU/g limit may be applied only when the FBO can demonstrate that this level will not be exceeded throughout shelf life (3-5).

Commission Regulation (EU) 2024/2895 clarifies the practical consequences of insufficient evidence. Where the FBO cannot demonstrate that *L. monocytogenes* will remain at or below 100 CFU/g throughout shelf life, the criterion „not detected in 25 g” also

applies to products already placed on the market during their shelf life. The amendment, therefore, does not introduce a new microbiological limit but strengthens the role of documented, product-specific evidence in determining which criterion to apply. Its regulatory objective is to ensure a consistent level of public health protection from production to distribution where such demonstration is not available (4).

This issue has direct practical relevance to HACCP-based procedures (Hazard Analysis and Critical Control Points), food safety management systems and official control, including official veterinary control in establishments producing foods of animal origin. The central question is no longer limited to whether a product has been tested against a given limit, but rather whether the selected criterion is supported by evidence regarding product characteristics, process design, packaging, storage conditions, shelf-life justification, growth potential, and environmental monitoring and verification activities.

This review explains how Regulation (EU) 2024/2895 affects the practical application of criterion 1.2 for *L. monocytogenes* in RTE foods of animal origin, with particular emphasis on the evidence required to justify the use of the 100 CFU/g limit throughout shelf life. The article focuses on the consequences of this evidence-based approach for FBOs, HACCP/FSMS documentation and official veterinary control.

Biological and technological relevance of *Listeria monocytogenes* in RTE foods of animal origin

Commission Regulation (EC) No 2073/2005 defines ready-to-eat food 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, microorganisms of concern” (3). This definition is particularly important for foods of animal origin consumed without further heat treatment, including cooked, sliced meat products, pâtés, smoked or lightly preserved fish products, soft cheeses, and other refrigerated RTE products (14).

The importance of *L. monocytogenes* results from several properties of this microorganism. It may be introduced into a plant through raw materials, including meat, fish and milk, as well as through personnel, equipment or environmental contamination. It may also persist in the production environment, including on food-contact surfaces, in drains, on equipment, on slicers, in wet areas, and in other hard-to-access niches (18, 21). Persistence in the processing environment is facilitated by its ability to adhere to surfaces and form biofilms; under experimental conditions, early biofilm development may occur within 24–48 h (20).

A separate but equally important issue is the behavior of *L. monocytogenes* in the food itself. This pathogen can survive and, under favorable product and storage

conditions, multiply at refrigeration temperatures (1, 7, 10). From a regulatory perspective, even limited growth in the product may be relevant: an increase from 10 to 100 CFU/g represents a 1-log increase. In challenge testing, growth potential is assessed for a specific food, and a value exceeding 0.5 log₁₀ CFU/g is considered evidence that the food can support the growth of *L. monocytogenes* (1, 7, 9). For this reason, refrigerated storage alone does not always constitute a sufficient control measure.

The risk is not limited to the product’s microbiological status immediately after production. A product in which the level of *L. monocytogenes* is very low after packaging may become non-compliant with the food safety criterion if its characteristics and storage conditions allow the microorganism to grow during distribution, retail sale or storage by the consumer. Therefore, assessment of RTE foods must include both the potential for contamination and the growth potential of *L. monocytogenes* throughout the shelf life (1, 7).

The need to control growth throughout shelf life is supported by the 2018 scientific opinion of the EFSA BIOHAZ Panel. The opinion indicated that quantitative modeling suggests that more than 90% of invasive listeriosis cases are associated with the consumption of RTE foods containing more than 2000 CFU/g of *L. monocytogenes*. This conclusion does not diminish the importance of the 100 CFU/g limit but reinforces the need to prevent the microorganism from reaching high levels during the declared shelf life (6).

Amendment of criterion 1.2 of Regulation (EC) No 2073/2005

Commission Regulation (EC) No 2073/2005 is not a static legal act. Since its adoption, it has been successively amended in response to advances in scientific knowledge, experience gained from official food controls and the needs of industrial practice. By 2020, the Regulation had been amended 10 times, the most recent amendment being Commission Regulation No. 2020/205 of 14 February 2020. A further amendment, of particular importance to producers of ready-to-eat foods, was introduced by Commission Regulation (EU) 2024/2895 of 20 November 2024 and took effect from 1 July 2026.

