CENTRE DE LIAISON DES INDUSTRIES TRANSFORMATRICES DE VIANDES DE L'U.E.
LIAISON CENTRE FOR THE MEAT PROCESSING INDUSTRY IN THE E. U.

www.clitravi.com www.ecff.eu www.eucolait.eu www.chilledfood.org/listeria

Industry Listeria Group

INDUSTRY LISTERIA GROUP RESPONSE TO EC CONSULTATION ON *L. MONOCYTOGENES* (Lm) CRITERION 1.2b

Technical Summary

Contents

Summary

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* (Lm) in foods when it has been enforced. **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.** Many millions of datapoints have been collected by industry on products throughout shelf life (e.g. Day of Production, End of Life), and on environmental management to verify ongoing safety. This holistic approach to management of the risk from Lm has contributed to the low rate of listeriosis, for example in Ireland and the UK which is consistently markedly below the overall European listeriosis rate since the legislation is being enforced including commercially, demonstrating that **the current legislation is effective as it stands, when enforced.**

It is assured by enforcing adherence to HACCP-based principles/GHP/Guides/guidance & best practice (including shelf life establishment), and action plans, and requires continuous compliance verification by FBOs, customers, third party auditors and CAs. **This means that foods produced in this way will automatically fall under 1.2a and not 1.2b.** Epidemiology shows clear food safety benefit of this and is, we contend, sufficient to fill any perceived legal gap, so no new le.g.al Lm limit is necessary. The proposals are a move by EU away from risk- to hazard-based law and from science, taking no account of differing virulences of Lm strains, published QMRAs or multifactorial listeriosis mitigation analyses.

Proposal text clarifications needed:

- Footnote (2): ‘absence’ must be changed to ‘not detected’ (ND). Non-detection does not guarantee absence. This is a technical wording error.
- ‘the values observed’ referred to are those from by CA testing, not done by the FBO. Any detection by the FBO needs to be supported by evidence of criterion 1.2a compliance.
- Methods for FBOs can be validated alternatives to ISO-11290-2 or ISO-11290-1

We propose instead of 1.2b ND throughout life:

1. Current law must be enforced at all stages of supply and distribution as this is known to be effective in reducing listeriosis (One Health data for Ireland & UK)
2. Failing this, a quantitative limit of 10 or 20 cfu/g as defined by EN/ISO 11290-2 throughout life would reflect public health and sustainability policy needs without disincentivising FBOs from carrying out monitoring testing so reducing control.

More detail is given in this document including on issues with enforcement and compliance (e.g. reformulation to achieve 1.2b compliance leading to criterion 1.3 being applicable), what is established best effective practice production/environment controls and hygiene efficacy verification, and on shelf life differences for comparable products on the European market.

Complete absence of Lm is a commendable goal but for certain foods (e.g. raw produce/minimally processed foods not processed in pack/handled post-process) it is unrealistic and unattainable given natural Lm ubiquity. It may be present at low levels (a positive in a sample) but without posing a food safety issue even at end of shelf life in fresh products with natural competitive microflora. Such low levels are unlikely to be reflected in challenge testing since inocula may be much greater than natural and Lm used is unstressed. Historical data is real and the most powerful evidence of control.

The ND proposal linked to proof that 100 cfu/g is not exceeded throughout shelf life will result in CAs not waiting for proof especially for foods produced in one MS and distributed in another, leading to scientifically unnecessary recalls, food waste and reduced food security and without a sound technical or even le.g.al basis (see consultation response comments made by the CZ authority and DE enforcers).

Products may test ND when leaving the producing FBO but later in the chain may be positive but without a clear view on their history (e.g. local temperature abuse, cross-contamination at point of sale/use).

Despite temperature control being critical to minimising Lm growth potential there is no general EU commercial temperature law. Domestic fridges perform variably and consumer education is needed (e.g. thermostat use, Use By Date compliance) in addition to improved fridge temperature performance to protect public health and reduce food waste, as recognised by EU One Health Reports (2018: more than 1/3 listeriosis cases are due to growth at the consumer handling stage, 2023: outbreaks mainly relate to household consumption).

Assured compliance with 1.2b as proposed would require reformulation (e.g. pH<3.3) making many foods unpalatable, or in-pack processing (e.g. heat, HPP, irradiation) with very limited applicability due to organoleptic effect/low public acceptability, and would put such foods into criterion 1.3. However, many foods would not be viable despite not presenting food safety risk.

Much more legal emphasis is needed on production environment controls/active management and enforcement of current criteria 1.2a/b, with GMP/GHP and 'search and kill'. **FAO/WHO found post-process contamination to be the primary root cause (RC) of 79/88 listeriosis outbreaks where a RC was identified**.

End-product control, including challenge testing, diverts resources from critical HACCP PRPs (e.g. cleaning, disinfection and environmental hygiene monitoring). All FBOs must comply with 2073/2005 Food Safety Criteria including SMEs who often have limited means so would be expected to reduce testing at critical production stages or divert funds away from hygiene control to testing. **Testing is not a control but a stream of data can verify shelf life/hygiene compliance.**
These points are strongly supported in an authoritative peer-reviewed paper by many recognised global leaders in *Listeria* science, control & risk assessment (Farber et al 2021).

