





# BTSF ACADEMY

## Testing for compliance with microbiological criteria (product monitoring)

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

Reminder of key relevant concepts

2

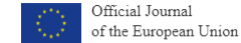
Cooked ham (Category 1.2.a)

3

Ice cream (Category 1.3)

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# BTSF Lm criterion in (EC) No 2073/2005



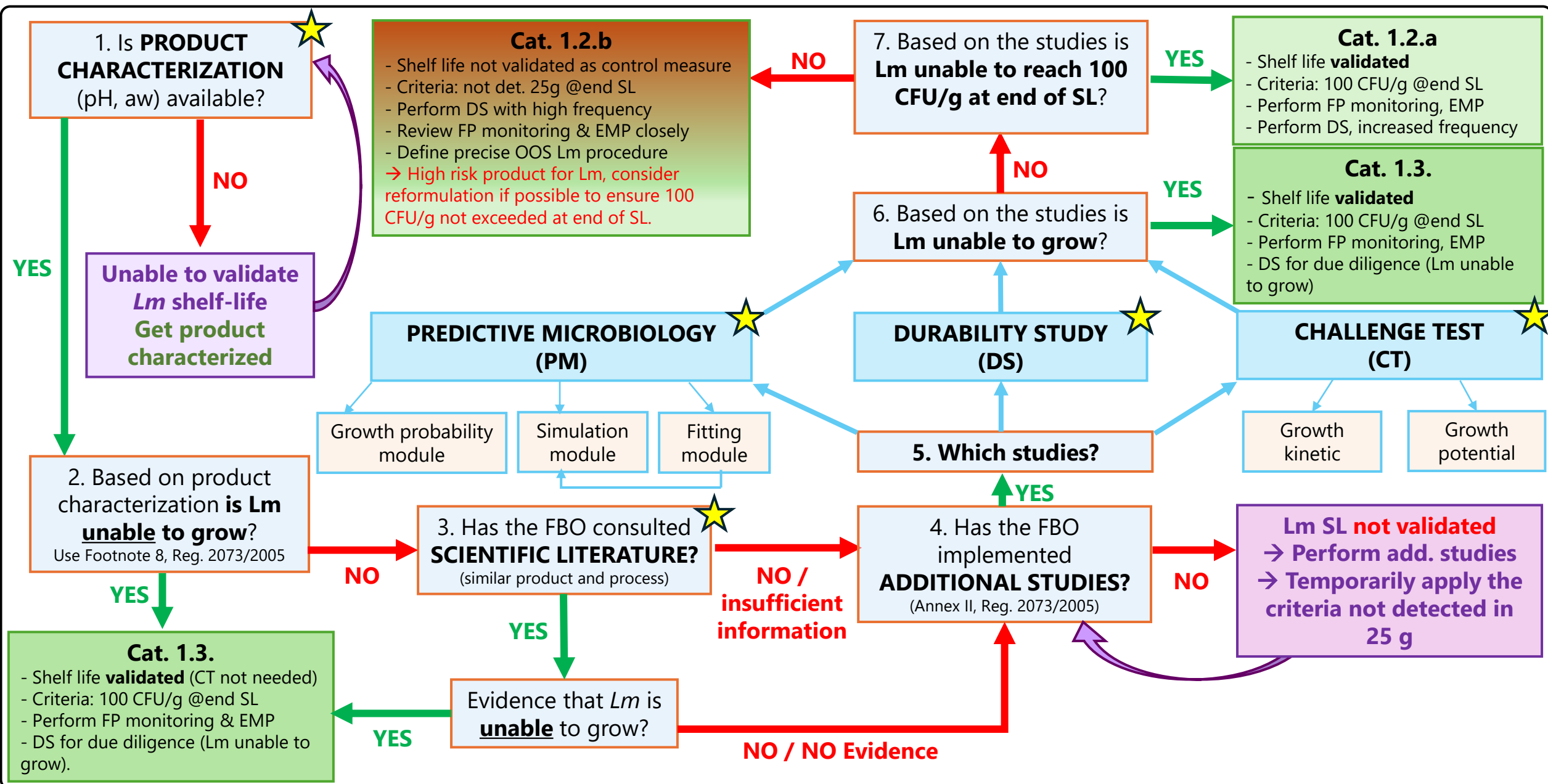
Food category	Micro-organisms/their toxins, metabolites	Sampling plan <sup>(1)</sup>		Limits <sup>(2)</sup>		Analytical reference method <sup>(3)</sup>	Stage where the criterion applies
		n	c	m	M		
1.1 Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes <sup>(4)</sup>	<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 <sup>(5)</sup>		EN/ISO 11290-2 <sup>(6)</sup>	Products placed on the market during their shelf-life
		5	0	►M9 ↓ Not detected ◀ in 25 g <sup>(7)</sup>		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 <sup>(4)</sup> <sup>(8)</sup>	<i>Listeria monocytogenes</i>	5	0	100 cfu/g		EN/ISO 11290-2 <sup>(6)</sup>	Products placed on the market during their shelf-life

