

Listeria monocytogenes: A Regulatory Perspective

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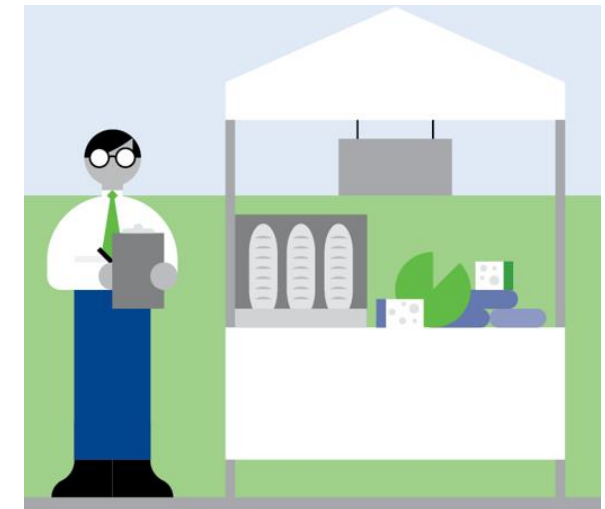
2023 Symposium on *Listeria monocytogenes* in Foods Session 5: *Listeria monocytogenes*: Detection, Infection and Control

25th May 2023



Presentation overview

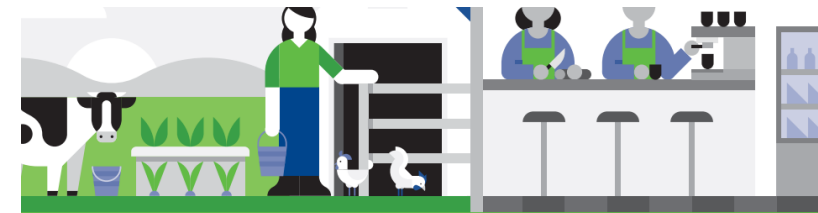
- Who is the FSAI?
- Role of food safety legislation in the EU
- *L. monocytogenes* in Regulation 2073/2005
- Environmental monitoring of *L. monocytogenes*
- FSAI Information & Resources



