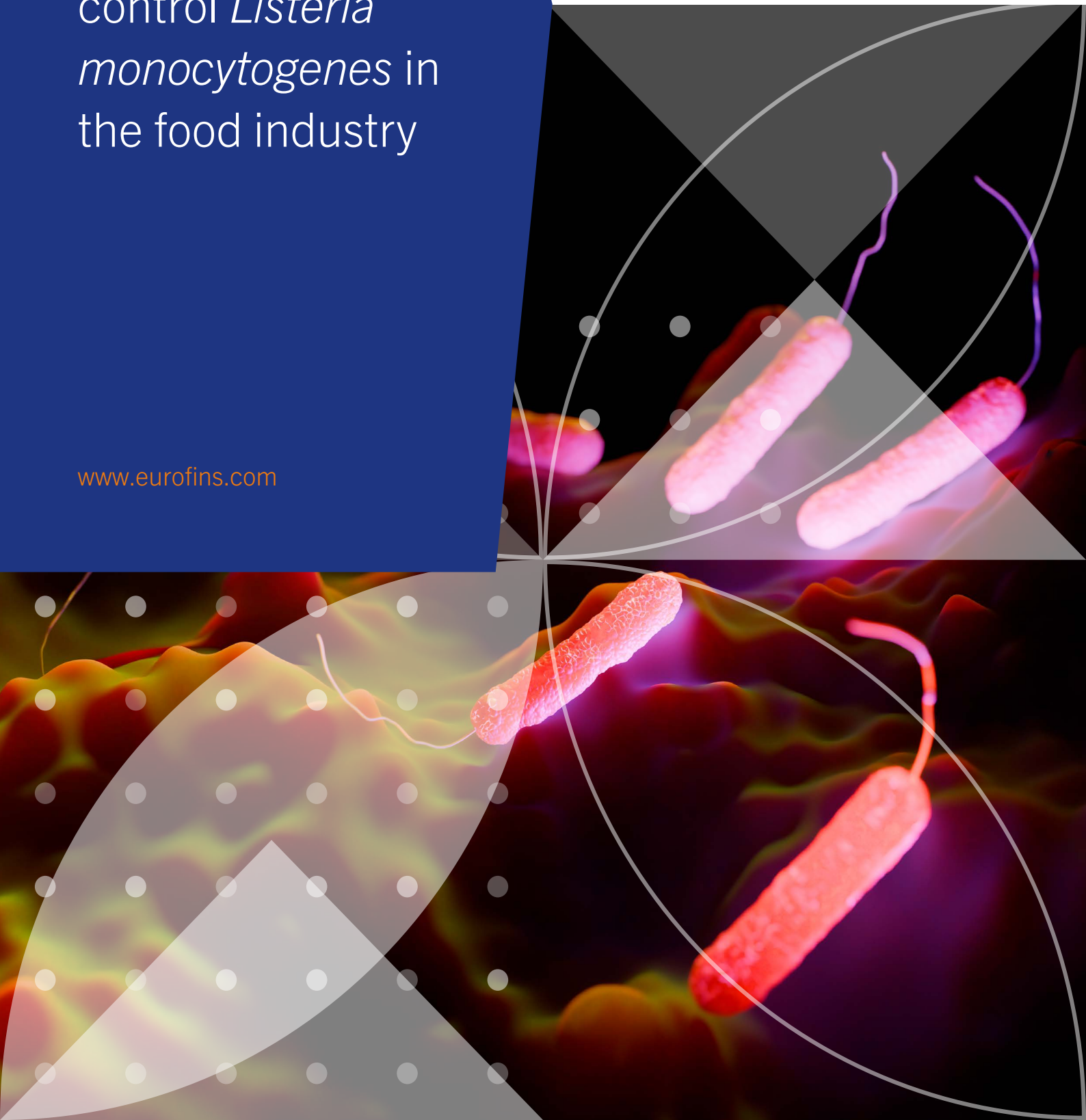


Guide to  
control *Listeria*  
*monocytogenes* in  
the food industry

Testing for life

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# List of abbreviations

<i>LM</i>	<i>Listeria monocytogenes</i>
CCP	Critical Control Point
CP	Control Point
OPRP	Operational PreRequisite Program
PRP	PreRequisite Program
GMP	Good Manufacturing Practice
HACCP	Hazard Analyses and Critical Control Points
FSS	Food Safety Solutions
GHP	Good Hygiene Practice
FSSP	Food Safety and Spoilage Predictor

## Manual on managing risks with *Listeria monocytogenes*

This manual has been carefully developed by the experts at Eurofins Food Safety Solutions (NL) from the Competence Centre for Microbiological Risk Assessments. It is specifically designed to support manufacturers and retailers in the European Union in effectively managing the risks associated with *Listeria monocytogenes*. This manual includes the revision of the guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs effective per 1 July 2026.

## Message from the authors

We, the team at the Competence Centre for Microbiological Risk Assessments, understand the challenges faced by businesses in the food industry regarding the control of *Listeria monocytogenes*. This manual reflects our collective expertise in and dedication to providing practical guidance to help you meet these challenges head on. Our goal is to offer clear, actionable insights that will assist in safeguarding public health while ensuring compliance with food safety regulations.

