



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 *L.monocytogenes*

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

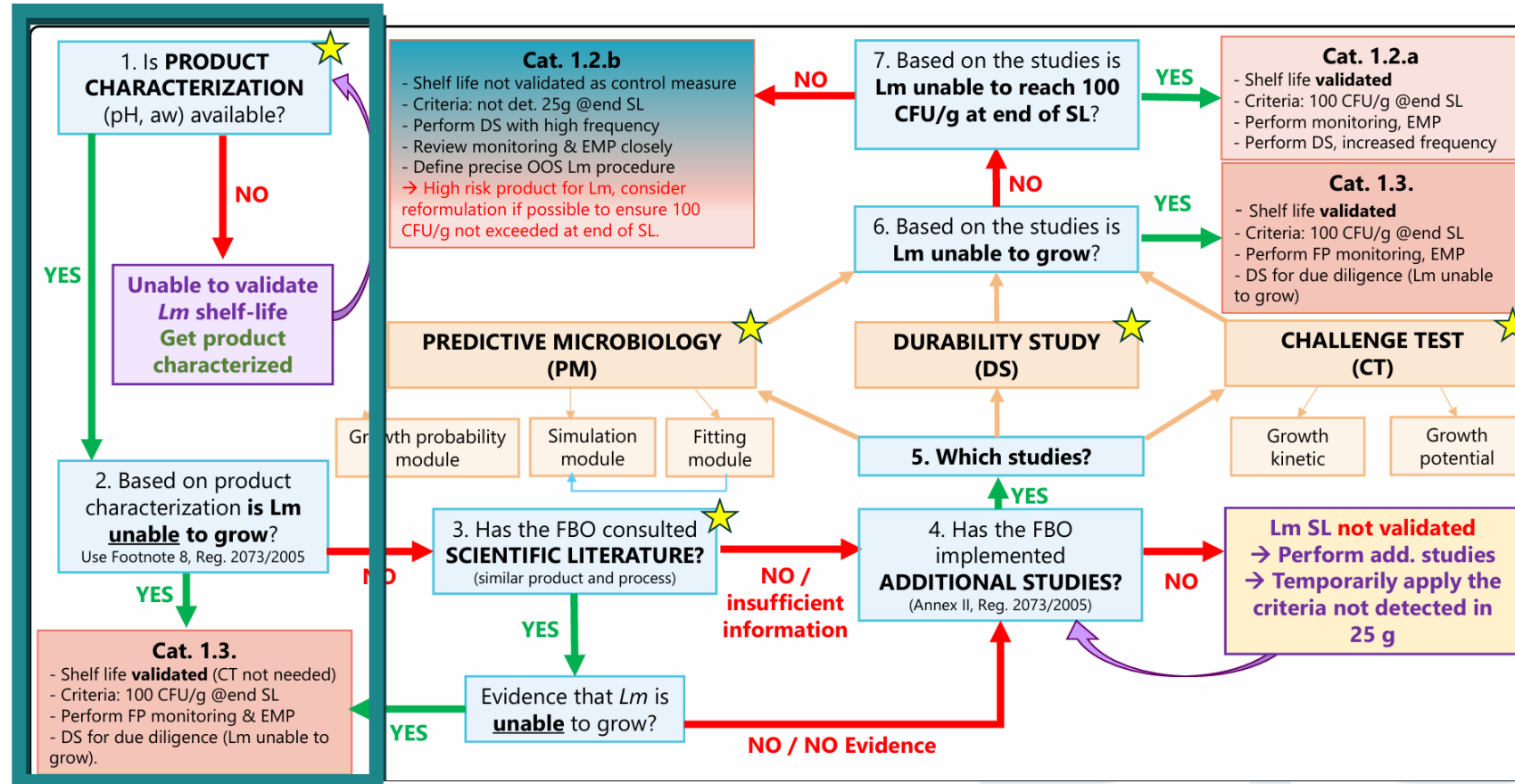
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Gathering information
as the first step of a RTE food shelf-life study

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

Annie Beaufort (AB consultant)

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Decision tree for shelf-life study of a RTE food

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Key points of the presentation

- Choosing the product for shelf-life validation
- Product description and condition of use
- Intrinsic and extrinsic characteristics of the food
- Historical data

