# Technical Lobbying Document (v15.3)

## Contents

# L. MONOCYTOGENES CRITERIA, CHALLENGE TESTING & ENVIRONMENTAL CONTROL – DRAFT RESPONSE MATERIAL FOR EC CONSULTATION

## Introduction

We recognise the importance of the Microbiological Criteria for Foodstuffs Regulation 2073/2005 and how it has helped facilitate delivery of the effective control of *Listeria monocytogenes* in foods. It has done this by allowing industry to focus efforts on controls to prevent contamination of foods through effective raw material, people and environmental controls whilst using testing of product to verify the efficacy of these controls to ensure the safety of product throughout its shelf life. Much data has been collected on products throughout shelf life, and on environmental management to verify ongoing safety. This holistic approach to management of the risk from *L. monocytogenes* has contributed to the low rate of listeriosis, for example in the UK which is consistently markedly below the overall European listeriosis rate.

Our Members adhere to the application of HACCP-based principles, Good Hygiene Practices and action plans agreed with retail and other customers, national or [1]European level Guides. These practices include continuous compliance verification conducted by the FBOs themselves, their customers (particularly in the case of own label foods), third party auditors and respective Competent Authorities.

Proposals to mandate challenge testing of products is likely to undermine this strategic approach to management of *Listeria.* We are extremely concerned that it will polarise attention on a single challenge test to demonstrate safety to the detriment of the much more comprehensive approach adopted successfully for many years. A challenge test can never encompass all of the potential variation in product formulation and processing and is usually a single event in the long sales life of a product. Challenge testing also involves artificially contaminating product and changing the intrinsic characteristics of the product. The organisms are not wild strains found in the manufacturing environment or in their natural state. Factors such as attachment or the very low levels of contamination cannot be replicated.
By routinely testing, the levels of naturally occuring organisms can be continually assessed over time and shelf life through all variances of produce batches, volume and hygiene conditions. It grossly oversimplifies how pathogens may behave in prepared foods without a comprehensive understanding and appreciation of the complexities of microbiology in food processing plants - so many things are changed and a laboratory-derived result most likely presents an erroneous picture of

[1] For example, “European Guide to Good Practice for Smoked and/or Salted and/or Marinated Fish” published by the European Commission on their Guidance Platform. The Guide was endorsed by EU Member States at the 3/7/18 meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF). https://essa-salmon.org/_library/_files/2018_11_09_Press_Release_-_ESSA_Guide_publication.pdf

what happens in practice. It also bears no relevance to food safety management through environmental controls, which are critical to assuring RTE food safety and breaches of which are commonly the root cause of outbreaks.

We firmly believe that safety of products vulnerable to contamination with *L. monocytogenes* is far better managed through a broader suite of controls that have been demonstrably effective for many years than by challenge testing.

## Comments

### 1. Shelf Life Establishment and Epidemiologically Effective Alternatives to Challenge Testing

Shelf life establishment using storage trials coupled with day of production (production hygiene) and end of life (monitoring appropriateness of shelf life) sampling of food, with trend analysis including extensive data from environmental sampling has been used by the UK's chilled RTE food industry supplying its and Ireland's EUR15+bn market for more than two decades. This approach takes into account the effect on *Listeria monocytogenes* of raw material, process and environmental controls as well as behaviour in the food. EFSA/ECDC epidemiological (Table 1 and Figure 1) and industry data demonstrate this approach assures safety as it contributes to the UK's low national listeriosis incidence, which is consistently well below the European average. From 2006 it has been used to also demonstrate compliance with *L. monocytogenes* criteria in EU Reg 2073/2005, in line with legislative requirements.

Critically, UK industry recognises the risk to food safety of *Listeria monocytogenes* in the production environment from potential post-process contamination as full segregation has been implemented for more than 3 decades. Any discovery of *Listeria spp.* through sampling is followed up by aggressive corrective actions and root cause analysis in ways which are recognised and codified by national and global certification schemes and in Government and industry guidance (Table 2). There is a large amount of commercial and Competent Authority experience supporting this approach and an extensive sampling dataset of more than 4 million datapoints underpinning it in our industry alone (Table 3). This dataset represents >£40m expenditure in sampling and testing, indicating the huge management commitment and resourcing that has been put in the place in UK industry.

Criteria 1.2 a/b in 2073/2005 are clear as written, and, when adhered to, provide for a high level of consumer protection. Changing the legislation, particularly as proposed with the *mandatory introduction of challenge testing to set shelf life, critically ignores the prerequisite of assuring and monitoring production area hygiene and continuous routine monitoring of the product.

Standard industry thermal processing of 70°C for 2 minutes equivalent[2] delivers a 6.6 log reduction of *L. monocytogenes* ($D_{70}$=0.3). Challenge testing simply demonstrates process efficacy, which is already delivered by HACCP-based systems, with related validation.

Post-process contamination is recurrently found to be the root cause of outbreaks[3] (2002) (see also table 4), hence it requires exceptional resourcing. Funds must be spent on environmental controls and hygiene to prevent it in a timely manner, not on unnecessary, costly and narrowly applicable challenge testing.

Safe food, whether or not challenge-tested to set shelf life, cannot be made in an unhygienic production area. On the other hand, storage trials are proven to be effective in setting shelf life, particularly for short shelf life chilled prepared foods (e.g. 1-10 days), such as those in the UK, Ireland and Finland, and when coupled with DOP, EOL and environmental monitoring data, trending and acting on adverse trends as 2073/2005 requires and as CODEX[4] allows for.

There are additional reasons challenge testing is inappropriate as a mandatory requirement:

- It cannot replicate factory conditions, nor can it replace the volume of experimental data and professional knowledge which underpin *Listeria* safety in the UK and Ireland chilled food chain.
- It does not allow for historical data to be taken into account or data from similar products. The challenge test would only cover an individual product. What happens if very minor changes are made to a product, such as change of a supplier / grower / country of origin. It is impractical to challenge test every time there is a minor change, however these could affect the initial loading.

[2] ECFF Recommendations for the Production of Prepacked Chilled Food. European Chilled Food Federation (2006), https://www.ecff.net/wp-content/uploads/2018/10/ECFF_Recommendations_2nd_ed_18_12_06.pdf

[3] The Control and Management of *Listeria monocytogenes* Contamination of Food. FSAI (2005)

[4] Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods *CAC/GL 61 – 2007* (2009).

* It is acknowledged that Belgian government guidance exists on challenge testing and Netherlands authorities are requiring challenge testing of various chilled foods

- Shelf life would therefore be set by a third party that has no knowledge of the raw materials, manufacturing areas and processes. Food safety is the responsibility of the FBO and Technical experts of the FBO must be involved as they have a detailed knowledge of all aspects of the product and those similar.
- It does not reflect the actual control of the supply chain resulting in low levels (primarily Not Detected) and low prevalence. The inoculum used in challenge testing is typically a lot higher than is normally detected due to the laboratory needing to aim higher to ensure viable organisms are present. Quorum sensing effects result in exaggerated growth rates from challenge testing compared with realistic levels and prevalence, artificially reducing shelf life.
- Challenge testing simply demonstrates (e.g. thermal) process efficacy, which is already delivered by HACCP-based systems, with related validation.
- It does necessarily not reflect production plants' environmental hygiene where measures such as low ambient temperature and use of biocides stress any *Listeria* present, reducing viability and vitality.
- Testing costs per recipe are in the order of EUR10,000-15,000 and results only apply to that particular formulation. It is therefore highly costly in a rapidly changing marketplace and not viable for SMEs in particular. FBOs' profit margins are generally in the order of 1-2%, so EUR500k-EUR1.5m worth of each food would need to be sold to pay for the cost of its challenge test.
- It therefore diverts companies' and Competent Authorities' money away from implementing meaningful everyday hygiene controls.
- Hundreds of thousands of different foods around the EU and from countries exporting to the EU would be required to be tested yet there is insufficient laboratory capacity, which would remove foods from the market even if their safety were substantiated through DOP, EOL and environmental data. This would reduce consumer choice and damage SMEs in particular as they are least likely to have technical resource and access to laboratories.
- Given the high inocula, choice of particularly rapid growing strains and their log-phase status when inoculated, it would result in unnecessary shelf-life reduction leading to an increase in waste, particularly on the Continent where shelf lives are longer than in the UK (Tables 5-10), Ireland and Finland, thereby impacting negatively on Climate Change and the EU's SDG12.3 and food security commitments.
- DOP/EOL + environmental sampling will always be required by industry to demonstrate manufacturing control, even if challenge testing has been carried out, so it would be an additional cost on manufacture, increasing food prices
- The EU changing 2073/2005 with respect to criteria 1.2a/b would introduce:
    - requirements that are not in line with CODEX/WTO, so creating a Technical Barrier to Trade, and
    - confusion for enforcement. If for example a food found was to be positive for *L. monocytogenes* but had had its shelf life set using challenge testing how would it be treated? Would it need to be recalled?