Please note:

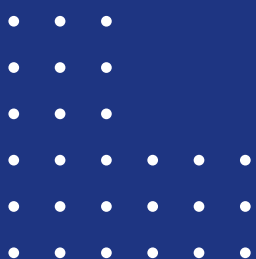
- This document is copyrighted and may not be reproduced or used for training purposes
- For inquiries regarding this document, please contact us at [CCMRA@ftb.nl](mailto:CCMRA@ftb.nl)

This manual is intended as a guide for controlling *Listeria* in food products and does not carry specific approval from national food authorities. While the information provided is based on current knowledge and best practices in food safety, users are advised to consult with relevant regulatory authorities and experts in their jurisdiction to ensure compliance with local regulations and standards. Eurofins FSS makes no representations or warranties of any kind about the completeness, accuracy, reliability, suitability, or availability of the information contained herein for any purpose. Any reliance you place on such information is therefore strictly at your own risk.

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# Study risk analysis and *Lm* control

Controlling *Listeria monocytogenes* (*Lm*) is a highly important task for food producers, due to the fact that *Lm* can grow in refrigerated products and carries potential health risks. In this document, the steps taken by Eurofins Food Safety Solutions (FSS) to ensure the safety of food products regarding *Lm* are documented. The information in this document is based on the revised guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC)

No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [1]. The decision tree below provides a schematic overview to estimate the risk of outgrowth of *Lm*. In addition, it indicates how to manage this risk. For a more extensive decision tree, see the guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation No 2073/2005 of November 2005 on microbiological criteria for foodstuffs [1]. Chapters 1 to 10 describe the approach to controlling *Lm*.

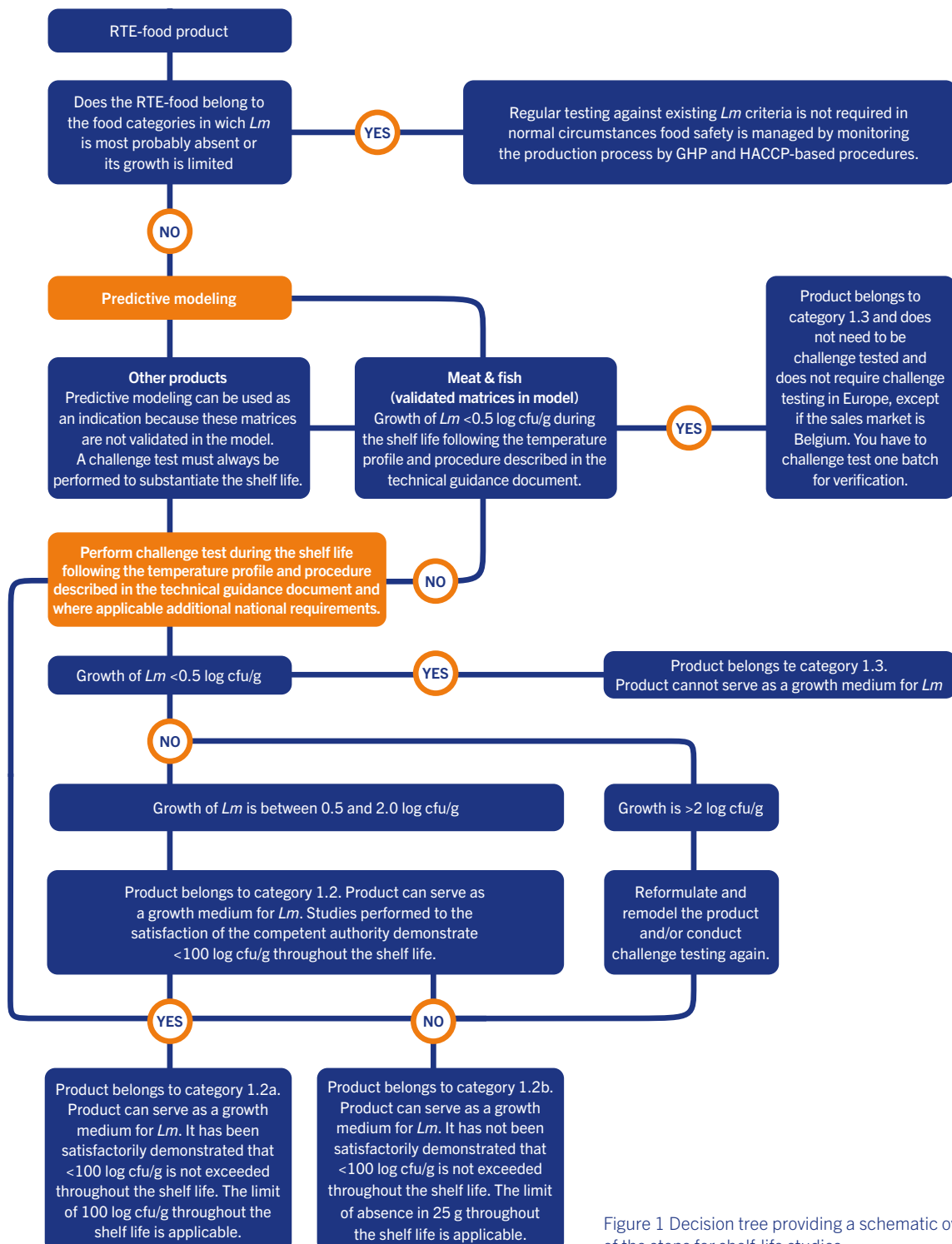


Figure 1 Decision tree providing a schematic overview of the steps for shelf-life studies.

# 01 Record the properties of the raw materials

Data is collected on the relevant physical (pH, aw and dry matter or moisture), chemical (salt, organic acids, preservatives, nitrite, phenols) and microbiological (*Lm* no limit/*Lm* absent in 25 grams/*Lm* <100 cfu/g) properties of the raw materials.