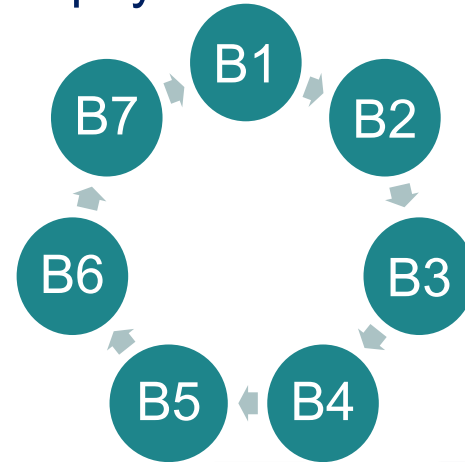
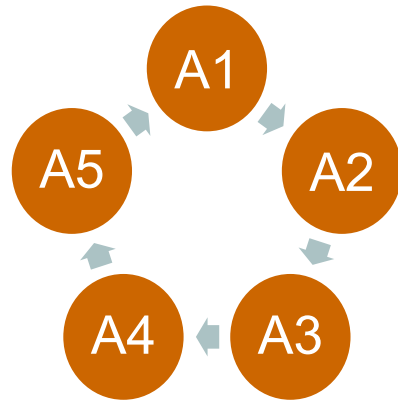
Based on DG SANTE guidance document

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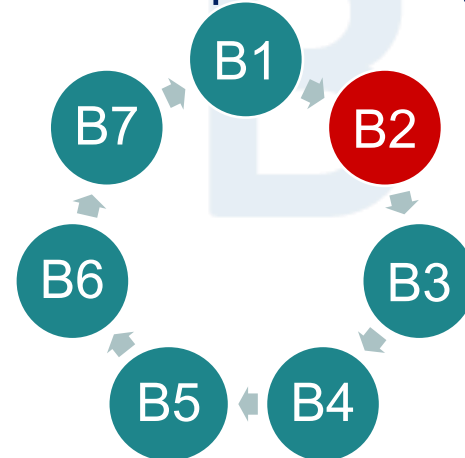
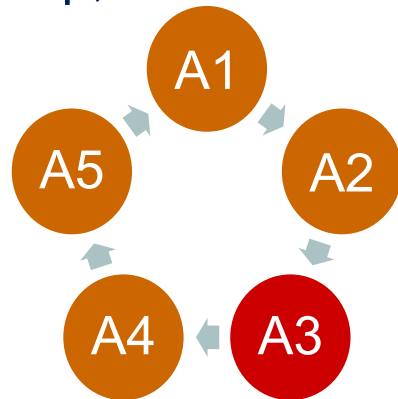
Choosing the product for shelf-life validation

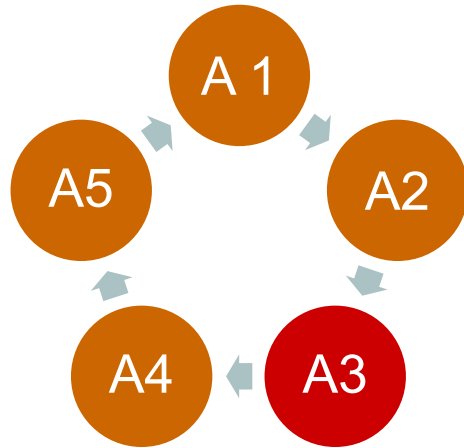
If the FBO has a wide range of foods, he has to:

- classify the products into groups with similar physico-chemical characteristics




- then, in each group, he selects the food that best supports the growth of Lm

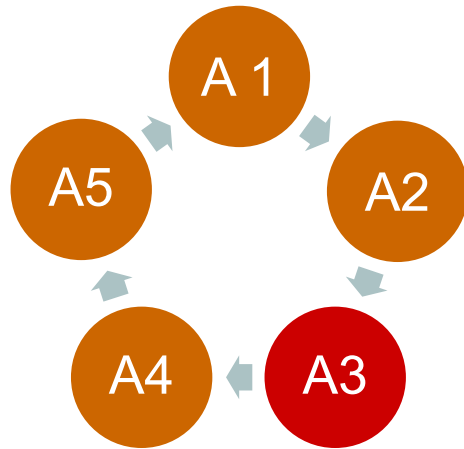




Choosing the food that best support the growth of *L.m.* may be obvious.