The distinction between ready-to-eat foods able and unable to support the growth of *L. monocytogenes* should not be based solely on the product type, but on the combined effect of intrinsic and extrinsic factors. The factors relevant to this distinction, together with their practical implications for product classification, are summarized in Table 1. Products generally regarded as capable of supporting growth may include certain chilled meat products, smoked or lightly preserved fish products, soft cheeses, pâtés, delicatessen products, prepared salads, sandwiches and other minimally processed refrigerated foods. Conversely, products

Tab. 1. Comparison of food categories 1.2 and 1.3 under Annex I, Chapter 1 of Regulation (EC) No 2073/2005, as amended by Regulation (EU) 2024/2895, according to their ability to support the growth of *Listeria monocytogenes*

Criterion	Food Category 1.2 RTE foods that are ABLE to support the growth of <i>L. monocytogenes</i>	Food Category 1.3 RTE foods that are UNABLE to support the growth of <i>L. monocytogenes</i>
General definition	Ready-to-eat foods, other than those intended for infants or for special medical purposes, in which <i>L. monocytogenes</i> may grow during shelf-life	Ready-to-eat foods, other than those intended for infants or for special medical purposes, in which <i>L. monocytogenes</i> is not expected to grow during shelf-life
Schematic representation of the possible behaviour of <i>L. monocytogenes</i> in food during shelf life. NOTE! The initial level is illustrative and does not represent a universal contamination level for RTE products	Growth during shelf life	No growth during shelf life
Risk interpretation	The likelihood component of risk increases because even low-level contamination can lead to bacterial multiplication before the end of shelf life	The likelihood of growth is reduced because intrinsic and/or extrinsic factors prevent or effectively limit multiplication during shelf-life
Regulatory indication of inability to support growth	Not applicable as an automatic classification. If the product does not meet the conditions indicating an inability to support growth, or if such an inability has not been demonstrated, it should be assessed as potentially capable of supporting growth	Products with: • $\text{pH} \leq 4.4$, • $\text{aw} \leq 0.92$, • $\text{pH} \leq 5.0$ and $\text{aw} \leq 0.94$, • or a shelf-life shorter than 5 days are considered unable to support the growth of <i>L. monocytogenes</i> under Regulation (EC) No 2073/2005
Growth potential	A product is considered able to support growth when the growth potential of <i>L. monocytogenes</i> exceeds $0.5 \log_{10}$ CFU/g during shelf-life	A product is considered unable to support growth when the growth potential of <i>L. monocytogenes</i> is $\leq 0.5 \log_{10}$ CFU/g during shelf-life
Intrinsic characteristics	Product properties may allow growth; e.g., pH, water activity, salt content, nutrient composition, and competing microbiota do not provide sufficient inhibitory barriers	Product properties inhibit growth, e.g., sufficiently low pH, low water activity, high salt content, the presence of preservatives, organic acids, a competitive microbiota, or a combination of several hurdles
Extrinsic characteristics	Storage and packaging conditions may permit survival and growth, especially during refrigerated storage, extended shelf life, vacuum packaging, or modified-atmosphere packaging, if not supported by adequate inhibitory factors	Storage and packaging conditions prevent growth or maintain the product's inhibitory effect, e.g., freezing, short shelf life, validated storage temperatures, shelf-stable conditions, or packaging combined with effective intrinsic hurdles
Examples of products	Certain chilled meat products, cooked sliced meat products, pâtés, delicatessen products, smoked or lightly preserved fish products, soft cheeses, prepared salads, sandwiches and chilled ready meals	Certain dried foods, acidic products, frozen products, shelf-stable products, hard cheeses, some fermented products and some dry-cured meats, provided that the absence of growth has been adequately demonstrated
Key evidence	Product characterization, physicochemical data, shelf-life data, scientific literature, historical data, finished-product testing, environmental monitoring and, where necessary, challenge testing or predictive modeling	
Purpose of evidence	To demonstrate that <i>L. monocytogenes</i> will not exceed 100 CFU/g throughout shelf life	To demonstrate that the product characteristics or inhibitory factors prevent growth of <i>L. monocytogenes</i> throughout shelf life

