

Activities of the European Union Reference Laboratory for *Listeria monocytogenes*

Guidance Documents on *L. monocytogenes* shelf-life studies for ready-to-eat foods

Hélène Bergis

EURL *Listeria monocytogenes*

- Anses – Laboratory for food safety named in 2006 as European Union Reference Laboratory for *Listeria monocytogenes* (EURL Lm)
- Coordination of NRL network
 - At least 1 National Reference Laboratory / EU Member State
 - 36 NRLs, including Norway and Switzerland

EUR Lm mandate

➤ Regulatory framework: EC Regulation 2073/2005 on microbiological food criteria

➤ Lm: food safety criteria applicable to ready-to-eat (RTE) foods

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	Absence 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	Absence in 25 g ⁽⁷⁾	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has 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

EUR Lm mandate

- Article 3 of EC Reg. 2073/2005: food business operators (FBOs) shall conduct studies
 - In accordance with Annex II
 - In order to investigate compliance with the criteria throughout shelf-life
- In particular RTE foods able to support Lm growth and that may pose a Lm risk for public health



Activities of the EURL Lm

➤ 3 types of activity

1. **Coordination of NRL network**
2. Analytical development
3. Scientific and technical support to the EC / DG SANTE and other European organizations

1. Coordination of NRL network

- Annual workshops
- Proficiency tests (PT)
- Training sessions, video tutorials on EURL website (Lm PFGE typing & profile interpretation)
- Scientific & technical advice to NRLs
- Participation to national meetings
- EURL Lm database on PFGE profiles of Lm food isolates

1. Coordination of NRL network

- EURL guides for NRLs/national official labs
 - Developed in collaboration with some NRLs (WGs)
 - Measurement uncertainty / Lm enumeration
 - Sampling techniques of surfaces of food processing environment for Lm analysis
 - **3 Guides on shelf-life studies**

1.1 Guide on shelf-life studies

- EURL Lm Technical Guidance Document (TGD) for conducting shelf-life studies on Lm in RTE foods

- Version 3 – 6 June 2014

<https://sites.anses.fr/en/minisite/listeria/european-union-reference-laboratory-listeria-monocytogenes-0>

https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_technical_guidance_document_listeria_in_rte_foods.pdf

- Drafted by EURL Lm + WG of 11 NRLs Lm
- Approved by EU Member States (MSs)
- Directed to labs: technical guidance to conduct SL studies
 - Challenge tests
 - Durability studies

1.1 Guide on shelf-life studies

- Challenge tests (CT) & Durability studies
 - Additional studies mentioned in Annex II of EC Regulation 2073/2005
 - Part of the tools to assess compliance of RTE foods to Lm limit of 100 cfu/g at end of the shelf-life
 - Other tools cited in Annex II
 - Physico-chemical characteristics of the product & type of packaging
 - Scientific literature and research data
 - Predictive mathematical modelling

1.1 Guide on shelf-life studies

1. Challenge test assessing growth potential (δ)

- 1st intention test, artificial contamination
 - Use
 - To classify RTE foods
 - When $\delta > 0.5$: food classified as RTE food able to support Lm growth (cat 1.2 of Reg. 2073/2005)
 - When $\delta \leq 0.5$: food classified as RTE food unable to support Lm growth (cat 1.3 of Reg. 2073/2005)
 - To quantify Lm behavior in RTE foods of cat 1.2
 - To calculate [Lm] at production
 - ↪ not to exceed 100 cfu/g at end of the shelf-life
-
- ❖ Pros: relatively simple, direct use of results
 - ❖ Cons: lack of flexibility (valid only for the storage conditions applied)

1.1 Guide on shelf-life studies

2. Challenge test assessing maximum growth rate (μ_{\max})

- 2nd intention test, artificial contamination
- Use
 - To estimate [Lm] at day “x” of the shelf-life, if initial [Lm] known
 - To estimate max allowable [Lm] at day of production, to comply with 100 cfu/g at end of the shelf-life
- ❖ Pros: drawbacks of (1) solved, more information
- ❖ Cons: need of knowledge on predictive microbiology, longer and more expensive

1.1 Guide on shelf-life studies

3. Durability study

- Natural contamination
- Use to estimate the proportion of RTE foods exceeding 100 cfu/g at the end of shelf-life, after a storage period reflecting the foreseeable conditions of distribution and storage.
- ❖ Pros: more realistic
- ❖ Cons: only when Lm prevalence is high

1.2 Guide on laboratory proficiency

- EURL Lm Guidance Document to evaluate the competence of laboratories implementing challenge tests & durability studies related to Lm in RTE food
- Version 2, 2018

<https://sites.anses.fr/en/minisite/listeria/eurl-lm-guidance-document-evaluate-competence-laboratories-implementing-challeng-0>

https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance-comp-labs.pdf

- Drafted by EURL Lm + WG of 7 NRLs
- Approved by EU Member States (MSs)

1.2 Guide on laboratory proficiency

- Intended for
 - National Competent Authorities (CAs)
 - NRLs
 - Other organizations in charge of assessing laboratories conducting CT/Lm
- Harmonized approach to evaluate the competence of laboratories conducting shelf-life studies :
 - expertise needed to design, conduct and interpret a study
 - technical competence of the laboratory

1.3 DG SANTE Guide

- Guidance document (GD) on Lm shelf-life studies for RTE foods, under EC Reg. 2073/2005
https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_mc_guidance_document_lysteria.pdf
- Drafted by DG SANTE with WG of national CAs & EURL Lm, & approved by all MSs
- Directed to food business operators (FBOs), producers of RTE foods

1.3 DG SANTE Guide

- Objectives
 - To provide general principles for decision on when and which SL studies are needed
 - To guide FBOs producing RTE foods
 - To identify Lm risk in their products
 - To demonstrate to the satisfaction of CA that their products will comply with Lm criteria until end of SL
 - To understand range of different approaches available (Annex II of Reg. 2073/2005)
+ to choose the appropriate one
 - To classify their RTE foods into cat 1.2 (Lm able to grow) or 1.3 (Lm unable to grow) of Reg. 2073/2005

1.4 EURL Lm Training tool

- European training tool on food shelf-life studies related to *Listeria monocytogenes*
- Drafted by EURL Lm with WG of 6 NRLs and 3 CAs (to be finalized in 2019)
- Directed to CAs, personnel involved in the evaluation of SL and/or given guidance in their implementation
- Aim : To provide an overview of the tools available for shelf-life determination dedicated to Lm.

1.5 INTERNATIONAL STANDARD

- EN ISO 20976-1 « Microbiology of the food chain- Guidelines for conducting challenge tests of food and feed products

Part 1 : Challenge tests to study growth potential, lag time and maximum growth rate

- Publication for the first half of 2019



Thank you for your attention