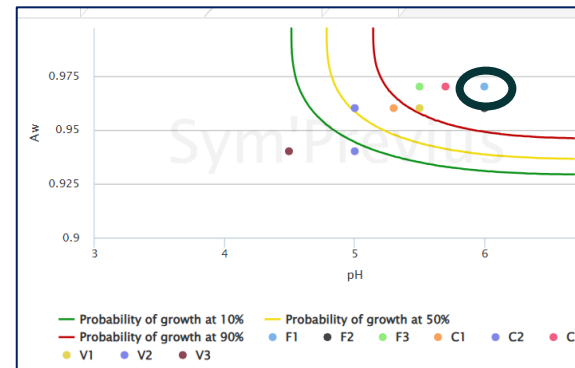
	pH	a_w
A1	4.7 ± 0.2	0.95 ± 0.01
A2	5.0 ± 0.2	0.96 ± 0.01
A3	4.8 ± 0.2	0.95 ± 0.01
A4	4.7 ± 0.2	0.95 ± 0.01
A5	4.9 ± 0.2	0.96 ± 0.01



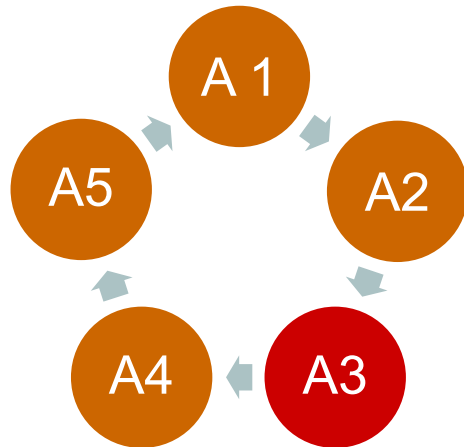
If not obvious, **why not relying on predictive microbiology?**

The FBO can use the **growth/no growth interface module of Sym'Previus**.

The software displays the growth probability of the bacteria regarding 2 variable factors (pH and a_w) and 1 or 2 fixed factors (T, lactic acid).

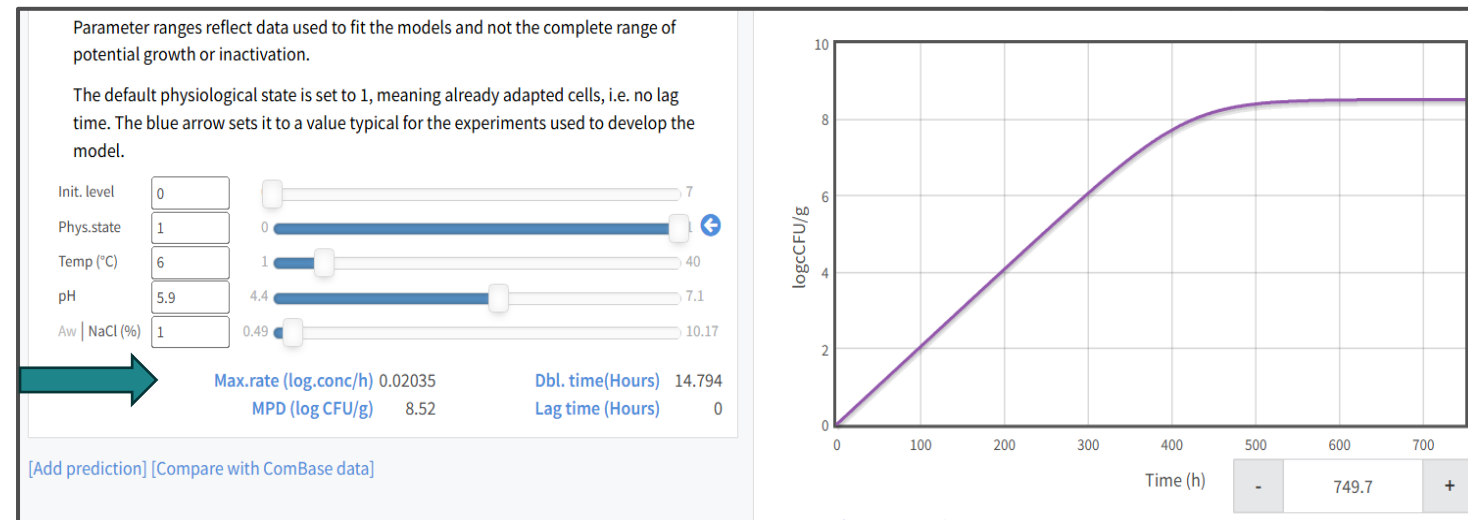


The food with the highest growth probability will be chosen for validation of the shelf-life.



