



BTSF ACADEMY

Organisation and implementation of training activities to strengthen understanding, implementation and enforcement of EU law in the area of Sanitary and Phytosanitary (SPS) standards in EU Member States and neighbouring non-EU countries

STM - Microbiological shelf-life studies of ready-to-eat foods related to *Listeria monocytogenes*

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Lithuania, Session 1: 14- 17/04/2026; Session 2: 05-08/05/26



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Overview of Regulation no. 2073 2005

STM - Microbiological shelf-life studies of
ready-to-eat foods related
to *L.monocytogenes*

Mariem Ellouze

Lithuania, Session 1: 14- 17/04/2026;

Session 2: 05-08/05/26

1 Lm Microbiological Criteria in Regulation no. 2073 2005

2 Focus on Studies of Annex II (Food characterization, scientific literature & additional studies)

3 Shelf life setting, validation, verification and monitoring

BTSF Microbiological criteria in general

Codex Alimentarius, 1997

- A Microbiological criterion defines the acceptability of a product or a food batch based on the absence or presence, or number of micro-organisms (including parasites), and / or quantity of their toxins / metabolites per unit of mass, volume, area or batch.
- There are **food safety criteria** and **process hygiene criteria**.
- Food safety criteria are often deduced from a risk assessment to protect public health.
- Criteria should enhance food safety and be feasible in practice .

BTSF Microbiological criteria in general

Codex Alimentarius, 1997

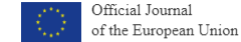
- Component of a Microbiological criterion:
 1. Hazard of concern
 2. Analytical method
 3. *Sampling plan (number of samples and size of the analytical unit)*
 4. Microbiological limits
 5. The food to which it is applicable
 6. The step of the food chain where the limit applies
 7. The actions to be taken when unsatisfactory results are obtained

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BTSF Microbiological criteria (EC) No 2073/2005

- The regulation (EC) No 2073/2005 harmonized the microbiological **food safety** and **process hygiene** criteria for foodstuff in Europe.
- Member states cannot have different national **food safety criteria** but can have other or stricter national **process hygiene criteria** (used only during processing, not when products are on the market).
- **The responsibilities** of the FBOS are to
 1. To demonstrate compliance with the Microbiological Criteria at the relevant steps
 2. To establish a sampling and testing scheme to substantiate their HACCP as relevant
 3. To establish, follow and assess trends (results over time) and take action in case of deviation
 4. To provide an adequate response in case of non-compliance

BTSF Lm criterion in (EC) No 2073/2005



Food category	Micro-organisms/their toxins, metabolites	Sampling plan ⁽¹⁾		Limits ⁽²⁾		Analytical reference method ⁽³⁾	Stage where the criterion applies
		n	c	m	M		
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes ⁽⁴⁾	<i>Listeria monocytogenes</i>	10	0	►M9 ↓ Not detected ◀ in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2 Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	<i>Listeria monocytogenes</i>	5	0	100 cfu/g ⁽⁵⁾		EN/ISO 11290-2 ⁽⁶⁾	Products placed on the market during their shelf-life
		5	0	►M9 ↓ Not detected ◀ in 25 g ⁽⁷⁾		EN/ISO 11290-1	Before the food has left the immediate control of the food operator, produced it
1.3 Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes ⁽⁴⁾ ⁽⁸⁾	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-2 ⁽⁶⁾	Products placed on the market during their shelf-life

2024/2895
COMMISSION REGULATION (EU) 2024/2895
of 20 November 2024
amending Regulation (EC) No 2073/2005 as regards *Listeria monocytogenes*
(Text with EEA relevance)

Products placed on the market during their shelf-life

→ Implementation date is 01.07.2026

BTSF Why a stage of application during shelf-life

Product testing alone, cannot give enough information about the batch



→ To ensure food safety, we need to rely on a full Quality and Safety Management System based on the application of HACCP and control measures.

→ For RTE foods and *L. monocytogenes* shelf life is considered a control measure since the storage duration of certain RTE foods may allow Lm growth and this needs to be assessed through dedictaed studies not only through FP testing.