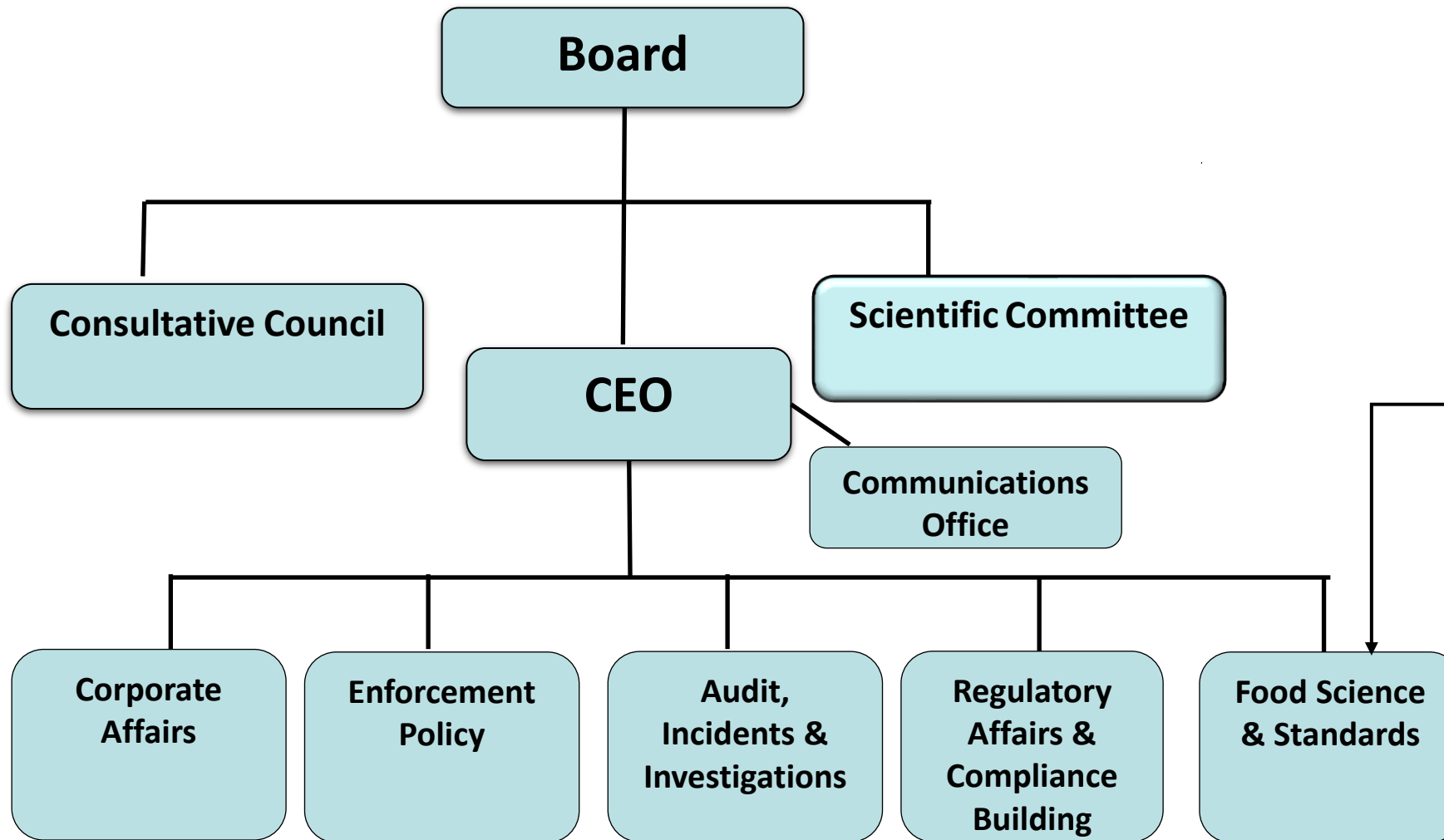
Who is FSAI?

- The Food Safety Authority of Ireland (FSAI) was established under the Food Safety Authority of Ireland Act, 1998
- Statutory, independent and science-based body
- National responsibility for co-ordinating the enforcement of food safety legislation in Ireland through service contracts with official agencies
- Manage risks in the food chain
- Respond effectively to any national or international food incident or crisis
- Detect and prevent breaches of food law
- Take action to protect consumers

www.fsai.ie



Organisation Structure - FSAI



Biological Safety team:

- Advice and technical support to food business operators (FBO's) & official agency staff
- Compliance with microbiological criteria:
 - Regulation 2073/2005
 - *L. monocytogenes*
 - Shelf-life
 - Environmental monitoring
- Microbiological risk assessment
- Microbiological foodborne outbreaks
- Training and guidance

Role of food safety legislation in the EU

- Increase consumer confidence in safety of food they buy
- Integrated approach to food safety 'from farm to fork'
- Feed production, primary production, food processing, storage, transport and retail sale
- Primary responsibility rests with the food (or feed) business operators
- Competent authorities ensure effective system of enforcement in place for the production of safe food





General Food Law

- Regulation (EC) No 178 of 2002
- The central piece of European food and feed law
- Contains general obligations and responsibilities for
 - **Food and feed businesses**
 - **Competent authorities**
- Requirements: Food safety, risk analysis, risk communication, traceability, withdrawal and recall...