unable to support growth are those in which the physicochemical properties of the food and/or the conditions of storage prevent multiplication of *L. monocytogenes* during shelf life. This applies, in particular, to products with low pH ($\text{pH} \leq 4.4$), low water activity ($\text{aw} \leq 0.92$), a combined inhibitory effect of pH and water activity ($\text{pH} \leq 5.0$ and $\text{aw} \leq 0.94$), a very short shelf life (less than 5 days), or products kept frozen, since freezing prevents bacterial growth. However, for frozen RTE foods, the conditions after thawing must also be considered. If the product is intended to be stored and consumed after thawing, and the declared shelf life after thawing exceeds 5 days, *L. monocytogenes* may grow during this post-thaw period unless other

validated intrinsic or extrinsic factors prevent growth. Therefore, the classification of a frozen RTE product as unable to support growth should take into account not only frozen storage, but also the intended storage conditions and duration after thawing (7, 8).

The regulatory change introduced by Commission Regulation (EU) 2024/2895 specifically relates to food category 1.2 in Annex I to Regulation (EC) No 2073/2005, which covers ready-to-eat foods that can support the growth of *L. monocytogenes*, except for foods intended for infants and foods for special medical purposes. This category is subject to two alternative microbiological criteria: a quantitative limit of 100 CFU/g and a qualitative criterion of „not detected in 25 g”. The

amendment does not introduce a new microbiological limit. However, it fills a regulatory gap in the previous wording by extending the application of „not detected in 25 g” to products already on the market for which the FBO has not demonstrated that *L. monocytogenes* will remain below 100 CFU/g throughout shelf life.

Food category 1.2 should not be interpreted as requiring the simultaneous fulfillment of two sequential microbiological requirements: „not detected in 25 g” at the end of production and „not exceeding 100 CFU/g” during placing on the market. These are two alternative criteria applied under different regulatory conditions. This principle was already present in the previous wording of Regulation (EC) No 2073/2005 and remains unchanged after the revision introduced by Regulation (EU) 2024/2895. The microbiological limits themselves have also not changed; the revision concerns the scope and timing of application of the qualitative criterion „not detected in 25 g” when the FBO cannot demonstrate that *L. monocytogenes* will remain below 100 CFU/g throughout shelf life (3, 4).

Thus, the quantitative limit of 100 CFU/g applies when the FBO can demonstrate control of *L. monocytogenes* growth throughout shelf life, whereas, in the absence of such demonstration, the qualitative criterion „not detected in 25 g” applies. Therefore, the choice of criterion depends on documented evidence supporting control of *L. monocytogenes* during shelf life, rather than on an obligation to apply both limits cumulatively (1, 7, 10). Treating these criteria as sequential requirements for the same product situation may lead to a misinterpretation of criterion 1.2, because it conflates the qualitative detection of the microorganism in 25 g with the quantitative assessment of its level in the product (1, 3, 4, 7, 10).

The previous interpretative gap in criterion 1.2 for products placed on the market during shelf life

The previous wording of criterion 1.2 created an interpretative gap in a specific but practically important situation. The quantitative limit of 100 CFU/g applies only to products placed on the market during their shelf life, where the FBO can demonstrate that this level will not be exceeded. Where such a demonstration was not available, the qualitative criterion „not

detected in 25 g” was explicitly linked to the stage before the food had left the immediate control of the producing FBO (3).

An intermediate situation could therefore arise: the product had already been placed on the market, for example, in a warehouse, retail outlet or other distribution setting, but the operator did not have sufficient evidence that *L. monocytogenes* would remain at or below 100 CFU/g until the end of shelf life. The uncertainty concerned whether such a product should be assessed against the quantitative limit, given that it was already on the market, or against the stricter qualitative criterion, given that the essential demonstration of growth control was missing.