- An assessment is made as to whether a raw material is used for finished products where no elimination or reduction step is applied.
- The specifications of the raw materials are established, and certain suppliers of raw materials are approved to ensure high-quality supplies. This management measure must comply with Regulation No 853/2004 of the European parliament and of the council [2].
- Raw materials used are included in a research plan to verify that the products supplied meet the criteria for *Lm*.

# 02 Record the production process in detail

The documentation of production processes by which *Lm* is eliminated or reduced to an acceptable level is collected, as well as how post-contamination is prevented.

- All production processes are described and recorded in detail (this has been done as part of the HACCP study).
- The processes that are important for the elimination, reduction or growth limitation of *Lm* are described.
- Critical control measures are determined.
- All measures associated with a Critical Control Point (CCP) or Control Point (CP)/Operational Prerequisite Program (OPRP) to control *Lm* should be implemented.

## 03 Establish type and level of hygiene measures

The type and level of hygiene measures to prevent post-contamination with *Lm* should be established. Checks to assess the risk of contamination should be performed.

### Hygiene measures can be classified as:

- **Personal hygiene:** personal care, clothing and hygienic operations
- **Process hygiene:** hygienic design of machines and installations; work execution.
- **Industrial hygiene:** hygiene of the process environment (walls, cooling installations, access restrictions)
- **Cleaning and disinfection:** interim, daily, periodic corrective actions following monitoring
- **Monitoring:** visual, swabs, pathogens.

### For effective control, the following steps should be followed:

- Evaluate the routing of the product, raw materials, personnel, waste, packaging materials, etc., and determine whether to prevent cross contamination. For products that do not undergo an *Lm* elimination step, this concerns all stages of the production process, starting from the raw material. For products where an *Lm* elimination step has been performed, it refers specifically to the stage between the elimination step and packaging into closed packages.
- Evaluate whether the product route could be optimised. Identify whether the equipment is designed to be easy to clean and decontaminate. Assess critical locations that are hard to reach or clean.
- Assess the placement of cooling units and the airflow to prevent post-contamination via that route.
- Assess adequate places to wash and disinfect hands. Also ensure compliance with procedures for changing at breaks, toilet use and accessing production areas.
- Evaluate the use of disposable materials, i.e. when to use and how often to replace them.
- Assess the cleaning plan, the frequencies of cleaning and disinfection, the effectiveness of the cleaning and disinfecting agents used, and the correct dosage.
- Assess whether all hygiene measures are effective and whether they can lead to post-contamination.
- Adjust measures and/or take additional measures; reassess whether all hygiene measures are acting accordingly.
- Create a schedule of critical areas and equipment to be monitored for the presence of *Listeria* spp and/or *Lm*.

### It is recommended that the following types of areas are sampled:

- A.** Places where there is or may be contact with the product.
  - B.** Objects that may cause contamination via indirect contact such as door handles, floors and walls.
  - C.** Places where there is no contact with the product, such as the evaporators of the refrigerators, drains or air vents.
- Establish the number and frequency of sampling for the areas identified in the previous step. The number of samples depends on the size of the company. It is recommended that a frequency of at least once every 2 weeks be used for critical areas. Choose the validated sampling material to be used. Include in the choice the surface area to be sampled. Preferably use sponge sticks, which can easily sample a large area. Swabs can be used for hard-to-reach areas. Sponges and clothes can be used to test even larger areas such as floors, walls and cooling units.
  - Establish a plan of action for measures such as cleaning, disinfection, retesting and possibly additional final product control in case of positive results. Consider whether product contamination may have occurred that could lead to growth exceeding 100 cfu/g within the shelf life.
  - Also look for a probable cause and review the cleaning plan for the area in which positive results are found more often.

## 04 Determine product composition & growth-inhibiting factors

It is important to provide insight into the composition of the product by understanding the physical/chemical parameters affecting *Lm* growth. The following things are important while doing this.

- The chosen product group should be justified, the homogeneity in the composition of the product should be considered, and the extrinsic factors like packaging, gas composition etc. should be evaluated.
- It is important to determine whether the product contains protective micro-organisms.
- It should be established whether the product consists of a single component or multiple components. Different intrinsic values should be measured or calculated per component and the worst-case scenario should be considered by using the most unfavourable values. The growth-inhibiting substances should be homogeneously distributed.
- The relevant chemical and physical values of the product should be measured. For a new product/recipe, a minimum of 5 samples from at least 3 different batches produced in 3 different occasions should be included to account for variation between batches and within individual batches. Analyse the worst-case product in the product group regularly and sample other products randomly to assess representativeness. Additionally, products must be re-analysed when there are changes to the recipe, process or products that affect product variation.
- When an additive is being broken down or formed during the process, it is recommended to measure the intrinsic factors over a longer period. Fermented meat products, among other products, pose a greater risk for *Lm* because the pH can change during the shelf life. Eurofins FSS can provide advice for handling fermented meat products.
- By using predictive models, it is possible to determine which parameters have the most effect (critical parameters) on the growth of *Lm* and therefore the biggest influence on the shelf life of a product.
- The gas composition of the packaging of a product is important. It should be considered that the product packaging could be open for a certain period in the consumer phase. The number of the hours/days for which the packaging is open should be determined and there should be a warning text on the packaging. When using the gas composition as a control measure, it must be demonstrated that it is maintained throughout the shelf life.
- The end products should be divided into product groups based on similar values, composition or processes. Within each product group, the product with the most favourable growth factors (worst case) should be selected. This product should be used to determine the growth of *Lm* as a representative outcome for the entire product group. It is necessary to support the model calculations for this worst-case product with a challenge test. Firstly, it needs to be assessed whether the final products in a product group belong to the same HACCP risk group. Additionally, it is necessary to evaluate if the products from that group are comparable in terms of process, homogeneity, general recipe and sensory shelf life. Next, the final products should be assessed based on the packaging method and storage temperature.