Unsafe food (Reg. 178/2002 Article 14)

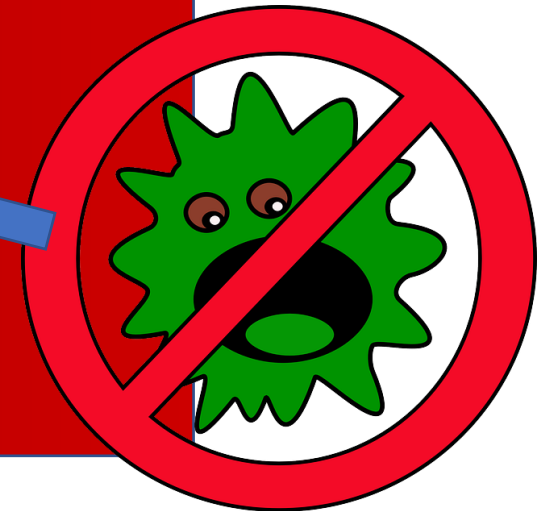
Food shall not be placed on the market if it is unsafe:



Unsafe food is defined as food which is:

Injurious to health
or

Unfit for human consumption



E.g. Due to contamination with pathogens like
L. monocytogenes at a level that is likely to cause illness



How to control the risk of unsafe food?

- Legal requirement (Regulation 852/2004) for all food businesses to have a **food safety management system** (FSMS) based on the principles of HACCP
- Good hygiene/manufacturing practices (GHP/GMP) necessary to maintain a hygienic environment
- Hazard Analysis and Critical Control Point (**HACCP**) to identify and control **hazards** (i.e. microbiological, chemical or physical) that could pose a danger to the preparation of safe food

Microbiological Criteria for Foodstuffs

Article 4

Regulation 852/2004 →

General and specific hygiene requirements

1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.
2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.
3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:
 - (a) compliance with microbiological criteria for foodstuffs;
 - (b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
 - (c) compliance with temperature control requirements for foodstuffs;
 - (d) maintenance of the cold chain;
 - (e) sampling and analysis.

Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs

Sets food safety criteria which should be met throughout the shelf-life following **reasonably foreseeable conditions of distribution, storage and use**

- **Annex I:**

1. Food safety criteria
2. Process hygiene criteria
3. Rules for sampling and preparation of test samples

- **Article 3 / Annex II:**

As necessary FBO responsible for the manufacture of the product shall conduct studies in accordance with **Annex II** to investigate compliance with the criteria throughout the shelf-life

➤ Applies to RTE foods **able to support** *L. monocytogenes* growth (Food category 1.2)

Manufacturer not required to conduct all studies listed

Annex II of 2073/2005 – the studies

1. Physico-chemical characteristics of the product

- pH, water activity (a_w), salt content, concentration of preservatives, type of packaging system, etc.
- Relatively inexpensive and technically simple information for FBO to gather

2. Consult available scientific literature and research data regarding growth and survival characteristics of the micro-organisms of concern

- FBO's own data on similar products, ICMSF, EFSA, Google, FSAI information centre, product development centres etc.

These two steps are the first pieces of information the FBO should gather.....



Annex II of 2073/2005 – the studies

Then, when necessary (based on the info from steps 1 and 2), the FBO shall conduct additional studies, which may include:

3. Predictive mathematical modelling established for the food in question e.g. ComBase
<https://www.combase.cc/index.php/en/>
 4. Tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable conditions of distribution, storage and use
= **Challenge study**
 5. Studies to evaluate the growth or survival of the micro-organism of concern that may be naturally present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use
= **Durability study**
-



L. monocytogenes in Regulation 2073/2005

Chapter 1. Food safety criteria

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 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