The Food Safety Authority of Ireland noted this issue in *Guidance Note No. 27*, indicating that the previous wording did not effectively specify a limit for category 1.2 foods sampled after leaving the immediate control of the producing FBO, where the operator could not demonstrate compliance with the 100 CFU/g limit throughout shelf life (10). The same regulatory gap is also reflected in the recitals to Regulation (EU) 2024/2895.

This situation may be illustrated by a chilled RTE product, such as fish salad, sandwich spread or sliced fish, with a shelf life of 21 days. Such a product may support the growth of *L. monocytogenes* and therefore fall within category 1.2. If the producer does not possess sufficient shelf-life data, predictive modeling or equivalent evidence to show that the level of *L. monocytogenes* will remain at or below 100 CFU/g until the end of shelf life, the use of the quantitative limit cannot be properly justified.

If, for example, an official control sample collected from a retail outlet on day 12 is positive for *L. monocytogenes* in 25 g but remains below 100 CFU/g, the previous wording created interpretative uncertainty. The product was already on the market, but the operator had not fulfilled the condition required to rely on the 100 CFU/g limit. Under Regulation (EU) 2024/2895, this situation is clarified: in the absence of the required demonstration, the criterion „not detected in 25 g” also applies to products already placed on the market during their shelf life (4). The three practical scenarios that may arise under criterion 1.2 for RTE foods capable

Tab. 2. Scenarios covered by the previous wording of criterion 1.2 and the interpretative gap clarified by Regulation (EU) 2024/2895

Scenarios	Product status	Evidence supporting the 100 CFU/g limit throughout shelf life	Previous wording of Regulation (EC) No 2073/2005	After Regulation (EU) 2024/2895	Practical meaning
1	Product still under the immediate control of the producing FBO	No	“Not detected in 25 g”	“Not detected in 25 g”	Already covered before the amendment
2	Product placed on the market during shelf life	Yes	100 CFU/g	100 CFU/g	Already covered before the amendment
3	Product placed on the market during shelf life	No	Interpretative gap	“Not detected in 25 g”	Gap clarified by Regulation (EU) 2024/2895. The absence of evidence now leads to the qualitative criterion also at the market stage

Tab. 3. Practical interpretation of criterion 1.2 before and after Commission Regulation (EU) 2024/2895

Element	Before the amendment	From 1 July 2026	Practical consequence
Product category	RTE foods able to support the growth of <i>L. monocytogenes</i> , other than foods intended for infants and foods for special medical purposes	The same product category is retained	The amendment does not change the scope of criterion 1.2
100 CFU/g limit	Applicable if the FBO could demonstrate that the product would not exceed 100 CFU/g throughout shelf life	Remains applicable only where such demonstration is available	The 100 CFU/g limit is conditional on documented evidence and cannot be applied automatically
“Not detected in 25 g” criterion	Applied where the 100 CFU/g limit was not demonstrated, mainly before the food had left the immediate control of the FBO	Applies also to products placed on the market during their shelf life if the FBO has not demonstrated that the 100 CFU/g limit will not be exceeded	This is the key practical change introduced by Regulation (EU) 2024/2895
Main control question	Frequently reduced in practice to the question of whether the product was sampled before or after leaving the immediate control of the FBO	Has the FBO demonstrated control of <i>L. monocytogenes</i> throughout the entire shelf life?	The focus shifts from the sampling stage to evidence of growth control

of supporting the growth of *Listeria monocytogenes*, including the scenario that previously represented the interpretative gap clarified by Regulation (EU) 2024/2895, are presented in Table 2.

Thus, the revision shifts the key question from the sampling location or regulatory stage of the product to documented evidence of growth control throughout shelf life. The practical issue is no longer only whether the product was sampled before or after leaving the immediate control of the producing FBO, but whether the operator has demonstrated, to the satisfaction of the competent authority, that *L. monocytogenes* will not exceed 100 CFU/g throughout the entire shelf life. Consequently, the most important change introduced by Regulation (EU) 2024/2895 is not the establishment of a new microbiological limit, but the extension of the application of the criterion “not detected in 25 g” to products placed on the market where such demonstration is not available. The differences between the previous and the new practical interpretation of criterion 1.2 are presented in Table 3.