If more than 4 factors are involved, the FBO can use a **growth module**.

For each food, the software displays the graph of the evolution of the bacteria according to the time and extracts parameters of the curve, in particular, maximal growth rate.



The food with the highest maximal growth rate will be chosen for validation of the shelf-life.

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Product description and condition of use

The food being chosen, the FBO should include:

- the list of ingredients
- the RTE food status (RTE or not)
- the process

He should also give information about:

- good manufacturing and hygiene practices
- application of HACCP
- quality control indicators and verification measures

He should determine which criterion to apply

He should provide details regarding:

- labelling consideration (e.g use by date)
- information about storage, distribution and retail display
- instructions for use: storage conditions after opening, cooking instructions, recommendations related to the consumption

The FBO should also provide information regarding:

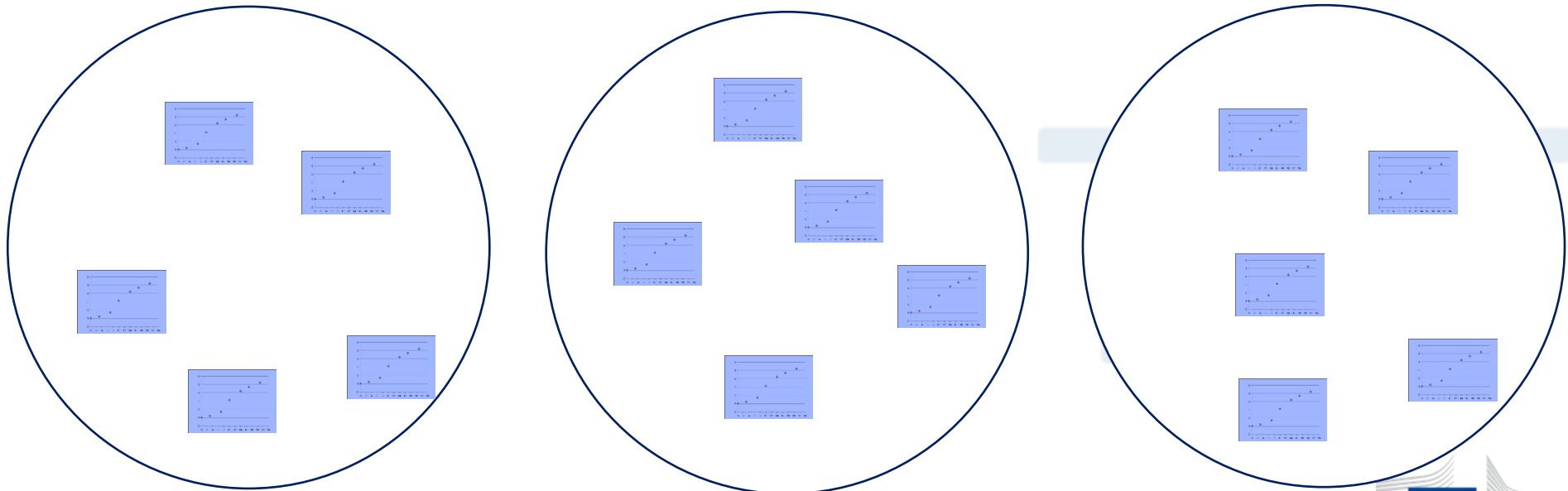
- pH
- a_w (water activity)
- water content and salt content (%)
- preservatives
- natural microbial flora
- added micro-organisms
- composition of modified atmosphere packaging
- reasonably storage conditions for each stage of the cold chain

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Intrinsic and extrinsic characteristics of the food

The data must show **extra-batch variability** and **intra-batch variability**.