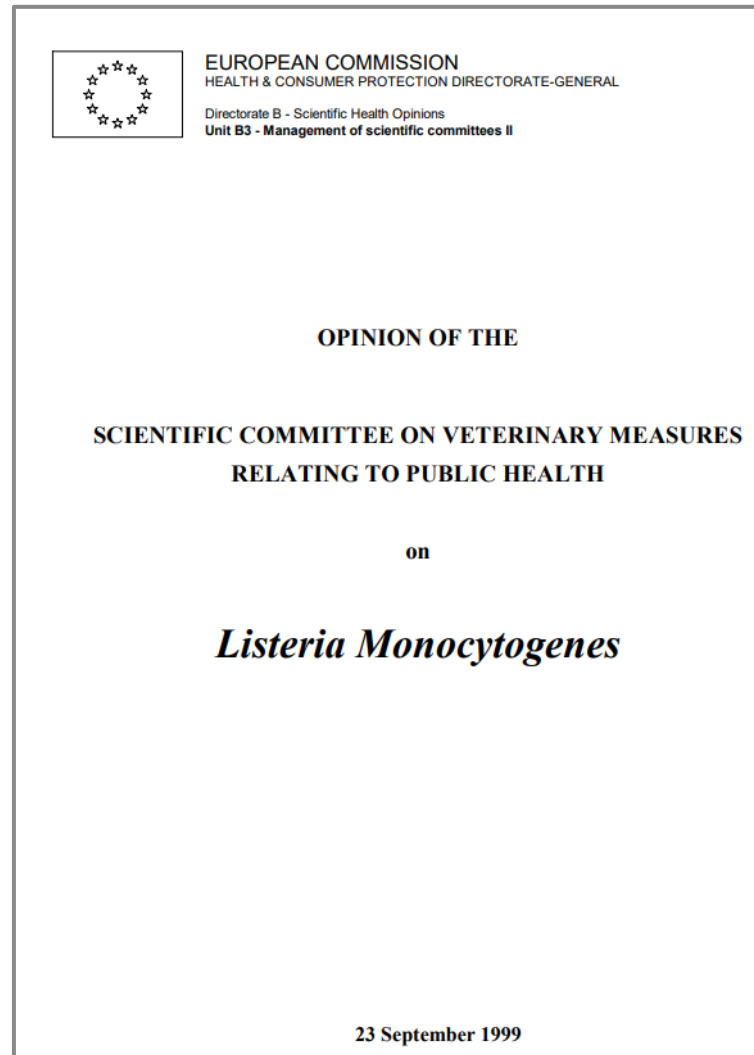
Enumeration method – what numbers present – less sensitive method

Legislative gap: No 'not detected in 25 g' criterion for food placed on the market

Risk assessed under Art. 14 Reg. 178/2002

Detection method – enriched to recover injured cells – more sensitive method

Why is the criterion limit 100 cfu/g?



- *L. monocytogenes* ≤ 100 cfu/g of food at the point of consumption considered to be low risk to consumers with a **healthy immune system**
- Higher hospitalisation and fatality rate in those belonging to vulnerable groups
- Does this limit present an unacceptable risk to those who are vulnerable to contracting listeriosis?
- FSAI awareness raising campaign for health and social care organisations
- Actions to reduce the risk of listeriosis when serving chilled ready-to-eat food to vulnerable groups

Problem 1: Which food category applies?

- **1.1** – infants and special medical purposes
- **Automatically 1.3** (unable to support growth) if*:
 - Shelf-life is four days or less
 - pH is ≤ 4.4
 - Water activity is ≤ 0.92
 - Combined pH is ≤ 5.0 and water activity is ≤ 0.94
 - Other scientific justification (e.g. frozen food)
- **1.2** (supports growth *L. monocytogenes*) if it can't be shown to fall into 1.1 or 1.3



*Footnote 8 of Chapter 1. Food safety criteria in Regulation 2073/2005

For more information see **FSAI Guidance Note 27**

<https://www.fsai.ie/publications/guidance-note-27-on-the-enforcement-of-commission>



Problem 2: Which Food cat 1.2 criterion applies?

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 business operator, who has produced it

⁽⁵⁾ This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life.

⁽⁷⁾ This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

Need to be able to demonstrate *L. monocytogenes* won't exceed 100 cfu/g limit throughout the shelf-life if present in the ready-to-eat food the food business operator is manufacturing

Example where we need more information on shelf-life.....