Durability testing should very rarely be required (i.e. a new factory using new raw materials and a new product process), as shelf life can be determined by the more important sources of information such as product characteristics and historical data etc.

**Key Points Regarding Challenge Testing and assurance of Food Safety**

A. Challenge testing should not be mandatory where FBOs have data supporting the safety of their food and performance of their food safety management systems.

B. Effort should instead be placed particularly on ensuring FBOs have sufficient resources to implement effective preventative actions including cleaning, and monitoring factory hygiene and to undertake aggressive corrective actions if a suspect result is found. This would be the benefit of all industry and society as a whole.

C. We propose that an Industry publishes guidance setting out effective environmental hygiene management using monitoring and preventative and corrective actions and how to interpret this data and relate it to other results from raw materials, components and product. This would give much-needed detail to support good hygiene practice particularly for SMEs and for enforcement not only by Competent Authorities but also commercially, e.g. by FBOs buying ready to eat ingredients from suppliers and for final product retail customers.

**See Appendix 1 for an internationally agreed standard longstanding approach to effective environmental monitoring and its appropriate use in environmental hygiene management.**

## 2. Implications of Moving Away from 100 cfu/g to Zero Tolerance/Not Detected in 25g

To manufacture minimally processed foods, i.e. those that cannot be cooked, it is crucial to have and use an approved supply of raw material from reputable suppliers, and a manufacturer that uses HACCP principles, supported by PRPs especially GHP and GMP. All controls therefore need to be validated, verified and monitored to ensure they are robust, and where an adverse result is obtained, immediate remedial action taken. For the control of *Lm,* environmental monitoring for *Listeria* species is vitally important to detect inadequate cleaning practices or harbourage points which can potentially harbour *Lm* in equipment or the environment and grow, potentially contaminating product at unsafe levels.

A complete absence of *Listeria monocytogenes (Lm)* should always be a commendable goal, however, for certain foods e.g. raw produce and minimally processed foods not processed in pack or handled post-processing in making a final food, it is an unrealistic and unattainable requirement.

**Testing cannot be a guarantee of food safety.** Not detecting *Listeria* in a 25g sample does not guarantee absence in a whole batch, and if *Listeria* is detected in a 25g sample, it does not imply that the whole batch is contaminated. Therefore, confidence in food safety management systems can only be gained by risk assessment, having suitable controls in place supported by PRPs and the regular monitoring of these controls over time to allow remedial action in a timely manner.

Most documented *Lm* outbreaks have been caused by major failures in processing or cross contamination post process, which has allowed the growth of *Lm*, either in a long-life product, or in the manufacturing environment where it has not been discovered and actioned. Active and aggressive environmental hygiene assurance is critical to the control of an environmental pathogen such as Lm - See Appendix 1.

The 100/g limit specified in EC 2073/2005 allows the manufacturer to actively search for *Listeria* species in the manufacturing environment, in components, in raw materials and verify the control of *Lm* by testing finished product.

A zero tolerance/Not Detected (ND) approach is an unrealistic expectation and will not remove the fact that *Listeria* is ubiquitous in the environment and therefore will occasionally be present in minimally processed foods and chilled wet manufacturing environments.

**The consequences of having only a zero-tolerance/ND limit are:**

1. As seen in the USA, testing on finished product will reduce from fear of finding *Lm* and facing product recalls, with the associated damage to brand reputation and cost to the industry.

2. Testing of food contact surfaces within the manufacturing environment will similarly reduce as this will indicate that the food was in contact with this location and can be deemed to be possibly contaminated.

3. Testing will become focused around non-food contact surfaces which may allow sources of contamination to be identified, however cross contaminated food contact surfaces which are then likely to cross contaminate processed food will go undetected, allowing *Listeria* to grow on the surface over time.

4. Subsequent contamination of finished product will also be undetected, putting the health of the consumer at risk.

5. A proactive approach to the control of *Listeria* will be prevented, as potential cross contamination of food contact surfaces or the food itself will not be identified in a timely manner. Contamination, especially of food contact surfaces, must be proactively identified to allow immediate action to be taken. The levels of *Lm* associated with "unavoidable" contamination of minimally processed products are very low, and the risks are minimal if multiplication does not, or cannot, occur during storage, distribution and preparation. This requires proactive monitoring.

6. A zero-tolerance criterion will result in a 'policing' of this legislation rather than encouraging FBOs to understand the risk, monitor by taking appropriate samples and putting controls in place to proactively manage *Listeria*.

7. Trending of *Listeria* results will be limited and the identification of harbourage points or potential biofilms and actioning their removal will be slower, compromising food safety assurance.

The legislation, as currently written in EC 2073/2005, requires an FBO to fully understand their products and proactively routinely monitor for *Listeria*, keeping any risk to a minimum and allow immediate action to be taken following any detection of *Listeria*. **What is needed is clear guidance to FBOs and enforcers on safe food production for high risk foods with respect to *Listeria*, and environmental hygiene monitoring and the appropriate use of consequent data to actively and continuously assure food safety.**

**See Appendix 1 for environmental hygiene management guidance summarising established industry best practice.**

## 3. Implications of reducing the 100 cfu/g limit to 20 cfu/g

CFA data (see Table 3) indicates that >99.99% of its members' 1,050,585 RTE food samples over the period 2011-2022 had unquantifiable *L. monocytogenes* even at the end of life, i.e. <20 cfu/g. This is the result of best practice implementation, working with the aim of *L. monocytogenes* being so well controlled that it is "Not Detected". Best practice is to use a well-designed and thorough sampling programme continuously monitoring food and environment to assure controls' efficacy and acting swiftly to effectively address detections. This best practice approach not only applies to *L. monocytogenes* but also to other *Listeria* species.

This approach is however not standard particularly among SMEs and FBOs not supplying own label to major UK multiples.

It should be noted that use of 10 cfu/g as LOD doubles the plating cost of mthods, making it likely to reduce the amount of sampling done by FBOs given fixed budgets.

In previous discussion with UK Government agencies on potential consequences of 10 or 20/g as a limit for *L. monocytogenes* in RTE foods FSA's analysis of CFA's headline data showed that there would be no public health benefit in reducing the 100 cfu/g limit since counts occurr so rarely when best practice is in place.

Emphasis should therefore be on implementing best practice controls and monitoring (see Appendix 1) in RTE food production and storage including for sale, particularly where such foods are sold unpackaged or are directly handled (e.g. sliced) prior to packaging or consumption.

**Table 1: ECDC/EFSA ONE-Health Listeriosis Rates/100k Population by Country 2016-2021**

| 2016 | Cases | Rate | 2017 | Cases | Rate | 2018 | Cases | Rate | 2019 | Cases | Rate | 2020 | Cases | Rate | 2021 | Cases | Rate |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Spain | 362 | – | Spain | 284 | – | Estonia | 27 | 2.05 | Spain | 505 | – | Spain | 191 | – | Spain | 224 | – |
| Finland | 67 | 1.22 | Iceland | 6 | 1.77 | Finland | 80 | 1.45 | Estonia | 21 | 1.59 | Finland | 94 | 1.7 | Iceland | 5 | 1.4 |
| Belgium | 104 | 0.92 | Finland | 89 | 1.62 | Spain | 370 | 0.89 | Iceland | 4 | 1.12 | Slovenia | 26 | 1.2 | Finland | 70 | 1.3 |
| Germany | 697 | 0.85 | Denmark | 58 | 1.01 | Sweden | 89 | 0.88 | Sweden | 113 | 1.1 | Iceland | 4 | 1.1 | Denmark | 62 | 1.1 |
| Slovenia | 15 | 0.73 | Germany | 726 | 0.88 | Denmark | 49 | 0.85 | Denmark | 61 | 1.05 | Malta | 5 | 0.97 | Sweden | 107 | 1 |
| Denmark | 40 | 0.7 | Lux | 5 | 0.85 | Lux | 5 | 0.83 | Malta | 5 | 1.01 | Sweden | 88 | 0.85 | Slovenia | 19 | 0.9 |
| Sweden | 68 | 0.69 | Sweden | 81 | 0.81 | Germany | 683 | 0.82 | Slovenia | 20 | 0.96 | Denmark | 44 | 0.76 | Belgium | 65 | 0.7 |
| Estonia | 9 | 0.68 | Belgium | 73 | 0.8 | Belgium | 74 | 0.81 | Finland | 50 | 0.91 | Norway | 37 | 0.69 | France | 435 | 0.64 |
| Switz | 50 | 0.6 | NL | 108 | 0.63 | Latvia | 15 | 0.78 | Belgium | 66 | 0.72 | Switz | 58 | 0.67 | Germany | 560 | 0.67 |
| France | 375 | 0.56 | Slovenia | 13 | 0.63 | Lithuania | 20 | 0.71 | Germany | 570 | 0.69 | Germany | 544 | 0.65 | Lux | 4 | 0.63 |
| Austria | 46 | 0.53 | France | 370 | 0.55 | Portugal | 64 | 0.62 | NL | 103 | 0.6 | Lux | 4 | 0.64 | Latvia | 10 | 0.53 |
| NL | 89 | 0.52 | Switz | 45 | 0.53 | Switz | 52 | 0.61 | France | 373 | 0.56 | Belgium | 54 | 0.59 | NL | 86 | 0.49 |
| EU EFTA EEA | 2,536 | 0.47 | EU EFTA EEA | 2,480 | 0.48 | Iceland | 2 | 0.57 | Portugal | 56 | 0.54 | NL | 90 | 0.52 | EU27 | 2,183 | 0.49 |
| Czech Rep | 47 | 0.45 | Portugal | 42 | 0.41 | France | 338 | 0.51 | Norway | 27 | 0.51 | France | 334 | 0.5 | EU27+EEA | 2,268 | 0.44 |
| Norway | 19 | 0.37 | Hungary | 36 | 0.37 | Slovenia | 10 | 0.48 | Lux | 3 | 0.49 | Austria | 41 | 0.46 | Austria | 38 | 0.43 |
| Lithuania | 10 | 0.35 | Austria | 32 | 0.36 | EU EFTA EEA | 2,549 | 0.47 | EU EFTA EEA | 2,621 | 0.46 | Portugal | 47 | 0.46 | Italy | 241 | 0.41 |
| Lux | 2 | 0.35 | Scotland | 18 | 0.33 | Norway | 24 | 0.45 | Austria | 38 | 0.43 | Latvia | 8 | 0.42 | Estonia | 5 | 0.38 |
| UK | 201 | 0.31 | Lithuania | 9 | 0.32 | Ireland | 21 | 0.43 | Switz | 36 | 0.42 | EU27 EFTA EEA | 1,876 | 0.42 | Switz | 33 | 0.38 |
| Scotland | 16 | 0.3 | Poland | 116 | 0.31 | NL | 69 | 0.4 | Hungary | 39 | 0.4 | Hungary | 32 | 0.33 | Norway | 20 | 0.37 |
| Italy | 179 | 0.3 | Estonia | 4 | 0.3 | Poland | 128 | 0.34 | Ireland | 17 | 0.35 | Italy | 147 | 0.25 | Hungary | 35 | 0.36 |
| Latvia | 6 | 0.3 | Norway | 16 | 0.3 | Austria | 27 | 0.31 | Italy | 202 | 0.33 | Scotland | 13 | 0.24 | Poland | 120 | 0.32 |
| Portugal | 31 | 0.3 | Ireland | 14 | 0.29 | Slovakia | 17 | 0.31 | Slovakia | 18 | 0.33 | Cyprus | 2 | 0.23 | Scotland | 17 | 0.31 |
| Ireland | 13 | 0.28 | Czech Rep | 30 | 0.28 | Czech Rep | 31 | 0.29 | Poland | 121 | 0.32 | Estonia | 3 | 0.23 | Ireland | 14 | 0.28 |
| Poland | 101 | 0.27 | Italy | 164 | 0.27 | Italy | 178 | 0.29 | Latvia | 6 | 0.31 | UK | 148 | 0.22 | UK | 186 | 0.27 |
| Hungary | 25 | 0.25 | UK | 160 | 0.24 | Hungary | 24 | 0.25 | Czechia | 27 | 0.25 | Greece | 20 | 0.19 | Lithuania | 7 | 0.25 |
| Malta | 1 | 0.23 | Slovakia | 12 | 0.22 | UK | 168 | 0.25 | UK | 154 | 0.23 | Poland | 62 | 0.16 | Slovakia | 13 | 0.24 |
| Greece | 20 | 0.19 | Croatia | 8 | 0.19 | Scotland | 12 | 0.22 | Lithuania | 6 | 0.21 | Czechia | 16 | 0.15 | Czechia | 24 | 0.22 |
| Slovakia | 10 | 0.18 | Greece | 20 | 0.19 | Malta | 1 | 0.21 | Bulgaria | 13 | 0.19 | Slovakia | 7 | 0.13 | Greece | 21 | 0.2 |
| Croatia | 4 | 0.1 | Bulgaria | 13 | 0.18 | Greece | 19 | 0.18 | Croatia | 6 | 0.15 | Croatia | 5 | 0.12 | Croatia | 8 | 0.2 |
| Bulgaria | 5 | 0.07 | Latvia | 3 | 0.15 | Romania | 28 | 0.14 | Scotland | 7 | 0.13 | Ireland | 6 | 0.12 | Cyprus | 1 | 0.11 |
| Romania | 9 | 0.05 | Romania | 10 | 0.05 | Bulgaria | 9 | 0.13 | Cyprus | 1 | 0.11 | Bulgaria | 4 | 0.06 | Romania | 11 | 0.06 |
| Cyprus | 0 | 0 | Cyprus | 0 | 0 | Cyprus | 1 | 0.12 | Greece | 10 | 0.09 | Romania | 2 | 0.01 | Bulgaria | 3 | 0.04 |
| Iceland | 0 | 0 | Malta | 0 | 0 | Croatia | 4 | 0.1 | Romania | 17 | 0.09 | Lithuania | 0 | 0 | Malta | 0 | 0 |
| | | | | | | | | | | | | | | | Liecht | 0 | 0 |
| | | | | | | | | | | | | | | | Portugal | 0 | 0 |

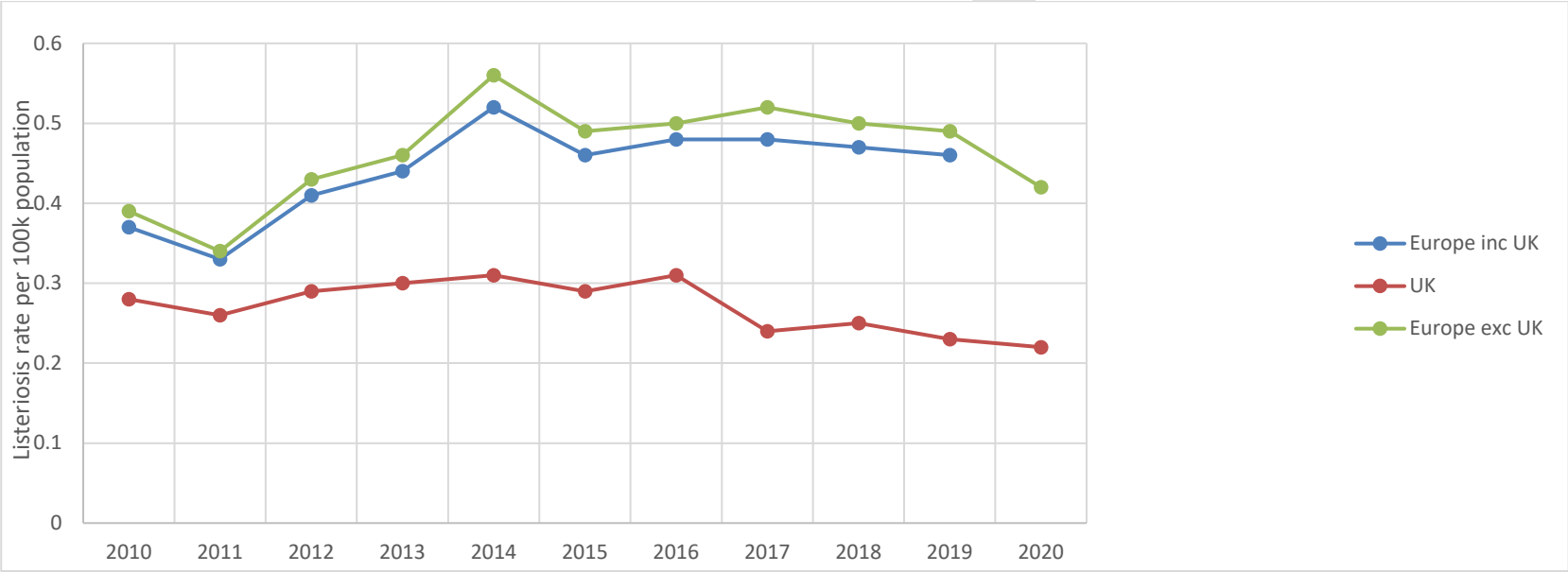
[a] Human listeriosis data for Switzerland include Liechtenstein to 2020

UK 2020 data: Food Security Report 2021. Eng+Wales from UKHSA Oct 2022. Scotland from FSS (2021 provisional). UK 2021 from UKHSA (provisional).
Sentinel system coverage: Belgium: 2016-21 80%, Spain: 2016-21 no info. EU One Health 2021 Zoonoses Report www.efsa.europa.eu/en/efsajournal/pub/7666

**Figure 1. Comparative European and UK Listeriosis Rates 2010-2020**

Epidemiology shows that 100/g limit drives sampling/monitoring, compliance with best practice and when enforced commercially achieves high levels of consumer protection

UK (and IE) listeriosis rates are consistently well below European (EU + EEA + EFTA) mean. Note ECDC/EFSA figures inc UK as EU MS to 2019:




Day of Production (DOP) and End of Life (EOL) sampling, trending and analysis works as a means of demonstrating control and shelf life appropriateness

Aggressive management of controls including continuous environmental sampling to find *Listeria spp,* attacking with hygiene and is an effective strategy for factory hygiene control

**Data sources:**

**Europe 2010-20:** **EFSA/ECDC One Health Reports (includes UK 2015-19):** https://www.ecdc.europa.eu/en/all-topics-z/food-and-waterborne-diseases-and-zoonoses/surveillance-and-disease-data/eu-one-health

**UK 2020:** **UK Food Security Report December 2021**: https://www.gov.uk/government/statistics/united-kingdom-food-security-report-2021/united-kingdom-food-security-report-2021-theme-5-food-safety-and-consumer-confidence

**Table 2. Environmental Management – National and global certification schemes and in Government and industry guidance**

| Author | Year | Title | Web link |
|---|---|---|---|
| ANSES, EURL | 2012 | Guidelines on sampling the food processing area and equipment for the detection of Listeria monocytogenes. Version 3. | https://eurl-listeria.anses.fr/en/system/files/LIS-Cr-201213D1.pdf |
| BRCGS | 2022 | Global Standard - Food Safety. Issue 9. | https://www.brcgs.com/product/global-standard-food-safety-(issue-9)/p-13279/ |
| Chilled Food Association (CFA) & British Retail Consortium (BRC) | 2006 | Guidance on the Practical Implementation of the EC Regulation on Microbiological Criteria for Foodstuffs. Edition 1.2. | https://www.chilledfood.org/wp-content/uploads/2015/07/BRC_CFA_Micro_Criteria_Guidance_Ed_1.2.pdf |
| Chilled Food Association | 2018 | *Listeria* Management Guidance | |
| CFA, BRC, Food Standards Agency | 2010 | Shelf life of ready to eat food in relation to *L. monocytogenes* - Guidance for food business operators | https://www.chilledfood.org/wp-content/uploads/2015/08/Shelf-life-of-RTE-foods-in-relation-to-Lm-FINAL-v1.1.1-23-3-10-with-worked-examples.pdf |
| CODEX Alimentarius Commission | 2009 | Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods *CAC/GL 61 – 2007* | http://www.fao.org/input/download/standards/10740/CXG_061e.pdf |
| European Chilled Food Federation | 2006 | Recommendations for the Production of Prepackaged Chilled Food. 2nd edition. | https://www.ecff.net/wp-content/uploads/2018/10/ECFF_Recommendations_2nd_ed_18_12_06.pdf |
| European Commission | 2013 | Guidance document 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. (POOL/G4/2013/11510/11510-EN.doc) | https://ec.europa.eu/food/document/download/44257174-bf8c-4214-a60d-6790a7ca4109_en |
| European Commission | 2005 | Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs | |
| Food Safety Authority of Ireland | 2005 | The Control and Management of Listeria monocytogenes Contamination of Food. ISBN 1-904465-29-3. | https://www.fsai.ie/workarea/downloadasset.aspx?id=1234 |
| Food Standards Scotland | 2014, 2022 | Safe Smoked Fish Tool | https://safesmokedfish.foodstandards.gov.scot/assessment/3049 |

| | | | |
|---|---|---|---|
| Profel | 2020 | Hygiene guidelines for the control of Listeria monocytogenes in the production of quick-frozen vegetables. | https://profel-europe.eu/_library/_files/PROFEL_Listeria_mono_guidelines_November2020.pdf |
| Ruokavirasto | 2020 | Elintarvikkeiden mikrobiologiset vaatimukset komission asetuksen (EY) No 2073/2005 soveltaminen sekä yleisiä ohjeita elintarvikkeiden mikrobiologisista tutkimuksista - Ohje elintarvikealan toimijoille. Ohje 4095/04.02.00.01/2020/ 4. | https://www.ruokavirasto.fi/globalassets/tietoa-meista/asiointi/oppaat-ja-lomakkeet/yritykset/elintarvikeala/elintarvikealan-oppaat/elintarvikkeiden-mikrobiologiset-vaatimukset_4095_04_02_00_01_2020_4_liitteet-yhdistetty.pdf |
| Sainsbury's Supermarkets. | | ~~Code of Practice for the Monitoring and Control of Listeria spp. In Sainsbury's Brand Products. COP 19~~Food Safety Manual, version 2. | |
| USA FSIS | 2014 | FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products. | https://www.fsis.usda.gov/sites/default/files/import/Controlling-Lm-RTE-Guideline.pdf |
| US FDA | | USA FSMA Key Facts about Preventive Controls for Human Food | https://www.fda.gov/media/108775/download#:~:text=the%20facility%20is%20maintained%20in,hazard%20requiring%20a%20preventive%20control. |

**Table 3. Chilled Food Association Data: *Listeria monocytogenes* sampling by UK chilled prepared food producers 2011 -2022**

| | | |
|---|---|---|
| RTE food prevalence (1,050,585 samples) | ~0.6% Lm at any point during shelf life, of which | |
| | ~0.01% with Lm present at quantifiable levels, i.e. >20 cfu/g LOQ (Note: 10/g is common LOQ used) | |
| Production environment prevalence (1,947,956 samples) | Food contact surfaces | ~0.3% Lm (~964k samples) |
| | Non-Food contact surfaces | ~2.5% Lm (~984k samples) |

**Source: Chilled Food Association**

**Table 4: Major Fatal Listeriosis Outbreaks & Root Causes**

| Country (year) | Outcomes and Root Causes |
|---|---|
| **UK (1987-9)** | >17 dead, 200+ cases. Pâté imported from Belgium. **Post-process hygiene** |
| **France (1992)** | 92 dead, 272 cases. Jellied pork tongue. **Post-process hygiene** |
| **USA (1998-9)** | 17 dead, 4 miscarriages/stillbirths, 101 cases. Cooked meat products. Contamination from air filtration unit maintenance. **Post process hygiene** |
| **Canada (2008)** | 24 dead, 57 cases. CAD 27m. Cooked sliced meat products. Dirty slicer. **Post-process contamination** |
| **Denmark (2009)** | 2 dead, 8 cases. Cooked sliced beef. **Post-process contamination** |
| **Australia (2009)** | 4 dead, 8 miscarriages, 35 cases. Cooked sliced meat product. **Post-process contamination** |
| **Finland (2012)** | 3 dead, 20 cases. Cooked meat product. **Post-process contamination** |
| **Denmark (2014)** | 17 dead, 41 cases. Cooked meat (rullepølse). **Post-process contamination** |
| **Italy (2016)** | 4 dead, 1 miscarriage, 24 cases. Cooked RTE meat product. Post-process contamination |
| **South Africa (2017-18)** | 216 dead, 455 miscarriages, 1060 cases. Cooked RTE meat products. **Post-process contamination** |
| **Netherlands, Belgium (2017-19)** | 3 dead, 21 cases. Cooked meat product. **Post-process contamination** |
| **Spain (2019)** | 3 dead, 38 miscarriages, 222 cases. Cooked meat product. **Post-process contamination** |
| **Germany (2019)** | 7 dead, 1 miscarriage, 112 cases. Cooked meat product. **Post-process contamination** |

**See:** Table A2 in *Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring. FAO (2022). www.fao.org/3/cc2400en/cc2400en.pdf. **79 out of 88 listeriosis outbreaks where a root cause was identified were found to be due to post-process contamination.**

**Table 5: Shelf lives of seafood products sold in the UK**

| Product | VP/MAP | NaCl | Shelf life (chilled) | Process | Notes |
|---|---|---|---|---|---|
| **Cold smoked salmon** | VP | Aq >3.5% from top to bottom of salmon side | 16 days | 22-30°C, 12-24h | UK major multiple |
| | | *unknown* | 1-6 weeks | | International (range) |
| | VP or MAP | 3% | 10 days | 22-30°C, 12-24h | UK major multiple |
| **Cold smoked salmon side** | VP | 2.2% | ≥14 days | 22-30°C, 12-24h | UK: Sold on eBay. 'Despatch overnight by express carrier' |
| **Hot smoked salmon** | VP | salt + sugar added: not s/life critical | 9 days | ≥74°C centre | UK major multiple |
| **Hot smoked mackerel** | MAP | 1.5-2.5% aq | 6-9 days | 72°C/2 mins or 66°C/10 mins | UK. Shelf life limited to control scombrotoxin |
| | VP | 1.75% | 13 days | | |
| **Cold smoked trout** | MAP | Aq >3.5% from top to bottom of salmon side | 16 days | 22-30°C, 12-24h | UK. Shelf life limited in practice by organoleptic quality. (10% $O_2$, 50% $N_2$, 40% $CO_2$) |
| **Cooked prawns** | MAP | 1% | 8 days | Equiv to 70°C/2 mins | UK. Alternatively use MAP with up to 10% $O_2$ to prevent syneresis (30:70 $CO_2$:$N_2$ or 40:60 $CO_2$:$N_2$) |
| **Cooked prawns (shell-on or peeled)** | MAP | 1.5% | 9 days | Equiv to 70°C/2 mins | UK major multiple |
| **Live mussels** | MAP | none added | 6-7 days<br>8-9 days | None | From NL<br>Canada |
| **Cooked mussels** | VP (cooked in bag) | 1.2% | 10 days | Equiv to 70°C/2 mins | UK: Bought frozen by brand owner, sold on defrost |
| | | | ≥14 days | Equiv to 70°C/2 mins | UK major multiple: NL import. |
| | | | ≥21 days | Equiv to 70°C/2 mins | UK retail: EU import. |
| | | | 1 year | Retort process | New Zealand |
| **Seafood sticks** | VP | 1% | 21-28 days | 90°C/10 mins | Bought frozen by brand owner, sold on defrost |

Source: Industry data

***Published in: C. botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (FSA Project B13006)**

**Table 6. Examples of Non-UK VP Fish (NaCl, Shelf life, Process details)**

| Product | % NaCl | Shelf life | Notes |
|---|---|---|---|
| Cold smoked rainbow trout | | 25 days at 0-3°C | Smoked at 20°C |
| Cold smoked rainbow trout | 2.0<br>2.9 | 14 days<br>14 days | Finland national Food Agency recommends 10-14d. If whole chain controlled (0-3°C) 21d possible. |
| Hot smoked rainbow trout | <br>2.3 | 25 days at 0-3°C<br>10 days | Smoked at 80°C<br>Imported from France & Spain |
| Cold smoked salmon | | >5 months | USA |
| Cold smoked salmon | 3.3 | 14 days | Finland |
| Cold smoked salmon | | 21-50 days | Denmark |
| Cold smoked salmon | | 4-6 weeks | Australia |
| Cold smoked salmon | | 6 weeks | New Zealand |
| Hot smoked salmon | 1.6 | 14 days | Finland |
| Raw (gravad) salmon, sliced | 2.9 | 14 days | Not smoked. Includes unspecified amount of sugar |

Source: FSAI (2004), Industry data, Vehmaan Savut OY (2006)

***Published in: Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (FSA Project B13006)**

**Table 7: Swedish Smoked/Gravad Salmon Shelf Lives**

| Shelf life | % of salmon with indicated shelf life |
|---|---|
| ≤1 week | 6 |
| 2 weeks | 4 |
| 3 weeks | 48 |
| 4 weeks | 11 |
| 5 weeks | 29 |
| 6 weeks | 1 |

Source: Rosengren and Lindblad (2003)

***Published in: Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (FSA Project B13006)**

**Table 8. Swedish Smoked/Gravad VP Salmon Shelf Lives**

| Shelf life (days) | Type | No. samples with indicated shelf-life |
|---|---|---|
| 21 | cold smoked | 1 |
| 21 | gravad | 2 |
| 22 | cold smoked | 9 |
| 22 | hot smoked | 1 |
| 22 | gravad | 8 |
| 25 | gravad | 1 |
| 26 | gravad | 1 |
| 29 | cold smoked | 1 |
| 31 | cold smoked | 4 |
| 31 | gravad | 5 |
| 36 | cold smoked | 6 |

Source: Mandorf (2003)

***Published in: Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (FSA Project B13006)**

**Table 9: Examples of UK Pre-packed Multiple Retailer Deli Meat (NaCl, Shelf Life, CCPs)**

| Product | VP/MAP | % Salt | Shelf Life (days) | Heat Process | Preservative |
|---|---|---|---|---|---|
| Cooked chicken breast pieces | MAP | 0.5 | 10 | >70°C/2 min | |
| Cooked chicken joints | MAP | 1.0-1.3 | 15 | >70°C/2 min | |
| Cooked turkey breast | MAP | 1.8-2.0 | 15 | >70°C/2 min | |
| Par-cooked breaded chicken (fried) | MAP | 0.75 | 10 | | |
| Honey cured ham | MAP + $O_2$ scavenger | 1.0 | 15-25 | >70°C/2 min | Sodium nitrite |
| Smoked ham | MAP + $O_2$ scavenger | 2.3 | 15-25 | >70°C/2 min | Sodium nitrite |
| Cooked ham | VP | 2.1 | 28 | >72°C/2 min | Sodium nitrite |
| Turkey ham | MAP | 1.0 | 15-25 | >70°C/2 min | Sodium nitrite |
| Cured sliced meat | MAP | 2.3 | 21 | 72°C/2 min | Sodium nitrite |
| Cured cooked sliced meat | VP | 2.3 | 23 | >72°C/2 min | Sodium nitrite |
| Cured raw meat | MAP | 2.0 | 28 | | Sodium nitrite |
| Bacon | MAP | 3.5 | 26 | | Sodium nitrite |
| Bacon | VP | 3.1 | >30 | | Sodium nitrite |
| Sausage | MAP | 1.5 | >13 | | Sulphur Dioxide |

Source: Industry data

***Published in: Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (FSA Project B13006)**

**Table 10. Examples of Non-UK Pre-packed Multiple Retailer Deli Meat (NaCl, Shelf life, Processes)**

| Product | % Salt | Shelf Life | Heat process | Preservative | Country |
|---|---|---|---|---|---|
| MAP honey roast ham | | 4 weeks | | Sodium nitrite | Australia |
| MAP hickory smoked ham | | 4 weeks | | Sodium nitrite | USA |
| Cured sliced meat MAP | 2.1 | 4-8 weeks | | Sodium nitrite | Italy |
| Cured sliced meat VP | 2.0 | 2-3 weeks | >70°C/2 min | Sodium nitrite | Finland |
| MAP pancetta | | 3 weeks | | Sodium nitrite | Australia |
| Uncured sliced meat MAP | | 2-4 weeks | >70°C/2 min | | Italy |
| Hot smoked game VP | 1.5-1.6 | 14 days | >70°C/2 min | | Finland |
| MAP cooked meat | | 75-84 days | | | USA |
| VP frankfurters | | 2 months | | Sodium nitrite | USA |
| VP cooked pork shoulder | | 6 weeks | | Sodium nitrite | USA |
| MAP Cooked chicken | | 4 weeks | | | Australia |
| MAP Cooked turkey | | 5 weeks | | | Australia |
| VP Cooked chicken | | >3 weeks | | | Spain |
| VP Cooked chicken wieners | | 46 days | | | USA |
| VP jalapeno beef log | | 1 year | | | USA |
| Sausages | | 18-30 days | >70°C/2 min | Sodium nitrite | Ireland |

Source: Industry data

***Published in: Clostridium botulinum* in vacuum packed (VP) and modified atmosphere packed (MAP) chilled foods. Final Project Report July 2006 (Project B13006)**

**Appendix 1**

## PRINCIPLES OF AN ENVIRONMENTAL MONITORING PROGRAM FOR THE MANAGEMENT OF *LISTERIA MONOCYTOGENES*

Since *Listeria* (*L.*) *monocytogenes* (*Lm*) is an environmental contaminant occurring widely in both agricultural (soil, vegetation, silage, faecal material, sewage, water), aquacultural, and food processing environments, some foods are more likely to be contaminated e.g., raw vegetables, fish and meat.
Although frequently present in raw foods of both plant and animal origin, sporadic cases or outbreaks of listeriosis are generally associated with ready-to-eat (RTE), refrigerated foods, and often involves the post-processing recontamination of cooked foods.
Control of *Lm* for many RTE products will typically require a stringent application of Good Hygienic Practice and other supportive programs. These prerequisite programs, together with HACCP provide a successful framework for the control of *Lm*.

## MICROBIOLOGICAL CROSS-CONTAMINATION

Microbiological cross-contamination is a major issue with respect to *Lm*. It can occur through direct contact with raw materials, personnel, aerosols and contaminated utensils, equipment, etc. Cross contamination can occur at any step where the product is exposed to the environment, including processing, transportation, retail, catering, and in the home.
An effective environmental monitoring program is an essential component of a *Listeria* control program, particularly in establishments that produce RTE foods that support growth and may contain *Lm*.[5]

If *Lm* is allowed to harbour and grow in a RTE product manufacturing environment, even a RTE product which cannot support the growth of *Listeria* could be cross contaminated with a high level, >100cfu/g, of *Lm*, exceeding the criterion in EU Reg 2073/2005 and potentially be hazardous to health.

However, if *Lm* is closely monitored and well controlled in the manufacturing environment, a RTE product that allows the growth of *Lm* can be consistently produced safely. It is accepted that *Listeria* can be isolated from some manufacturing areas e.g., drains and waste routes, due to their nature. By close monitoring, risk assessment and review of known harbourage sites, the risk of cross contamination by *Listeria* can be minimised and, in some cases, prevented from contaminating food contact surfaces and therefore RTE products.

**It is imperative to actively find any *Listeria spp* in a processing environment as *Listeria spp*, other than *Lm,* are used as indicators of potential sources, cross contamination routes, harbourage points and biofilms, to be able to proactively manage and control the spread of *Lm* to food contact surfaces quickly and effectively. It is important to note that only *Lm* is a human pathogen and the isolation of any other *Listeria spp* does not indicate a food safety risk. It is not a legal requirement to report or act upon the detection of *Listeria spp* in finished products.**

[5] CAC/GL 61 - 2007 Adopted in 2007; Annexes II and III adopted in 2009. Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods

The key steps for the control of *Lm* are as follows:

1. **Product design.** Understand the structure, composition and characteristics of the product to establish the level of control required for its safe production and ensure potential growth of *Lm* is prevented or minimised
2. **Raw material Risk Assessment**. To include water, air, ice, steam, packaging etc. and establish any potential risk of contamination from all incoming raw materials. Determine any further processing or controls required to minimise contamination of the manufacturing area and ensure a safe finished product. Good stock control systems must be in place.
3. **Premises design and layout.** Ensure processed materials are not re contaminated by people, equipment or manufacturing areas which have been in contact with unprocessed materials. Determine the barrier mechanisms (segregation) in place to prevent contamination and which require monitoring.
4. **Equipment.** Must be well designed to prevent harbourage and allow for easy cleaning. Where equipment is found to have harbourage areas, these must be eliminated by redesign or repair or the frequency and depth of machinery strip downs must be validated, verified and monitored to prevent harbourage of *Listeria*. Equipment which is infrequently used must be re-sanitised immediately prior to use.
5. **Building work / renovations / maintenance.** Work must be managed to prevent contamination of both food or the manufacturing environment by any debris, contamination or equipment used. A risk assessment must be carried out and controls in place prior to the work commencing. In addition to building work, this includes repairs to equipment, fabric, floors, blocked pipework and drains and installation of new equipment.
6. **Waste management.** Ensure the correct routes through the manufacturing area to prevent recontamination of processed foods by waste. Waste must not accumulate.
7. **Cleaning and disinfection.** The manufacturing areas and equipment must be cleaned and disinfected to eliminate *Listeria* from food contact surfaces and reduce levels on non-food contact surfaces e.g. floors to a minimum. Cleaning methods must be validated, verified and monitored. Cleaning carried out during production must be risk assessed to ensure that product or ingredients are not cross contaminated. Niche environments should be eliminated. Hygiene and production schedules must be monitored to ensure adequate time and resources are available. A risk assessed and regularly reviewed environmental swabbing plan must be in place to enable continual monitoring of cleaning practices to ensure their continuing efficacy.
8. **Personal hygiene**. This includes hand washing, use of appropriate PPE dedicated to specific areas and according to the risk of cross contamination, and general good practices of the manufacturing staff to prevent cross contamination.
9. **Removal of water - humidity and ventilation.** Water and condensation provide moisture for bacteria including Lm to survive and potentially grow. Isolate wet areas and eliminate standing water. Remove hoses before production and eliminate aerosols. Adequate ventilation is required to prevent condensation and humid air must be exhausted. Where possible, heat air after cleaning to aid drying.
10. **Storage**. Storage areas must be temperature controlled with good air flow, designed to prevent cross contamination and condensation and allow for regular cleaning without risking cross contamination of processed food.
11. **Training.** All personnel must be appropriately trained for their duties with particular attention to food safety and the risk of cross contamination, including *Listeria*. Sources of contamination must be understood as well as the way *Listeria* can be transferred onto food contact surfaces and potentially onto processed food. Personnel should be encouraged to identify potential risk.

12. In addition, **temperature control** throughout the supply chain (field to fork) is a crucial part of producing safe chilled food.

## CORE PRINCIPLES

An effective environmental monitoring program is essential to control Lm in RTE manufacturing facilities as it can be used to monitor the effectiveness of control of e.g. premises, equipment, building work / renovations, waste management, cleaning and disinfection, personal hygiene, ventilation and storage areas.
"Occasional positive results (i.e. for *Listeria* species) should not be seen in isolation as a failure of control but as verification that the monitoring program is effective. An environmental program which is not capable of detecting contamination may be misleading as the business believes that the environment is under control when in fact it may not be so." [6]

**Visual inspections** are a key support to the environmental monitoring program as any location or swabbing point that is visually dirty requires cleaning and disinfection.

**Swabbing using ATP monitors** offer good support and give instant results and are useful for hygiene staff training. The results do not directly relate to the presence of *Listeria spp*, but can provide a general indication of cleanliness quicker than microbiological testing.

The necessity for an environmental monitoring program is highest for RTE foods that support *Lm* growth and that are not given a post-packaging listericidal treatment[7]. Recontamination from the environment has led to many of the recognised outbreaks of listeriosis. One effective element of managing this risk is to implement a monitoring program to assess control of the environment in which RTE foods are exposed prior to final packaging.

An environmental monitoring program for *Listeria* must be considered separately to the routine environmental swabbing program for indicator organisms. Since much is known about *Listeria* swabbing locations, they can be chosen to increase the likelihood of detection. For example, any potential harbourage points that are difficult to access and clean, wet / damp areas, cracks and crevices, areas with condensation, periodically cleaned locations. Where there is only a decontamination process separating low risk from high care, samples and swabs should be taken from potential harbourage points in low risk to prevent *Listeria* building up within the environment and machinery.

**Sampling plans** must be reviewed minimum annually and when there are any changes to the manufacturing areas or renovation work being carried out. Following a Listeria detection or incident investigation, any sources highlighted may require adding to the sampling plan to ensure it is routinely monitored. This should involve a multi-functional team of experienced people who know all the equipment and processes. Swabs should cover all shifts, days of the week and all manufacturing areas that handle open RTE food.

**The aim** is to LOCATE *Listeria*, therefore if all results are Not Detected, the swabbing location should be changed to be more exploratory.

[6] FSAi Control and management of *Listeria monocytogenes* contamination of food 2005 P29
[7] Text based on CAC GL 61 2007 ANNEX I: Recommendations for an Environmental Monitoring Program for *Listeria monocytogenes* in Processing Areas

## DEVELOPING AN ENVIRONMENTAL SAMPLING PROGRAM

A generic environmental monitoring program is not possible for manufacturing environments, due to the variations in size, complexity and risk. A number of factors (a – i) should be considered when developing the sampling program to ensure the program's effectiveness:

### a) Type of product and process/operation

The need for and extent of the sampling program should be defined according to the characteristics of the RTE foods (supporting or not supporting growth), the type of processing (listericidal or not) and the likelihood of contamination or recontamination (exposed to the environment or not). In addition, consideration also needs to be given to elements such as the general hygiene status of the plant or the existing history of *Lm* in the environment. Environmental swabbing for *Listeria* in low-risk areas is required where product is decontaminated prior to being transferred to a high care area. This is to ensure that *Listeria* is prevented from building up in low risk and cross contaminating ingredients therefore ensuring the decontamination process remains effective.

### b) Type of samples

Environmental samples consist of both food contact and non-food contact surface samples. Food contact surfaces, in particular those after the listericidal step and prior to packaging, have a higher probability of directly contaminating the product, while for non-food contact surfaces the likelihood will depend on the location and practices. When to take samples must be considered, either after cleaning, during production or at the end of production. Sampling after cleaning verifies the cleaning method or if repeated isolations are obtained, help identify the presence of a biofilm that will require removal. Sampling product after e.g., 2 hours of production or at the end of production may improve the chance of isolating *Listeria* as any organisms harbouring in crevices or undetected biofilms may be expelled and potentially cause widespread contamination. Any equipment or areas that are cleaned periodically should be sampled PRIOR to cleaning to validate the frequency of clean, as well as post cleaning to validate the efficacy. Raw materials may serve as a source of environmental contamination and may therefore be included in the monitoring program.

### c) Target organisms

While this document addresses *Lm*, effective monitoring programs should also involve testing for *Listeria spp*; their presence is a good indicator of conditions supporting the potential presence of *Lm*. Where appropriate and shown to be valid, other indicator organisms may be used[10].

### d) Sampling locations and number of samples

The number of samples will vary with the complexity of the process and the food being produced. Locations should be considered a risk that are chilled, damp / wet, undisturbed e.g. difficult to clean or access or damaged and are in the proximity of food. Guidance on potential risk locations can be taken from Appendix 1,

published literature, and based on process experience, expertise or in plant surveys. Sampling locations should be reviewed on a regular basis (minimum annually). Additional locations may need to be sampled depending on special situations such as major maintenance or construction or when new or modified equipment has been installed or when changes in working shift patterns are required.

**e) Frequency of sampling**

The frequency of environmental sampling would be based primarily on the factors outlined under subheading "*Type of product and process/operation*". It should be based upon risk assessment and defined according to existing data on the presence of *Listeria spp*. and/or *Lm* in the environment of the operation under consideration. In the absence of such information sufficient suitable data should be generated to correctly define the appropriate frequency. These data should be collected over a sufficiently long period as to provide reliable information on the prevalence of *Listeria spp.* and/or *Lm* and the variations over time. The frequency of environmental sampling may need to be increased as a result of finding *Listeria spp*. and/or *Lm* in environmental samples. This will depend on the significance of the findings (e.g., *Lm* and a risk of direct contamination of the product). Frequency of sampling may be decreased if historical data demonstrates effective controls are in place. Routine sampling must be carried out according to a schedule, ensuring all production days and shifts are covered.

**f) Sampling tools and techniques**

It is important to adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example, sponges (Fig 1) may be used for large flat surfaces, swabs (Fig 2 & Fig 3) may be more appropriate for cracks and crevices and areas that are hard to access, or scrapers (Fig 4) for biofilms / hard residues.

Fig 1

Fig 2

Fig 3

Fig 4


**g) Taking environmental samples**

All personal taking environmental samples must be appropriately trained.

Check swabs / sponges have been stored correctly and are within date.

Prior to taking samples hands must be washed and dried.

All swabs and sponges must be pre-moistened with either:

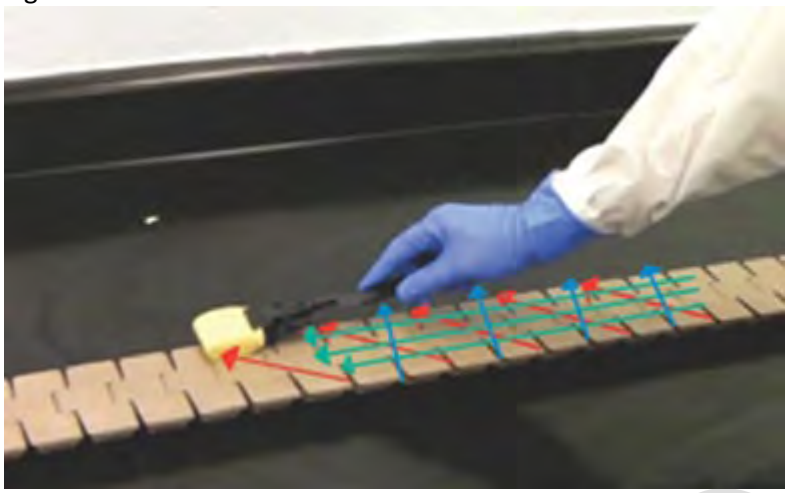
i. Neutraliser effective against the cleaning chemical used e.g., sodium thiosulphate for chlorine, universal neutraliser for QACs or
ii. General buffered diluent e.g., peptone for sponges and swabs taken during or at the end of production

There are many other cleaning agents used e.g., peracetic acid – the effectiveness of any neutraliser used must be assessed in consultation with the testing laboratory.

A surface area of approx. 30x30cm is recommended where possible (templates should not be used as they can transfer contamination), however if this is not possible the trained personnel should swab areas in a consistent way for each location to enable results to be compared and trended. Swabs must be taken by

swabbing or wiping the sponge over the surface vertically and horizontally, if a swab is being used it should be turned whilst wiping the surface (Fig 5). Sponges must be held through a sterile plastic bag or sterile disposable gloves.

Fig 5



Under certain circumstances it may be possible to composite (pool) certain samples without losing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the exact location of the positive sample.

Carefully replace the swab / sponge back into the container provided without touching the sample or inside of the container.

After using a swab / sponge containing neutraliser, the sampling point should be recleaned or wiped using an alcohol wipe.

Samples must be stored at 5°C +/- 3°C[8] and ideally tested within 24 hours of the sample being taken. Label the samples with enough detail to enable trends to be monitored, e.g. date, time, **exact** location, pre/ post clean, during production etc.

The time of **taking the sample**, and the time of the analysis being carried out should be recorded.

[8] Note: EURL doc states 1-8°C during transit and 3°C+ 2°C storage: https://eurl-listeria.anses.fr/en/system/files/LIS-Cr-201213D1.pdf

**h) Analytical methods**

The analytical methods used to analyse environmental samples should be suitable for the detection of *Lm* and of other *Listeria spp* and based upon ISO 11290-1. Considering the characteristics of environmental samples, it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately. Best practice is for isolation of *Listeria spp* to be speciated and isolates of *Lm* held at the laboratory for a defined period of time by the FBO to allow further analysis and comparisons to be carried out.

Enumeration of *Listeria* is not usually required for environmental samples and results should be reported as cfu/swab.

**i) Data management**

The monitoring program should include a system to record the data and their evaluation, e.g. performing trend analyses. All species of *Listeria* must be recorded and trended, however the focus must be on *Lm*. A long-term (e.g., annual) review of the data is important to revise and adjust monitoring programs. It can also reveal low level, intermittent contamination that may otherwise go unnoticed. Results and trends must be assessed weekly, individual positive results require investigation, but more importantly trends must be identified quickly. Therefore, results must be recorded in a simple visual way to be able to recognise trends over a period of time (usually by week or month).

These could include:

- bar charts of percentage fails (not absolute numbers)
- graphs representing environmental performance against product results and even environmental swabbing for indicator organisms
- spreadsheets plotting product results against processes; equipment used, shift patterns, production days and times or
- factory mapping i.e. placing marks on the locations and dates where *Listeria* has been detected, (sometimes referred to a measle or bubble maps). Factory mapping should only be used for stationary swab locations, and mapping should restart if actions have been taken to eliminate sources.

