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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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Responsibilities of FBOs based on relevant European guidance documents and an ISO standard related to shelf-life studies

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

Annie Beaufort (AB consultant)





- DG SANTE Guidance document on *Listeria monocytogenes* monitoring and shelf-life studies for RTE foods, under Reg. 2073/2005 (2025)
- EURL Lm Technical Guidance document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to *L.monocytogenes* (2021)
Amendment 26 February 2026
- EURL Lm Guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *L. monocytogenes* in RTE foods (2023)
- EFSA Guidance on date marking and related food information: part 1 and part 2 (2020 and 2021)
- ISO 20976-1: 2019 Guidelines for conducting challenge tests - Part 1: Challenge tests to study the growth potential, lag time and the maximum growth rate

This guidance helps **FBOs producing RTE foods** comply with Regulation (EC) No 2073/2005 about one specific point: **criteria regarding *Listeria monocytogenes***.

It also assists **laboratories** involved in shelf-life studies and **competent authorities**.

[biosafety_fh_mc_guidance_document_lysteria.pdf](#)

The guidance clarifies the role of the parties involved:

❖ FBO

- Classifies foods as RTE or non-RTE
- Determines if the product supports the growth of *Lm*
- Validates and verifies the shelf-life of the RTE food
- Put in place an Environmental Monitoring Program
- Updates shelf-life after any change (recipe, process, packaging, site...)

❖ Laboratory

- Provides results of predictive microbiology, challenge tests, durability studies

❖ Competent authority

- Verifies the classification, the studies, and the corrective actions.

The guidance underlines the **competence** and **responsibilities of the lab.**

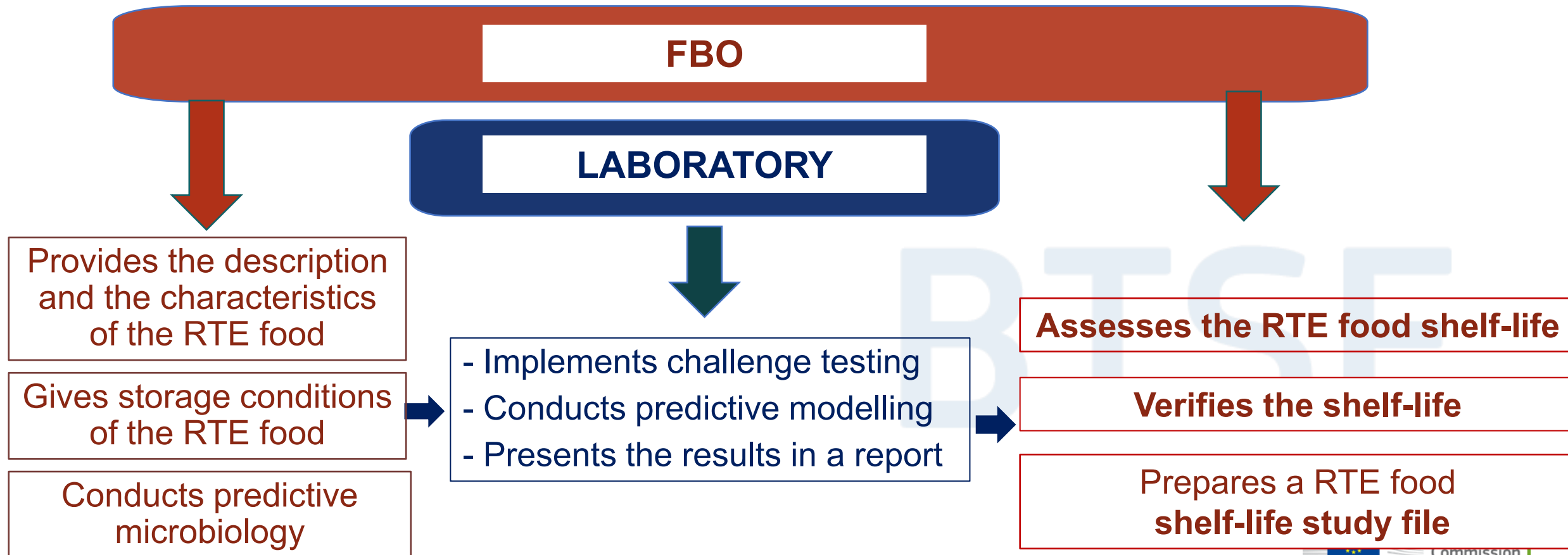
The laboratory is asked:

- to have expertise in microbiology, food science, and statistics
- to operate under a quality assurance system

The laboratory must:

- conduct predictive modelling
- implement challenge tests and durability studies
- produce a report describing *Lm* behaviour in the product

For assessing the shelf-life of a RTE food:



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EURL Lm Guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods (2023)

This guidance is intended for **accreditation bodies, NRLs, CAs**

It lists requirements mentioned in **the ISO standard 20976-1** and in **the EURL Lm Technical Guidance Document (TGD)**