- To consider extra-batch variability, the FBO should collect data from a minimum of 3 batches.
- To consider intra-batch variability, he should collect data from a minimum of 5 test units per batch.



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Intrinsic and extrinsic characteristics of the food

An example of **results showing the extra-batch and intra-batch variability**.

	pH	a _w	Organique acid (%)	Total microflora (log cfu/g)
Batch 1	5.5	0.98	1	4.80
	5.3	0.98	0.99	4.48
	5.4	0.97	0.99	5.00
	5.4	0.98	1	5.14
	5.3	0.97	1.1	4.75
Batch 2	5.5	0.98	1.3	4.80
	5.3	0.97	0.99	4.48
	5.5	0.97	0.99	5.00
	5.4	0.98	1	5.14
	5.4	0.97	1.1	4.75
Batch 3	5.2	0.98	1.2	5.10
	5.3	0.97	0.99	5.05
	5.3	0.97	0.99	5.00
	5.4	0.98	1	5.14
	5.4	0.97	1	4.75

The FBO should analyze the variability of the characteristics.

In case of a marked variability, the FBO should:

- identify the root causes of the variability
- lower, if possible, this variability to an acceptable threshold.
- test more batches

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Intrinsic and extrinsic characteristics of the food

The guide doesn't mention how **to quantify the variability of a factor** and **fix its limits**.

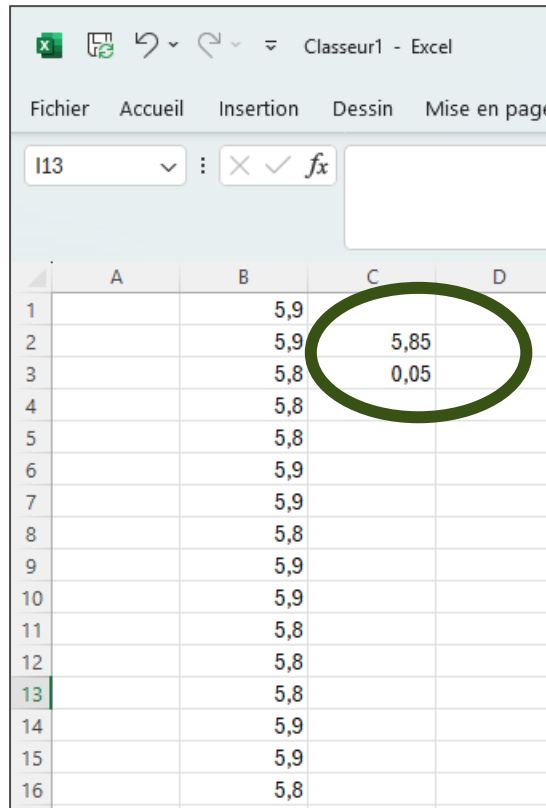
To quantify the variability of a factor, it is possible to rely on a statistical parameter: sigma (σ)

- a low σ indicates that the values are close to the mean.
- a high σ indicates a high dispersion of the values.

To define for each factor the production specification:

- the first step consists on **calculating mean and σ from a series of measures considered as acceptable**.
- the second step consists on **using these acceptable mean and σ to define the production limit specification**.

Example : how to fix limits for pH



	A	B	C	D
1		5,9		
2		5,9		
3		5,8		
4		5,8		
5		5,8		
6		5,9		
7		5,9		
8		5,8		
9		5,9		
10		5,9		
11		5,8		
12		5,8		
13		5,8	5,85	0,05
14		5,9		
15		5,9		
16		5,8		

- First step: **calculating mean and σ from a series of measures considered as acceptable (without outliers).**

$$\text{Mean} = 5.85 \quad \sigma = 0.05$$

- Second step: **defining the limits.**

- lower limit: $\text{mean} - 2 * \sigma = 5.75$ * could be 3 (more tolerant)
- upper limit: $\text{mean} + 2 \sigma = 5.95$

- Conclusion: **the correct pH range is between 5.8 and 6.0**

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The data collected allow:



To **classify the food in cat. 1.2 or 1.3** of the EU regulation 2073/2005 (Annex I)