FBOs and enforcers need clear guidance on safe high risk food production, environment hygiene (monitoring and appropriate consequent data use) to assure food safety actively and continuously.

Established best practice set out by industry needs to be taken up by RTE chilled FBOs across the board, and enforced.

Detailed Comments

1. Implications of changing criterion 1.2b to Not Detected throughout shelf life

Our Members adhere to le.g.islation including 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.

The EU General Food Law 178/2002 and hygiene legislation including 852/2004, which explicitly state it is the Food Business Operator's responsibility to put safe food on the market, together with numerous Guidance Documents and industry's best practices (see Tables 2 and 11) is considered to be sufficient to fill a possible gap in the current legislation as identified by the "Estonian court case" and no additional legal limit on Lm in 2073/2005 is considered necessary.

The proposals lack scientific basis, taking no account of differing virulences of Lm strains or published scientific Quantitative Microbiological Risk Assessment or multivariate listeriosis mitigation studies. They signify a move by the EU/EC away from risk-based to hazard-based legislation.

In addition:

- In footnote (2) of the proposal the word 'absence' must be changed to 'not detected' in any of the sample units (25g). Non-detection does not guarantee absence.
- It must also be clarified that 'the values observed' are those obtained by Competent Authority testing and not that carried out by the FBO, as any detection in 25g by the FBO will need to be supported by the evidence outlined above that the criterion of 100 cfu/g will not be exceeded.
- It should be clarified that the method for FBOs can be a validated alternative method to ISO-11290-2 (enumeration) or ISO-11290-1 (detection).

A complete absence of 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.

Lm is ubiquitous in nature and puts a constant pressure on contamination of raw material and production environment. The main effort to avoid Lm contamination of products put on the market should be on GMP/GHP and a "search and kill" strategy to eliminate Lm from the production environment before the product is put on the market. All efforts put on end product control, including challenge testing, divert financial resources away from cleaning and disinfection and environmental hygiene monitoring, which are critical prerequisite requirements of HACCP. It should also be kept in mind that the food safety criteria of 2073/2005 have to be met by all operators, including SMEs which often have limited means for such testing, which would be expected to lead to reduced testing at critical stages of production or diverting funds away from critical hygiene control to testing.

[1] For example, "European Guide to Good Practice for Smoked and/or Salted and/or Marinated Fish" published on the EC Guidance Platform and endorsed by EU Member States at SCOPAFFon 3/7/18 . https://essa-salmon.org/_library/_files/2018_11_09_Press_Release_-_ESSA_Guide_publication.pdf

Lm may be present at low levels in food products (and testing positive in a 25g sample), but without posing a food safety issue at the end of shelf life. This is for example the case in fresh products with a natural competitive microflora. Such low levels of Lm contamination are likely to be not correctly reflected in any challenge testing because the level of inoculation in challenge testing is much higher than natural, and Lm often grows more rapidly than when naturally occurring. See Section 2 below.

A stream of data (food: Day of Production (DOP) and End of Life (EOL) and environment) supporting HACCP is instead an active food safety measure, as the current Regulations require.

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 and active use of data of these controls over time to allow remedial action in a timely manner.

Chilled Food Association (CFA) headline data (see Table 3) indicates that >99.99% of its members‘ >1,000,000 RTE food samples over the period 2011-2022 had unquantifiable Lm even at the end of life, i.e. <20 cfu/g. This is the result of best practice implementation, working with the aim of Lm 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 Lm but also to other *Listeria* species.

This approach is however not standard particularly among SMEs and FBOs not supplying own label to major multiples with supplier assurance protocols.

In previous discussion with UK Government agencies on potential consequences of 10 or 20/g as a limit for Lm in RTE foods the Food Standards Agency'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 occur so rarely when best practice is in place.

Putting a zero tolerance of Lm in 25g (i.e. ND) during the total length of the durability period on the market may result in products testing negative (ND) when leaving the immediate control of the producing FBO while later in the chain these products may test positive on 25g without a clear view on the history of the sampled products (e.g. local temperature abuse in the distribution chain, cross-contamination at the point of use or sale such as in delicatessens/foodservice). It would therefore make producing FBOs responsible for abuse of food even though it is not under their control.

It is likely that extending the zero tolerance of Lm in 25g and pairing its application to delivering proof that the product will not exceed the limit of 100 cfu/g throughout the remaining shelf life will result in many practical problems, in particular when products are produced in one MS and distributed in another. It may prove to be very time consuming to provide such proof "in time" in relation to the product shelf life to the questioning Competent Authority, leading to unnecessary recalls, food waste and reduced food security, and without a sound scientific basis.

This point is reflected in the CZ Government's and DE enforcers' responses to this consultation.

In addition, compliance with such a proposal for 1.2b would require either reformulation to kill Lm (e.g. pH<3.3), which would not only place such products under criterion 1.3, but would render many foods unpalatable, or in-pack processing (e.g., thermal, HPP, irradiation), which would be of extremely limited applicability without destroying food organoleptic and structure or having low public acceptability of the technology (e.g., irradiation).

Many foods would not be viable on the market despite their not presenting food safety risk if such reformulation/treatment were the only compliance option. This would be disproportionate.