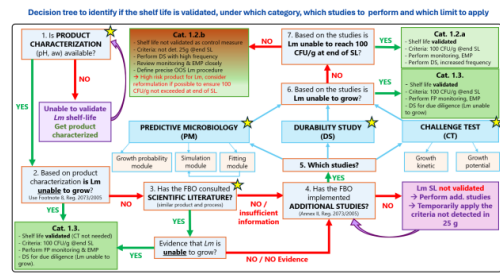
2024/2895  
COMMISSION REGULATION (EU) 2024/2895  
of 20 November 2024  
amending Regulation (EC) No 2073/2005 as regards *Listeria monocytogenes*  
(Text with EEA relevance)

Products placed on the market during their shelf-life

→ Implementation date is 01.07.2026

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



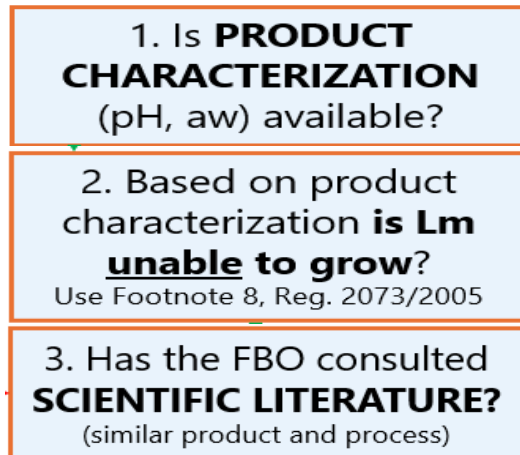


# BTSF Steps to evaluate shelf life



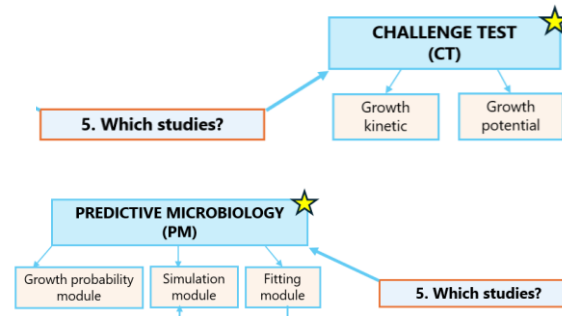
SL: Based on historical products, products on the market, literature

Category attribution based on Footnote 8 Reg.2073/2005

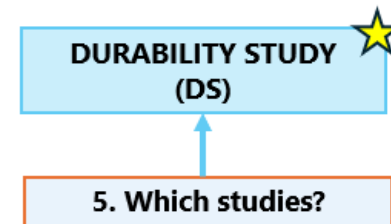


→ Category 1.3 according to Footnote 8 Reg.2073/2005,  
→ Validation not required

- 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.

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## Each RTE food is different

### 1. Setting

### 2. Validation

### 3. Verification

### 4. Monitoring

#### Market, brief, litt.

- Set target shelf life
- Identify the Lm category (1.1 / 1.2a / 1.2.b / 1.3) based on footnote 8 (or identify need for additional studies and define what they are)
- Decide if validation and verification are required or go directly to FP monitoring

#### CT or PM

- 3 inoculated batches,
- 5 sampling points throughout the SL
- Enumerate Lm & background flora
- Measure pH and aw
- Reasonably foreseeable conditions of storage & use
- Lab study

#### CT or PM

- n non inoculated batches
- 3 sampling points throughout the SL
- Enumerate Lm & background flora
- Measure pH and aw
- Reasonably foreseeable conditions of storage & use
- Lab study

#### FP testing

- n batches non inoculated batches
- 1 sampling time @ end of SL
- Enumerate 5 Lm samples
- Reasonably foreseeable conditions of storage & use
- Factory storage (and analysis?)