Basis for applying the 100 CFU/g limit

The term „demonstration” should not be understood as a single satisfactory analytical result, but as evidence that *L. monocytogenes*, if present, will not exceed 100 CFU/g at any point during the stated shelf life of the product. It refers to a documented, product-specific assessment showing that, under reasonably foreseeable conditions of distribution, storage and use, the level of *L. monocytogenes* will not exceed 100 CFU/g throughout the declared shelf life (1, 3, 7). In this respect, Regulation (EU) 2024/2895 does not introduce a new EU regulatory concept. The obligation to demonstrate compliance with the 100 CFU/g limit throughout shelf life was already embedded in Regulation (EC) No 2073/2005 and remains unchanged. The amendment clarifies, however, that where such a demonstration is unavailable, the criterion „not detected in 25 g” also applies to products already on the market during their shelf life.

Regulation (EC) No 2073/2005 does not establish legally binding intermediate limits between „not detected

in 25 g” and 100 CFU/g for food category 1.2. Any lower internal levels used by an FBO should therefore be regarded as establishment-specific risk-management tools rather than additional EU microbiological criteria. Their purpose is to maintain a sufficient safety margin and to support compliance with the 100 CFU/g limit throughout shelf life (3, 7, 10). This approach follows from the requirement to demonstrate compliance throughout shelf life and from guidance recommending that such demonstration should be based on product-specific evidence, including product characteristics, shelf-life studies, predictive modeling, challenge testing and historical data (1, 7, 10).

The assessment should start with a product-specific description of intrinsic and extrinsic factors relevant to the survival and growth of *L. monocytogenes*, including pH, aw, salt content, antimicrobial substances, processing, packaging atmosphere, competing microbiota, storage temperature and time. These factors should be assessed together, as the microbiological stability of RTE foods often results from several interacting hurdles rather than from a single inhibitory factor, consistent with the hurdle technology concept (1, 7, 13).

Where uncertainty remains, shelf-life studies are particularly important. They should reflect actual and reasonably foreseeable conditions of distribution, storage and use, including possible deviations in the cold chain. Overly optimistic assumptions about storage temperature may underestimate *L. monocytogenes* growth and lead to an excessively long declared shelf life (7).

Challenge testing may be required when the growth potential of *L. monocytogenes* cannot be reliably assessed using simpler evidence, such as product characteristics, historical data or predictive modeling. Such testing requires appropriate microbiological competence, a justified inoculation strategy, relevant strains and careful interpretation of growth under controlled but product-relevant conditions (1, 6, 7, 20).

Growth potential, commonly denoted as Δ , is expressed as the difference between the highest observed concentration during storage and the initial concentration of *L. monocytogenes* in the product. According to

the EURL *Listeria monocytogenes* Technical Guidance Document, ready-to-eat foods are considered able to support the growth of *Listeria monocytogenes* when the growth potential exceeds 0.5 log₁₀ CFU/g under the tested shelf-life conditions (9).

The practical relevance of this approach was illustrated by Pniewski et al., who applied challenge testing to RTE, uncured, vacuum-packed pork bars with dried plasma and showed that product classification depended on product-specific behavior at defined storage temperatures. Their results supported classifying the tested product as an RTE food capable of supporting the growth of *L. monocytogenes*, corresponding to category 1.2 of Regulation (EC) No 2073/2005(19).

For example, a chilled RTE sandwich spread with a declared shelf life of 21 days and modified-atmosphere packaging cannot be assessed solely on the basis of satisfactory finished-product results obtained on the day of production. To justify the use of the 100 CFU/g limit, the establishment should evaluate product pH, aw, salt and preservative content, the packaging atmosphere, actual storage conditions and relevant scientific or historical data. If these data do not sufficiently resolve uncertainty, shelf-life studies, predictive modeling or challenge testing may be required.

Accordingly, challenge testing should not be treated as a routine screening tool, but as a structured shelf-life study requiring a competent laboratory, scientifically justified test design and interpretation in line with the European Commission/DG SANTE guidance, the EURL *Listeria monocytogenes* Technical Guidance Document and EN ISO 20976-1.