- Ready-to-eat
 - Shelf-life 5 days or more
 - pH 5.9, a_w 0.96
 - Food category 1.2
 - Environmental Health Officer (EHO) takes official control sample at manufacturer level
 - Results are:
 - *L. monocytogenes* detected in 25 g (2/5 sample units)
 - *L. monocytogenes* <10 cfu/g (5/5 sample units)
 - Product is on the market
 - 5 days remaining on shelf-life
 - **Is this an unsatisfactory result?**
- } Does not automatically fall into food category 1.3

So we go to the manufacturer...

- *L. monocytogenes* in your product
- Detected in 25 g (albeit at <10 cfu/g)
- Can you demonstrate the limit of 100 cfu/g won't be exceeded in the remaining 5 days of shelf-life?

Food category 1.2

Footnote 5: Allowed up to 100 cfu/g if manufacturer can demonstrate limit of 100 cfu/g won't be exceeded throughout shelf-life



Footnote 7: If FBO unable to demonstrate, limit of not detected in 25g applies to products **before they leave the immediate control of the manufacturer**

Shelf-life test results

The Pretend Food Company – Product X

Realistic temperature?

Stored at 5°C				
Test	Day 0	Day 5	Day 10	Day 15
<i>L. monocytogenes</i>	ND in 25 g	ND in 25 g	ND in 25 g	ND in 25 g
<i>L. monocytogenes</i>	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
<i>Salmonella</i>	ND in 25 g	ND in 25 g	ND in 25 g	ND in 25 g
<i>S. aureus</i>	<20 cfu/g	<20 cfu/g	<20 cfu/g	<20 cfu/g
<i>E. coli</i>	<10 ²	<10 ²	<10 ²	<10 ²
TVC	10 ⁴	10 ⁴	10 ⁴	10 ⁵
Yeasts and moulds	<10 ³	<10 ³	<10 ³	<10 ³

- All results have been not detected in 25 g @ <10 cfu/g for *L. monocytogenes* in food stored at 5°C
- Shows that *L. monocytogenes* was not present in the batches tested for the shelf-life study
- Does not provide any information on how *L. monocytogenes* will grow in product throughout shelf-life
- **How quickly will limit of 100 cfu/g be exceeded if *L. monocytogenes* is present?**

Storage temperatures @ ≤5°C – may over estimate shelf-life

“...reasonably foreseeable conditions of distribution, storage and use”
(Reg. 2073/2005 Article 3.1)


Table 7 Recommended experimental storage temperature conditions to evaluate potential growth of *L. monocytogenes* in chilled ready-to-eat food ^a

Stage of cold chain	Storage (incubation) temperature			Storage (incubation) duration			
				Duration justified by detailed information	Or if not known	Shelf-life ≤21 days	Shelf-life >21 days
Manufacturer storage and distribution	Temperature justified by detailed information ^b	Or if not known	7 °C			Duration justified by detailed information	Or if not known
Retail			7 °C	One third of the shelf-life	Half of the remaining shelf-life ^c		
Consumer			10 °C	One third of the shelf-life	Half of the remaining shelf-life		

^a Table adapted from Table 4 on page 22 in “*Technical guidance document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to Listeria monocytogenes, Version 4 of 1 July 2021*” (European Union Reference Laboratory for *Listeria monocytogenes*, 2021a).

^b Temperature justified by detailed information and based on the 95th percentile of the food business operator’s data observation and the 95th percentile of the observations for the country where the stage of the cold chain is located.

^c The remaining shelf-life is calculated by subtracting 7 days from the full shelf-life duration assigned.