Post-process contamination has been shown by FAO/WHO[2] to be the primary root cause of 79 out of 88 listeriosis outbreaks where a root cause was identified. This corroborates that much more emphasis is instead needed on production environmental controls and active management and enforcement of the current criteria 1.2a and 1.2b.

Even without temperature abuse, Lm may grow at low temperatures from initially undetectable levels at or immediately after production, which adds to the uncertainty whether a positive in 25g during shelf life is of real food safety concern. Temperature control is critical to minimising potential for growth of Lm. There is no EU legislation for commercial temperature performance. In addition, domestic fridges perform variably and consumer information and education in thermostat usage and use by date compliance in addition to improvements in fridge performance is needed not only to protect food safety and public health, but also to reduce food waste from spoilage (see[3]). This is recognised in EFSA/ECDC various One Health Reports. The 2018 Report[4] indicated that more than one third of listeriosis cases are due to growth in the consumer handling stage. The 2023 One Health Report[5] stated that outbreaks, mainly relating to the consumption of RTE foods (cold smoked salmon, meat and meat products, dairy products and frozen vegetables) are not necessarily linked to social and community events, but to consumption of these RTE foods in households.

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

Chilled food production[6] and environmental hygiene management[7] guidance has been issued by European industry summarising established industry best practice. See Tables 2 and 11 for summaries of various applicable established guidance already in use. Best practice set out by industry needs to be taken up by RTE chilled FBOs across the board, and enforced.

[2] www.fao.org/3/cc2400en/cc2400en.pdf
[3] www.ecff.net/wp-content/uploads/2018/10/ECFF_letter_to_European_fridge_manufacturers_February_2013_ID_22201_CECED-1.pdf
[4] EFSA/ECDC (2018) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC700954/
[5] EFSA/ECDC (2023) https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8442
[6] ECFF (2006) Recommendations for the Production of Prepackaged Chilled Food. 2nd edition, www.ecff.eu/wp-content/uploads/2018/10/ECFF_Recommendations_2nd_ed_18_12_06-2.pdf
[7] ECFF (2023) Principles of Environmental Monitoring Programme for Management of *Lm.* www.ecff.eu/wp-content/uploads/2023/10/Principles-of-an-environmental-monitoring-program-for-L-monocytogenes-v1-10-7-23.pdf

We propose:

1. Instead of zero tolerance/Not Detected in 25g for criterion 1.2b that the current legislation is enforced at all stages of the supply and distribution chain as that approach is shown to be effective at reducing listeriosis, as shown in the ECDC/EFSA One Health data for Ireland and previously the UK.
2. Failing this, instead of Not Detected in 25g a quantitative limit of 10 or 20 cfu/g as defined by EN/ISO 11290-2 throughout shelf life would reflect public health protection and sustainability policy needs without disincentivising FBOs from carrying out monitoring testing, reduction in which would result in reduced control.

These points are strongly supported in an authoritative peer-reviewed open access paper published in Food Control (2021) by many recognised global leaders in *Listeria* science, control and risk assessment[8].

2. 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 successfully by the Irish and UK 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 Lm of raw material, process and environmental controls as well as behaviour in the food. EFSA/ECDC epidemiological (Table 1, Figures 1 and 2) and industry data demonstrate this approach assures safety as it contributes to Ireland's and the UK's low national listeriosis incidences, which are consistently well below the European average. From 2006 it has been used to also demonstrate compliance with Lm criteria in EU Reg 2073/2005, in line with legislative requirements.

Critically, Irish and UK industry recognises the risk to food safety of Lm 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 since 2003 (food) and 2006 (environment) of more than 5 million datapoints underpinning it in the UK's chilled prepared food industry alone (Table 3 shows RTE food data and environment data headlines). This dataset represents >£50m expenditure in sampling and testing, indicating the huge management commitment and resourcing that has been put in the place in the Irish and 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 would critically ignore the prerequisite of assuring and monitoring production area hygiene and continuous routine monitoring of the product.

Any proposals to mandate challenge testing of products would undermine this strategic approach to management of *Listeria.* We are extremely concerned that it would polarise attention onto 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

[8] Farber *et al* (2021), *Alternative approaches to the risk management of* Listeria monocytogenes *in low risk foods.* Food Control, 123. https://www.sciencedirect.com/science/article/pii/S095671352030517X?via%3Dihub

organisms are not wild strains found in the manufacturing environment nor in their natural state, nor stressed. Factors such as attachment or the very low levels of contamination cannot be replicated.

By routinely testing, the levels of naturally occurring 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 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 Lm is far better managed through a broader suite of controls that have been demonstrably effective for many years, than by challenge testing as such testing takes no account of, nor does it reflect post-process hygiene.

Standard industry thermal processing of 70°C for 2 minutes equivalent[9] delivers a 6.6 log reduction of Lm (D_{70}=0.3). Challenge testing simply demonstrates process efficacy, which is already delivered by HACCP-based systems, with related validation. It has no bearing on production area hygiene. Post-process contamination is recurrently found to be the root cause of outbreaks[3] (2023), [10] (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 – see Tables 5-10), 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[11] 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.

[9] 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
[10] The Control and Management of *Listeria monocytogenes* Contamination of Food. FSAI (2005)
[11] 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.
- If the EU were to change 2073/2005 with respect to criteria 1.2a/b this would introduce:
    - requirements that are not in line with CODEX/WTO as agreed at the December 2008 CCFH session, so creating a Technical Barrier to Trade, and
    - confusion for enforcement. If for example a food found was to be positive for Lm 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 have published internationally-agreed Industry guidance[12] 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 gives 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. **It needs to be taken up by RTE chilled FBOs across the board, and enforced.**

[12] https://www.ecff.eu/wp-content/uploads/2023/10/Principles-of-an-environmental-monitoring-program-for-L-monocytogenes-v1-10-7-23.pdf

3. Implications of Moving 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 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[3]. Active and aggressive environmental hygiene assurance is critical to the control of an environmental pathogen such as Lm. See Appendix 1.

A quantitative limit 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 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.

   In the USA commercial agreements not to test raw materials/components are frequently in place resulting in lack of information consequently available to food producers to give assurance of safety, or to enable risk-based decisions to be taken, or to have access to safety-related traceability data in the event of an issue. This can and does result in widescale and/or prolonged withdrawals from the market of contaminated foods, exposing consumers to risk for extended periods of time.

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/ND 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 European industry best practice.

Table 1: ECDC/EFSA ONE-Health Listeriosis Rates/100k Population by Country 2018-2022

2018	Cases	Rate	2019	Cases	Rate	2020	Cases	Rate	2021	Cases	Rate	2022	Cases	Rate
Estonia	27	2.05	Spain	505	–	Spain	191	–	Spain	224	–	Denmark	86	1.5
Finland	80	1.45	Estonia	21	1.59	Finland	94	1.7	Iceland	5	1.4	Finland	70	1.3
Spain	370	0.89	Iceland	4	1.12	Slovenia	26	1.2	Finland	70	1.3	Sweden	125	1.2
Sweden	89	0.88	Sweden	113	1.1	Iceland	4	1.1	Denmark	62	1.1	Spain	437	0.95
Denmark	49	0.85	Denmark	61	1.05	Malta	5	0.97	Sweden	107	1	Slovenia	20	0.95
Lux	5	0.83	Malta	5	1.01	Sweden	88	0.85	Slovenia	19	0.9	Belgium	87	0.94
Germany	683	0.82	Slovenia	20	0.96	Denmark	44	0.76	Belgium	65	0.7	Switz	78	0.89
Belgium	74	0.81	Finland	50	0.91	Norway	37	0.69	France	435	0.64	Estonia	11	0.83
Latvia	15	0.78	Belgium	66	0.72	Switz	58	0.67	Germany	560	0.67	Germany	548	0.66
Lithuania	20	0.71	Germany	570	0.69	Germany	544	0.65	Lux	4	0.63	France	451	0.66
Portugal	64	0.62	NL	103	0.6	Lux	4	0.64	Latvia	10	0.53	Hungary	64	0.66
Switz	52	0.61	France	373	0.56	Belgium	54	0.59	NL	86	0.49	EU 27	2738	0.62
Iceland	2	0.57	Portugal	56	0.54	NL	90	0.52	EU27	2,183	0.49	EU27+EFTA	2848	
France	338	0.51	Norway	27	0.51	France	334	0.5	EU27+EFTA	2,268	0.44	Lux	4	0.62
Slovenia	10	0.48	Lux	3	0.49	Austria	41	0.46	Austria	38	0.43	Portugal	63	0.61
EU + EFTA	2,549	0.47	EU + EFTA	2,621	0.46	Portugal	47	0.46	Italy	241	0.41	Italy	345	0.58
Norway	24	0.45	Austria	38	0.43	Latvia	8	0.42	Estonia	5	0.38	Norway	30	0.55
Ireland	21	0.43	Switz	36	0.42	EU27+ EFTA	1,876	0.42	Switz	33	0.38	NL	94	0.53
NL	69	0.4	Hungary	39	0.4	Hungary	32	0.33	Norway	20	0.37	Iceland	2	0.53
Poland	128	0.34	Ireland	17	0.35	Italy	147	0.25	Hungary	35	0.36	Austria	47	0.52
Austria	27	0.31	Italy	202	0.33	Cyprus	2	0.23	Poland	120	0.32	Czechia	48	0.46
Slovakia	17	0.31	Slovakia	18	0.33	Estonia	3	0.23	Ireland	14	0.28	Slovakia	25	0.46
Czechia	31	0.29	Poland	121	0.32	UK	143	0.21	UK	184	0.27	Lithuania	13	0.46
Italy	178	0.29	Latvia	6	0.31	Greece	20	0.19	Lithuania	7	0.25	Latvia	8	0.43
Hungary	24	0.25	Czechia	27	0.25	Poland	62	0.16	Slovakia	13	0.24	Poland	142	0.38
UK	168	0.25	UK	154	0.23	Czechia	16	0.15	Czechia	24	0.22	Ireland	17	0.34
Malta	1	0.21	Lithuania	6	0.21	Slovakia	7	0.13	Greece	21	0.2	UK*	151	0.26
Greece	19	0.18	Bulgaria	13	0.19	Croatia	5	0.12	Croatia	8	0.2	Malta	1	0.19
Romania	28	0.14	Croatia	6	0.15	Ireland	6	0.12	Cyprus	1	0.11	Croatia	5	0.13
Bulgaria	9	0.13	Cyprus	1	0.11	Bulgaria	4	0.06	Romania	11	0.06	Cyprus	1	0.11
Cyprus	1	0.12	Greece	10	0.09	Romania	2	0.01	Bulgaria	3	0.04	Bulgaria	5	0.07
Croatia	4	0.1	Romania	17	0.09	Lithuania	0	0	Malta	0	0	Greece	7	0.07
									Liecht	0	0	Romania	14	0.07
									Portugal	0	0	Liecht	0	2

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

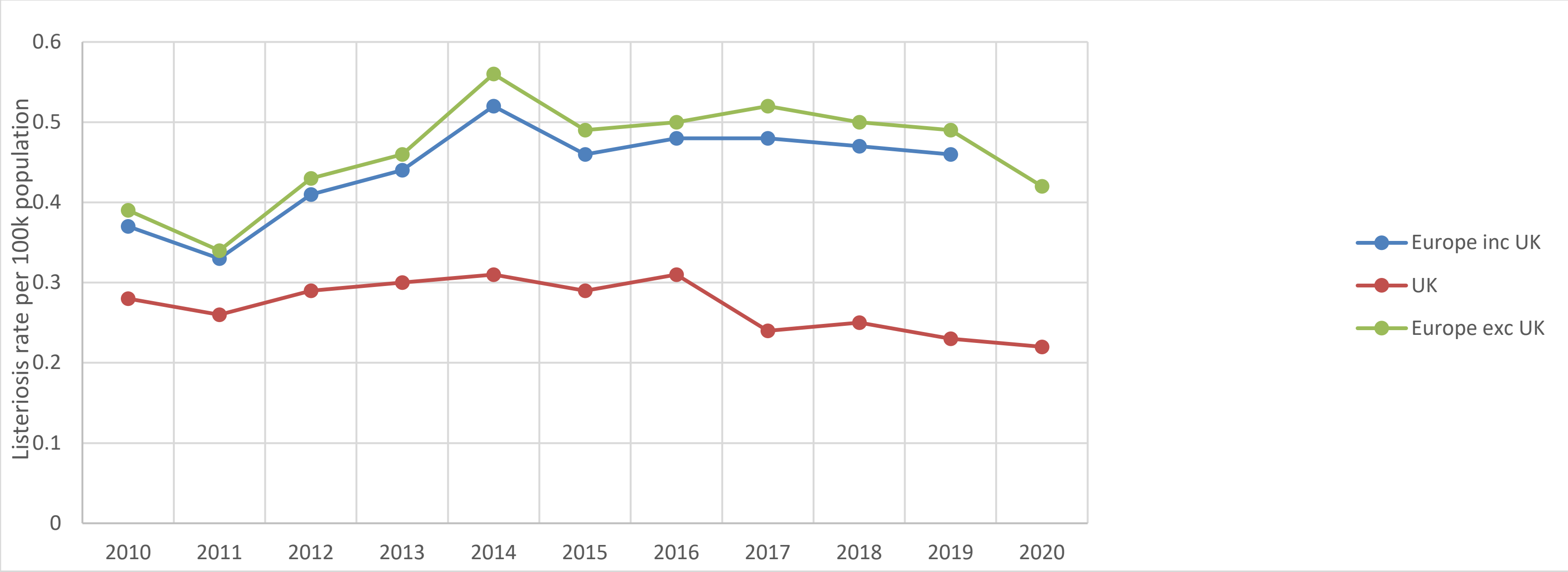
UK 2020 data: Food Security Report 2021. Eng+Wales from UKHSA Oct 2022. Scotland from FSS (2021 provisional). UK 2022 from UKHSA (provisional).

Sentinel system coverage: Belgium: 2016-21 80%, Spain: 2016-21 no info. EU One Health 2022 Zoonoses Report https://www.ecdc.europa.eu/sites/default/files/documents/EFS2_8442.pdf