Implications for Food Safety Management System

The amendment to criterion 1.2 has direct implications for HACCP-based procedures, particularly regarding documentation, validation, and verification. For category 1.2 RTE foods, the microbiological criterion should not be treated as an isolated table entry or as a matter of final-product testing alone. The producer should not limit the documentation to a statement that the 100 CFU/g limit applies to the product. Application of this limit requires evidence that *Listeria monocytogenes*, if present, will not exceed 100 CFU/g throughout the entire stated shelf life. Therefore, the selected microbiological criterion should be logically linked to the product description, intended use, hazard analysis, control measures, shelf-life justification, and verification of system effectiveness. These elements correspond to the practical implementation of HACCP principles and to the broader operation of the FSMS (1, 3, 4, 7, 15).

In hazard analysis, *L. monocytogenes* should be considered not only as a microorganism potentially present in raw materials, but primarily as a hazard associated with contamination or recontamination from the processing environment. This is supported by environmental sampling studies showing that *L. monocytogenes*

may be detected at substantial levels in food-processing environments; in one European study involving 2242 environmental samples, *L. monocytogenes* was detected in 32% of samples from meat-processing environments and 8.8% from dairy-processing environments (18). Activities performed in the finished-product zone, such as cooling, slicing, portioning, mixing, packaging and post-process handling, require particular attention, especially where the product is no longer subjected to a process capable of eliminating *L. monocytogenes*. Experimental transfer studies further support this concern: in a commercial deli slicer model, at the highest inoculation level of approximately 10⁸ CFU per blade, *L. monocytogenes* was still recovered from the 30th slice, with populations decreasing logarithmically to approximately 10² CFU per slice (20).

Consequently, the HACCP plan and FSMS documentation should demonstrate how the establishment controls both the possible presence of *L. monocytogenes* in raw materials and the risk of post-process contamination from the production environment. Regulation (EC) No 2073/2005 explicitly links this risk to environmental sampling: FBOs manufacturing RTE foods that may pose a *Listeria monocytogenes* risk for public health „shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme” (3). Environmental monitoring should therefore be treated as an essential verification element of the HACCP-based FSMS, particularly where RTE products may become contaminated after a reduction step and are no longer subjected to a process capable of eliminating the pathogen.

The program should be risk-based and cover relevant processing areas, food-contact surfaces, slicing and packaging equipment, personnel and equipment routes, and non-food-contact sites that may act as sources of contamination or niches. This is particularly important in the context of Regulation (EU) 2024/2895, which reinforces the need for FBOs to demonstrate that *L. monocytogenes* will not exceed 100 CFU/g throughout the entire shelf life where the 100 CFU/g criterion is applied (4, 5, 10, 11, 18, 21).

This link between the selected microbiological criterion, the processing environment and post-process contamination should then be reflected in the validation and verification of control measures. Validation should demonstrate that the adopted solutions are capable of maintaining *L. monocytogenes* at or below 100 CFU/g until the end of shelf life under reasonably foreseeable storage and distribution conditions. In practice, this may include evidence that the applied heat treatment or other reduction step is effective (14), that the product formulation and packaging do not support unacceptable growth, and that the declared shelf life is justified by shelf-life studies, predictive modeling or challenge testing, where necessary. Such evidence should be product-specific and reviewed whenever relevant changes are introduced, including changes to

formulation, packaging, process parameters, storage temperature, shelf life or the production environment.

Verification should then confirm that these assumptions remain valid in routine practice. This may be supported by product testing, including end-of-shelf-life testing where relevant; environmental monitoring in risk zones; trend analysis of product and environmental results; review of deviations and complaints; internal audits; and assessment of corrective actions. The frequency of verification activities should be risk-based rather than fixed, taking into account the product category, growth potential, shelf life, production volume, previous results, environmental monitoring trends and any changes in the process or product. In practice, verification may combine periodic product testing with routine environmental monitoring of food-contact and non-food-contact surfaces in the finished-product zone, followed by trend analysis and documented corrective actions when *L. monocytogenes* is detected. Where the available evidence does not sufficiently support the assumption that *L. monocytogenes* will remain at or below 100 CFU/g throughout shelf life, additional shelf-life studies, predictive modeling or challenge testing should be considered (1, 2, 7, 10, 15-18, 21).