# 05 Determining the storage conditions from production until consumption

- Determine the storage temperature and residence time within your own company. Include any in-house transport, external transport and storage at distribution centres. The in-house storage time is one-third of the shelf life for a shelf life less than 21 days at a temperature of 7°C. For a shelf life of more than 21 days, this is 7 days at a temperature of 7°C. If a producer wants to deviate from this time/temperature distribution, a justification must be provided, showing that at least 95% of the time, the temperature is storage is below the alternative temperature
- Determine the storage temperature at retail level. If the storage temperature at the seller is not known, assume 7°C. The storage time is half for a shelf life of more than 21 days. For a shelf life of less than 21 days the storage time is one third of the remaining shelf life.
- Determine the storage temperature at the consumer level. If this is not known, use the storage temperature as prescribed in that country. In most European countries, this is 10°C. In the Netherlands and Belgium the temperature at consumer level is 9°C (laid down in national guidelines). The storage time is the remaining shelf life.

Table 1 Overview of storage conditions throughout the cold chain [3].

Stage of cold chain	Storage (incubation) temperature			Storage (incubation) duration			
				Shelf-life (SL) ≤21 days		Shelf-life (SL) >21 days	
At manufacturer level	Temperature justified by detailed information*	Or if not known	7°C	Duration justified by detailed information	Or if not known	1/3 SL	7 days
At retail level	Temperature justified by detailed information**	Or if not known	7°C	Duration justified by detailed information	Or if not known	1/3 SL	1/2 (SL-7)
At consumer level	Temperature justified by detailed information**	Or if not known	10°C	Duration justified by detailed information	Or if not known	1/3 SL	1/2 (SL-7)

\* The 95<sup>th</sup> percentile of the FBO's data observation.

\*\* The 95<sup>th</sup> percentile of the observations for the country where the stage of the cold chain is located.

## 06 Determine whether the product can serve as a growth medium for *Lm* (category 1.2 or 1.3)

### Category 1.3

#### The product cannot serve as a growth medium for *Lm*

- Products with a  $\text{pH} \leq 4.4$  or  $\text{aw-value} \leq 0.92$  and products with a  $\text{pH} \leq 5.0$  and  $\text{aw-value} \leq 0.94$  can be categorised as products where growth of *Lm* is not possible (category 1.3). This also applies to products with a shelf life shorter than 5 days (production day +4 days). However, if modelling or analysis shows the possibility of outgrowth above 100 cfu/g before the expiry of the selected shelf life, you should reduce the shelf life even further. The following product/product groups can be categorised as 1.3:
  - Fresh, uncut and unprocessed fruits and vegetables (excluding sprouted seeds)
  - Bread, biscuits and similar products
  - Bottled water, soda, beer, cider, wine, distilled drinks and similar products
  - Sugar, honey and confectionary (including cacao and chocolate products)
  - Living bivalve molluscs
  - Additionally, frozen products with a shelf life < 4 days after thawing also fall into this category, provided the effectiveness is substantiated. A large amount of background flora can inhibit the growth of *Lm*, but the product cannot be classified as category 1.3 without additional study.

For this category 1.3, no additional measure applies. The shelf life of the product will be assessed by means of spoilage microorganisms and sensory characteristics; an additional *Lm* study is not necessary. A monitoring programme of <100 cfu/g during the end of shelf-life applies.

### Category 1.2

#### The product can serve as a growth medium for *Lm*

- Category 1.2 covers RTE foods which are able to support the growth of *Lm* with two subcategories:
  - Category 1.2a is reserved to RTE foods that support *Lm* growth but for which evidence is provided that *Lm* will not exceed 100 cfu/g throughout the shelf life.
  - Category 1.2b is reserved to RTE foods that support *Lm* growth but for which there is none or no satisfactory evidence is provided that *Lm* will not exceed 100 cfu/g throughout the shelf life.
- To determine whether the product can serve as a growth medium for *Lm* (category 1.2), a predictive model and/or a calculation based on growth potential and/or growth rate study can be used. A threshold value of 0.5 log cfu/g growth is applied.



# 07 Determining the initial contamination of *Lm* for model calculations and challenge testing

In the guidance document on *Lm* shelf-life studies for ready-to-eat food, the commission of the European communities refers to an initial contamination level for *Lm* that must be applied to all fresh raw materials and to products that do not undergo *Lm* elimination. It is possible to deviate from this if a justification is provided. The justification must be based on the following three aspects:

## A. Elimination

A product that is pasteurised in the final package is free of *Lm*. If it's not possible for post-contamination to occur, there is no risk for *Lm*. Products that have a growth potential higher than 0.5 log for *Lm*, that are being removed from the pasteurisation packaging, might pose a potential risk. For products that do not undergo complete elimination, the initial contamination level can be set at 1 cfu/g. Validation of the heating process is crucial. For example, you might use post-pasteurisation of closed packages and hot filling of liquid products, immediately followed by closing and inverting the packaging to kill all vegetative *Listeria* germs. Ensure that the shelf life is also validated for the period after the packaging has been opened.

## B. Prevention

There are many measures to prevent post contamination. A company can keep the incidence and the level low through good practice and monitoring. A product can be post-contaminated via direct contact with contaminated material, indirect contact with contaminated surfaces, dust particles and aerosols in the air, human contact, and condensation droplets.

Tests on presence of *Lm* must be performed for validation and verification that the preventive measures for post-contamination are effective. There are a few important things to consider when doing so:

- The producer must establish sampling and testing frequencies in the context of GMP and HACCP principles. Regulation 2073/2005 mandates that processing areas and equipment must be systematically sampled.
- A sufficient number of tests must be performed.
- The production company must map out the places in the company that are most vulnerable to *Lm*.
- For the purpose of determining growth potential in a model, a starting level of 1 cfu/g will result in the actual growth potential without the need for additional calculations.

## C. Inhibition

The most important factor for inhibition is temperature control. The lower the storage temperature, the less likely *Lm* will grow. But also other intrinsic factors play an important role in the inhibition of *Lm*: pH, salt, moisture, organic acids and preservatives.

Inhibition in the production area is controlled by multiple factors such as temperature, presence of food, effectiveness of cleaning and disinfection.

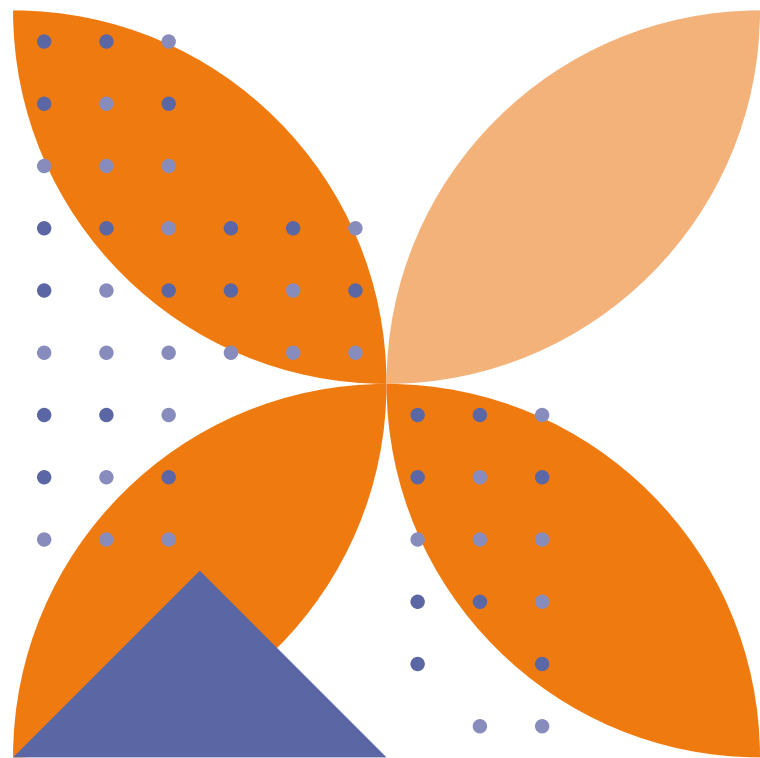
## 08 Determine the realistic initial contamination level

Preventing post-contamination with *Listeria monocytogenes* (*Lm*) is crucial, especially for products in category 1.2 that can support *Lm* growth and are not heat-treated in sealed packaging. If post-contamination risks are controlled, this must be well-supported by evidence, considering the number of steps between contamination elimination and packaging. The use of aseptic filling equipment lowers the risk compared to high-risk packaging areas.

For category 1.3 products, the initial contamination can be based on historical data, as there is no *Lm* growth during shelf life, and the maximum growth is 0.5 log, equating to a maximum initial contamination of 30 CFU/g. For category 1.2 products, historical data should support the initial contamination level. For products undergoing an elimination step to reduce *Lm*, an initial contamination level of 1 cfu/g is recommended to be applied.

To demonstrate adequate post-contamination control, companies should:

- Perform environmental swabs at points of contact with the product and areas that could indirectly lead to contamination, adjusting testing frequency as needed. Any deviations must be investigated and addressed.
- Conduct product testing at the beginning and end of shelf life, including *Lm* presence/absence tests and colony counts, to determine the contamination level. If contamination exceeds limits, corrective actions should be taken and a recall initiated.
- Consider reducing the product's shelf life if contamination issues are recurrent.



# 09 Determining the growth potential

An important part of the risk analysis involves gaining insight into the growth rate or growth potential of *Lm* in the product during the desired shelf life.

This can be carried out by using predictive models and through challenge tests. Growth models and challenge tests both approximate reality but never provide absolute certainty. Besides the fact that the exact degree of initial contamination is not known, both methods only offer an estimation of the growth potential in practice. One reason for this is that both growth models and challenge tests are based on studies conducted with a select number of *Lm* strains. Repeating the test with different strains, with different growth characteristics, can lead to different results. However, aligning the shelf life with the growth potential will always enhance the safety of the products.

## Predictive growth models

Growth models are based on large numbers of tests. An advantage of growth models is that they average out random variations, ensuring consistent results for a given product composition at a specific temperature gradient. However, the results of growth models approximate reality less closely than a challenge test.

A predictive model is chosen based on the 'model fit'. The better the model matches the process or the matrix of the product, the more reliable the growth prediction will be. At Eurofins FSS, the **Food Safety and Spoilage Predictor (FSSP)** or **Combase** are used most often to predict growth. The desired shelf life, market area and the chemical composition are necessary for the model calculations of the product.

In the model calculations, the lag phase is not included as any potential contamination might already occur in the growth phase. Also, the effect of competing flora/protective flora on the growth of *Lm* is not considered, unless it can be demonstrated that this competing flora is always present on the product. When using the gas composition as a CCP, it is permissible to use the gas composition in the calculation in the predictive model. If not, it is not permissible to use it. It is necessary to support with a challenge test.

FSSP is validated for meat and fish products; it is the most reliable for these products. For other food products, it is possible to get an indication of the growth potential of *Lm* with FSSP and Combase; however, a challenge test is always needed for these matrices.

The use of phenols in smoked products can be included in FSSP, but the analysis results regularly raise questions. According to the Dutch authority (NVWA), too high values are often used because polyphenols such as salicylic acid and stramic acid are also included. It is unclear on which substances the FSSP model is based. Separately, phenol should be determined using the same analytical method used to establish the FSSP model. The Dutch authority (NVWA) referred to research by Mejholm and Dahlggaard (2007), which is based on research by Cardinal et al. (2004). If phenols were determined according to the analytical methods they used, it is, in the NVWA's opinion, likely that the results would be in line with the results used to develop the FSSP model."

It is recommended to always perform a challenge test to support/validate the results of the model calculations.

A. Practical overview of a growth potential test of smoked salmon (all timepoints in threefold).

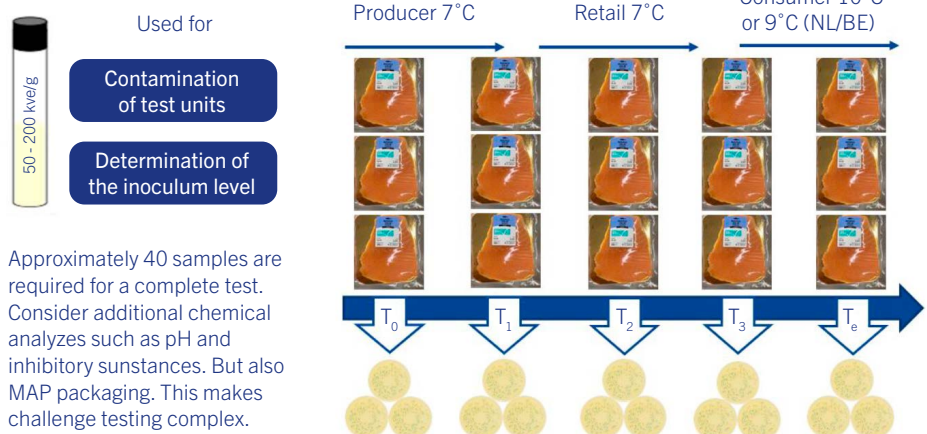


Figure 2 Growth potential test (overview)

B. Results of the growth potential test for smoked salmon. The conclusion is based on the highest growth value. In this example 2.22 log cfu/g.

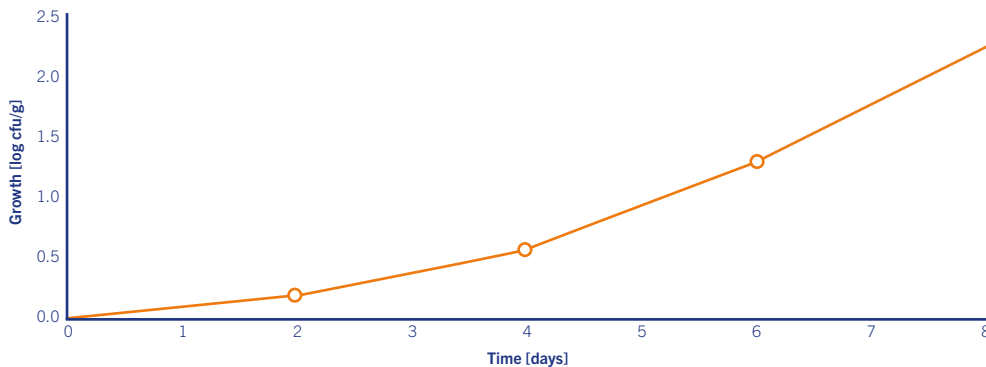


Figure 3 Growth potential graph

### Challenge testing

Challenge tests are practical tests conducted on the actual product. The product is intentionally contaminated with a known quantity of *Lm*. A drawback is that the results are more dependent on variations and chance than model calculations. There are two types of challenge tests.

### Growth potential

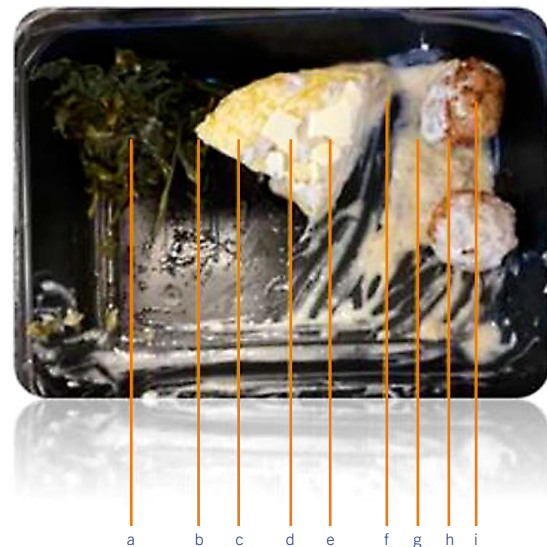
The first type of challenge test determines the growth potential of *Lm* during a shelf life. In this form of challenge testing, three separate batches of a product are intentionally contaminated. In each batch, at least seven samples are initially contaminated with *Lm*. The *Lm* count is determined in three samples within 24 hours of initial contamination, in three samples at intermediate points of the shelf-life and in one sample at the end. This sample amount is standard in Europe for products that are homogeneous, but it is possible to add samples to enhance the reliability of the test and improve the accuracy. The execution of a challenge test is carried out according to the Technical Guidance Document on challenge tests and durability studies for assessing the shelf-life of ready-to-eat foods related to *Lm* [3].

### Growth rate

The other type of challenge test determines the maximum growth or growth rate of *Lm* in a product. Multiple samples are initially contaminated with *Lm*. The product is stored for a period, longer than the shelf-life, at a constant temperature. During this period, multiple *Lm* counts are performed. This way, the growth rate can be determined between periods. A few important points to keep in mind while performing a growth rate test are:

- Growth rate tests can only be performed with category 1.2 products, which are products in which *Lm* growth is possible.
- The test should be aborted when the product is visibly spoiled, e.g. with mould.

C. Practical overview of contamination of composite dish.



- [a] Spinach
- [b] Border surface between spinach and omelette
- [c] Omelette
- [d] Cheese flakes
- [e] Border surface between omelette and cheese flakes
- [f] Border surface between omelette and mushroom sauce
- [g] Mushroom sauce
- [h] Border surface between mushroom sauce and vegan mince ball
- [i] Vegan mince ball

Figure 4 Critical surfaces in a composite dish

It is recommended to always perform a challenge test to support/validate the results of the model calculations. In case there is uncertainty regarding the ability of a ready-to-eat food to support the growth of *Listeria monocytogenes*, it is required to perform a challenge test.

# 10 Determining the actual shelf life of the product

## Category 1.2 products

- The classification of a RTE food with regard to its ability to support the growth of *Lm* shall be based on product-specific evidence. The use of generic assumptions or data derived from other products is not sufficient unless their relevance for the product concerned can be scientifically justified.
- Evidence used to demonstrate compliance is required to be sufficiently robust and reproducible and reflects foreseeable conditions of production, distribution and storage, including reasonably foreseeable worst-case scenarios.
- The shelf life must be determined based on the study conducted, which should be based on literature reviews, product characteristics, predictive models, and challenge tests. In this process, products may be grouped to avoid the need for a study for each individual product. If the shelf life is satisfactorily substantiated, the criterion of < 100 cfu/g during the shelf life applies (category 1.2a). If not, the criterion absent/25 gram during the shelf life and till the end of the shelf life is applicable (category 1.2b). Using predictive models and/or challenge tests, the shelf life can be determined based on the growth potential and the actual initial contamination. As a standard, an initial contamination of 1 cfu/g can be assumed for a product where *Lm* has not been detected in 25 grams per batch (n=5).
- If a product can serve as a growth medium for *Listeria monocytogenes* but the risk of *Lm* is controlled by demonstrating that recontamination is prevented (for example, through an aseptic filling process), the shelf life can be established based on, among other factors, microbiological (including spoilage organisms) and sensory properties. The use of predictive models and/or challenge tests is not necessary. The shelf life can be longer than what would be indicated by the predictive model and/or challenge tests.
- If the outcome of the study indicates a shorter shelf life than desired, the producer will need to accept a shorter shelf life, reformulate the product, and/or adjust the process conditions.

## Category 1.3 products

Determine, based on EU Regulation 2073/2005, or substantiate with a predictive model or challenge test, that a product cannot serve as a growth medium for *Listeria monocytogenes*. Then establish the shelf life of the product based on other sensory, chemical, and/or microbiological parameters. However, do not exceed the shelf life which was tested in the predictive model or challenge test.



# Validation

The study's validation must align with the Codex Alimentarius, General Principles of Food Hygiene (referred to as Codex) [4]. Before implementing an HACCP plan, it must be validated to ensure the control measures effectively manage the hazard of *Lm*. Key elements to evaluate include hazard identification, critical control points (CCPs), control limits, control and management measures, frequency and type of CCP monitoring, corrective actions, frequency and type of verifications, and the information to be recorded.

Validation is necessary for any changes that could impact *Lm* hazard control. This includes alterations in products and processes, new packaging, modifications in the production environment, and/or changes in equipment. Validation may also involve scientific research, additional studies, and guidelines from governmental agencies. According to Principle 6 of the Codex, validation should establish verification procedures to ensure the *Lm* control system functions as intended. This validation must occur at least annually and whenever there are changes in any relevant circumstances as specified in the Guidance Document on *Lm* shelf-life studies for ready-to-eat foods [1].

The study and control of the *Lm* hazard should be incorporated into the production company's Quality Manual. This manual should include a procedure detailing the HACCP system, based on the Codex and Regulation EU 852/2004 [2], assessing food safety risks and outlining the control measures. Key points include the HACCP team, a description of final products and their intended use, the use of the decision tree for identifying CCPs, a description of raw materials and ingredients, process descriptions, prerequisite programmes, hazard identification and assessment, determination of CCPs, monitoring procedures for CCPs, follow-up on deviations, and verification and validation of the HACCP system. Additionally, the quality system can provide more detailed descriptions and outcomes on these subjects. In procedures regarding product development, attention should be given to the way new products are incorporated in the *Listeria* study.