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

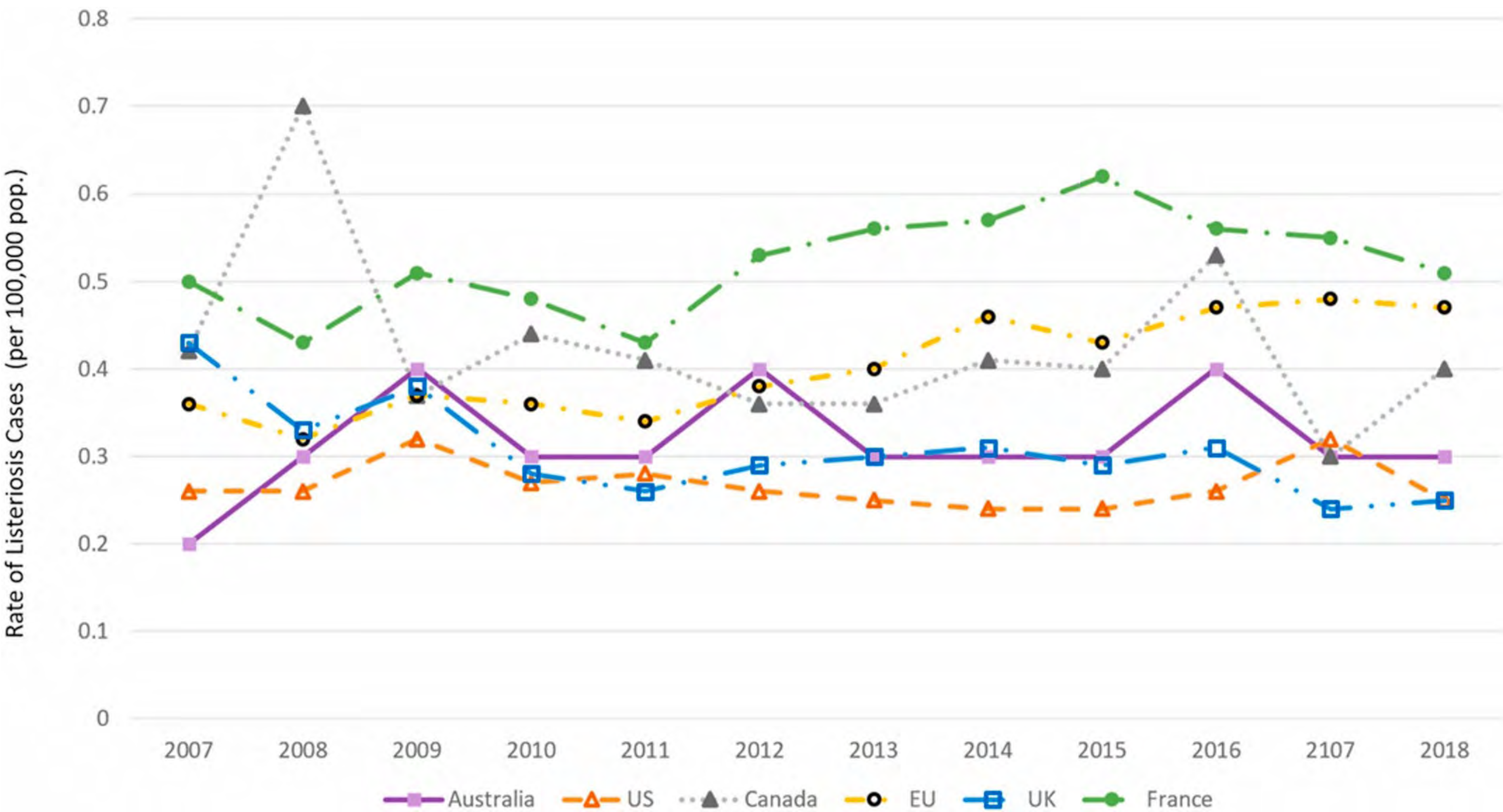
Aggressive management of controls including continuous environmental sampling to find *Listeria spp,* attacking with hygiene and is an effective strategy for factory hygiene control

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

Figure 2. Incidence* of reported listeriosis, 2007–2018 (Australia, United States, Canada, European Union, United Kingdom, and France)



* Rates of listeriosis per 100,000 population reported to Australia, the US, Canada, the EU, the UK and France, 2007–2018.

Data sourced from National Public Health Systems. Published in Farber *et al* (2021)[8].

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

Author	Year	Title	Web link
ANSES, EURL	2023	Lm Technical guidance document on sampling food processing area. Version 4	https://zenodo.org/records/8406616
BRCGS	2022	Global Standard - Food Safety. Issue 9.	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
CFA	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
CFA	2023	Principles of an Environmental Monitoring Programme for the Management of *L. monocytogenes*	https://chilledfoodassociation.myshopify.com/products/principles-of-an-environmental-monitoring-program-for-the-management-of-listeria-monocytogenes
CFA	2023	Action on the Detection of *L. monocytogenes* including at levels below the LOQ	https://chilledfoodassociation.myshopify.com/products/action-following-the-detection-and-or-enumeration-lm-or-listeria-spp-in-food
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	2023 2006	Principles of an Environmental Monitoring Programme for the Management of *L. monocytogenes* Recommendations for the Production of Prepackaged Chilled Food. 2nd edition.	https://www.ecff.eu/wp-content/uploads/2023/10/Principles-of-an-environmental-monitoring-program-for-L-monocytogenes-v1-10-7-23.pdf https://www.ecff.eu/wp-content/uploads/2018/10/ECFF_Recommendations_2nd_ed_18_12_06-2.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 *L. monocytogenes* Contamination of Food. ISBN 1-904465-29-3.	https://www.fsai.ie/getmedia/b89e141f-e1b5-4d1f-a63b-2eb00d110e84/listeria_report.pdf
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		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 2012 -2023

RTE food prevalence (1,082,604 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 (150 countable 2012-2023)
Production environment prevalence (2,075,061 samples)	Food contact surfaces ~0.3% Lm (1,047,099 samples)
	Non-Food contact surfaces ~2.6% Lm (1,027,962 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 contamination + temperature abuse**
France (1992)	92 dead, 272 cases. Jellied pork tongue. **Post-process contamination**
USA (1998-9)	17 dead, 4 miscarriages/stillbirths, 101 cases. Cooked meat products. Contamination from air filtration unit maintenance. **Post process contamination**
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%	$\geq$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	$\geq$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 8-9 days	None	From NL 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
			$\geq$14 days	Equiv to 70°C/2 mins	UK major multiple: NL import.
			$\geq$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 2.9	14 days 14 days	Finland national Food Agency recommends 10-14d. If whole chain controlled (0-3°C) 21d possible.
Hot smoked rainbow trout	 2.3	25 days at 0-3°C 10 days	Smoked at 80°C 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)**

Table 11. Shelf Life and Production Microbiology Guidelines/Guidance

Author	Year	Title	Web link
BRCGS	2022	Global Standard - Food Safety. Issue 9.	https://www.brcgs.com/store/global-standard-food-safety-(issue-9)/p-12187
Chilled Food Association (CFA)	2008	*Listeria* Management Guidance	
	2016	Microbiological Testing & Interpretation (2nd ed)	http://tinyurl.com/CFAMTIGv2
	2023	Principles of an Environmental Monitoring Program for Management of Lm	https://bit.ly/3PBIu5p
	2023	Action on detection &/or enumeration of Lm or L. spp in food inc at <LOQ	http://tinyurl.com/LmDetectionAction
	2024	The Role of Microbiological Testing for Chilled Food Business Operators	https://tinyurl.com/microtestingrole
CFA, British Retail Consortium (BRC), Food Standards Agency (FSA)	2010	Shelf life of RTE food in relation to Lm – Guidance for FBOs	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
	2006	Guidance on the Practical Implementation of the EC Reg 2073/2005 on Microbiological Criteria for Foodstuffs (ed 1.2)	https://www.chilledfood.org/wp-content/uploads/2015/07/BRC_CFA_Micro_Criteria_Guidance_Ed_1.2.pdf
CODEX Alimentarius Commission	2009	Guidelines on the Application of General Principles of Food Hygiene to the Control of Lm 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
EC	2013	Guidance document on Lm shelf-life studies for RTE foods, under Reg (EC) No. 2073/2005 of 15/11/05 on micro criteria for foodstuffs. (for FBOs)	https://ec.europa.eu/food/document/download/44257174-bf8c-4214-a60d-6790a7ca4109_en (POOL/G4/2013/11510/11510-EN.doc)
Food & Biocides Industry Group	2016	Biocides in Cleaning and Disinfection	https://www.chilledfood.org/wp-content/uploads/2018/08/Biocides-Cleaning-and-Disinfection-working-document-industry-guidance-18-10-16-with-updated-best-practice-example-FBIG-logo-in-progress.pdf
Food Safety Authority Ireland	2005	Control & Management of Lm Contamination of Food. ISBN 1-904465-29-3.	https://www.fsai.ie/getmedia/b89e141f-e1b5-4d1f-a63b-2eb00d110e84/listeria_report.pdf
	2022	Validation of Product Shelf Life (Revision 5). ISBN: 1-904465-33-1	https://www.fsai.ie/getmedia/2d6fc2de-7e55-4ebf-808d-453f72c460ab/guidance-note-no-18-validation-of-product-shelf-life-(revision-5)-2.pdf
Food Standards Scotland	2014	Safe Smoked Fish Tool (2022 revision)	https://safesmokedfish.foodstandards.gov.scot/assessment/3049
Profel	2020	Hygiene guidelines for the control of Lm in the production of quick-frozen vegetables	https://profel-europe.eu/_library/_files/PROFEL_Listeria_mono_guidelines_November2020.pdf

Appendix 1

European Chilled Food Federation
www.ecff.eu

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

Contents

1. Introduction and Context

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*.

This guidance sets 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 gives 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.

2. 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.

 ISBN: 9781901798241

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*.[1]

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.

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.

[1] 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

 ISBN: 9781901798241

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.

3. 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." [2]

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[3]. Recontamination from the environment has led to many of the

[2] FSAI Control and management of *Listeria monocytogenes* contamination of food 2005 P29

[3] Text based on CAC GL 61 2007 ANNEX I: Recommendations for an Environmental Monitoring Program for *Listeria monocytogenes* in Processing Areas

 ISBN: 9781901798241

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.

4. <u>Developing an Environmental Sampling Program</u>

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) <u>Type of product and process/operation</u>

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) <u>Type of samples</u>

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.

 ISBN: 9781901798241

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 section 8, 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

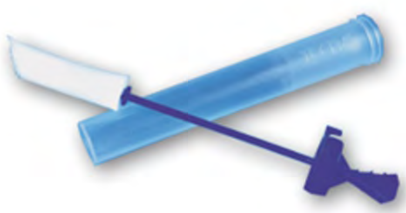
The frequency of environmental sampling would be based primarily on the factors outlined under subheading "*Type of product and process/operation*". It should be based upon risk assessment and defined according to existing data on the presence of *Listeria spp*. and/or *Lm* in the environment of the 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



 ISBN: 9781901798241

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.

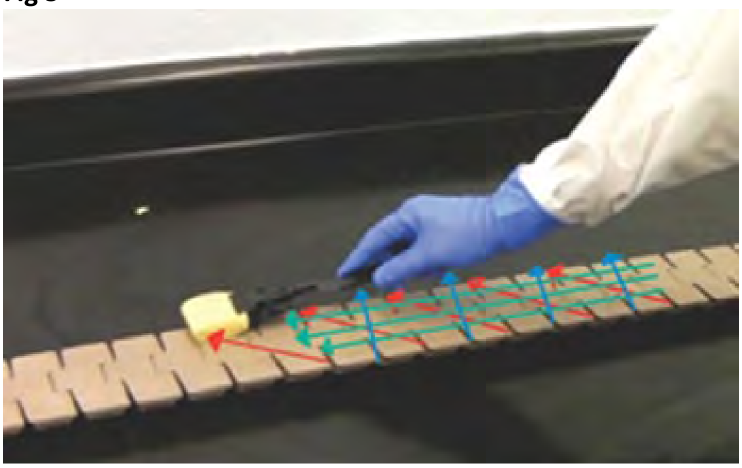
All swabs and sponges must be pre-moistened with either:

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



 ISBN: 9781901798241

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[4] 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.

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.

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

ISBN: 9781901798241

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.

5. 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 section 9).

Both corrective and preventative actions must be considered.

All actions must be validated, monitored and verified.

6. 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.

 ISBN: 9781901798241

- 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

7. 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.

8. 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.

 ISBN: 9781901798241

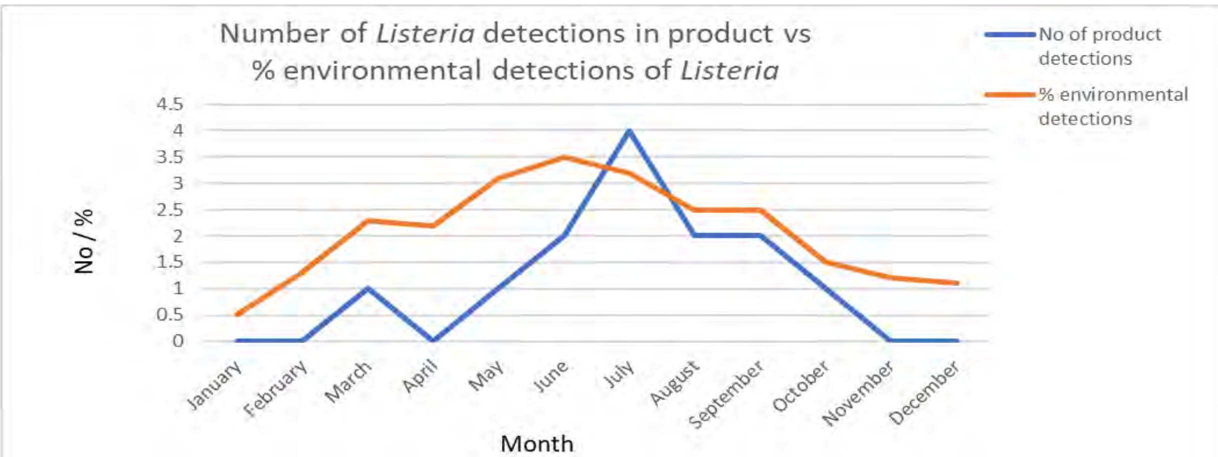
9. Examples of Actions

- 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.

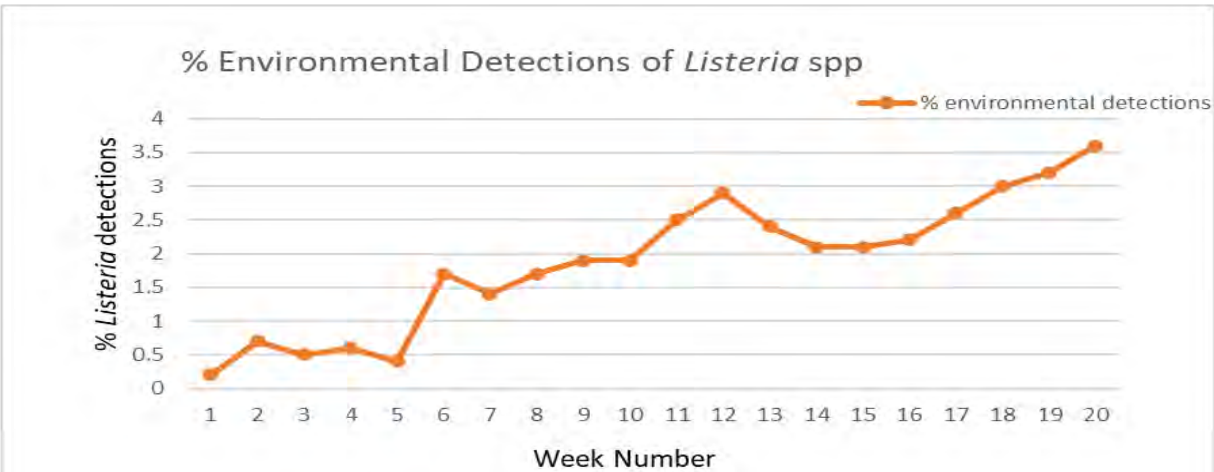
10. Examples of Trending

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:



 ISBN: 9781901798241