1

Lm Microbiological Criteria in Regulation no. 2073 2005

2

Focus on Studies of Annex II (Food characterization, scientific literature & additional studies)

3

Shelf life setting, validation, verification and monitoring

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(EC) No 2073/2005 on Micro. Criteria

ANNEX II

The studies referred to in Article 3(2) shall include:

- specifications for physico-chemical characteristics of the product, such as pH, a_w , salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and
- consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:

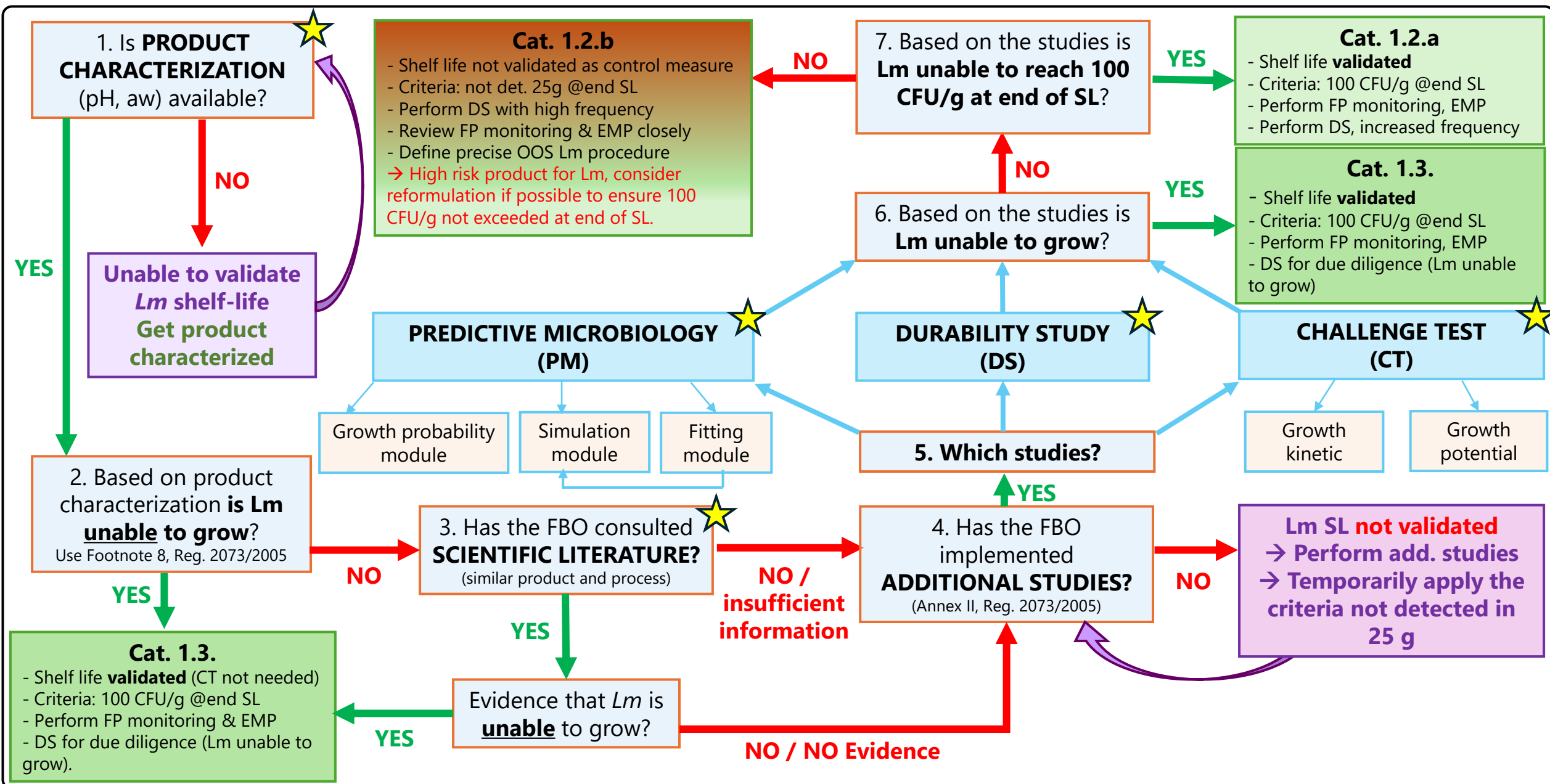
- predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,
- tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,
- studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage conditions.