Creating an overview of *Lm* control for each product group can also be beneficial. For this purpose, Eurofins FSS can conduct a *Lm* check, i.e. a quick check for retailers as to whether their RTE private label products meet the legal requirements for *Lm* food safety. This includes checking the category (1.2 or 1.3) in which the product belongs, seeing if a challenge test or predictive modelling has been performed, and if samples of the product have been checked against limit values.



# Monitoring and verification

The control of *Lm* is fundamentally based on adhering to Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP). The prerequisites for managing the hazard of *Lm* must be defined, implemented, and evaluated. The HACCP system must incorporate specific measures needed to control *Lm*.

## Monitoring

Monitoring involves collecting new and recent information at regular intervals to determine whether the (hygiene) parameters related to the process or conditions stay within the predefined limits. This process also provides insight into the performance of the processes. Monitoring covers environmental studies and physical, chemical, and microbiological parameters significant to the preparation and/or packaging process. These measurements should align with the HACCP system requirements. When deviations occur, corrective actions are necessary to regain control over the process. Additionally, an assessment must be made regarding what should be done with the non-compliant products. General comment: It may be relevant to point out that positive release does not guarantee absence of *Lm* and that this can only be used as a temporary measure. Additionally, environmental monitoring is an important tool to verify the effectiveness of control measures for *Lm* in food processing environments. The environmental monitoring programme should be designed in a risk-based manner and adapted to the specific processing environment.

## Verification

Verification is the process of confirming, during or after implementation, that all process control measures (including GMP/GHP) are consistent with the design, effective, and have met the intended goals. Specifically, it ensures that the *Lm* contamination level in the final product remains below the threshold where *Lm* can grow to exceed 100 cfu/g within the product's shelf life. Verification also involves evaluating the risk of *Lm* contamination of final products. The verification process checks if all measures effectively prevent detectable *Lm* contamination in ready-to-eat products or if the contamination level is sufficiently low to prevent it from exceeding the limit of 100 CFU/g within the shelf life.

Verification must include a detection test and a count on the same sample. If *Lm* is detected in the detection test, resampling and counting cannot be used as corrective actions, as the prevalence may be such that *Lm* is not present in all samples. This situation results in an unknown contamination level in the initial sample. Without a count, the product must not be marketed or must be recalled.

Effective monitoring of *Lm* control in raw materials and production processes can help determine the verification frequency based on the Regulation on Microbiological criteria and risk analysis. The verification frequency should be selected in such a way that it provides a reliable assessment of compliance with the criteria.

# Course of action for determining *Lm* in end products

The design of the production environment, processes, recipe formulations, packaging, storage conditions, and shelf life must ensure that the product meets the criteria in Regulation (EC) No 2073/2005 regarding *Lm* throughout its entire shelf life [6]. Properly designed research plans concerning the environment, hygiene, raw materials, semi-finished products and final products should provide a reliable picture of the effectiveness of the measures to control *Lm*. External reports from customers, consumers, and regulatory authorities also contribute to assessing the level of control.

Despite all measures, it is practically impossible to rule out deviations entirely. The most critical deviation concerns final products. If *Lm* is detected in the final product, it is potentially a food safety issue and must be addressed according to a predetermined action plan. This action plan should include:

- A recall and incident procedure. This procedure should first determine whether a recall or withdrawal action is necessary. If necessary, the customer and relevant food safety authorities must be informed.
  - If the criterion of 100 cfu/g cannot be exceeded during the shelf life, a recall is not needed. The procedure should specify which competent officials are involved in responding to the detected deviation. The approach should establish both the nature and extent of the deviation.
  - If the criterion of 100 cfu/g can be exceeded during the shelf life, a recall must take place. It is crucial to act quickly to prevent unsafe products from being sold or consumed. Suspect products in the supply chain must be isolated.
- Relevant parties must be informed as necessary, including governmental authorities, industry associations, customers, consumers, and certification bodies.
  - Unsafe products must be removed from the supply chain (up to and including the consumer) and destroyed. In other cases, a precautionary principle might be applied, leading to limited recalls from distribution centres and stores.
  - A thorough analysis must be conducted to determine the cause of the deviation, including examining monitoring data.
  - It must be assessed whether HACCP and GMP have been followed or if there are any shortcomings that need to be addressed. Redesigning the process and or the recipe may be necessary to prevent recurrence.
  - Based on the deviation, it must be checked whether the risk analysis and the study forming the basis for *Lm* control were properly conducted. If necessary, the risk analysis and study design must be adjusted. It should be determined whether this is an isolated incident or a structural problem and if it affects other products. If necessary, relevant products should be subjected to the (modified) risk analysis and studied again.

# References

- [1] C. o. t. E. communities, "Guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs," SANCO/11510/2013, Revision of 18 December 2025. Commission of the European communities, Brussel, 2008.
- [2] T. E. p. a. t. c. o. t. E. union, "Regulation No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs," Official Journal of the European Union, 2004.
- [3] EURL, "EURL *Lm* technical guidance document on challenge tests and durability studies fo assessing shelf-life of ready-to-eat foods related to *Listeria monocytogenes*," anses, Maisons-Alfort, 2021.
- [4] FAO en WHO, "Codex Alimentarius, General Principles of Food Hygiene," Food and Agriculture Organization of the United Nations and World Health Organization, 1969.
- [5] O. J. o. t. E. Union, "Regulation No 852/2004 of the European Parliament and of the council," Official Journal of the European Union, 2004.
- [6] T. c. o. t. E. communities, "Commission regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs," Official journal of the European Union, 2005.

More information?  
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