Since Commission Regulation (EU) 2024/2895 has applied from 1 July 2026, the use of the 100 CFU/g criterion for category 1.2 RTE foods requires more than a declaration in a product specification. It should be supported by product-specific evidence showing that the behavior of *L. monocytogenes* has been considered in relation to the formulation, process, packaging, storage conditions, shelf life and environmental contamination risk.

This has direct relevance for official control, including official veterinary control in establishments producing foods of animal origin. When reviewing the microbiological sampling plan and the application of food safety and process hygiene criteria, the competent authority should be able to assess not only which criterion has been selected, but also why that criterion is justified for the product concerned. Regulation (EC) No 2073/2005 requires the FBO to demonstrate, „to the satisfaction of the competent authority”, that the product will not exceed 100 CFU/g throughout shelf life. Therefore, the documentation should be sufficiently clear, traceable and scientifically justified to allow such an assessment.

In practical terms, the 100 CFU/g limit remains available only where the evidence supports its use. If the documentation does not demonstrate control of *L. monocytogenes* throughout shelf life, the applicable reference point is the stricter criterion „not detected in 25 g” for products placed on the market during their shelf life (1, 3, 4, 7, 10).

Non-compliant results and corrective actions

A non-compliant result for *L. monocytogenes* should be interpreted in relation to the criterion that applies

to the product. Where the applicable criterion is „not detected in 25 g”, detection of *L. monocytogenes* in any sample represents failure to meet the food safety criterion. Where the 100 CFU/g limit is justified by adequate shelf-life evidence, an unsatisfactory result occurs when this limit is exceeded during shelf life (3, 4).

The response should not be limited to confirming the analytical result. The FBO should determine the regulatory status of the affected product, identify the scope of potentially implicated batches, and assess whether the finding may reflect a wider failure in the FSMS. The investigation should consider the raw material, production line, processing date, post-processing handling, packaging operations, storage conditions and environmental monitoring history. Corrective action should therefore address both the affected product and the underlying cause of the non-compliance.

Where the product has been placed on the market, the FBO should assess whether withdrawal is required. If the product may have reached consumers and poses a health risk, a recall and notification to the competent authority should be considered in accordance with applicable food law requirements. The competent authority then determines whether further communication, including notification through the RASFF system, is necessary (4, 10, 12).

A non-compliant result should also trigger a review of the assumptions supporting the selected criteria. In particular, the FBO should reassess product classification, the evidence supporting the 100 CFU/g limit, the adequacy of shelf-life studies, the effectiveness of environmental monitoring, and the corrective actions previously applied. In this sense, an unsatisfactory result is not only a product event, but also a verification signal for the HACCP/FSMS (1, 7, 10).

Regulation (EU) 2024/2895 does not modify the numerical limits established for *Listeria monocytogenes* in category 1.2 RTE foods. Its practical effect lies in clarifying the consequences of insufficient evidence. The 100 CFU/g limit can be applied only where the FBO demonstrates, to the satisfaction of the competent authority, that this level will not be exceeded throughout the entire shelf life. Without such a demonstration, the applicable criterion is „not detected in 25 g”, including products already placed on the market during their shelf life.

The amendment, therefore, changes the practical interpretation of criterion 1.2 from a mainly stage-based question to an evidence-based one. The decisive issue is not only where the product is sampled but also whether the FBO can justify the selected criterion with product-specific documentation. This requires integration of shelf-life justification, product characteristics, process controls, environmental monitoring and verification activities within the HACCP/FSMS.

For FBOs, competent authorities and official veterinarians involved in the supervision of foods of animal

origin, the key message is that the selected microbiological criterion must be auditable. A product specification stating „100 CFU/g” is not sufficient unless the supporting documentation explains why this limit is appropriate for that product and under the declared conditions of distribution, storage, and use. Regulation (EU) 2024/2895, therefore, makes the evidence supporting the criterion a central element of compliance with food safety requirements (1, 3, 4, 7, 10).

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Corresponding author: Agnieszka Jackowska-Tracz, DVM, PhD, Associate Professor; e-mail: agnieszka_jackowska_tracz@sggw.edu.pl