1

Reminder of key relevant concepts

2

Cooked ham (Category 1.2.a)

3

Ice cream (Category 1.3)

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# BTSF

## Each RTE food is different



pH=6.1  
aw=0.96

1. Setting

2. Validation

3. Verification

4. Monitoring

<u>Market, brief, litt.</u>	<u>CT or PM</u>	<u>CT or PM</u>	<u>FP testing</u>
pH & aw combinations allowing growth according to Footnote 8	Result of CT shows limited growth on 3 batches, due to Lactic Acid Bacteria  → Category 1.2.a → Limit= 100 CFU/g @end SL	4 Durability Studies (DS) with time temperature abuse throughout first calendar year  Frequency reduced to 2 DS throughout following calendar years	Voluntary testing at end of production (limit 10 CFU/g)n=5 samples every month  FP Monitoring at end of SL (limit 10 CFU/g) n=5 samples every week.

1

Reminder of key relevant concepts

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# BTSF

## Each RTE food is different



pH=?  
aw=?

1. Setting

2. Validation

3. Verification

4. Monitoring

### Market, brief, litt.

18 months

Frozen Product !

→ What is expected in this case?



FINAL - 12 March 2025

[euroglaces\\_reactive\\_statement\\_on\\_listeria - final - 12\\_march\\_20252025421356512682139.pdf](https://euroglaces.org/reactive-statement-on-listeria-final-12-march-20252025421356512682139.pdf)

#### REACTIVE STATEMENT

*Listeria monocytogenes* has no growth potential in Edible Ices

The following statement can be used reactively, if challenged by authorities or other stakeholders:

*"The production process of edible ices (\*) includes a kill step (pasteurisation) to eliminate pathogens (targeting L. monocytogenes) from the mixes, and foresees that the temperature of the finished products at the end of manufacturing is lower than -18°C.*

*Edible ices are maintained at a temperature below -18°C throughout their entire shelf-life (stored, transported and marketed), and are also consumed in a frozen state.*

*Various scientifically substantiated documents, literatures and studies (referenced below) demonstrate that Listeria monocytogenes cannot grow in foodstuffs during storage in a frozen state.*

*Therefore, edible ices automatically fall under safety criterion 1.3. of Commission Regulation (EC) No 2073/2005, which means that the limit value of 100 cfu/g applies for edible ices throughout their entire shelf-life."*

(\*) Edible ices is the generic term for different subcategories such as dairy ice cream, ice cream, milk ice, water ice, fruit ice and sorbet.

### !! Caution !!

No growth does not exclude persistence.

For this category precedent case with Blue Bell Ice cream with 3 deaths



[Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products | Listeria | CDC](#)

# BTSF Each RTE food is different



pH=?  
aw=?

1. Setting

2. Validation

3. Verification

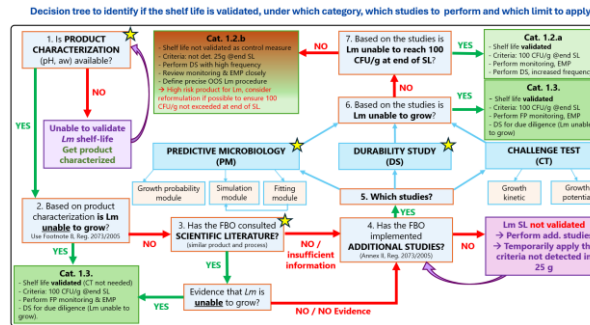
4. Monitoring

Market, brief, litt.

18 months

Category 1.3

pH=6.1  
aw=0.98



- Product characterization is still required in this case, otherwise in case of temperature abuse, we can't know how Lm will behave
- **Validation** would not be required
- **Verification** including reasonably foreseeable conditions of use is advisable, can substitute monitoring

**Monitoring**

is required.

- Voluntary testing at end of production (limit 10 CFU/g)n=5 samples every month
- FP Monitoring at end of SL (limit 10 CFU/g) n=5 samples every week.

**EMP** every batch target Zone 1, zone 2, zone 3 and zone 4

# BTSF Keep in touch



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[EU Spotify](https://open.spotify.com/playlist/37i9dQZF1DX0XUx1Q8WjYq)

# BTSF ACADEMY

Thank you!

European Commission  
European Health and Digital Executive Agency (HaDEA)  
Established by the European Commission

B-1049 Brussels/Belgium  
[HaDEA-BTSF-PROJECTS@ec.europa.eu](mailto:HaDEA-BTSF-PROJECTS@ec.europa.eu)

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Address : Viale Parioli 96 - 00197 Roma - Italy  
Phone: Tel/Fax +39.06.8080111  
Email: [info@opera-italy.eu](mailto:info@opera-italy.eu)  
Website: [www.opera-italy.eu](http://www.opera-italy.eu) / [www.opera-btsftraining.eu](http://www.opera-btsftraining.eu)