1. Characterize the food product for the **foreseen shelf life**
2. Consult scientific literature and prove relevance to food product
3. Predictive microbiology models relevant to the food !
4. Challenge tests
5. Durability studies

→ Consider different sources of variability !

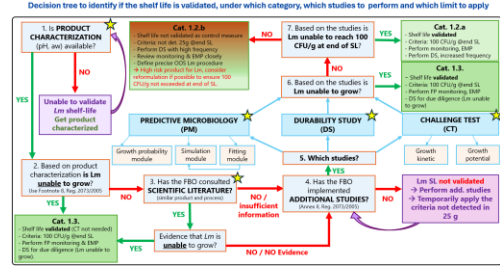
Decision tree to identify if the shelf life is validated, under which category, which studies to perform and which limit to apply



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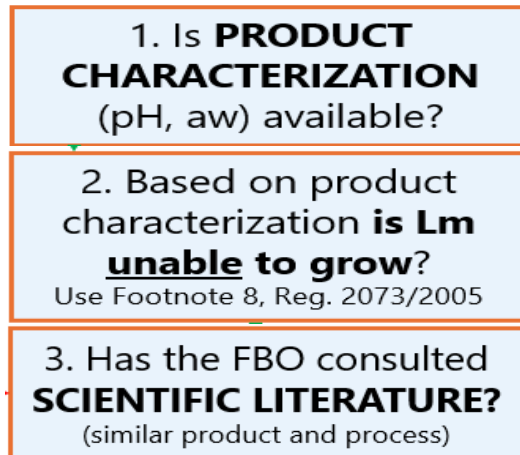


BTSF Steps to evaluate shelf life



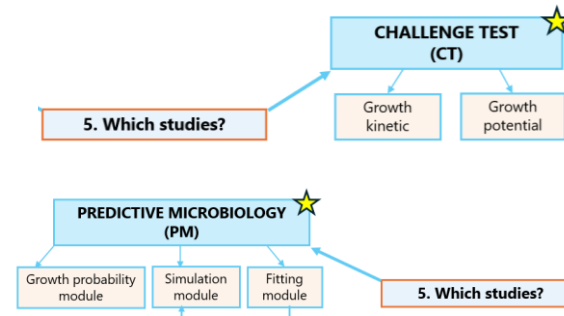
SL: Based on historical products, products on the market, literature

Category attribution based on Footnote 8 Reg.2073/2005

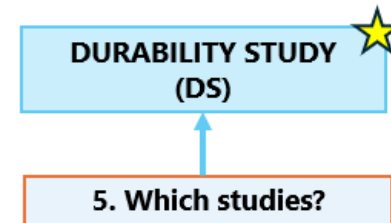


→ Category 1.3 according to Footnote 8 Reg.2073/2005,
→ Validation not required

- Challenge test studies (growth potential or maximum specific growth rate)
- Predictive Microbiology studies,
- Combination of both



- Durability studies



- Regular testing and trending, (at end of production) and end of shelf life

Cat. 1.3.

- Shelf life **validated**
- Criteria: 100 CFU/g @end SL
- Perform **FP monitoring**, EMP
- DS for due diligence (Lm unable to grow)

Cat. 1.2.a

- Shelf life **validated**
- Criteria: 100 CFU/g @end SL
- Perform **FP monitoring**, EMP
- Perform DS, increased frequency

Cat. 1.2.b

- Shelf life not validated as control measure
- Criteria: not det. 25g @end SL
- Perform DS with high frequency
- Review **FP monitoring** & EMP closely
- Define precise OOS Lm procedure
- High risk product for Lm, consider reformulation if possible to ensure 100 CFU/g not exceeded at end of SL.

BTSF Keep in touch



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Thank you!

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