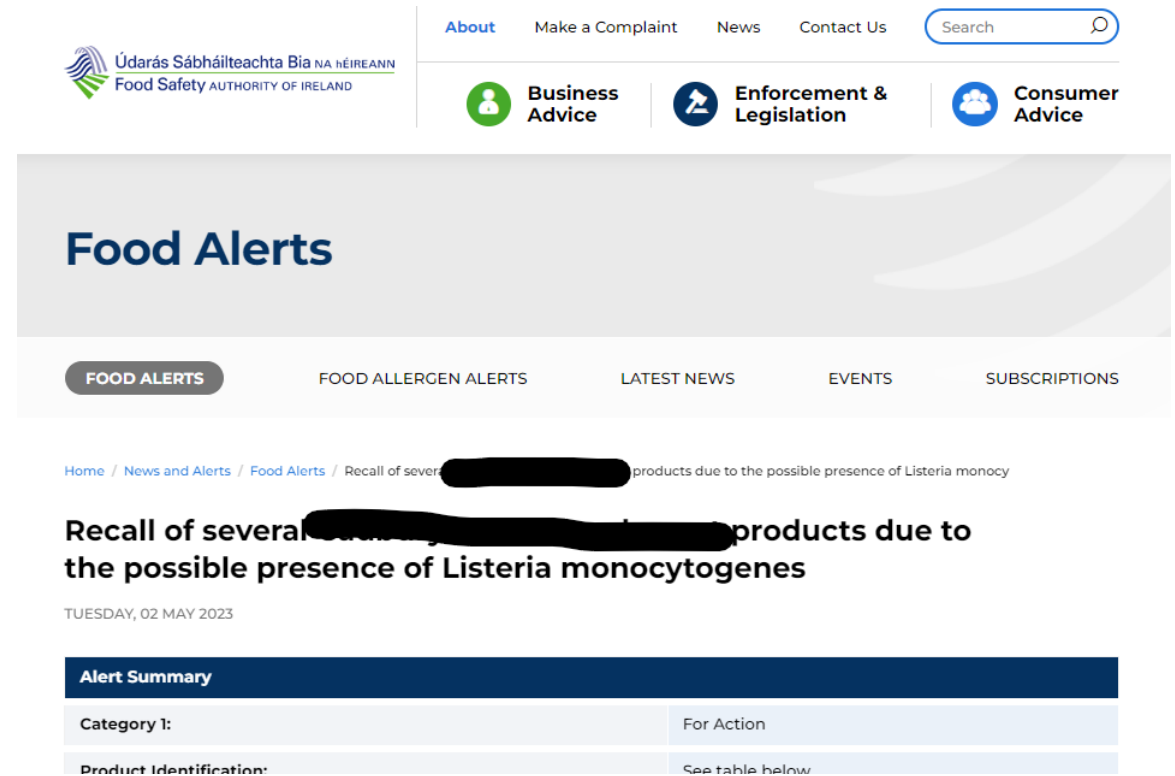
18 GUIDANCE NOTE

Validation of product shelf-life (Revision 5)

<https://www.fsai.ie/publications/guidance-note-18-validation-of-product-shelf-life>

In the absence of satisfactory evidence....

- FBO can't demonstrate that *L. monocytogenes* in the product won't grow to more than 100 cfu/g during remaining shelf-life
- Therefore 'not detected in 25g' criterion limit applies under food category 1.2
- Unsatisfactory result for food safety criterion (Reg. 2073/2005 Article 7)
- Product still on the market = Recall



The screenshot shows the Food Safety Authority of Ireland website. The header includes the logo and navigation links: About, Make a Complaint, News, Contact Us, and a search bar. Below the header are three main service icons: Business Advice, Enforcement & Legislation, and Consumer Advice.

The main content area is titled "Food Alerts" and has a navigation bar with links for FOOD ALERTS, FOOD ALLERGEN ALERTS, LATEST NEWS, EVENTS, and SUBSCRIPTIONS. The current page is a recall alert titled "Recall of several [redacted] products due to the possible presence of Listeria monocytogenes" dated TUESDAY, 02 MAY 2023.

The "Alert Summary" table is as follows:

Alert Summary	
Category 1:	For Action
Product Identification:	See table below

Could the FBO have avoided a recall?

- Maybe?
- But would need to present more data on how *L. monocytogenes* grows or does not grow in their product

Guidance for labs how to conduct:

1. Challenge tests
2. Durability studies



EURL *Lm* TECHNICAL GUIDANCE DOCUMENT
on challenge tests and durability studies for assessing shelf-life
of ready-to-eat foods related to *Listeria monocytogenes*

Version 4 of 1 July 2021

- ❑ 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)
- ❑ EURL *Lm* Guidance document for FBO's 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 (2013 – **Being updated**)
- ❑ ISO 20976-1:2019 Microbiology of the food chain — Requirements and guidelines for conducting challenge tests of food and feed products — Part 1: Challenge tests to study growth potential, lag time and maximum growth rate

Do we expect all manufacturers to conduct challenge studies?

- No - they are an option to the FBO
- Other tools to correctly categorise as 1.2 or 1.3 (e.g. predictive micro, scientific literature)
- Could be useful if *L. monocytogenes* in product to avoid a recall **but only if** results show growth will be ≤ 100 cfu/g throughout shelf-life of food
- FBOs don't usually produce just one product = cost!



Conduct study on product **most likely to support *L. monocytogenes* growth** based on physico-chemical characteristics (e.g. pH, a_w), scientific literature and results of predictive modelling

Environmental monitoring of *L. monocytogenes*



Why carry out environmental monitoring (EM)?

- *L. monocytogenes* can be transiently or persistently present in the food processing environment
- Acts as an early warning system and integral part of controlling *L. monocytogenes*
- Identify sources of *L. monocytogenes* in the environment, water, equipment, or air that could cross-contaminate ready-to-eat food
- Identify and manage harbourage sites in the food manufacturing environment (e.g. hard to clean places, *L. monocytogenes* survival in biofilm)
- Assess the efficacy of the cleaning and disinfection programme
- Legal requirement!

Article 5.2 of Commission Regulation (EC) No 2073/2005

“Food business operators manufacturing ready-to-eat foods, which may pose a *Listeria monocytogenes* risk for public health, shall sample the processing area and equipment for *Listeria monocytogenes* as part of their sampling scheme.”

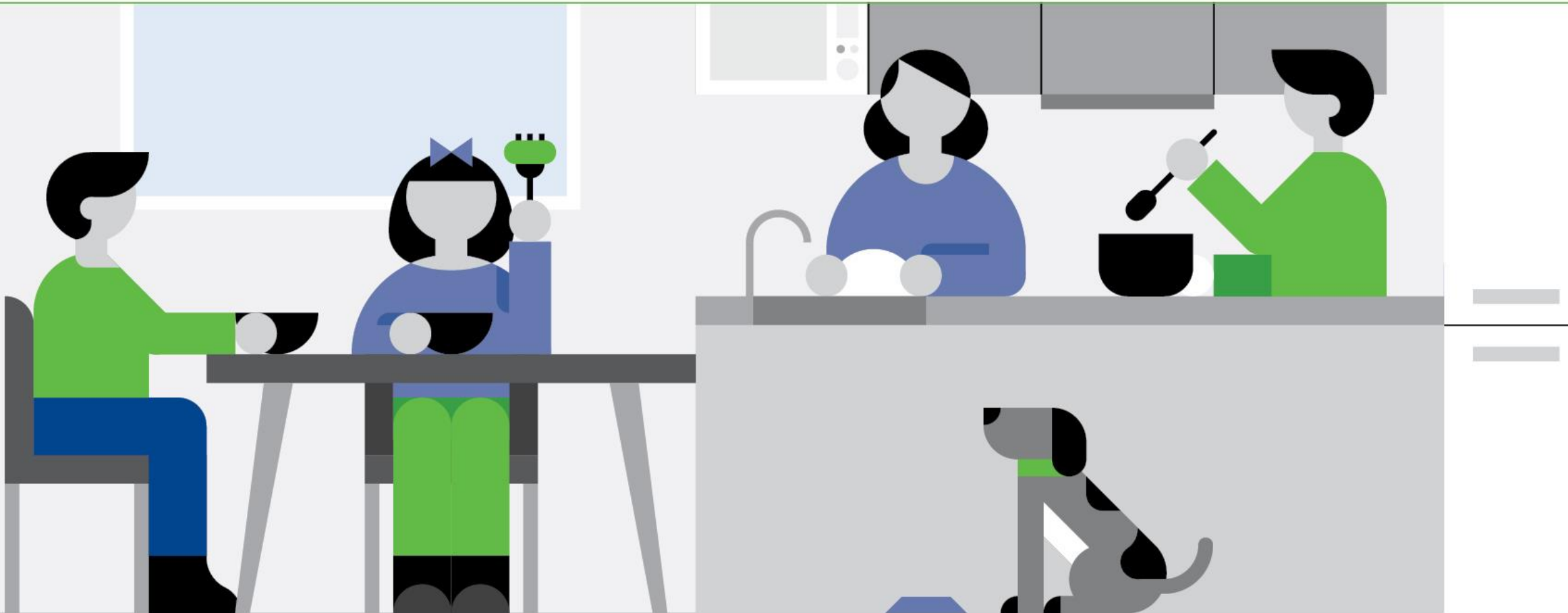
But no information on:

- How to design EM programme?
- Where and how to take samples?
- How to evaluate the test results and what to do in the event of a positive detection of *L. monocytogenes*?

Guidance available

What ?	Guidance	Link
Design EM programme	The Control and Management of Listeria monocytogenes Contamination of Food (FSAI, 2005)	https://www.fsai.ie/publications/the-control-and-management-of-listeria-monocytogen
Swabbing method	<p>Guidelines on sampling the food processing area and equipment for the detection of <i>Listeria monocytogenes</i> (EURL <i>Lm</i>, 2012 – Being updated)</p> <p>ISO 18593 Microbiology of the food chain — Horizontal methods for surface sampling (ISO, 2018)</p>	<p>https://eurl-listeria.anses.fr/en/minisite/listeria-monocytogenes/mandate</p> <p>https://www.iso.org/obp/ui/#iso:std:iso:18593:ed-2:v1:en</p>
Corrective actions for <i>L. monocytogenes</i> positive results in EM swabs	<p>Pages 28-33 of The Control and Management of Listeria monocytogenes Contamination of Food</p> <p>New FSAI guidance being developed!</p>	See Row 1

FSAI Information & Resources





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FSAI Training & eLearning



The screenshot shows the FSAI website interface. At the top left is the logo and name: **Údarás Sábháilteachta Bia NA hÉIREANN** and **Food Safety AUTHORITY OF IRELAND**. The top navigation bar includes links for **About**, **Make a Complaint**, **News**, **Contact Us**, and a **Search** box. Below this are three main service icons: **Business Advice** (highlighted with a red box), **Enforcement & Legislation**, and **Consumer Advice**. The main content area is divided into several sections. On the left, under **Running a Food Business**, there is a list of topics: **Allergens**, **HACCP - Food Safety Management System**, **Training and Online Learning** (highlighted with a red box), **Caterers**, and **Butchers**. The **Training and Online Learning** section contains sub-links for **eLearning** and **Webinars**. A large red arrow points from the **Business Advice** icon to the **Training and Online Learning** section. In the center, there is a graphic with food additive codes: **E124**, **E122**, **E104**, **E110**, **E120**, **E123**, and **E127**. On the right, there is a list of training modules: **Food Additives 2: takes you through an ingredients list of some commonly available products.** and **Microbiological Criteria - Regulation 2073/2005**, which includes **Module 1: Identifying Relevant Microbiological Criteria** and **Module 2: Sampling and Testing**. At the bottom left, there is a small illustration of a person in a white lab coat using a pipette.



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