Food category	Sampling plan		Limits m = M	Stage where the criterion applies
	n	c		
1.1 RTE foods intended for infants and RTE foods for special medical purposes	10	0	Not detected in 25 g	Products placed on the market during their shelf-life
1.2 RTE foods able to support the growth of <i>L. monocytogenes</i> other than those intended for infants and for special medical purposes	5	0	100 cfu/g	Products placed on the market during their shelf-life
	5	0	Not detected in 25 g	Products placed on the market during their shelf-life
1.3 RTE foods unable to support the growth of <i>L. monocytogenes</i> other than those intended for infants and for special medical purposes	5	0	100 cfu/g	Products placed on the market during their shelf-life

Effective July1, 2026

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The data collected allow:



To verify the **representativeness of the food received at the laboratory** for testing to the food regularly produced

- food composition
- pH, a_w
- potentially, organic acids, nitrites, phenol, ...
- background microorganisms
- gas atmosphere

BTSF **Historical data**

The guide proposes potential sources of historical data:

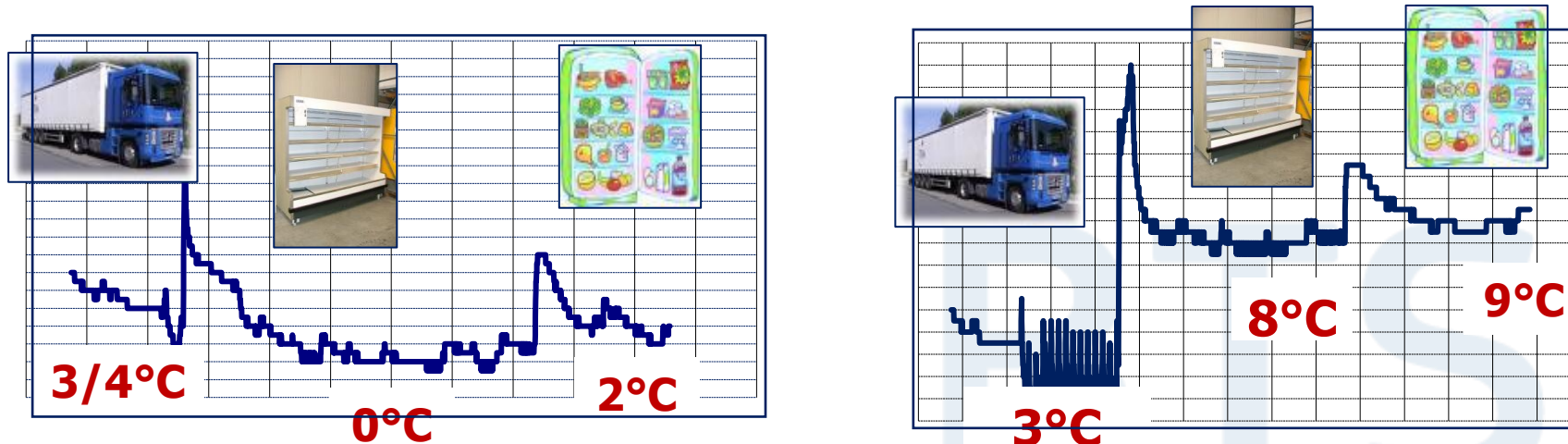
- Results of monitoring checks (e.g. temperatures, pH, a_w etc.)
- Results of analyses regarding:
 - ingredients
 - finished product throughout shelf-life
 - water and environmental samples
- Records of cleaning and disinfection procedures
- Records of official controls
- Records of corrective actions linked to non-conforming results
- Records of complaints
- Records of recalls and withdrawals

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The guide proposes also storage conditions as historical data:

But it mentions that “they have to be taken with caution due to their variability”.

Example: thermal evolution of sales units of smoked salmon



The graphs clearly illustrate the variability of the thermal profiles

Temperatures mentioned in the TGD Lm are 7°C at manufacturer and at retail and 10°C at consumer

DG Sante guidance document emphasizes that the **validation of the shelf-life of RTE foods regarding *Lm* is the responsibility of the Food Business Operator.**

It underlines that the **FBO must prove its foods meet *Lm* criteria throughout their entire shelf-life.**

It points out that the **credibility of the shelf-life study depends partly on the quality of its supporting documentation.**

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Thanks for your attention

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Thank you!

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