It provides an approach to evaluate the competence of laboratories conducting challenge tests and durability studies regarding *Lm*, based on:

=> expertise

=> technical skills

This assessment may be **undertaken through an audit or based on a report**

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EURL Lm Guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods (2023)

The laboratory must demonstrate its knowledge related to:

- food microbiology, food science, predictive modelling, statistics
- EU Regulation No 2073/2005 + ISO 20976-1/2019 + EURL Lm TGD

It is recommended for the laboratory to be accredited for:

- *Lm* detection/enumeration
- pH, a_w , other physico-chemical parameters

If not accredited, the laboratory must:

- apply good laboratory practices
- implement metrological controls
- participate to proficiency testing

EURL Lm Guidance document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods (2023)

The guidance provides an example of a **checklist** to assess the competence of the laboratory performing a challenge test

	Specifications of ISO 20976-1 and EURL <i>Lm</i> TGD	Yes	No	Comment
Batches				
Number of batches to be tested	At least 3 batches	<input type="checkbox"/>	<input type="checkbox"/>	
	One batch for μ_{max} , if inter-batch variability of pH and a_w have no significant impact on the growth rate of <i>Lm</i>	<input type="checkbox"/>	<input type="checkbox"/>	
	Use of the inter-batch physico-chemical variability calculator	<input type="checkbox"/>	<input type="checkbox"/>	
Representativeness of the batches	Batches representative of the regular production process variability	<input type="checkbox"/>	<input type="checkbox"/>	

European Commission asked EFSA to help FBOs:

- 1/ To decide between “use by” date and “best before” date
- 2/ To determine a validated shelf-life

The aim is to protect consumers and reduce food waste.

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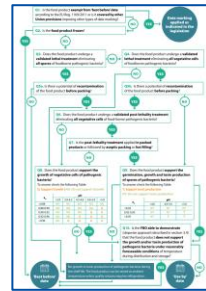
EFSA Guidance on date marking and related food information (part 1)

1/ To decide between “use by” date (safety) and “best before” date (salubrity):

- **EFSA identified pathogenic and spoilage microorganisms able to grow in prepacked refrigerated foods** under reasonably foreseeable conditions
- **EFSA listed factors affecting growth:**
 - intrinsic factors and extrinsic factors
 - implicit factors (background microflora)
- **EFSA identified factors influencing the shelf-life of the food:**
 - raw materials & ingredients
 - processing environment
 - manufacturing steps

EFSA Guidance on date marking and related food information (part 1)

EFSA proposed a Decision Tree to determine which date is required



- **“Use by” date** → Foods prone to growth of pathogenic microorganisms
- **“Best before” date** → Foods prone to growth of spoilage microorganisms and sensory or nutritional deterioration

2/ To help to determine a validated shelf-life, EFSA proposed the following steps:

- Identification of the **relevant pathogenic and spoilage microorganisms** and **their initial levels**
- Characterisation of the **factors affecting the growth** of microorganisms
- Assessment of the **growth of microorganisms** in the food all along the shelf-life

European Commission asked EFSA to help FBOs with:

- 1/ **The assessment of a secondary shelf-life of foods**
- 2/ **The thawing of frozen foods**

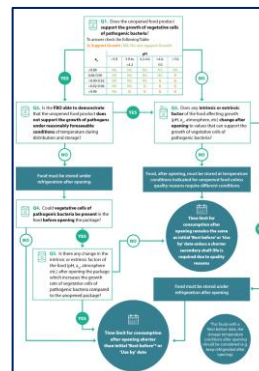
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EFSA Guidance on date marking and related food information (part 2)

1/ To help to assess a secondary shelf-life, EFSA:

- ➔ Explained the changes when opening a package:
 - changes in microorganisms: introduction of microorganisms
 - changes linked to extrinsic, intrinsic, implicit factors
- ➔ Proposed a decision tree to determine whether the time limit after opening remains the same or not



2/ To help concerning thawing of frozen foods, EFSA focused on **pathogens** and summarised how:

- To avoid **contamination** and **growth** during thawing
- To reduce **potential contamination** when using thawed food
- To avoid **growth** after thawing
- To **inform consumers that most frozen foods are not RTE** and that these food need to be sufficiently cooked after thawing

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ISO 20976-1/2019 “Microbiology of the food chain - Guidelines for conducting challenge tests - Part 1: Challenge tests to study the growth potential, lag time and the maximum growth rate”

ISO 20976 is a **standard for laboratories** performing challenge tests

It sets out the **protocols for conducting challenge tests** on vegetative bacteria, spore forming bacteria, yeasts that do not form mycelium:

- challenge test assessing the growth potential
- challenge test assessing growth kinetics: lag time, maximum growth rate

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To conclude

European guides and ISO 20976 -1/2019 help the FBO to comply with Annex II of the Regulation (EC) No 2073/2005 on microbial criteria for foodstuffs

They are complementary to assist FBOs to assess, validate and verify and monitor food shelf-life

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Thanks for your attention

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Thank you!

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