British Frozen Food Federation

Guide to the Management of Listeria in Food Processing

British Frozen Food Federation
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Foreword

Listeriosis is a serious foodborne disease in the UK, and causes severe health complications to people every year. Listeria reduction therefore remains a key area of focus in the Food Standards Agency Strategic Plan 2015-20.

We very much welcome the British Frozen Food Federation's Guide to the Management of Listeria in Food Processing and its aim of helping food businesses understand and control Listeria.

This considered and practical approach should help food businesses to manage and control risks, resulting in food that is safe for consumers.

Catherine Brown
Chief Executive - Food Standards Agency

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Introduction

The British Frozen Food Federation Guide to the Management of *Listeria* in Food Processing is a guide that applies to food businesses involved in the production and preparation of ready to eat (RTE) and ready to defrost and eat (RTDE) foods.

The purpose of the guidance is to help small businesses understand the actions that they should be taking to proactively manage and reduce, as far as possible, the incidence of *Listeria spp*. and in particular the pathogen *Listeria monocytogenes* in the materials, processes and products in their control.

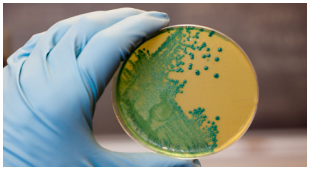
Furthermore, should a positive be found, or should a business find itself at the centre of an alleged *listeriosis* case, this document may be useful in providing guidance on the appropriate actions to take and what might be expected by way of enforcement.

I would like to thank members who contributed directly to the production of this guidance document to make it possible.

I hope that you find this information useful.

Brian Young
Chief Executive
British Frozen Food Federation

1. About *Listeria*



Listeria spp. is a genus of Gram-positive, rod-shaped bacteria, containing a number of species including *L. monocytogenes, L. innocua, L. welshimeri, L. seeligeri, L. ivanovii* and *L. grayi*. Although the first four have all been implicated in human infection, nearly all cases of human *Listeria* infection are caused by *L. monocytogenes*.

At least 13 different serotypes of *L. monocytogenes* are known. All can cause the disease *listeriosis* in humans, but most cases are caused by serotypes 1/2a, 1/2b and 4b. The majority of reported foodborne outbreaks have been caused by serotype 4b.

Listeriosis is relatively uncommon compared to *E. coli* and *Campylobacter* but it causes more deaths than both of them put together in the UK. The disease commonly requires hospitalisation and has a mortality rate estimated at 30%. Infants, the elderly, pregnant women and the immunocompromised are particularly vulnerable. Therefore it is of critical importance that it is carefully managed and controlled in the production environment.

A wide range of foods have been implicated in outbreaks e.g. sandwiches, sandwich fillers, mould ripened soft cheeses, paté, cooked sliced meats, pizza toppings, cold smoked salmon, RTE fish/shellfish, RTE salads and vegetables, RTE snack/buffet items, cream based cakes/desserts. Whilst this is not an exhaustive list, it gives a small business a sense of what types of foods are at greatest risk.

The incubation period varies from 1 to 90 days (averaging 30 days). Beginning with flu-like symptoms, sometimes accompanied by nausea, vomiting and diarrhoea; they can develop into meningitis and septicaemia. The infective dose is uncertain, although it is generally considered to be high for healthy individuals, with food contamination rates of > 1,000 cells/g being required.

Listeria is widely present in the environment including in the soil leading to the contamination of raw material. It is commonly found in produce (salad and vegetable materials), raw meat, cured meats (such as ham and bacon), dairy products and raw fish.

It is notable in that *Listeria* is able to grow at chill temperatures, reportedly as low as -1.5°C and thrives in damp chill conditions, even in the presence of salt. The minimum water activity for the growth of *L. monocytogenes* is 0.92 and it is able to grow in environments of up to 10% salt and survive in concentrations of 20 – 30%.

Although *Listeria* will not grow in frozen foods it survives well, except under acid conditions. Under ideal conditions the pH range for *Listeria* growth is 4.3 – 9.4 although it will survive outside these limits. The organism can also grow under both aerobic and anaerobic conditions though its growth is inhibited by high concentrations of carbon dioxide.

The organism can be particularly persistent and often difficult to find and eradicate in the processing environment because it is so tolerant of unfavourable conditions. It can form biofilms on production surfaces and standard biocides and hygiene practices are often ineffectual, therefore different approaches are required.

Listeria is relatively easy to destroy by cooking to temperatures above 70°C for 2 minutes or equivalent; however robust precautions must then be taken to ensure that post processing contamination does not take place before or during packing operations.

2. The regulatory framework

Commission Regulation (EC) No 2073/2005 on the microbiological criteria for foodstuffs came into force on 1 January 2006. The Regulation defines the microbiological standards that certain foods must achieve with respects to specified pathogenic bacteria, including *L. monocytogenes*. The Regulation can be downloaded from the Commission Eur-lex website: http://tinyurl.com/oddyv8n

L. monocytogenes standards are set out in the food safety criteria chapter of the regulation and comprise:

1.1 Absence in 25g for Ready to Eat (RTE) and Ready to Defrost and Eat (RTDE) foods intended for infants and for special medical purposes, the limit applies throughout the shelf life of the food.

1.2 For other RTE / RTDE foods that are able to support the growth of *L. monocytogenes* there are two criteria. They are: not exceeding 100 colony forming units (cfu)/g or (cfu)/ml for the duration of the shelf life of the product; and, if the food business operator (FBO) cannot demonstrate this, the absence in 25g before the food has left the control of the FBO.

1.3 For RTE/ RTDE foods other than those intended for infants and for special medical purposes that are unable to support the growth of *L. monocytogenes*, the cfu count must not exceed 100cfu/g for the duration of the product shelf life.

The Commission has also developed a number of guidance documents to assist in the implementation and interpretation of the regulation including:

- guidance aiming to assist food businesses in identifying the *L. monocytogenes* risk in their food products and to provide general principles for the determination on when and which shelf-life studies are needed through a simple decision tree;
- guidance for specialised laboratories on how to conduct shelf-life studies (especially durability studies and challenge tests) for *L. monocytogenes* in RTE foods;
- guidance on swabbing and sampling in food processing areas and on equipment.

Further information along with the above guidance can be found on the microbiological criteria regulation can be found on the Commission Website: http://tinyurl.com/b3ppk8

The National Regulator in the UK who is responsible for the implementation of the microbiological criteria regulation is the Food Standards Agency (FSA); the FSA has a strategy in place to reduce the incidence of *Listeriosis.* More information can be found on their website: http://tinyurl.com/o3cca8c

More general responsibilities for food business operators can be found in Regulation (EC) 178/2002 laying down general principles and requirements of food law. In particular Article 19 obligates a food business operator to withdraw food which it believes is not in compliance with food safety law, and to notify the competent authority (FSA for the UK) and the consumer of the reason for withdrawal.

3. Management and monitoring for the prevention of *L. monocytogenes*

3.1 Management

- The business should have a technically competent individual with the responsibility and authority to manage *Listeria* controls. If the competence is not present within the organisation it should be sought externally or good quality training sourced.

- This individual should attend HACCP team meetings as required, so that proposed controls can be reviewed by the multi-disciplinary team. The use of a multi-disciplinary team is useful as the different qualifications and experience will help identify issues with equipment design, process and product handling issues, and share the experience the team has of identifying and resolving issues.

- Standard HACCP principles should be applied regarding the nature of materials used, processes undertaken and customer handling of the product.

- Useful sources of background information when considering potential risks include the FSA Annual Incident Report, which identifies recalls notified by the industry due to the potential of contamination, and the Chief Medical Officers Report, which covers trends in food illness outbreaks. These can be found on the FSA and Public Health UK websites respectively – see section 10.

3.2 Product design

- Consideration of any specific vulnerable customer groups should be undertaken e.g. supply to hospitals or care homes.

- Where possible for RTE and RTDE products, design in microbiological hurdles for *L. monocytogenes*: This could be the use of antimicrobial ingredients, control of pH or water activity (a_w) to restrict the growth of the bacteria.

- Modelling tools can be used as part of product development so that the risk of growth over product shelf life has been assessed, is known and taken into account in determining a suitable shelf life for the product. Record of the assessment should be retained on file. In addition to predictive models, challenge tests and historical data can play a role in determining an appropriate shelf life for chilled RTE products.

- The safety of the food produced cannot be based on end product testing as absence of a particular microorganism cannot be guaranteed. This is a particular issue for *L. monocytogenes*, as it is ubiquitous, being found in the environment, in soil, vegetation, as well as in ingredients such as raw milk, raw meat and fish, unprocessed salad ingredients, it is difficult to avoid.

- For RTDE products consideration has to be given to any defrost process carried out by the customer and shelf life after the product has been defrosted to ensure that products will comply with regulatory, customer and internal requirements at the end of shelf life.

- As frozen ready meals /pies/ pizzas etc. will be reheated or cooked by the customer this process should be sufficient to kill any *Listeria* present. On this basis the risk from *Listeria* being present is much reduced and these products are not generally considered to be RTE/RTDE. For reheated food there is a reliance on the instructions for use being adequate. Where such products are ready to thaw and eat cold they are RTDE.

- It is critical for these products that the procedures for determining instructions for use are very clear. Verification that the instructions for use achieve the specified time / temperature combinations should be in place and records maintained.

- Catering customers would also not wish to have the potential for cross contamination in their facility so may wish to set microbiological targets for ready to reheat products similar to RTE/RTDE products.

3.3 Factory controls

- Being able to survive and grow in chilled conditions means *Listeria* will also continue to grow in numbers in the food factory environment, such as in drains and free standing water, unless good manufacturing/hygiene practices are applied.

- The primary controls are based on the application of the HACCP principles and the controls applied will determine the microbiological quality of the product. Often these include criteria that can be measured on line such as temperature, time, pH, water activity etc. as well as the application of good manufacturing/ hygiene practices.

- Sampling and testing plans are used to verify that these controls are satisfactory to provide confidence that the finished product standards required will be met.

- The level of sampling should be based on the HACCP risk assessment completed by the HACCP team. As each operation is unique there are no standard frequency / level of testing plans available. The greater the risk the higher the level of sampling.

- Sampling and testing plans need to be commensurate with the nature and size of the food operation and reflect aspects such as the raw materials, production processes and the final product application.

- In frozen products *L. monocytogenes* does not grow but will not be reduced in number. As a result controls should be focused on processes prior to freezing and there is no need to complete shelf life analysis for pathogens during storage under frozen conditions; any defrost life however, should be considered.

- *Listeria* can be difficult to find so a testing programme should be in place for indicator organisms such as *Enterobacteriaceae* – enteros- (these will be indicative of poor hygiene, not *Listeria*, but failure will highlight areas where conditions may be advantageous for *Listeria* colonisation). Include speciation when results are above target to assist investigation and identify trends in results.

3.4 Microbiological sampling and testing

- As the Regulations have set criteria for *Listeria spp*. at the end of shelf life of RTE/RTDE products it is critical that samples intended to be sent to the laboratory for testing are handled in such a way that there is no impact on the levels of bacteria reported in the test results.

- Ensure that procedures are in place regarding the storage of samples prior to delivery to the laboratory, transportation to the laboratory and handling and storage within the laboratory. Times and temperatures of samples at each stage should be taken and records maintained.

- A maximum time between sampling and testing should be set as part of the management procedure, or memorandum of understanding if testing is by an external laboratory. It should be a shorter period where the product being sampled is not pre-chilled.

- Instructions for testing should be agreed in advance – use the expertise of the laboratory to ensure that protocols meet the businesses needs. Such as whether initial tests are simply based on presence / absence or whether enumerations should be completed in parallel. Likewise for ribotyping to be completed, if specified, the laboratory would need to know that they had to retain samples until a decision re further analysis is required.

- Ensure that laboratories used for testing can demonstrate that they are using an accredited method and are engaged in continuous competency assessment scheme – i.e. ring testing.

- Where results are required urgently, rapid test methods should be specified whereas for routine analysis standard / traditional methods (taking more time) may be appropriate and more cost effective.

- Clear targets and standards should be in place that are consistently and robustly applied for suppliers and internally for operational and hygiene teams. Often these will be derived from customer requirements. Such targets must be specific about whether they apply to *Listeria species* or specifically *L. monocytogenes*.

- As part of the *Listeria* controls any sample plans for environmental monitoring, raw materials, process control or finished product should be agreed, published and communicated to key personnel prior to production.

3.5 Escalation of results

- Microbiological performance of key indicator organisms including *Listeria* species and *L. monocytogenes* in food business operations producing RTE and RTDE foods should be a site Key Performance Indicator (KPI).

- The escalation of results above target levels for *Listeria* species or *L. monocytogenes* should be agreed and communicated clearly to those responsible for responding to this data, both internally within the organisation and, where appropriate, to the brand owner.

- Action plans should be agreed in advance for where positive results are reported – e.g. targeted/increased sampling. These may need to be adjusted for particular unforeseen circumstances; agreed procedures and responsibilities for this should be in place.

- Above target levels should immediately initiate an investigation and be reported and discussed at senior management / director level meetings.

- It is likely that a root cause analysis would need to be completed, if the cause has not previously been identified, and corrective actions put in place to minimise the potential for a recurrence of the contamination.

3.6 Continuous improvement and risk management

- A routine auditing and monitoring programme based on risk assessment should be in place and regularly reviewed with respect to the appropriateness of sampling points and the frequency of each one. A review should be carried out specifically on the results of microbiological investigations or when changes to the site are made.

- Risk of microbiological failure of key pathogens in product should be considered as part of the risk register of any operation producing RTE or RTDE foods and crisis management plans kept current.

- Operators must not be complacent; a continuous improvement plan should be in place to actively seek and identify potential areas for issue and for the development of an ongoing, rolling and prioritised action plan.

4. Environmental control

4.1 Water

- Water is a common transmission vector of *Listeria* either directly e.g. via water in use as an ingredient, or when used to rinse surfaces / equipment, or indirectly e.g. via aerosols / condensation. Care of the use of water and water potability is critical in controlling the presence of *Listeria*.

4.1.1 Water used for hygiene

- Dry clean on product changeovers where at all possible, devise a planning schedule that takes into account speciation or allergen cross contamination to eradicate wet cleans, whilst maintaining food safety and a hygienic environment.

- Restrict pressured water systems and limit or eliminate use during production hours.

- Carry out low pressure cleaning, aerosols from hoses can spread *Listeria* throughout the whole environment and infect refrigeration and air conditioning systems.

- Minimise aerosols, from all possible sources, for example from squeegees, air hand driers and boot washers.

- Do not neglect refrigeration and air handling units, ensure condensate pipes are kept clear, clean and captive and the units are on the hygiene schedule with appropriate procedures.

- Keep food storage and product transfer areas as dry as possible, minimise wet cleaning and eradicate hoses where possible, except during designated and planned hygiene.

- If wet cleaning is unavoidable carry out a risk assessment on the potential for cross contamination, introduce mitigating practices to control risks.

- Investigate and eradicate any areas of persistent condensation.

4.1.2 Water mains and pipework

- Mains water at source is not normally a cause of *Listeria* contamination but should be considered in any investigation. Know where your water comes from as well as who supplies it. Be aware of the supplier's performance which will be available on their website.

- Where water is stored on site ensure procedures are in place for monitoring the water quality at this point as well as at points of use. Treatment to remove bio film build up may be required.

- Water distribution pipe work should be reviewed to ensure that there are no dead legs and particular care should be taken where an outlet is not in regular use as the effectiveness of the water chlorination will reduce over time.

- Maintenance of the water hygiene standards required to prevent legionella presence should ensure that *Listeria* are not present also. (For further advice refer to your Safety, Health and Environment representative regarding L8 guidance on the control of Legionella.)

4.2 Environmental design and maintenance

- Design for good drainage and zero tolerance for pooling of water in production and storage areas; investigate and eradicate any condensation build-up. Damp and water are ideal vectors for growth, spread and cross contamination by *L. monocytogenes* and other *Listeria*.

- Design and construction in all product areas should be of smooth, non porous surfaces that are easy to clean; design out potential harbourage niches, and, build in a product flow that segregates treated RTE and RTDE material and product from raw materials and waste.

- Any team working on the development of a site or process must include representation by someone who is technically competent to assess microbiological risk.

- Building and maintenance activity is particularly risky from a *Listeria* perspective, as it can disturb harbourage points and actively spread contamination. The business should have in place regular cross-functional team meetings between technical, hygiene and engineering teams to work collaboratively to plan routine and non-routine work. This should ensure that equipment and fabric maintenance activity is managed and controlled with respect to *Listeria* and the appropriate controls and decontamination procedures are in place.

- Design should always consider how the area and equipment will be cleaned. Design should facilitate the dismantling of equipment and when and how high standards of hygiene will be maintained.

4.3 Hygiene

- Cleaning schedules should consider *Listeria* hazards and be carried out on a frequency based on the risks as identified through monitoring and audit. Some may need to be as frequent as every 20 minutes.

- Ensure chemicals and cleaning procedures are suitable for the soil that they are expected to deal with and to avoid build-up of biofilm, scale, fat or protein deposits.

- Be conscious of biofilm build up and incorporate the use of specific detergents within the cleaning schedule to combat build up.

- Implement controls to ensure that the correct chemical strengths and contact times are strictly adhered to.
- Ensure that cleaning procedures include manual scrubbing.
- Ensure the procedures are in place to monitor the performance of, maintain and clean hygiene equipment, including washroom equipment such as tray and rack washers and mobile equipment such as squeegees and brushes.
- Consider where it would be more appropriate to employ single use / disposable cleaning materials, such as cleaning cloths, scotch pads and sanitiser wipes.
- Use terminal sanitiser as recommended by your cleaning chemical provider.
- As bacteria can become resistant to the chemical compounds used in sanitisers, consider a planned and routine change to cleaning chemicals to shock any *Listeria*, and break the cycle.
- There have been considerable developments in hygiene interventions over recent years, consider ozone, steam and UV in addition to standard fogging and manual cleaning protocols.
- Use the expertise provided by the cleaning chemical provider on equipment design, the appropriate chemicals to use, the cleaning schedule, procedures and training.

- Ensure that hygiene procedures strictly adhere to top down policy, after drains have first been cleaned. Ensure the cleaning procedures are appropriate for the control of *Listeria*. For example, consider if once cleaning is complete drains are treated with a foam cleaner or steam and left unrinsed.
- Deep clean schedules should include disassembly of equipment as far as is possible – to ensure an acceptable level of access. Do not store equipment or parts on the floor during disassembly. Some equipment redesign may be required.

- Conduct regular cross-functional team hygiene meetings; involve operations, technical and engineering as appropriate.
- Do not neglect the hygiene team, be conscious that they often operate outside normal production hours and can therefore be isolated from their colleagues and the management team.
- Cleaning equipment can be a source of bacteria. Include them in your swabbing plan and replace them regularly or where necessary.

4.4 Handling

- Check hygiene on items such as soap and hand towel dispensers, particularly the presence of potential harbourage points that are difficult to clean.
- Consider hand contact points such as door handles and equipment switches and sanitise regularly through the day. Introduce controls on the basis of risk, considering key traffic flows, breaks and shift changes.
- Clean up operations should be carried out by separate operators to product handlers or those who handle product contact packaging.
- Be rigorous about policies and practices for changing handlers' gloves and protective clothing standards including hair coverage and jewellery policy.
- Ensure that handwashing facilities are continuously well stocked, particularly at break times and that hand wash water is reliably and consistently at an appropriate temperature that encourages handwashing.

- Exclude food handlers who are sick, from working in RTE or RTDE food areas.

4.5 Temperature control

- Be rigorous in the temperature control of chilled ingredients, intermediates, end products and the environment. Ensure that product and materials are at or below 5°C, (4°C for poultry and 2°C for minced meat) at all times.
- Have controls and monitoring in place throughout the process. It is easy to overlook intermediate products and temperature increases during processing. For example, controlling excessive volumes of product standing by processing lines waiting for processing or accumulating prior to return to chilled storage. Especially where this is post cook processing such as prior to slicing / dicing or packing, when the product is particularly vulnerable to re-contamination.

4.6 Audit

- Devise a *Listeria* Management checklist and an accompanying audit which focuses on areas that are known to be growth niches or transfer sites for *Listeria*.
- Audit each shift's hygiene practises regularly to an agreed schedule.
- Carry out frequent cross functional team hygiene audits, including areas outside normal line of sight such as air handling units, internal pipework, couplings and tanks as well as dismantled equipment and examining seals.
- Carry out fabric and maintenance audits focussing on hygienic design and potential harbourage points. Work with the engineering team to eliminate problem areas.
- When auditing don't forget waste streams and their handling and routes for collection and disposal.

5. Environmental monitoring

5.1 Get to know the areas of highest risk

- A key to the prevention of *Listeria* is the prevention of the colonisation of the production environment. FBOs should have an active programme for the identification and eradication of harbourage niches or hygiene protocols that manage the risk. A comprehensive environmental monitoring programme is essential where there is a risk of Listeria contamination of RTE/RTDE products.

- *L. monocytogenes* is most commonly found in wet or soiled places where it can grow and survive, but it can also be found on visibly clean surfaces.

- In addition to food contact surfaces include high or known risk areas identified from hygiene and fabric audits and investigations. Sampling and the frequency of monitoring of these areas should be on the basis of the risk of cross contamination to food products with direct food contact areas as the highest risk.

- Harbourage risks within the food environment are individual to each operation; so identification requires a detailed and specific review of the entire environment. Some areas to consider that are easy to overlook include:

    - Any areas of damp or where condensation can build up – e.g. nitrogen tunnel/ pipe work conveying chilled products.
    - Anywhere you can't see, e.g. inside equipment, seals, pipe joints, hollow rollers used for conveyor belt operation, drains should be considered as part of a segregation barrier and have non return mechanisms.
    - Overheads, - e.g. pipe work, conduits, evaporators including evaporator drains
    - Waste removal routes
    - Areas of damaged equipment or fabric, e.g. remove replace, make good e.g. cracked storage bins, damaged floors, frayed conveyors

- Consider transfer vectors. They should be included as part of the monitoring and management plan:

    - People, consider the risk associated with anywhere hands go, door handles, equipment switches, soap dispensers.
    - Water – particularly where water is stored post receipt and before use. Where water distribution systems are long, complex or old check at points of use, taps, hoses or valves where water is used as an ingredient.

- Consider common pieces of equipment, particularly those which are portable, e.g. – tote bin wheels, cleaning equipment, slicers, mixers, conveyor belts, peelers, shredders, hoppers, dispensers, temperature probes and scales.
- Protective clothing, e.g. goggles, gloves and boots.
- Aerosols, e.g. air handling units, aerosols from hygiene rooms or cleaning activity and boot washers. Establish positive air pressure to ensure dirty air is not dragged in from dirty areas (including from drains) to clean areas.
- Cleaning equipment, protocols must be place to ensure they are working correctly and are maintained in good repair – e.g. tray and rack washers, squeegees, hoses.

- Identify harbourage points and then investigate degree of travel and modes of transfer, putting mitigating controls into place.

5.2 Environmental monitoring and sampling

- Eliminate sampling errors by comparing results taken by different teams e.g. QA and Hygiene swabs. Ensure that training is verified and / or refresher training made available.
- Review monitoring points regularly and/or in response to changes in the business or incidents to ensure that new risks are identified and monitored. Don't allow the sampling plan to become 'routine' mix up the sampling points so that they vary over a weekly / monthly period.
- Consider when is the best time to take swabs depending on the nature of the monitoring or investigation; for example, to determine efficacy of cleaning, swab after cleaning; whereas, to determine the most appropriate frequency of cleaning, swab at intervals during production, or; to identify or find *L. monocytogenes*; swab prior to cleaning.
- When determining control mechanisms for Listeria, swab key floor transfer/harbourage areas at 2 hour intervals to determine the regrowth rate. Understanding this will assist in setting the appropriate sanitation interventions and frequency in high risk areas.
- A 2 hour interval is suggested because at the time of cleaning, residue from cleaning chemicals can result in some bacterial cells surviving but being too damaged to be cultured and identifiable in the laboratory. If this is the case, after a period of recovery time there will be sufficient cells present that can be identifiable in the laboratory.
- A time gap also allows for other causes of contamination to become apparent such as dislodging of any remaining debris or if seals are failing, the normal operation of equipment can cause the bacteria held behind the seal to be released.

- When looking for *Listeria*, advice is to swab the largest area possible. For conveyors / tables then at least 100 x 100cm is recommended. This will not be possible for harder to access points such as pipe work.

- The methodology in using swabs can have a significant impact on recovery of the organism in the laboratory. For example, swabs should be moist when sampling unless the sample is being taken from a wet area. Detailed information on the use of of swabs and data to demonstrate the survival of low numbers of the target organism over the specified timescales between sampling and testing should be available from the swab provider or lab.

- For routine sampling establish the surface area to be swabbed and be consistent in the surface area.

- Follow up swabs can refine the search area and look into particular spots.

- Test the swabs as soon as practicably possible after they have been taken and store refrigerated.

6. Raw material and supplier management

6.1 Sourcing policy

- As part of your HACCP plan complete a risk assessment of your raw materials based on the potential for microbiological contamination.

- Establish sourcing policies to minimise the potential for the introduction of *L. monocytogenes* into the production environment. This might include ingredients that have been specifically treated to minimise the risk and or delivery with certificates of analysis or conformance. E.g. the use of cooked frozen chicken rather than fresh chicken.
- Have more than 1 approved supplier for high risk raw materials or other contingency in place.
- Rigorously enforce supplier procurement standards taking into account customer microbiological policies, where appropriate.
- Consider obligating the supplier to provide a certificate of analysis (COA) or certificate of conformance (COC) with each batch of ingredient, particlarly for high risk ingredients.

6.2 Raw material sampling

- Sampling plans for raw materials should be focused on material types and risk of contamination.
- It is not necessary to include *Listeria* species in the microbiological test suite used for routine analysis for many products with low risk of contamination. Products that have received a heat treatment process in the packaging form e.g. canned vegetables, bottled fruit juice, and those that do not support the growth of *Listeria*; for example products with low water activity such as, cereals, biscuits, sugar, salt, flour, jams, chocolate products, fondant, do not need to be tested for *Listeria* species in normal circumstances.
- Where the material is going to be subsequently heat treated e.g. fresh/frozen raw meat and vegetables to be used in savoury products such as cooked pies and ready meals the presence of *Listeria* species will not be significant with regard to the finished product but may be a source of contamination of the production facility.
- From historical data or published data the risk assessment may identify ingredients that would not be automatically identified as a likely source but due to their long shelf life may be susceptible to very low levels of *Listeria* species being present occasionally. Examples include some cheeses and low salt cured meats e.g. cooked fresh bacon.

- It is recommended that protein sources such as cooked meats/fish/ liquid egg are monitored for *Listeria* species Even where used in products such as frozen ready meals / pies and pizzas that are intended to be heat treated and are not RTE / RTDE products, as where illness complaints from an enforcement officer are received these materials are often the focus of the investigation and this information is helpful in ruling such products out.
- Most significant are raw materials that are supplied which will not be subsequently treated and will be used in RTE / RTDE products. Examples would include fresh cream to be used in the production of cakes, cooked rice and pasta, custard etc.
- Monitor the quality of water at the points of use where this is used as an ingredient.
- Also monitor the quality of any ice where this is used as an ingredient or in contact with food to keep the food chilled.
- The number of samples and frequency will be determined by the risk assessment and based on the size of business and nature of product and processes involved.

- The use of hygiene indicator organisms such as *Enterobacteriaceae* or *coliforms* is likely to identify the potential for pathogens to be present before they are identified themselves.
- For lower risk ingredients the use of hygiene indicator organism tests can be used as first stage with *Listeria* species tests then being applied where non-conformance results are reported.

6.3 Managing raw material microbiological failures

- When a raw material fails to meet microbiological standards the supplier should be notified and instructed to initiate an investigation.
- Raw materials failing microbiological standards should be immediately quarantined, and uplift and replacement arranged.
- Increased surveillance should be put in place for the raw material until 3 clear consecutive results are received. Delivery of the same code / batch from supplier should be blocked.
- Consider mitigating strategies for particularly high risk raw materials i.e. more effective decontamination processes, pasteurised formats or even exclude from development.
- Good stock rotation and date monitoring procedures should be in place particularly for short shelf life raw materials.

7. Sample analysis

7.1 Devising a sampling plan

- Under well managed standard operating conditions the presence of *Listeria* should be rare and at a very low level when present. This makes targeting sampling resource more challenging. Where customer requirements have been specified these should be followed.

- Some small businesses may not have historical records due to the size and nature of the operation. However as the business develops you would expect that the review of existing risk assessments might identify that greater levels of analytical verification are required; i.e. as the volume of production or the number of customers increases the degree of impact becomes more significant and therefore the degree of risk.

- The risk assessment review should be completed by the HACCP team with the help of anyone who has specialised knowledge of this aspect of the operation, e.g. experience with issues associated with the process / operation being undertaken where appropriate.

- Where historical records of testing are limited use the risk assessment process to identify which products present the most risk.

- Consideration of historical results for hygiene indicator organisms can be useful in helping determine the level of sampling to be applied and target the resource for the most efficient control application.

- As frozen ready meals /pies/ pizzas etc. will be reheated or cooked by the customer this process should be sufficient to kill any *Listeria* species present. On this basis the risk from *Listeria* species being present is much reduced and these products are not considered to be RTE/RTDE. However there is a reliance on the instructions for use being adequate and satisfactory.

- Where reheating instructions do not achieve 70°C for 2 minutes or equivalent the product should be considered as a RTE / RTDE product.

- The way a sampling programme is introduced will be based on the output from the HACCP team but may start with product testing to demonstrate that the product is currently compliant with regulatory, customer and internal requirements.

- Such product, or surveillance testing could be followed by environmental monitoring, used to identify the risk of the operation being responsible for contamination of the product with *Listeria* species.

- Based on the information gained from this and assessment of the level of risk being presented, then more detailed routine sampling plans of product, work in progress at critical stages and raw materials would then be introduced. Initially for a product or process identified for further control and then across the facility.

7.2 Product surveillance

- Complete surveillance tests to verify that the current product controls are adequate.
- Consider the operation in terms of materials used and process flows with the potential to cause cross contamination of finished product.
- Samples of product may be grouped based on type of material e.g. species of protein or nature of operation e.g. slicing / dicing operations and mixing operations post heat treatment.
- Samples should be taken across production periods (start, middle and end of runs).
- Initially where simply presence / absence is required, samples can be composited for the initial screen to demonstrate there is no Listeria present to reduce costs.

7.3 Routine analysis

- Aim to achieve a balance between product analysis and environmental sampling. The product analysis is to validate the product controls and the environmental monitoring is to identify potential sources of cross contamination.
- Where there is a significant volume of RTE/RTDE product it is recommended that daily analysis is completed. Depending on the nature of product and historical test result data this may be completed by material type / production line with samples composited.
- Producers of frozen food products have the benefit of having a relatively long shelf life of the finished product during which the level of *Listeria* species present will not increase. Freezing does not eliminate *Listeria* but levels can be reduced. There is also sufficient time to test and establish whether *Listeria* is an issue.
- Where shelf life permits consideration of the implementation of positive release procedures should be considered.
- It would be expected that RTE/RTDE products being supplied to locations where there are known specific vulnerable groups, that these products would be positively released.
- Sampling plans should include samples of RTDE product at the end of shelf life post defrost. If the product is stored in chilled conditions post defrost then the storage temperature conditions for the test should reflect those used by the customer i.e. 8°C may be more appropriate than 5 °C for example.
- When considering routine analysis of product during processing consider key activities e.g. sampling post cooking or prior to and post mixing.
- Due to the potential of environmental contamination of *Listeria* species consideration should be given to whether it is appropriate to test immediately post cook, for example, or if the product is left exposed in order to cool then at the end of this process (prior to packing or the next process).
- For intermediate products then the nature of the intermediate product should be considered. Where the intermediate product does not support the growth of *Listeria* species due to the pH, water activity, packaging format, atmospheric control application then routine sampling is unlikely to be necessary.

8. Appropriate actions if sampling reveals *Listeria*

8.1 Internal actions

- Procedures should be in place covering the response to a positive result being reported.
- Notify internal stakeholders, initiate pre-prepared elements of investigation and mitigation plan.
- Check the brand owners' policy with respect to reporting limits and requirements and ensure that any communication is clear about the status of product and product test results.
- Even while any investigation into the sample handling and testing procedure is carried out consideration should be given to increasing levels of testing as a precautionary measure.
- This is important in reducing the impact of any subsequent confirmation of non compliance with required standards, as a common feature to identifying the root cause and rectifying issues is the delay in getting test data back.
- The increased sampling level would cover samples to aid the investigation into determining the source – such as testing prior to and after key operations such as slicing / mixing or specific raw materials known to be sources of *Listeria* naturally, vegetables, salads, cheese, cured meats.
- If there are low concentrations of the bacteria present, when detected it is not unusual for samples from the same batch of product to provide different results. If only one of several samples is positive it is likely that that this is indicative of a very low level of presence rather than it being an anomalous result.
- Take action that is appropriate to the result. If the result is confirmed as *L. monocytogenes* it should be dealt with as a food safety issue, otherwise it is not and should be dealt with as an indicator of hygiene issues that need to be identified and dealt with internally.
- Think carefully about the most appropriate action to take with regard to product on the market. Rejection or recall as a matter of procedure is not always the most appropriate reaction and could be counterproductive and create unnecessary reputational damage and consumer concern.
    - Frozen materials should be isolated whilst an investigation takes place.
    - Products that will be fully cooked before consumption, investigate to identify source and put solutions in place.
    - Products that have growth hurdles such as pH or water activity (a_w) check outgrowth potential over life. If product will not exceed 100 cfu/g over shelf life although there is no regulatory requirement to recall, it is important that it is thoroughly investigated and issues dealt with.
    - In some products there is an initial continued growth but then a gradual decline in bacterial numbers.
    - Products that have a very short shelf life of <5days (after processing / last treatment), if contamination levels are low, investigate to identify and eradicate sources.

In the event of a positive *Listeria* species notification initiate a deep clean of the production areas paying particular attention to identified high risk areas such as drains, traps, floors, corners, cracks, damaged fabric, joints etc. Follow up with an additional deep clean using alternate chemicals the following day but covering the same areas and reswab. The deep clean should have an additional layer of management ro ensure that it is sufficiently rigorous.

8.2 Managing communication

- Be familiar with customer recall and emergency withdrawal procedures; where they are the brand owners the decision to recall is theirs. Ensure that when contacting customers all of the available information that they require is prepared including information on the timelines for any outstanding analytical results.
- If the business is reporting environmental or non-pathogenic results as part of routine KPI's ensure that the actions being taken to deal with them is also clearly communicated to avoid causing unnecessary customer concerns about lack of control or management.
- Be mindful of the Regulatory requirements of Regulation 2073/2005 on the microbiological criteria of foods. If these have been exceeded for product in the public domain there is a requirement to report the result to the Local Authority and the Food Standards Agency (FSA). This is not required for internal withdrawal of product.
- As the National Competent Authority, the FSA maintains an official audit trail during the investigation of a food incident. It also arranges the issue of food alerts to local authorities, other government departments, trade organisations, and through the Rapid Alert System for Food and Feed (RASFF) notifications to the European Commission.
- Guidance and forms for the reporting of food safety incidents to the FSA can be found on the FSA website: http://tinyurl.com/pbso33j
- The regulatory requirement to withdraw product from the market relates to the presence of *L. monocytogenes* above the prescribed level at the end of the intended shelf life and not *Listeria* species.
- Customer requirements may vary and the need to withdraw product within commercial operations would only need to be notified if the decision is based on the maintenance of food safety. A precautionary measure or a recall that does not affect product in the public domain may not be required to be notified.

8.3 Investigations

- Any report of presence of *Listeria* species is an opportunity to learn more about the risks associated with products and process and to put controls in place. The opportunity should be optimised so that potentially more serious incidents can be avoided. The business should carry out shelf life assessment on remaining product to assess overgrowth of the pathogen in a real life scenario.

- Look for patterns and trends in hygiene indicator organisms (Total Viable Count (TVC) / Aerobic Colony Count (ACC) or *enterobacteriaceae* (enteros) / coliform bacteria) related to raw materials, equipment, processes and product that may help identify the source of contamination.

- The level of intervention will depend on the nature of the product and process. For example, if using materials in which *Listeria* may naturally be present and an isolated result is reported which is below the regulatory requirement simply sampling for a period of time to confirm that this is not an ongoing issue may be appropriate.

- Where there are more significant results or repeat results then the level of intervention will need to be greater. Review the risk assessment for the operation with the operation in practice to ensure that good manufacturing and hygiene standards are being maintained.

- Review critical process steps to ensure these are being applied as specified.

- Ensure any cleaning or cleaning in place operations are being applied as specified.

- Review environmental controls to ensure that there are no new areas of concern, e.g. changes in use of hoses, issues with doors/ventilation creating condensation, etc.

- If results relate to different products look for the common process conditions post any heat treatment applied where applicable – cooling vessels, such as mixing equipment, slicing / dicing equipment.

- Sample product at various stages of the production run to identify the location where contamination is occurring.

- Trace the equipment used in the production process, strip, examine, swab and clean, then swab again.

- In the event of a finished product fail result being reported; break down the product components test individually and as intermediates. Carry out a risk assessment on each to identify all possible contamination routes; be mindful of mobile equipment, such as dolly bins, trays and scales.

- Where specific ingredients are suspected of being the cause of the contamination, increase sampling levels on intake.

- The level of bacteria present on intake may be very low. To help rule out an ingredient, abuse tests can be completed. Retain the material at ambient temperatures for 24 hrs to accelerate the growth of bacteria. Then complete a presence / absence test. If found this confirms an extremely low level of presence and subsequent ribotyping of samples can help establish the causal link to the finished product. Enumeration of the level of abused samples would not be appropriate.
- Investigate whether genome / ribotyping sequencing is available as a mechanism to link results immediately with sources. As with *E.coli* where the identification of the pathogenic *E.coli O157* specifically can be significant in identifying the bacteria more specifically. In the same way identifying the *Listeria* species down as far as the ribotype provides more certainty of the source where a match is found. This can be expensive but is worthwhile in the long run as it speeds up future investigations and can assist in discussions with suppliers as strong evidence that they are the source of the contamination.
- For any ribotyping work it is normal that the technique / reporting is unique to the particular laboratory. In order to be able to compare results and match ribotypes it is important that the same laboratory is used. You may have to request suppliers use the same laboratory as yourself for your product so that results can be used to track and trace common sources.
- Plot any positive *Listeria* species results (environmental, raw material, intermediate or finished product) on a site map and use to assess and to determine if there are any trends, common connections, etc.
- The findings of the investigation should link back into a review of the HACCP plan to ensure the risk assessment and controls remain current and prevent reoccurrence.

8.4 Sampling protocol compliance

- The primary focus of the investigation will be to identify the potential cause of any *Listeria* species contamination that has arisen in the production facility. However due to the significance of the presence of *Listeria* species and in particular *L. monoctogenes* being reported, the investigation should also include verification that the handling of product / environmental swab samples has been correct. This will ensure that the results accurately reflect the safety status of the product.

- Whenever the presence of *Listeria* species is reported, the company should send any retained samples to be tested. This helps to validate that the handling of the initial samples has not compromised the integrity of the results.

- When having retained samples tested, be aware that the time lapse between the initial samples being taken and the time of testing of retained sampling may have an impact on the level of bacteria found.

- Retest materials or product affected or reswab to identify species and ribotype, including enumeration.

- Ensure the time lapse between sampling and testing / product temperature have not compromised any enumeration reported.

- Ensure any enumeration is completed at the same time as identification rather than subsequently to avoid the time lapse for a retest to commence having an impact on enumeration results provided.

- It is not necessary for the same lab to carry out all routine testing; in fact it is advantageous to use different laboratories to validate results. However for ribotyping the same laboratory will currently need to be used in order to compare results.

8.5 Root cause analysis and corrective action

- The investigations completed should be used as part of a root cause analysis study. This should be carried out to determine how and why the contamination occurred including whether the source was from product or environmental contamination.

- Once the root cause is established corrective actions should be identified that fully address the issues. Consider wider aspects that may have contributed to the root cause. For example an inadequacy in cleaning may require corrective actions that include: redesign of the equipment to facilitate cleaning; review of the chemicals and cleaning methodologies employed and the training and motivation of the hygiene team.

- Once the incident has been resolved ensure the HACCP team review the products, processes and procedures / sampling plans in place and make adjustments as appropriate. Maintain records of these reviews and actions taken.

9. What to expect if your premises are the suspected source of a food poisoning outbreak

We tend to think of food poisoning outbreaks as big events that are well publicised and involve large scale product recalls and lots of people falling ill. However, it is important to realise that an outbreak is defined as an instance in which two or more people suffer an illness caused by the same pathogen and between which there is a direct link. An outbreak may also be defined as an increase in the expected level of illness such as has been seen over the last few years in relation to listeriosis.

Involvement in an outbreak is therefore far more likely than may at first be believed and a business involved in RTE or RTDE foods should be prepared for that eventuality.

Local Authorities (LA's) are required to assist in the investigation and control of outbreaks and are provided with powers of entry, taking of samples, exclusion of food handlers, seizure and detention of food and ultimately the power to close premises. Therefore, should a premises be suspected as the source of an outbreak, the first point of contact is likely to be from the LA via their Environmental Health/ Consumer Protection Department. This first contact may be an unannounced visit or could be for a meeting to brief the business fully, review due diligence records and practices and an inspection of the premises. Dependent on the nature of the outbreak and the facts already at hand, this could be a formal interview conducted under caution; what is known as a PACE interview. Any information collected during a PACE interview can be used as evidence in the event of any prosecution. It should also be used as an opportunity to present evidence in defence of the business.

The outcome of the visit will follow the standard practices of enforcement and a report will be submitted to the Food Standards Agency (FSA) and Public Health England (PHE) or the equivalent organisation in the devolved nations. The business should request a copy of this report as it will not automatically be supplied.

Even if everything is found to be satisfactory following the initial visit, the incident will remain open until the LA advises that the matter has been closed. This is because the public health services have a responsibility to identify the primary source of all outbreaks and therefore all effort will be made to establish a perceived link until all options have been exhausted and the business's responsibility is either proven or disproven. Therefore, as further information arises from the ongoing investigation the business may be required to provide additional samples, information and to submit to a highly detailed site inspection including sampling of products and surfaces by agencies in addition to the LA. This could result in loss of production time measured in anything from hours to weeks depending on the risks identified.

In the most serious cases or where corrective actions have not been implemented, the ultimate sanctions are large fines, business closure and jail sentences following a court hearing. For this reason, the importance of maintaining food safety records, internal and external inspection reports and the ability to trace suppliers cannot be stressed enough, for this is the only way to demonstrate that all due diligence has been taken in safeguarding the general public.

10. Further sources of information

- FSA Guidance on the management of outbreaks of foodbourne illness in England and Wales:
  http://tinyurl.com/povlkrt

- FSA Scotland guidance on smoked fish production on contamination by *Listeria Monocytogenes*:
  http://tinyurl.com/povlkrt

- Food Standards Agency Annual Report of Incidents:
  http://tinyurl.com/nqmg6e6

- Food Standards Agency Annual Science Report and Chief Scientists Report:
  http://tinyurl.com/qep6llw

- Examples of Sources of Product Contamination with *Listeria monocytogenes* (not exhaustive), can be found under the 'Food Safety and Zoonoses' section:
  http://tinyurl.com/q7jk2uc

- The EFSA Zoonoses Report 2013 http://tinyurl.com/no8ep65 provides EU data on deaths attributable to *Listeriosis*

Contributors

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