Trending should only be carried out for routinely sampled locations to enable comparisons to be made. Samples taken for investigation should be recorded and trended separately. When reviewing trends, i.e. locations where *Listeria* is consistently not detected over time should be reviewed as well as locations where *Listeria* has been detected. positive results. These can be replaced by an alternative location or a be sampled less frequently. If *Listeria* is expected but not detected, the exact sampling location or method of sampling should be reviewed.

**Actions in the event of *Listeria* detections**

The purpose of the monitoring program is to find *Lm* or other *Listeria spp* if present in the environment. Generally, manufacturers should expect to find them occasionally in the processing environment. There is no requirement to inform enforcement agencies but an appropriate action plan should be designed and established to adequately respond to *Listeria* detections. Investigations should initially confirm appropriate CCPs continue to be in place and monitoring data should

be checked e.g. temperature monitoring, chemical concentrations followed by investigations into the hygiene procedures and controls. All data leading up to the positive result / trend should then be reviewed, rather than immediately collecting further samples without planning. This review will include microbiological results for finished product, component, raw material, hygiene (including ATP if used), including indicator organisms as well as any previous investigation sample results. Therefore, investigations can be planned and targeted to establish the contamination source or verify actions. Actions may include observing practices, auditing cleaning / production methods, dismantling equipment and taking swabs from inside, collecting component samples from different points of production. These results need to be received and reviewed before further action and samples are taken. The manufacturer should react to each positive result; however, the nature of the reaction will depend upon the level of contamination, likelihood of contaminating the products and their expected use. The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of recontamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices and testing of product. Particular attention must be paid to any increasing trends, in which case a multi-disciplinary team is needed to develop and effective action plan which is routinely monitored and actions verified. Molecular methods to further type isolates held by the laboratory, may identify common sources of contamination. (Examples of actions are given in Appendix 2).

Both corrective and preventative actions must be considered.

All actions must be validated, monitored and verified.

**ADDITIONAL SAMPLES TO BE TAKEN**

In addition to the use of sponges and swabs used for environmental sampling, other samples must be taken to assess potential cross contamination. These include:

- Raw material samples on intake and in high care manufacturing areas
- Component samples within the manufacturing area or from equipment after processing. This can allow the detection of Listeria that is not removed during cleaning, harbouring within equipment and is released while the equipment is used. Component samples can also be used to detect any cross contamination from the surrounding environment and practices.
- Finished packed product, as this sample incorporates all raw materials, processes, equipment, handling, storage. Samples must be routinely tested either at point of manufacture (if growth of *Listeria* is not supported) or end of the shelf life (if growth is supported OR if this is unknown). This is to build data to demonstrate compliance with EU Regulation 2073/2005. Any positive results must be enumerated to demonstrate the criterion of 100cfu/g has not been exceeded.
- Hand swabbing (or gloves if worn) to monitor hand hygiene, especially in high care / high risk areas where product is handled.
- Condensate samples e.g., from evaporators, this will monitor any *Listeria* in the evaporators or any dead legs in the pipework or extraction hoods to identify moisture trap points. Work in progress samples (components awaiting assembly) from the production lines or in storage, to assess any potential cross contamination.
- Rinse water taken from pipework or CIP systems to assess the effectiveness of the cleaning and any potential harbourage points or dead leg
- Water, ice, compressed air samples, air samples at the high care /low risk interface.
- Product debris i.e. particles of food that may accumulate under belts, on scrapers and at transfer points

## ENFORCEMENT ASPECTS

**Testing of final packed product cannot guarantee food safety.** Food safety can be demonstrated by HACCP plans supported by PRPs and all the records and data to demonstrate control. This includes validation data for critical processes and cleaning methods, monitoring records which includes microbiological results for environmental sampling, component (WIP) samples, and verification data for finished products e.g., monthly pathogen testing. In addition, food safety can be demonstrated by temperature records, traceability, staff training, raw material risk assessment etc. All data/records must be readily available in response to Competent Authority investigations or visits.

Demonstrating these data are regularly monitored trended and reviewed and any adverse results / trends are investigated and actioned in an appropriate timescale generates confidence that the HACCP plan is ensuring food safety.

## PARTICULAR RISK POINTS

**Materials**
Raw materials, packaging, films

**Manufacturing Equipment**
Conveyors (especially those that are linked or frayed), sealers, condenser and chiller units, blast freezers, spiral freezers, seals, hollow equipment (frames, shafts, rollers), flow wrap machines, condensation hoods, slicers, scales, filling and mixing equipment, bearings, valves, equipment used to transport food ingredient from one location to another especially wheels, containers, buttons, exposed screw heads, or poorly finished welds or damage on food contact equipment, injection equipment, motor housings, pumps. Hand utensils and storage. Equipment tipping machines which may allow drip from the undersides / wheels to contaminate food contact surfaces. Under equipment that is too close to the floor to allow thorough cleaning
Periodically cleaned / in frequently used equipment. Lubricating oil (should include listericidal agent)

**Cleaning and maintenance equipment**
Cleaning equipment (squeegees, floor cleaners, tray-wash, brushes, bin washers) engineering boxes, tools and materials.

**Manufacturing environment**
switches, plugs, storage areas especially for raw materials, ingredients and cleaned equipment, drains, wall floor junctions, cracks in floors and walls, door frames (especially if damaged), damaged pipes and hoses, electrical wires under / overhead machinery, lagging, pipework, air steam, condensation Waste, waste routes and waste hatches.

**Building work**
Exposed insulation and hidden sources of contamination, debris.

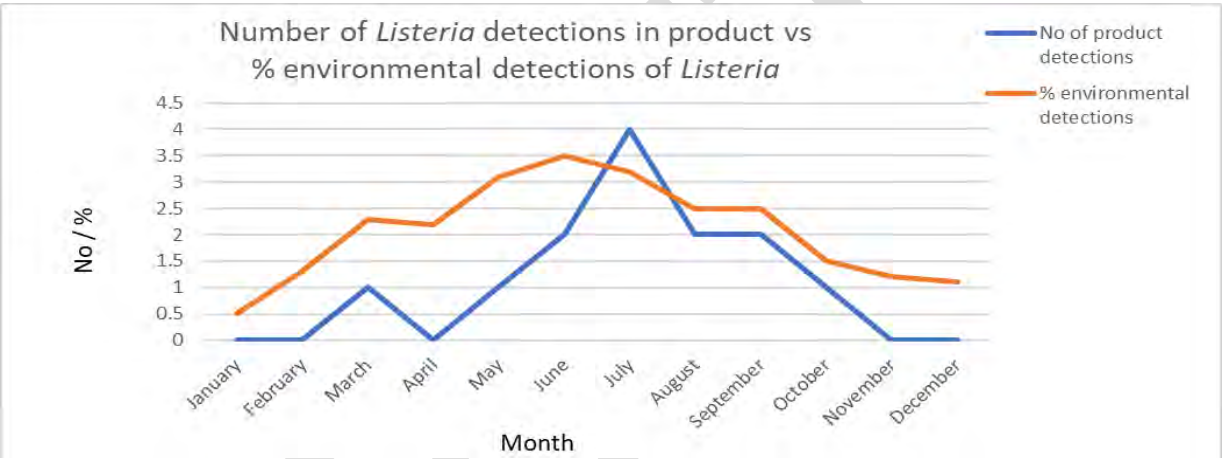
**EXAMPLES OF ACTIONS**

- Have there been any changes to cleaning methods / practice?
- Have there been any changes to suppliers / products / ingredients?
- Have there been any changes to the manufacturing process?
- Observe manufacturing practices – take appropriate samples
- Observe cleaning practices– dismantle and swab internal areas
- Review equipment / fabric condition – take swabs if necessary
- Redefine the depth of dismantle for routine cleans and periodic cleans
- Review cleaning method and practice
- Revalidate, verify and add monitoring of any revised cleaning method or practices
- Heat equipment parts (if possible) to >70°C. This can be carried out to immediately eliminate contamination, **however** this either needs to be added as a routine procedure and the frequency must be defined by routine monitoring or replaced by a thorough review of the routine hygiene procedure.

## EXAMPLES OF TRENDING

**Keep trends simple and up to date**

The following are examples of simple trends using made up data for demonstration purposes only. Plotting average results per month shows how increasing environmental detections has most likely caused contamination of product.




However, when the environmental data is plotted weekly, the increasing trend in the first 20 weeks can be identified earlier and the business can action and see the effects in a much timelier manner: