Practical Considerations in the Management of *Listeria*

Edition 1, 15/10/08

Chilled Food Association

PRACTICAL CONSIDERATIONS IN THE MANAGEMENT OF *LISTERIA*

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PRACTICAL CONSIDERATIONS IN THE MANAGEMENT OF *LISTERIA*

EDITION 1

1. Introduction

1.1 Overview

Listeria monocytogenes (Lm) is an environmental zoonotic pathogen with a high level of human mortality. It is found in soil and water and animals can carry Lm without appearing ill.

Lm has been found in a variety of raw foods, such as uncooked meats and vegetables, as well as in processed foods that become contaminated after processing. ***Lm*** is killed by heating; however contamination may occur after cooking but before packaging. Lm can easily become established in the factory environment since chilling and general good levels of hygiene reduce the number of competitors, and wet conditions can encourage its survival and growth.

Legal limits have been set at EU level for Lm in food and areas used for the manufacture of ready to eat (RTE) foods are required by EU law to be swabbed for the organism, although swabbing for *Listeria spp* as an indication of the presence of Lm is confirmed by FSA as being acceptable.

Specific Lm strains appear to persist in the environments of food production areas over time. Lm control strategies therefore need to address the control and eradication of persistent strains to reduce the risk of finished product contamination from environmental sources. However, Lm is likely to be consistently reintroduced into processing plants from a variety of sources, including personnel, equipment, and raw materials and control strategies must take account of this.

This guidance aims to provide pointers for the practical management of Lm, both in its prevention of entry to a factory and in dealing with its establishment, thereby minimising risk to the consumer and to your business. The guidance is not exhaustive but is designed to assist in identifying key issues to be addressed.

To be successful in the implementation of this guidance all management must be committed to compliance. Awareness of the issues should be made throughout your business through specific training and via transparency of sampling results, for example as Key Performance Indicators.

1.2 Legal position

EU law (Regulations 852/2004 and 853/2004) requires that HACCP principles be applied when manufacturing all products. The management of the microbiological risks at each stage of manufacturing process must be considered. For chilled foods, the risks from contamination with and growth of Lm must be considered as part of the HACCP plan.

More information on HACCP can be found in the CFA's "Best Practice Guidelines for the Production of Chilled Food".

Microbiological testing may be appropriate at certain stages to verify that the HACCP is adequate, operational and effectively in control. Monitoring raw materials and factory hygiene may also be important. Final product microbiological testing is often used to verify that the overall process is in control.

More information on the role and practical use of microbiological testing is given in CFA's "Microbiological Testing and Interpretation Guidance".

Manufacturers' and brand owners' obligations with respect to criteria for *Listeria monocytogenes* for ready to eat foods are set out in the EU Microbiological Criteria for Foodstuffs Regulation (MCR) (2073/2005, as amended). Legislation also defines the action to be taken if the microbiological criteria are exceeded (see section 6).

2. *Listeria* spp

2.1 Background

Listeria monocytogenes was first isolated and described in 1926. It is prevalent worldwide and is associated with serious disease (listeriosis) in a wide variety of animals, including man. Lm is an extremely adaptable environmental bacterium capable of existing both as an animal pathogen and plant saprophyte with a range of regulated virulence factors. Most cases of listeriosis arise from the ingestion of Lm-contaminated food. Listeriosis is the greatest foodborne cause of human death in the UK and Europe. A number of forms of listeriosis are easily recognised, such as encephalitis, abortion and septicaemia. Human mortality rates are exceptionally high. However, owing to its relatively long incubation period (70 days reported) it is often difficult to trace the source of listeriosis.

2.2 Growth/survival characteristics, lethal rates

Lm is a psychrotroph, capable of growing at refrigeration temperatures and withstanding relatively high salt concentrations.

Table 1: Commonly accepted growth boundaries of Lm[1]

Microorganism and growth boundaries[2]	Min temp (°C)	Min pH	Min aw	Aerobic / anaerobic[3]
L. monocytogenes	-0.4[1]	4.3	0.92	Facultative

It is the most heat-resistant vegetative pathogen. Lethal rates (based on 6D equivalents) are given below.

Table 2: Lethal rates for *Listeria monocytogenes*[4]

Temperature (°C)	Time (mins, secs)
60	43'29"
61	31'44"
62	23'16"
63	17'06"
64	12'40"
65	9'18"
66	6'49"
67	5'01"
68	3'42"
69	2'43"
70	2'00"
71	1'28"
72	1'05"
73	0'48"
74	0'35"
75	0'26"
76	0'19"
77	0'14"
78	0'10"
79	0'06"
80	0'05"
81	0'04"
82	0'03"
83	0'02"
84	0'02"
85	0'01"

[1] *Microorganisms in Foods. Vol. 5. Microbiological Specifications of Food Pathogens*. (1995), ICMSF, Blackie Academic and Professional; *ACMSF Report on Verocytoxin-Producing* Escherichia coli (1995), HMSO, London, ISBN 0-11-321909-1.

[2] Growth boundaries given under otherwise optimal conditions. Growth criteria will vary according to strain, temperature, and type of acid, solute and other factors, and will normally be higher in foods. However, variability in measurement, etc., must be allowed for - a margin of error must be incorporated.

[3] It is important to note that even aerobically processed foods may present a risk of growth of anaerobic organisms since they may have an anaerobic internal environment.

[4] *Heat Resistance* of *Listeria monocytogenes in Non-dairy Food Menstrua* (1989), Technical Memorandum No. 523, Campden Food and Drink Research Association, *Heat Resistance of Listeria monocytogenes in Homogenates of Chicken, Beef Steak and Carrot* (1989) JE Gaze, GD Brown, DE Gaskell and JG Banks, *Food Microbiology*, 6, 251-259

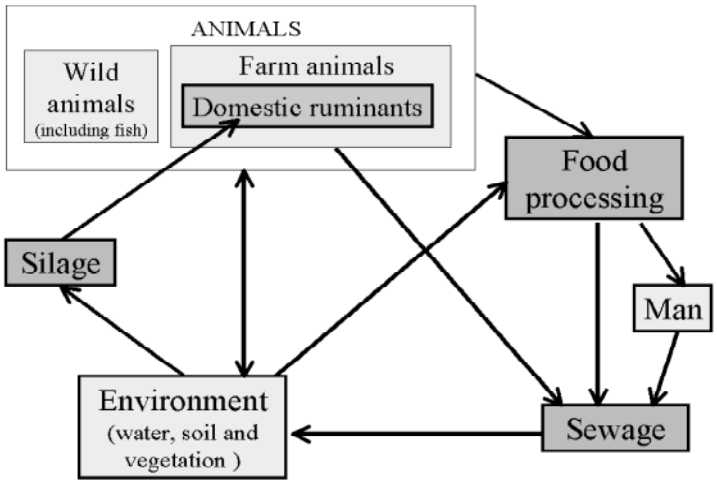
Notes

These data are based on laboratory studies and are supplied as an example of the necessary process to achieve a 6-log reduction of *Listeria monocytogenes*, the most heat-resistant vegetative pathogen of significance in chilled foods, and, as a consequence, all other vegetative pathogens, such as *Staphylococcus aureus*, *Campylobacter*, *E. coli* and *Salmonella*, will also be heat-inactivated (i.e. at least a 6-log reduction).

2.3 Ecology

Figure 1 highlights that animals and the environment are key sources of Lm, with transmission routes being many and varied between these sources, sewage (including manure and run-off), silage and foods.

Figure 1: *Listeria monocytogenes* transmission among habitats and host populations
(Ivanek *et al*, 2006)



As a consequence of these transmission routes Lm has been found in a variety of raw foods, such as uncooked meats, fish and vegetables, as well as in processed foods that have been re-contaminated after processing. Lm is killed by heating; however re-contamination may occur after cooking but before packaging.

Lm can easily become established in the factory environment since chilling and general good levels of hygiene reduce the number of competitors, and wet conditions can encourage its survival and growth.

The presence of Lm in food manufacturing environments, or other food-associated environments, generally can represent repeat or isolated introduction into a plant, followed by elimination within a short time frame (days to perhaps one week), or survival and multiplication (persistence) in a plant, e.g., in niches that cannot or are not appropriately treated to eliminate Lm over time (weeks to years). Persistent contamination has been reported not only for a variety of food manufacturing environments, including those for smoked fish, poultry, meat, and dairy foods, but also for retail environments.

Product contamination is often as a result of contamination during processing rather than by survivors from the raw material(s). Each factory may harbour its own unique type of Lm. It may be present in brines, colonise slicers and other equipment or be harboured in environmental niches e.g. in drains and on floors. The Good Manufacturing Practice (GMP)/Good Hygienic Practice (GHP) program in a food processing plant where Lm is an identified hazard, must focus on eliminating this organism from the environment and particularly from food contact surfaces. Environmental sampling for Lm (or *Listeria spp*) will be required to verify the efficacy of such actions.

Lm control strategies must address the control and eradication of persistent strains to reduce the risk of finished product contamination from environmental sources. However, Lm is likely to be consistently reintroduced into processing plants from a variety of sources, including personnel, equipment, and raw materials, and control strategies must also take account of this.

Sections 3, 4 and 5 provide information to help address these points.

3. Pointers for preventing *Listeria* from entering factories

The following is a non-exhaustive list of what to look for and how to look for it and is derived from companies' experience.

3.1 Raw material and product risk assessment

- Systematically apply appropriate criteria and procedures to the decision to accept a (new) raw material and/or supplier, i.e. Supplier Quality Assurance
- Apply a field to fork approach to minimising risk presented by produce raw materials (e.g. CFA Microbiological Guidance for Growers, 2nd edition)
- Be cognisant that proteins can also be a source contamination due to the potential for re-contamination after any processing. The risk assessment should take account of the amount of any handling by the supplier after any listeriocidal process.
- Know the source of the raw material including any processing and ensure that the supplier has an appropriate HACCP plan that takes account of any risks from contamination by Lm.
- Systematically apply appropriate criteria to accept or reject raw materials including microbiological testing where relevant.
- Verify whether the raw material is suitable for use in Low Risk/High Care/High Risk, i.e. whether it is RTE or requires particular handling or treatment such as processing further to reduce or control the risk

3.2 Raw material control

- Systematically apply specifications which are appropriate to the intended use of the raw material and ensure that the supplier(s) has/have agreed to and can comply with the required specification.
- Risk assess raw materials to determine supplier audit and testing frequency
- Carry out trend analysis and action including notification/follow up with supplier/increased testing/RAG (red, amber, green)
- Carry out positive release of raw material where appropriate (either by own analysis or on the basis of a Certificate of Analysis)
- Segregate high risk (RTE) ingredients from those which may be a source of contamination with Lm and from sources of environmental contamination.
- Implement dual sourcing of suppliers and co-trending to assist in managing the risk

3.3 Process Design and Control

- Ensure process design and relevant controls incorporate the requirement for a *Listeria*cidal process where relevant.
- Wash or pasteurise raw materials as required, based on risk assessment.
- Transfer raw material into the High Risk/High Care environment using appropriate procedures that will prevent cross-contamination.
- If produce washing or other disinfection methods use chlorinated water, a verification test for free chlorine levels should be implemented.
- Levels of other disinfectants used as part of the process should also be verified to an appropriate schedule.
- Movement from areas/jobs is to be kept to a minimum. For example, do not have an operative working in veg prep that then transfers to packing lines and from low to high Risk/High Care on the same shift; or a cheese grater in a busy corridor with clean equipment being stored in the same area.

3.3.1 Validating New Technologies

Periodically new technologies, equipment and processes are proposed for the control or removal of *Listeria*.

Before any new technology is introduced into the factory all available information must be obtained from the manufacturer, and scrutinised to ensure it has the backing of a reputable testing laboratory or institution.

A team must be established at the outset to agree a measurable approach on all aspects of the validation:

- Agree testing regime that will show validation of the process (I.e. check and compare pre / post treatment effects
- Consider whether the process is likely to cause any other issues, such as Health and Safety etc.

Only if it is agreed to proceed can controlled factory trials be initiated.

In some cases it may be appropriate to carry out small scale bench testing first in order to approve the system.

Larger scale trials should be carried out to build result validation.

A post-trial evaluation must be carried out to

- agree whether the measurable standard set has been achieved
- review all knock on effects
- set critical control points
- establish ongoing monitoring systems

Monitoring should include swabs, measurements etc, setting new control points, if appropriate.

3.4 Factory design and construction

- Build on barrier principles to ensure that High Risk/High Care area(s) are suitably segregated from Low Risk areas.
    - Determine precisely what comprises a barrier, bearing in mind that if a wheel or foot can be put over into High Risk/High Care, the barrier is not adequate.
    - Ensure wall/floor junctions are fully sealed so that there is no risk of seeping of waste water from low risk to high care/risk.
    - Do not locate contaminated equipment or materials near Low Risk/High Care/High Risk barriers.
    - Siting of equipment at barriers must take into account the direction of process/product flow, drainage, gaps, product entrapment, interlocks
- Drains
    - Design such that flows are away from High Care/High Risk
    - Have a plan of action of what to do if backing up occurs from the Low Risk area
    - Design drains to minimise risk, e.g. avoid pot drains since they require emptying
- Design the air handling system to minimise risk
    - Air handling systems should create positive air pressure in High Care/ High Risk
    - Avoid condensation, keep Relative Humidity low
    - Avoid build-up of contamination within air handling system units
    - Determine how to clean air handling systems or whether it is better not to
    - Environmental temperature should be controlled as appropriate
- Where possible, design out the potential for leaks to occur in the roof void and/or schedule regular inspection.

- Chillers should be hygienically designed and be easily cleanable

- Panel construction should be hygienically designed and be easily cleanable

- Plinths should be constructed with cleanability in mind and to minimise potential for harbourage

- Segregated/screened hygiene/cleaning areas should be provided within each production area to minimise the risk of cross-contamination during cleaning

3.5 Equipment design and construction

- Equipment should be designed for
    - Ease of strip down and quick release (design principles should be according to EHEDG guidance and CFA's Hygienic Design Guidelines)
    - Compliance with users' requirements specifications

- Equipment installation must be carried out hygienically
    - Engineers should be trained in hygiene principles and follow specified procedures
    - Barrier breakdown must be avoided
    - Pre-installation hygiene of second hand/rented equipment and its history including pre-use storage requires particular attention
        - Effective pre-installation cleaning must be carried out
        - Handover procedures to production must be specified and followed

- Equipment should be sited away from sources of contamination, e.g. drain flows, evaporators, air flows from raw material intake

- Consider placement of new machinery ensuring sufficient access to it in the area for cleaning

- Ensure that there is sufficient drainage for waste water

- Ensure that equipment is not sited over existing drains.

- Preventative maintenance schedules and frequencies must be in place and must take into account the hygienic management and cleaning of:

    - Belts,seals,wheels,pneumatic equipment, rollers
    - Tooling, e.g. sealing machines

3.6 High Care Barrier control

- Raw materials transfer into the processing area must be scheduled such that low Lm risk materials are introduced first. For example, when transferring into a high care area through a flume washer start with easy to wash/smooth surfaced vegetables and finish with those with a high surface area, e.g. leafy vegetables.
- Hygienically manage transfer across barriers of packaging, waste, product, raw materials and equipment etc; using for example:

- decontamination methods either manual or automatic in a disinfection tunnel
- double bagging
- interlock doors/cat flaps
- captive cleaning/hygiene and engineering equipment wherever possible

- Keep barrier areas clean and free from 'dirty' equipment

3.7 Personnel controls

- Hygienically manage Personal Protective Equipment (PPE)
    - Changing room design and layout must be considered with hygiene uppermost and cleaning frequency determined on the basis of risk, avoiding wet floors
    - Note that open designs minimises harbourage potential

- Effectively manage segregation of Low Risk/High Care/High Risk production, engineers and hygiene staff
- Personnel Hygiene
  - Ensure adequate and frequent hand washing (as described in the CFA hand washing training poster)
  - Implement glove control
  - Use dedicated “clean as you go” staff
  - Pay attention to movement between touching food/non-food contact surfaces – apply the clean hands principle, particularly with reference to
    - Tray handling
    - Scale staff
    - Waste handling
- Training programmes on hygienic practices should:
  - be specific on Lm control
  - include pre-briefing of agency staff prior to employment
  - be applied at all levels of management, auditing and engineering staff
  - be policed in terms of actual practice, being included in shift managers’/supervisors’ roles
  - highlight Golden Rules (non-negotiable) for Lm control
  - include engineering staff
- Contractors and building works must be managed from a hygiene perspective setting the rules on
    - Hygiene
    - Waste removal
    - Factory access
    - Standard factory behaviours, e.g. no smoking, no eating outside of designated areas such as canteens
  - Including briefing/training
  - Controlling area screening, e.g. using white walls
  - Defining whose role it is to brief, supervise, enforce/audit compliance
  - Including standard rules for routine maintenance

- Protocols in the case of fire and other alarms must be established and practised regularly

4. Pointers to Maximise Cleaning and Hygiene Efficacy

The following is a non-exhaustive list of what to look for and how to look for it and is derived from companies' experience.

4.1 Introduction

Listeria either enters the high risk area routinely from low risk areas across barriers or is persistent in the high risk area. Work carried out by CCFRA (Holah et al. 2004) showed that in five factories:

- The low risk areas of chilled food factories are likely to be contaminated with *Listeria* spp.
- Activities related to the floor are likely to be the largest risk factors in transferring pathogens from low to high risk (e.g. footwear, wheeled traffic, aerosols or splash)
- The high risk areas showed low levels of *Listeria* spp. indicating that barriers were working.
- There was evidence of low level but persistent *Listeria* spp. in the high risk environments.

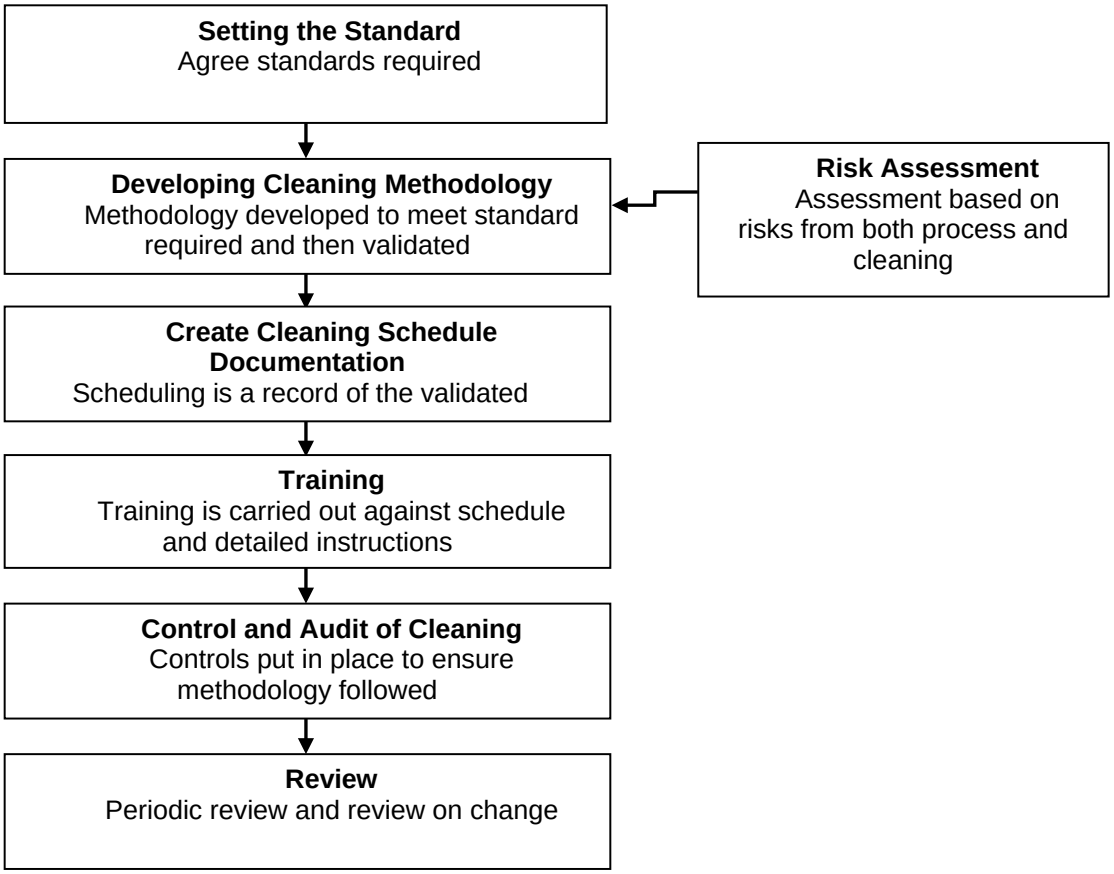
Good Manufacturing Practice and Good Hygiene Practice are important to control *Listeria* spp. in the high risk environment.

4.2 Development of the Cleaning Programme

The timing and frequency of clean should be set by risk assessment of the product and process. During the production process product contact surfaces will become contaminated with soil and micro organisms. This contamination may lead to deterioration in product quality and eventually an unacceptable product. By assessing product quality against production running time a frequency of clean can be determined that ensures product quality always remains acceptable. Potential cross contamination risks from the cleaning process must also be identified and risk assessed.

The flow chart below shows the process required to set up and review the Cleaning Program.

Figure 2: Cleaning Programme Development



Consider

- Is the cleaning programme appropriate to the product risk and the cross contamination risk?
- Does the cleaning programme cover all necessary equipment, surfaces and cleans e.g. Deep Clean, Hygiene Clean, Intermediate and Break Cleans?
- Where possible is equipment moved into a segregated/screened hygiene area for cleaning?
- Are special procedures needed for difficult-to-clean equipment?
- Is the cleaning programme consistently providing satisfactory results?
- Is the programme reviewed and validated after any change in the process. Consider new product, new equipment, change in layout or product and waste flows.
- Is environmental cleaning adequately covered?
- Ensure that the hygienic usage and management of recirculating systems is addressed, including for example:
  - Capkold coolers
  - Packaging equipment
  - Cookers
  - Tray washers
  - Spray tunnels

4.3 Cleaning Methodology

4.3.1 Developing Cleaning Methodology

The cleaning methods should be developed and trialled to see if they meet the standards required. Competent and trained hygiene management together with third party consultants, such as reputable chemical suppliers, using a risk assessment approach should define the frequency and devise the methodology of cleaning for each area of the process. The cleaning process should then be risk assessed to see if any direct or cross contamination issues occur by utilising the methodology.

4.3.2 Design of Verification Programme

The verification process is part of the design and review of cleaning methodology. The process is used to validate a proposed cleaning methodology and then as part of management review to monitor performance against standards. This then enables development of the process in the drive for continuous improvement.

Microbiological testing, ATP monitoring, protein testing or specific allergen tests can be used for the verification of cleaning. (See also section 4.10 below)

4.3.3 Dry Cleaning

Dry Cleaning refers correctly to cleaning where no liquid detergents or disinfectants are used; however, it is also commonly used to refer to cleaning where disposable impregnated wet wipes or damp disposable cloths are used. In the food industry it is usually found in processes where the presence of water could affect the quality and consistency of the product; such as bread, pastry, biscuits, cereals etc. or create conditions that enhance microbial growth.

Dry cleaning is a purely mechanical process that relies on the soil being physically removed (brush, vacuum). The nature of brushes and vacuums mean that 100% removal of soils will not be achieved (Holah, Middleton et. al., 2004). Consideration must be given to following brushing or vacuuming with wiping with detergent / disinfectant dampened cloths to increase overall soil removal.

Consider - Minimising Potential for Cross Contamination by Dry Cleaning

Tools used for cleaning can become a major route of cross contamination.

- Cloths and scourers should be disposed of after use.

- Brushes, scrapers and other tools must be cleaned, disinfected and stored hygienically for later use.
- Tools should be clearly defined for area of use; for example, **floor use only** or **food contact use only**. In addition specific tools should be kept for cleaning of surfaces that have allergenic material on them where segregation is critical.
  A colour code system can be used to assist. It is vitally important that the system is clearly defined and managed.
- Vacuum cleaners tools such as nozzles and hoses will become contaminated and will need thorough cleaning.
- The vacuum cleaner, if mobile, rather than a fixed central installation will exhaust air locally. Regular cleaning and replacement of filters to ensure no particulate materials are blown out of the unit is critical.
- Airlines are sometimes used to dislodge soil from difficult to access areas; essentially moving it to an area that can be accessed by a dustpan and brush or vacuum. Unfortunately airlines will impart energy to fine particulate matter making it airborne and allowing it to spread over large areas. Where the use of airlines cannot be avoided, use them in combination with a vacuum to remove as much airborne matter as possible.
- Airlines should be filtered to ensure that they don't in themselves become a source of contamination.

4.3.4 Manual Cleaning

Manual cleaning refers to the cleaning process where the detergent is applied via a cleaning tool such as cleaning cloth, scourer or brush. It also refers to cleaning of parts that are put to soak in detergent solution before physical action.

Manual cleaning provides a flexible method of cleaning for a variety of equipment and surfaces and has little risk of cross contamination caused by aerosols or overspray; however the control and cleaning of cleaning tools is vital to ensure no cross contamination.

4.3.5 Foam and Gel Cleaning

Foam cleaning refers to the cleaning process where the main detergent is applied as foam and Gel cleaning where the main detergent is applied as a gel. The improvement in foam technology, such as long cling foams, and the introduction of different types of foam detergents have made it a process that can be used, with benefit, in many situations. A common misconception of foam and gel cleaning is that it negates the need for any type of physical action (such as scrubbing with a brush or scourer). Physical energy must be applied after suitable detergent contact time.

With low pressure rinsing however, this is not the case and it is essential that surfaces are mechanically agitated prior to rinsing.

The main advantages of foam and gel cleaning in comparison to manual cleaning are:

- The detergent solution can be applied to large and difficult to reach areas in a short period of time
- An extended detergent contact time between the soil and the detergent
- A reduction in the time of clean
- Less manpower required
- Control of detergent use
- Safer application of hazardous detergents

Consider – Minimising Potential for Cross Contamination by Wet Cleaning

- Are food contact items being cleaned on the floor? This must be prohibited.
- Are wash down hoses running over equipment or surfaces? Use of ceiling-mounted retractable hoses can limit this issue. However the potential for *Listeria* harbourage into the hose mounting must be addressed.

- All wash down systems whether low, medium or high pressure will cause overspray which can lead to cross contamination if no controls are put in place; however high pressure systems also create aerosols which add another vector of cross contamination.
- Cleaning tools are a major source of contamination. Cleaning tools and their management generally receive low priority; this was aptly demonstrated in a food industry wide survey by CCFRA which showed that of all cleaning tools tested 35% were *Listeria* positive.
- The correct choice of tools, the management of cleaning of tools and the designation of specific tools for different purposes (usually identified by a colour coding system) is essential.
- Wash down water may be contaminated by holding tanks or by pipework. Routine cleaning to remove debris and biofilms followed by disinfection is essential.
- Are there any breaches of the low risk / high risk barrier during cleaning? For instance cleaning equipment transfer, Water in drains running from low risk through high risk, water on floors overflowing across barriers.

4.3.6 Floor Cleaning

Floor cleaning can be carried out using manual methods such as a mop/brush and bucket, by utilising the washdown system or by a dedicated floor cleaning machine. The most appropriate method will depend on the access to the floor area, time of cleaning and the size of the floor area.

Consider – Minimising Potential for Cross Contamination by Floor Cleaning

- All methods create overspray which can travel vertically onto food contact surfaces. Work by CCFRA showed that the potential for cross contamination of food contact surfaces from floors was real and measurable.
- The distance of vertical and horizontal travel by floor cleaning solutions varied dependant on the method of clean (Holah et.al. 1993). The greatest vertical and horizontal travel of cleaning solutions occurs when using a high pressure washdown gun, followed by medium pressure washdown gun, low pressure washdown gun, floor cleaning machine with mopping and brushing creating the least travel.
- Cleaning tools must be of hygienic design to enable them to be easily cleaned and disinfected. Consider use of single blade squeegees.
- Cleaning equipment must be included in the cleaning schedule.

4.3.7 Tray and Rack Washing Machines

Washing machines come in many shapes and sizes and are generally built for the cleaning of a specific size and type of item. The short contact time with detergent and the relatively low impact energies of the wash nozzles means that to clean effectively high chemical energies are required. In most situations a high alkaline low foam detergent at 0.25% to 1% v/v is used at 55 to 75ºC.

The washing machines must be managed correctly with regular cleaning of the machine and filters, regular changing of wash solutions, inspection of wash and rinse nozzles and control / monitoring of detergent temperatures and strengths.

The efficacy of a clean is dependent on correct original design of the machine for the items being cleaned and correct operation and maintenance.

Consider – Minimising Potential for Cross contamination by Washing Machines

Washing machine internal surfaces will during normal operation become contaminated with mineral scale, protein and biofilms. These deposits should be routinely removed to reduce the risk of contamination of the washed items.

Significant issues arise within areas of the machine where microbial growth can occur e.g. intake and exit to the machines:

- Strip curtains are often found with resident populations of pseudomonas and *Listeria* spp..
- Drying sections can become contaminated.

4.3.8 Cleaning in Place (CIP)

CIP is the cleaning of pipework or vessels (tanks) by passing cleaning fluids through the pipework or spraying inside the vessel.

It is important to note that for equipment to be effectively cleaned by CIP it must be designed to do so.

For instance an automatic depositor head designed for CIP will incorporate a mode where all of the depositor head seals become exposed to cleaning solutions. With a normal depositor the head will require full dismantling for manual cleaning and it is not possible to effectively clean this type of depositor by recirculation or CIP.

With **vessel cleaning** it is wise to seek advice from a sprayhead manufacturer to ensure the correct sprayhead/s are used to give complete coverage.

When vessels have internal structures (e.g. scraped surface paddles in a cooker) it is vital that the sprayhead design and position also ensures coverage of these internals as well as the vessel surface.

- Spray devices should be regularly removed for inspection and cleaning.
- Internal pipework, vessels, welded joints, unions and valves should all be of a hygienic cleanable standard (Curiel, Hauser, et. al. 1993)
- Ensure no pooling of liquids in the bottom of the vessel occurs; if feed rate is higher than scavenge rate then consider burst rinsing.

With **pipework cleaning** the CIP feed pump and circuit design should ensure a minimum flow rate of 1.5 m/s. this ensures that the fluid flow in the pipework is turbulent.

- Pipework routes should be of consistent diameter. A change in diameter will lead to lower cleaning velocities in the larger diameter pipework and therefore potentially poor cleaning.
- CIP flow rates should not be too high otherwise pipe hammer can occur. Pipe hammer is caused by rapid changes in liquid velocity and can lead to seal and pipework damage.
- Internal pipework welded joints, unions and valves should all be of a hygienic cleanable standard.
- Deadlegs should be avoided.
- A series of key inspection points should be checked before each clean, e.g. pump cavities and valve seats and manual dismantling and cleaning of these introduced.

4.4 Cleaning Chemicals

4.4.1 Choice of Detergent

The role of the detergent is to assist in the removal of soil from a surface. A number of factors must be considered when choosing a detergent. These include soil type, method of application, materials of construction of the surfaces being cleaned, water hardness, health and safety and many others. Most detergents combine emulsification properties with some type of chemical reaction.

Although there are thousands of detergent products available in the professional and domestic market they break down, broadly speaking, into the following:

- General purpose neutral or mildly alkaline detergents are used for hand cleaning by spraying or for soak cleaning (sinks). They rely largely on emulsification and suspension of soiling and are particularly effective on fats and oils.

- Sanitisers are neutral, mildly acidic or mildly alkaline detergent disinfectants that combine the cleaning properties of a neutral detergent with a degree of disinfection.
- Alkaline detergents are used where heavier soiling is encountered. They rely partly on chemical reaction to hydrolyse proteins or saponify fats. They can be applied in a number of formats including gels or foams for long contact times with open surfaces or as low foam products for recirculation cleaning such as dishwashing, traywashing and Cleaning in Place (CIP). They are effective on highly carbonised or polymerised soils.
- Alkaline / chlorinated detergents, either as foams or low foam products for recirculation, are used because of their excellent removal of the fats, proteins and biofilms.
- Acidic detergents can be used for mineral scale removal and protein removal.

4.4.2 Choice of Disinfectant

If the disinfection part of a cleaning process is to be effective, it is vital that the surface to be disinfected is free of food soil or chemical residues. The presence of soil or chemical residues may affect the disinfectant and prevent it from working effectively. Thorough rinsing of detergent and soil residues is essential prior to disinfection.

Effective cleaning will remove approx 99.9% (3 log reduction) of the bacteria on a surface but there may be considerable numbers still present. This is why the disinfection stage is required to help bring the bacterial numbers down to an acceptable level >99.999% (>5 log reduction).

The disinfectant chosen must be effective against the micro-organisms of concern and for the environment and food type. *Listeria* spp. are susceptible to most disinfectant types. Both oxidising disinfectants (e.g. sodium hypochlorite or peracetic acid) and non-oxidising such as quaternary ammonium or amphoteric based disinfectants typically achieve greater than $\log_{10}$ 5 reduction at 10ºC in challenge tests such as EN1276.

As long as the disinfectant has certified data showing its efficacy against the organism of concern (*Listeria* spp.) a change of disinfectant alone is unlikely to provide any benefit.

4.4.3 Spray Disinfection

Spray disinfection is the most common method for applying disinfectant to surfaces. It is versatile, gives good coverage and is economic on use of disinfectant solution.

It can be carried out using a variety of different applicators including Small trigger sprayers, Pump-up sprayers, Sprayers that operate using compressed air and also via wash-down systems at high, medium or low pressures.

4.4.4 Soak Disinfection

This is probably the most effective means of disinfection as the item to be disinfected is fully immersed in the disinfectant solution, giving good contact time to all surfaces. This type of disinfection method is usually confined to small items such as utensils, knives, blades, small machinery parts, cutting boards etc.

4.4.5 Aerial Disinfection or Fogging

Aerial Disinfection is used primarily for disinfecting airspace in production and processing areas. As micro organisms can be carried in the air and transferred to food contact surfaces it may be important, particularly in high risk environments, to disinfect the airspace.

Fogging should only be conducted after all cleaning and disinfection of food contact surfaces has taken place. It should never be used as an alternative to surface disinfection.

The disinfectant fog in the atmosphere helps to bring down any micro organisms onto the disinfected surfaces.

Consider

- Is the cleaning stage leaving a soil free and detergent free surface? Most detergent solutions will inactivate quaternary ammonium based disinfectants.
- Are there any biofilms forming that need to be removed using a detergent?
- What is the efficacy of the disinfectant against *Listeria* spp.? Consult with supplier.
- Is the disinfectant consistently being applied at the correct strength?
- Is this disinfectant strength verified?
- Is the disinfectant being applied to all required surfaces?
- Is fogging necessary to control airborne contamination?
- Is there any cross contamination of surfaces occurring during reassembly of equipment?
- Is there any cross contamination of surfaces occurring after cleaning and disinfection and prior to production?

4.5 Miminising Potential Cross Contamination by Cleaning Personnel

- Cross contamination by personnel can cause major issues with the end result of the clean. The vehicles of contamination include: Hands / Gloves, Protective wear – mainly overalls, aprons or wet suits and Footwear
- Transfer of personnel from low risk to high risk should be avoided if possible. If not then hand washing and changing procedures should be adopted where all protective wear including overalls, hairnet, hat, gloves and footwear are changed.
- Checks on laundered items should be carried out.
- Footwear should remain, where possible, captive to an area. If this is not possible consideration must be given to footwear washing to avoid cross contamination on floors.
- Production personnel involved in cleaning (typically on an Interproduct clean) must adopt very strict apron and glove changing and hand washing after cleaning and prior to production.
- Hand washing is important for microbial control. A proper handwash procedure including the use of a soft nail brush should be trained and monitored. Handwashing compliance can be poor but increases when the handwash facilities are good, the water temperature is comfortable, the handsoap mild and most importantly personnel understand the reason for handwashing.
- Ensure indirect food contact surfaces are routinely cleaned and disinfected (electrical panels, temperature probes bodies, handles)

4.6 Scheduling

It is the responsibility of the food manufacturer to document the cleaning procedures however the chemical supplier may assist with the process.

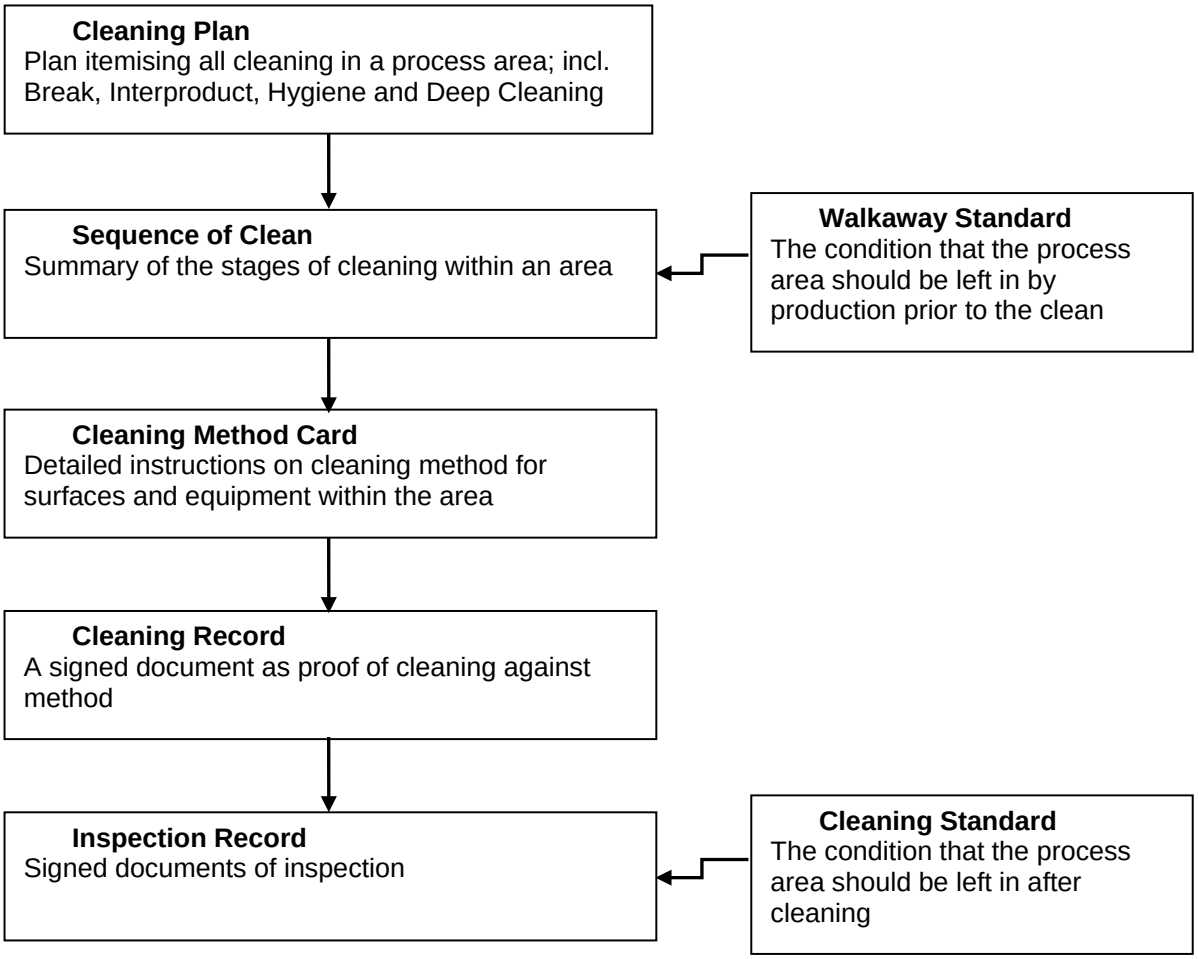
The purpose of the documentation is:

- For training of hygiene / production operatives
- As a reference for hygiene / production operatives
- To enable auditing of the process

The documentation can be very extensive since it must cover a number of different types of clean, the detail of cleaning and any controls required as defined by the risk assessment process.

A typical structure of cleaning programme is illustrated below.

Figure 3: Typical Cleaning Programme Structure



4.7 Training

Training of management and operatives is important to ensure that staff carry out their duties correctly and fulfil their potential by understanding:

- Their responsibilities within the team
- The standards required
- With good training confidence is promoted, job satisfaction increased, team spirit developed, performance improved and the amount of supervision required is reduced. Those companies that invest in the time and resources for training tend to reap the rewards of increased profitability. Training should be tested and recorded.

4.8 Control of Cleaning

It is important to monitor the energies that are used for cleaning to ensure that they are in line with those established when the methodology was validated. A record should be kept of the factors and if any are out of specification corrective action must be followed to restore to that defined in the methodology.

For **Open Plant Cleaning** this would involve:

- Checking that the physical strip down of equipment meets that defined on the schedule.

- Checking the chemical strengths of detergent and disinfectant as applied to surfaces. This will generally involve a simple test kit.
- Checking the strength of disinfectants on surfaces after application to ensure that no dilution or inactivation is occurring. This can be carried out using disinfectant specific test strips.
- Checking the water temperature and pressure of any washdown system. Water temperature and pressure are often critical to achieving a successful clean.

For **Cleaning in Place** (CIP) this would involve:

- Checking the physical set up of the cleaning route and the correct functioning of sprayheads.
- Checking the chemical strengths of detergent and disinfectant. Modern cleaning systems will generally monitor and record return flow conductivity (relates directly to chemical strength), return flow temperature and return flow rate.
- Unless the Cleaning in Place system automatically ensures the cleaning process parameters are met then the cleaning record should be analysed to verify that all parameters meet or exceed those achieved during validation.

4.9 Audit of Cleaning

Visual inspections after the cleaning process are important to ensure that the required visual standards are achieved and maintained. The inspection should be thorough and all areas should be covered including those outside the daily cleaning program.

Inspections after the cleaning process should make provisions for pass, caution or re-cleans. The results of any inspection (positive or negative) should be firmly communicated to relevant members of staff with a corrective action loop in place.

Where specific testing such as micro testing or allergen testing of product and the environment is required it is important to have a sampling plan in place so clear trends can be built up and any problems identified and actioned.

4.10 Swabbing Programmes

Swabbing should be used as ongoing verification that cleaning and hygiene regimes are effective. Testing can include general contaminants (e.g. Enterobacteriaceae) as well as Lm or *Listeria spp.*(See 4.10.1 below).

- Ensure that the following key areas are included within the specific *Listeria* swabbing regime (this may be on a “rotation” with all points being covered to an agreed schedule):

  - Floors and drains (including drain baskets), paying particular attention to any damaged areas
  - Cleaning equipment (e.g. squeegee blades)
  - Trolley/rack wheels and footwear
  - Hand contact surfaces
  - None routine equipment (i.e. ladders, engineering equipment).
  - Non food contact parts of production equipment and secondary contact parts.
  - Evaporators/searle units and drip pipes
  - Condensation on ceilings and equipment after cooking
  - Waste routes
  - Below ovens
  - Strip curtains
  - Tray washers
  - Stored clean equipment
  - Hose guns and hose pipes
  - Door seals
  - Consider swabbing hands/gloves

  Equipment/machinery should also be swabbed and the dismantling of these items is required.

In some factories, due to the nature of the products/processes (e.g. the use of raw prepared salad ingredients), the presence of *Listeria* is inevitable. In these cases the strict control and management of hygiene procedures as indicated above is of paramount importance

4.10.1 How to Sample

Sampling should include both product contact and non-contact surfaces after cleaning and disinfection and may use microbiological samples such as swabs, contact plates, rinses and/or non-microbiological indicator systems such as ATP swabs. Consider using sponges for sampling larger areas.

- **Rapid Hygiene Monitoring:** ATP swabbing and similar rapid hygiene monitoring systems give a result that can be interpreted before start-up. ATP results do not relate directly to microbial levels, but are an excellent indicator of hygiene. As such testing is relatively expensive, it is best used to monitor specific CCPs, e.g. food contact critical equipment such as slicing blades, and to train hygiene staff in cleaning. Manufacturers of systems will advise on the setting of standards.
- **Microbiological Testing:** The results of environmental microbiological tests are not available soon enough to be used for real time hygiene monitoring, but can be used to verify cleaning and disinfection, to evaluate trends and can also be used for investigation purposes. Investigation results should not be used to monitor trends. Any relevant additional sampling points highlighted in the investigation should be included in the routine sampling plan.
- **Air sampling:** Settle plates have limited use, but there may be certain circumstances where the verification of microbiological air quality can be helpful. Air samplers, which allow a set volume of air to be sampled, are also available.

Consider

- Creation of an emergency sampling plan to be applied in case of unacceptable results:
  - Around low risk / high risk barriers
  - Pre Clean
  - Post Clean
  - Pre Production
  - During Production
- Review of the sampling plan based on trends.
- Audit and review of auditors
- Audit and review of laboratory testing

4.11 Review

As with any system it is important to build in a review procedure. The total hygiene system should be reviewed on a regular, continuous basis but no less than annually. In addition a review must be carried out if there is a change in the process or products.

4.12 Additional Hygiene Controls/Considerations

- Slow releasing chlorine tablets can be added to drains to reduce the amount of *Listeria* growth during the day. These will only be effective if food debris is removed from floors and not put down the drains.
- Bowl choppers blades/arm should be removed and cleaned daily, blades split down weekly, seals replaced monthly, and the cleanliness of the underside of the machine monitored.
- An additional chlorination stage can be introduced on key pieces of equipment to assist in the control of *Listeria*.
- The aim is to remove *Listeria* from factories, but there are some environments where this will not be possible. However, control is still possible (i.e. minimisation of risk)
- The introduction of back pack sprayers could be considered for short term use (e.g. following a contamination incident).
- Annual chlorination of site water distribution pipe work should be considered.

- Ongoing testing of mains water should be conducted, ensuring that the furthest point from in-feed is tested as a minimum.
- Random microbiological testing of general detergents for indicator organisms should be considered.
- Biofilm formation may occur within ring main systems and microbiological sampling should take place to a predetermined schedule, based on risk assessment (consult with cleaning chemical supplier).
- Water is an excellent medium for the distribution of *Listeria*. It is imperative that the environment is as dry as possible and the use of water in cleaning operations, particularly during production must, be kept to an absolute minimum.
- Remove hose pipes where possible and use buckets and disposable cloths to clean. Avoid simply pouring water/chemical over the machinery.
- Physically segregate wet operations from production areas (e.g. cleaning, rinsing, draining).
- Condensation can also contaminate products. Ensure that adequate extraction is installed and catch trays, ducting and canopy drains are not causing an issue.
- Ensure that there is no pooling of water on floors. Ensure that each room/area has a sufficient fall to drain. Where necessary and as a temporary measure only (e.g. pending floor replacement/repair) pools of water must be frequently scraped away to drain.
- Audit the cleaning process for high care footwear and take swabs of the cleaning equipment and footwear to verify cleanliness.
- Ensure that all cleaning equipment is cleaned frequently and is stored clean and dry when not in use
- Ensure that the bottom two shelves on racks are not use for the storage of food. This increases the distance between the floor and food. If the racks contain drainage trays, then the base tray should contain a catch tray to prevent the draining water reaching the floor.
- Disinfectants can be rotated if there is any evidence of the development of resistance.

5. What to do if *Listeria spp i*s detected in the product or factory environment

5.1 Legal requirements

EU Legislation requires that action is taken if Lm is detected in product or environmental samples

5.1.1 Exceedance of MCR Annex I, Chapter 1 Criterion (Food Safety)

In the case of a food safety issue arising, timely action must be taken to protect consumer safety. Actions required relate to Article 19 of 178/2002/EC and include:

1. In the case of own label product manufacture, immediate liaison with the brand owner.
2. Brand owner i.e. food manufacturer or retailer in the case of retailer own label products to notify Local Authority and FSA (Food Standards Agency) and recall final product.
3. Remedial actions in the supply chain should involve the consideration of:-
   i) What to do to re-establish control and prevent re occurrence of the hazard
   ii) What to do with product and raw material held in stock or in the supply chain that might be out of specification
   iii) When the action taken should be completed, i.e. the time-scale for the action
   iv) Who has responsibility for the action

5.1.2 Presence of Lm in RTE product at no more than 100 cfu/g; Exceedance of MCR Chapter 2 Criterion (Process Hygiene); Adverse Monitoring Trends

If there is evidence that Lm will not exceed 100 cfu/g during shelf life notification of the Local Authority and FSA is not required.

Internal action is required if process criteria in Annex I, Chapter 2 of the MCR are exceeded and on discovery of any adverse monitoring trends.

Internal action will include:

- Traceability of the sample
- Review of microbiological testing results
- Investigate common influences
- Monitoring at key points to establish the source of contamination or the breakdown of the process, e.g. equipment and external influences such as water quality issues
- Take corrective action
- Verify that the corrective action has been successful. This may include increased sampling

5.2 Investigation protocols – When Listeria spp or Lm is detected either in the environment or product

The following is a non-exhaustive list what to look for and how to look for it during an investigation and is derived from companies' experience.

5.2.1 Summary of Common Sources/Vectors of Contamination

- Water
- Drains
  - Removing and handling of drain baskets
- Leaks/dripping pipes
- Evaporators
- Boot washers
- Hose pipes
- Aerosols
- Wheels
- Boots

- Blast chillers
- Damaged walls and floors
- Wall/floor junctions
- Mincing and slicing machines
- Sealed bearings
- Equipment which can be cleaned without being totally dismantled, e.g. multi-segmented vertical form filler tubes
- Damaged equipment
- Undersides and feet of equipment, tables
- Racking close to the floor - do not use bottom rack of kiln trolleys
- Poor practice: GMP/people/process/
- Management-induced shortcuts and/or changes
- Poorly cleaned equipment – lack of deep cleaning
- Positive air pressure breaches
- Wrong filters being used in air handling units
- Running order - contamination arising on the line from the previous run
- Raw materials
- Poorly managed engineering intervention of equipment or structure of factory.

5.2.2 Action on Detection

- **Establish a multi-disciplinary team to focus on the issue which will be managed by the Site Technical Manager/Hygiene Manager or Microbiologist but must have full Site support.**

  Ensure that all results and action plans are communicated to Senior Management Team

- Review HACCP plan focussing on CCPs for the control of Lm. Where possible, ensure that there is a suitable and adequate processing hurdle in place.

- Audit (unannounced) implementation of the HACCP plan focussing on Prerequisite Programmes and CCPs for the control of Lm

- This should include an unannounced audit of the cleaning methods covering all points detailed in section 4 above, including; cleaning regime, level of dismantling documentation, frequencies, chemicals used and finished hygiene standards taking swabs of key inspection points. The auditor should be accompanied by an engineer to assist in the dismantling of equipment/plant to its furthest point. This should include both production changeover cleaning and hygiene cleaning.

- Poor hygienic design of plant/equipment can be a source of *Listeria*. Conduct a detailed investigation into the hygienic design of all production equipment and look for locations where product debris or water can penetrate. Engineering input maybe required to improve the design and/or access.

- Whilst conducting the above audits document your findings and include any harbourage points for food debris and/or condensation that require engineering input on equipment or increased focus/frequency by the hygiene department.

- Obtain a site plan and plot where positive environmental swabs have been found listing date and species.

- Maintain the company environmental swabbing plan, but also introduce additional swabbing in areas that are not normally swabbed. Look for areas where you suspect *Listeria* could be present and swab both during production hours and on completion of hygiene cleaning.

- Products that have had a positive test for *Listeria* are to be tested on a weekly basis and be placed on a rapid test. This is in addition to the normal product testing.

- Eliminate/reduce water from the factory, where possible, especially during production. Review the amount and location of hose pipes within the factory and remove where feasible and replace with a bucket point.

- Audit the low risk/high care barriers in the factory and ensure that they are adequate.

- Audit existing transfer methods into and out of High Care/High Risk and ensure that procedures are being followed. Check the before and after micro results of items passed into high care

- Ensure that any drains crossing the low/high barrier run from high care to low risk and check that the drains are not "backing up" and forcing water back into high care.

- Review the production planning schedules for both lines and preparation areas to avoid potential cross contamination.

- Check that products/processes known to be a potential source of *Listeria* are not used as thoroughfares and are kept as separate as possible with no unnecessary equipment stored nearby.

- Highlight any structural issues that require repair and organise for completion. This includes damaged flooring, kerbs, walls etc

- Review Raw material controls, carry out additional raw materials testing if appropriate and audit key suppliers to ensure correct practices are in place

- Enhance Positive release of key materials for *Listeria* where relevant

- Audit the effectiveness of positive air pressure systems for High Care/High Risk areas and confirm that any structural changes have been accounted for.

- Audit hand washing and glove disciplines, conduct hand/glove swabs.

- Audit High Care/High Risk changing procedures, PPE, hygiene equipment and footwear hygiene standards e.g. ensure that captive high care footwear is really captive.

- Conduct locker searches to ensure that key equipment/utensils are not stored in personal lockers.

- Where a *Listeria* issue persists and a clear trend cannot be isolated, ribotyping can be useful

5.2.3 Key Questions

Review the historical information to assess trends and any common factors and this will highlight any actions that are required. Below are some basic questions that can be used as a check-list to assist in any investigation:

- Has the problem occurred before and if so, how was it solved?

- Are the "swab samplers" and lab staff adequately trained (see section 6 below)?

- At what stage of the production process is the product first contaminated?

- Do results show any trends across lines, shifts, raw materials, equipment, utensils, plant, dates, times and order of production schedule or after engineering maintenance?

- Have there been any major changes i.e. new equipment, new chemicals, building work, raw material changes, new suppliers, recipe changes?

- Check water sampling/testing regime. Is the furthest point from mains in-feed tested and when was the last chlorination of the pipework?

- Are key chemicals (detergents) regularly tested for concentration? (Consider micro sampling of general purpose detergents).
- Is there any evidence of leaks or other issues within the roof void areas that could be contaminating production areas?
- Where do drainage pipes from the toilets and canteen run and are they intact?
- Are the cooking and cooling processes reaching the required temperatures?
- Are any produce washing methods adequate to reduce Lm to an acceptable level? Consider whether a second wash is required and/or whether the supplier's site and washing methods should be audited.
- If a sanitising tunnel is used, is it fresh water fed with 360* jetting and are operatives fully aware not to stack items on the belt?
- Is the transfer and storage of packaging at all stages being carried out hygienically?.
- Are all staff adequately trained and are appropriate personnel aware of the issues and actions that they should be taking?
- Is any hygiene barrier sufficient and have any breaches been noticed?
- Is the cold chain effective before and after despatch?

5.3 Case Study

When monitoring for *Listeria* and in an attempt to fully remove Lm from an environment the following actions are suggested - this example is for a high care ready meal facility.

- All mobile/transferable equipment and machinery is taken into low risk.
- All of this equipment is cleaned within low risk.
- All fixed equipment within high care is thoroughly deep cleaned in situ.
- All footbaths/bootwashers are deep cleaned.
- Any equipment containing food (i.e. – within chills) is transferred into designated chills with an adjoining door. The area containing food is classed as "dirty" and the adjoining chill which has been deep cleaned is obviously designated clean.
- All floors, drains and walls (up to 6' high) are deep cleaned and chlorinated.
- All equipment within low risk is then passed through ovens/Fessmanns at 86°C for 20 minutes, back into the high risk area.
- Clean equipment is then taken to the clean transfer area and food transferred over the barrier. On completion the chill which contained the food is deep cleaned along with the equipment. This equipment could be transferred to low risk, heat treated and floor areas re-cleaned.
- No production, engineering or contractors are allowed into the high care area whilst this is being undertaken.

Monitoring should continue after the above and this should assist in ascertaining where the source/issue is.

6. Test Methodology and Frequency

It is of key importance to be aware that the safety of food is neither guaranteed nor controlled by microbiological testing.

Recital 5 of the EU Microbiological Criteria for Foodstuffs Regulations (2073/2005, as amended) (MCR) states that:

"The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with micro-organisms for which the criteria are set."

For Food Business Operators (FBOs) to ensure that microbiological criteria are met, every preceding point in the chain should be monitored. However, owing to seasonality for example, monitoring should be regular and planned to allow trends to be identified and acted upon appropriately.

6.1 Legal/FSA position

The EU Microbiological Criteria for Foodstuffs Regulations (2073/2005, as amended) require Lm testing to include enumeration for ready to eat food excluding that intended for infants or special medical purposes where presence is not permitted (25g samples). The Regulations stipulate a specific approach that all should be following, i.e.

- EN/ISO 11290-1 for detection
- EN/ISO 11290-2 for enumeration

However, according to the Regulation, alternative methods to these may be used as long as they provide equivalent results validated against the reference method given in Annex I of the Regulation. Alternative methods must be:

- validated against the reference method, and if a commercial kit, certified by a third party using an internationally accepted protocol, i.e. ISO 16140 or a similar protocol
  Or
- validated by an internationally accepted protocol and authorised by the Competent Authority.

In 2007 the FSA issued guidance, stating that:

'businesses must have confidence in the results of any testing carried out if they are to properly validate and verify their food safety management procedures' and 'Enforcement authorities will sample and test for a variety of reasons and it is the Agency's view that they should be able to choose sampling and testing methods that are fit for purpose as long as these have been validated and provide at least equivalent results compared to the reference method.'

The Regulations stipulate a certain level of sampling for official control purposes and by the Food Business Operator (FBO) for minced meat products. Otherwise sampling is to be determined by the FBO on a HACCP and hygiene control procedure basis, as set out in recital 23, Article 4.2 and Article 5.1 of the Regulation.

Article 5.3 of the Regulation states that:

"The number of sample units of the sampling plans set out in Annex I may be reduced, if the food business operator can demonstrate by historical documentation, that he has effective HACCP-based procedures."

Given this, the number of samples outlined in the Regulation applies when sampling is carried out for official control (enforcement) purposes only, i.e. "*to specifically assess the acceptability of a certain batch of foodstuffs or a process*" (Article 5.4). Otherwise, it is for the FBO to determine the frequency of sampling, based on HACCP.

6.2 Testing timings: finished product and ingredients at start and end of life

Historical data provides the best indication of the behaviour of an organism in a particular foodstuff. When present, *Lm* has usually contaminated the product from the environment. In a factory environment, natural contaminants are likely to be stressed and will grow slower than those that have been grown for use in inoculation studies, i.e. as is the case in predictive models and challenge testing.

Data on the levels of *Listeria monocytogenes* present at the beginning and at the end of shelf life can be used to assess its potential for growth.

For example, if *Listeria monocytogenes* was detected in a (ready-to-eat) cooked meat product at the beginning of shelf life at a level of <10 cfu per g, and end of life data on a representative sample from the same batch showed levels remained no more than 100 cfu/g, then the data helps demonstrate that from a *Listeria monocytogenes* perspective, the product remains within the food safety criteria set out in the MCR, over its shelf life. Under such circumstances, a low level (<10 cfu/g) detection during shelf life will not result in a product withdrawal.

This approach is the most valid providing that the end of life samples tested, have either followed the normal route of distribution, storage and retail, (e.g. sampling from the shelf for retail products) or have been stored at temperatures closely simulating those conditions.

The limitation of this method is that for most of the time *Listeria monocytogenes* should be absent in the foodstuff; it can therefore be difficult, or take time to acquire such data. It also provides no information on safe shelf life for new products, particularly if a new product is introduced that is significantly different from those usually produced at the manufacturing site.

Manufacturers should therefore construct a database for *Listeria monocytogenes* consisting of appropriate samples taken at the beginning and end of life for each RTE product

6.3 Laboratory accreditation

The selection and performance of a microbiological testing laboratory is key to assuring that accurate data are generated. Concerns include not only false positive results, but also false negatives, which may give an unwarranted sense of security.

Consideration must be given to the following in the selection of a microbiological testing laboratory:

- Accreditation by an appropriate approved body to ISO 17025 e.g. UKAS
- Schedule of accreditation must list the methods required
- Methods must be appropriate and validated for the sample type
- Contracts must be drawn up with the laboratory to include
    - out of hours contacts
    - methods
    - reporting systems
    - maintenance of the chill chain
    - sample and culture retention
    - visit requirements
    - confidentiality
    - insurance

Laboratory operating hours and sample collection must match the business needs (e.g. 7 day week including Bank Holidays?)

Initial visits are recommended to assess on site expertise, key contacts, capacity, work patterns and weekend and Bank Holiday cover. Follow up visits at regular intervals (announced and unannounced) should also be done.

6.4 Action on presumptives

It should be agreed in writing between the laboratory and the client at what stage results should be reported. Specifications/limits should be agreed to enable out of specification results to be identified.

Care must be taken to clearly discriminate between suspect, presumptive and confirmed results, and define which results require direct reporting by telephone to the client and which require immediate action by the laboratory and/or client, as set out in the table below.

Table 3: Findings, Laboratory Action and Communication of Results

Finding	Action by Laboratory	Communication
Suspect colony or presumptive	Confirmatory test according to the internal methodology or as agreed with the external laboratory	From the laboratory to the manufacturer, in line with written agreement. The manufacturer to advise the customer of the findings.
Counts exceeding the Report level	Carry out additional testing as agreed with the manufacturer or customer	Advise customer of exceedance, in line with written agreement
Presence of Lm	Carry out enumeration	The laboratory to advise the manufacturer, in line with written agreement.
Counts exceeding the food safety criteria set out in the MCR (Annex I, Chapter 1)	Carry out additional testing as agreed with the manufacturer or customer	**Retailer own label product**: Manufacturer to advise brand owner of exceedance. Brand owner to advise Competent Authorities of exceedance. **Branded product**: Brand owner to advise Competent Authorities of exceedance.
Counts exceeding the process hygiene criteria set out in the MCR (Annex I, Chapter 2)	Carry out additional testing as agreed with the manufacturer or customer	The laboratory to advise the manufacturer, in line with written agreement. Manufacturer to investigate and take effective corrective action.

7. References/Further Reading

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Microbiological Testing and Interpretation Guidance, CFA, 2006

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8. Definitions

Barrier: the point of separation between two different hygiene areas.

Chiller: Equipment designed to reduce rapidly the temperature of product to a specified chill temperature.

Chill store: A facility regulated to maintain product at a specified chill temperature.

'Clean-as-you-go': Maintenance of work areas in a clean and tidy manner at all times.

Cleaning: the removal of soil, food residue, dirt, grease or other objectionable matter.

Container: (i.e. primary package): any box, tin, plastic or other receptacle, or wrapper in direct contact with the food product.

Contaminant: Any biological or chemical agent, foreign matter, or other substance not intentionally added to food which may compromise food safety or suitability.

Contamination: The introduction or occurrence of a contaminant in a food product, ingredient or environment.

Decontamination: Removal or reduction of contaminant(s) to an acceptable level for safety or quality, i.e. destruction of *Listeria monocytogenes* in a product by heat and/or chemicals or other validated means equivalent to at least a 6 log reduction.

Recontamination: The post-process introduction of a contaminant into a food product.

Control measure: any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Control Point (CCP): a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Disinfection: the reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability.

Establishment: any building or area in which food is handled and the surroundings under the control of the same management.

FBO: see 'Food business operator'.

Food or foodstuff: (As defined by EU Regulation) any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance. Does not include feed, live animals unless they are prepared for placing on the markets for human consumption, plants prior to harvesting, medicinal products, cosmetics, tobacco and tobacco products, narcotic or psychotropic substances, residues and contaminants.

Food business operator (FBO): the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

Food handler: any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

High Care Area (HCA): an area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment and environment are managed to minimise microbiological contamination of a ready-to-eat or ready-to-reheat product containing uncooked ingredients. Specific requirements for High Care Areas are given in Section 2.2.

High Risk Area (HRA): an area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment and environment are managed to minimise microbiological contamination of a ready-to-eat or ready-to-reheat product comprising only cooked ingredients. Specific requirements for High Risk Areas are given in Section 2.4.

Hygiene schedule: Documentation of procedures appropriate for dismantling or clean-in-place, cleaning and decontaminating (including methods, dosages and chemicals), the frequency of use or equipment and the monitoring procedures to assure compliance with hygiene requirements. The schedule includes in-plant environmental screening and also documentation for personnel hygiene systems.

Low Risk Area (LRA): an area where GMP standards are in place and where either raw materials are received into a factory or where final packaged product is handled.

Monitor: the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Packaging materials: materials such as cardboard, paper, glass, plastic film, metal, etc., use to manufacture containers or packaging for refrigerated packaged food.

Packaging - Primary: material in direct contact with food.

Packaging – Secondary: material not in direct contact with food.

Pre-distribution storage: Storage on-site under conditions controlled by the manufacturer.

Primary preparation: Cleaning and trimming of raw materials.

Primary production: those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

Raw material: individual components as received at the factory, used in the preparation of a final product.

Ready-to-cook (RTC) Food: food designed by the producer or manufacturer as requiring cooking or other processing effective to eliminate or reduce to an acceptable level microorganisms of concern.

Ready-to-eat (RTE) Food: food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing, effective to eliminate or reduce to an acceptable level microorganisms of concern.

Ready-to-reheat (RTRH) Food: food designed by the producer or manufacturer as suitable for direct human consumption without the need for cooking, but which may benefit in organoleptic quality from some warming prior to consumption.

Secondary preparation: size reduction of raw materials following primary preparation.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan.