

Food Safety Scheme Manual

Appendix 3: Controlling *Listeria monocytogenes* in the food processing environment

A guide for developing an environmental monitoring program

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Definition

Term	Definition
High-risk areas	Areas within a facility where ready-to-eat (RTE) foods are handled or packaged
Listericidal step	A processing step capable of reducing the amount of <i>L. monocytogenes</i> that may be present in food to a safe level
Listeriosis	An illness caused by the ingestion of <i>L. monocytogenes</i>
Low-risk areas	Areas within a facility before the final critical control point specific for <i>L. monocytogenes</i> is applied. Generally, it is where the raw ingredients, materials and intermediary products are handled
Niches	Sites within the food processing environment where <i>L. monocytogenes</i> becomes established and grows (for example hollow rollers on conveyers, space between close fitting parts, cracked seals and valves)

Purpose and Scope

This document provides a guidance to food businesses on how to develop an environmental monitoring program for the detection of *L. monocytogenes* in the manufacturing environment.

The guidance has been developed for businesses producing ready-to-eat (RTE) foods where:

- the food does not receive a listericidal step; or
- after a listericidal step, the food is further processed, handled or packaged.

Businesses producing RTE meat products should refer to the document ‘*Standard 4.2.3 – Guidelines for the Management of Listeria*’ (2019) published by the Australian Meat Regulators Group.

Businesses producing RTE dairy products should refer to the document ‘*National Guidelines – Pathogen Management*’ (ISFR, 2013).

While those documents provide information on controlling *L. monocytogenes* in the environment, the principals involved in implementing an environmental monitoring program are generic and consequently can be applied to the detection of other food-borne pathogens such as *Salmonella*.

What is *L. monocytogenes*?

L. monocytogenes is a bacterium that is commonly present in the environment and in food processing facilities operating at chill temperatures. This means that it can be found in many raw foods including fruits, vegetables and meats. It is a recognised foodborne pathogen and is of particular concern for some people within the community including pregnant women, infants, the elderly and adults with a lowered immunity (for example organ transplant patients, HIV/AIDS patients, cancer patients and those on corticosteroid medication). In these people, listeriosis can result in severe illnesses, with mortality rates as high as 35%. For pregnant women, infection may also result in spontaneous abortion or stillbirths. In otherwise healthy people, and where present in food at high levels (for example $>10^7$ colony forming units per gram), the bacteria can cause a mild self-limiting illness (for example vomiting and diarrhoea).

L. monocytogenes presents a problem for chilled RTE foods as it has been shown to grow at temperatures as low as -1°C . It has also been shown to grow at temperatures up to 50°C . It generally doesn't tolerate acidic environments with the minimum pH for growth being 4.4. *L. monocytogenes* is generally not very heat resistant and pasteurisation treatment (72°C for 15 seconds) is sufficient to destroy vegetative cells.

Determining whether a RTE food will support the growth of *L. monocytogenes*

Information on the food characteristics, shelf life and growth rate can be used to determine whether a RTE food will or will not support the growth of *L. monocytogenes*. In general, a RTE food will not support the growth of *L. monocytogenes* if:

- the food has a pH less than 4.4 regardless of water activity; or
- the food has a water activity less than 0.92 regardless of pH; or
- the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
- the food has a refrigerated shelf life no greater than 5 days; or
- the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption).

To demonstrate the above, some form of evidence would be needed, which could include:

- laboratory analysis for pH and water activity – the laboratory analysis would need to be reconfirmed should product formulation or processing change. Further, it would be expected that the analysis be repeated at least yearly.
- product specification – verification that the product has a refrigerated shelf-life of no greater than 5 days or is a frozen food.

If none of the above applies, the Standard 1.6.1 of the Code also allows RTE products where the growth of *L. monocytogenes* is limited as being regarded as not supporting the growth of the microorganism. This includes:

- Where the level of *L. monocytogenes* will not increase by greater than 0.5 log cfu/g over the food's stated shelf life.
- Where the product does not receive a listericidal process, the level of *L. monocytogenes* does not exceed 100 cfu/g within the expected shelf life.

Where businesses intend to use limited growth rate, the business will be required to provide evidence that the food meets the above criteria. Further information on how this can be achieved can be found in the FSANZ publication '*Guidance on the application of microbiological criteria for Listeria monocytogenes in RTE food*', which can be found on their website www.foodstandards.gov.au

L. monocytogenes in the processing environment

L. monocytogenes is a problem in the processing environment because it forms biofilms which are difficult to dislodge during cleaning and provide protection against sanitisers for internal cells in the biofilm.

While a listericidal step is important for eliminating *L. monocytogenes* during the processing of foods, controlling *L. monocytogenes* in the processing environment is important for preventing post-processing contamination in these foods. Evidence has shown that when *L. monocytogenes* is detected in processed RTE foods, this is often due to recontamination after processing. For RTE foods that do not receive a listericidal step, controlling the processing environment is important to minimise the potential for these foods to become contaminated.

While end product testing remains an important part of producing RTE food, it becomes of little value for assessing and verifying control due to the low prevalence and sporadic nature of *L. monocytogenes* in the products. Also, if a product is found to be positive, there is no information on the mode of contamination or how to prevent further occurrences.

Therefore, an environmental testing program targeting *L. monocytogenes* and taking appropriate action when *L. monocytogenes* is detected, is a better, more cost-effective measure to minimise and prevent the risk of product being contaminated.

The general strategies of an environmental program are to:

1. Prevent the establishment and growth of *L. monocytogenes* and other *Listeria* spp. in the food processing environment, especially on food contact surfaces and surfaces near exposed foods.
2. Implement a sampling program to assess whether the processing environment is under control.
3. Respond to positive environmental test results to eliminate *L. monocytogenes* from the processing environment.
4. Further sampling to verify that the environment after cleaning & sanitation is now under control.
5. Review of overall results monthly to detect problems and trends.
6. Review of overall results quarterly to assess wider trends and measure overall progress towards continuous improvement.

General control

Before designing an environmental monitoring program, it is important to ensure the fundamentals of good hygiene practices and good manufacturing practices have been adequately addressed. These form part of the supporting program for a HACCP-based food safety program and assist with control of *L. monocytogenes* and other *Listeria* spp. In addition, businesses must ensure they follow the requirements of the Australian New Zealand Food Standards Code (the Code).

Incoming materials

All raw materials entering the processing areas are a potential source of *L. monocytogenes* contamination. These include ingredients, packaging materials, additives, processing aids and other chemicals. Some important points to consider are:

- unpacking of incoming products (for example to minimise contamination of packaging into production areas).
- purchasing product from reputable businesses that have a food safety program (FSP) or quality system in place for *L. monocytogenes*.
- it may be necessary to periodically test incoming product for *L. monocytogenes*.

Facility location, design and structure

The facility location, design and structure play a big part in controlling *L. monocytogenes* in the processing environment, especially for RTE foods that require post-processing handling and packaging. Facilities that are not specifically designed for these processes need to have exceptional controls on the systems. Some important aspects include:

- the areas around the facility should be sealed, adequately drained, and maintained in a clean and tidy manner.
- the internal area of the facility should be designed to facilitate cleaning & sanitation, have sufficient drainage, and not allow the pooling of water. This is especially important in high-risk areas.
- where possible, there should be a physical separation between low-risk and high-risk areas. Where this is not possible, procedures should be established to prevent cross-contamination from people, materials and equipment from low-risk to high-risk areas. Positive air pressure system in high-risk areas may need to be considered. Adequate decontamination facilities between high and low-risk areas also need to be installed.
- there should be sufficient space between equipment to allow both the facility and equipment be effectively cleaned and sanitised.
- overhead fixtures and equipment where dust and foreign matter can accumulate should be avoided, especially in high-risk areas.
- doors and windows, especially in high-risk areas, should be appropriately sealed.
- if renovations occur, normal production should be discouraged. If production continues, consideration should be given to create a physical barrier between the two zones. There would also be the need to increase the frequency of cleaning and sanitation and environmental monitoring. Increased food testing should also be considered.

Equipment design

All equipment, especially in high-risk areas, should be appropriate for use and of good hygienic design and construction. The equipment should be maintained in a good condition and parts replaced when worn or damaged. Some points to consider are:

- avoid dead spaces as they may permit the build-up of ingredients or product and are difficult to clean and sanitise.
- use smooth and non-porous product contact surfaces.
- repair leaking taps, hoses and water/steam/condensate lines as they can be a source of contamination into the environment and food contact surfaces.
- do not place cooling units, refrigerators and insect control devices above any product processing or production area. Processed product should not be exposed to contamination from above (for example condensate on overhead pipes).
- use hands-free taps on equipment such as hand basins and footbaths.
- use food grade lubricants.

Cleaning and sanitation program

Effective cleaning and sanitation are important in controlling and eliminating *L. monocytogenes* and other microorganisms in the processing environment.

Cleaning and sanitation are two separate operations:

- Cleaning – the removal of waste, dirt and grease from equipment, premises, and vehicle. It can include dry cleaning or wet cleaning with the use of detergents.

- Sanitation – the process of reducing the number of microorganisms present on equipment and within the premises. It can include the use of chemicals, hot water, or steam.

The way equipment and the processing environment is cleaned and sanitised depend on many factors. The program must be tailored to the individual businesses. Important points to consider include:

- develop a Standard Operating Procedures (SOP) for the cleaning and sanitising program, especially for high-risk areas.
- train all staff on the importance of the program. A training register should be kept.
- the program must include all equipment and items that are used by the business in the processing environment.
- food transport vehicles must be included.
- cleaning and sanitation equipment should be appropriate for use.
- use appropriate detergents and sanitisers for food processing environment and use them as per the manufacturer's instructions, especially the concentration and contact time. Consider rotating sanitisers to ensure optimum efficacy in reducing microbial numbers. The chemical supplier's advice should be sought.
- thoroughly clean and sanitise equipment after any maintenance or repair work and before being used in production.
- seek advice from equipment manuals or suppliers regarding the extent to which equipment should be dismantled to enable its adequate cleaning and sanitation.
- certain types of wet cleaning, such as pressure spray hoses, should be avoided during production times as there is a potential for droplets to contaminate the product, or for spray to splash from the floor or drains on to the equipment. If wet conditions are normal for production areas, periodic foaming or flooding of floors with sanitisers is recommended.
- dry cleaning should be considered during production times where there is a build-up of waste or debris.

Personal hygiene

Good personal hygiene practice is vital in all food processing facilities as it prevents the cross-contamination of food from people and equipment. For businesses producing RTE products that receive post-processing handling or packaging, it is especially important. Other points to consider include:

- all staff, including non-food handlers, should be trained and follow good personal hygiene practices.
- additional training should occur for all staff working in high-risk areas.
- visitors should follow good personal hygiene practices.
- hands-free taps on hand basins and footbaths should be considered especially in high-risk areas with access to soap solution and drying equipment.
- personal protective equipment/apparel such as disposable aprons, gloves, hairnets, and beard nets should be used by all people entering the processing environment. Alternative colour coverings should be considered for high-risk areas. Waterproof boots should be worn by processing staff working in wet areas, and foot baths containing a sanitising solution should be located at the entrance to the manufacturing areas.
- direct access to high-risk areas from low-risk areas should be avoided.

- when entering high-risk areas from low-risk areas, hand and boot washing and sanitation facilities should be available and used. Complete change of protective personal equipment (PPE) is required.

Environmental monitoring program for *Listeria*

An effective environmental monitoring program can prevent the establishment and growth of *L. monocytogenes* in the processing environment and prevent it from becoming a source of contamination in food. The purpose of the environmental monitoring program is to detect *L. monocytogenes* before it enters the product. The program should be designed to find any *L. monocytogenes* that may be present, followed by action to remove it from the environment.

The program should be seen as an investigative program. The detection of *L. monocytogenes* means that the program has been successful in identifying the source of contamination and allowing its elimination. An environmental monitoring program where *L. monocytogenes* is not detected does not mean that the processing environment is free from *L. monocytogenes*. It may mean that the design of the program is not sufficient to detect the microorganism and thereby not preventing the establishment or growth of the microorganism.

Design of environmental monitoring program

The design of the environmental monitoring program is specific to an individual business and should be risk-based, considering the prior history of a facility with respect to *L. monocytogenes*, target consumers and the complexity of the processing environment. The program involves sampling sites across the processing environment to determine the presence of *L. monocytogenes*.

Sample sites

Generally sample sites are categorised based on their ability to come in contact with food as shown in Table A3.1. The selection of sites should be based on risk assessment and biased toward areas where *L. monocytogenes* may be present or those where niches are known to occur. The sites tested at each sampling period should be chosen to ensure all sample sites are included over time.

Table A3.1. Classification of environmental sampling sites as part of an environmental monitoring program.

Priority	Examples of sample sites within the priority zone
Zone 1 – food product contact surfaces	Slicers, dicers, hoppers, seals, gaskets, filling heads, mixers, storage vats, feeders, spiral freezer, conveyors including rollers, tables, benches.
Zone 2 – non-food product contact surfaces	Floors, walls, ceilings, drain outlets, cold rooms, switches, floor joints, crevices, pools of water, condensate from refrigeration evaporators.

Number of sites and frequency of sampling

Sampling should be determined based on type of product, size of facility/production, number of staff and resources. The minimum requirement, even for the smallest processors, is five samples across both zones at one time, preferable three sites in Zone 1 and two sites in Zone 2. In an ideal environmental monitoring program, *L. monocytogenes* should be detected and subsequently eliminated in Zone 2 preventing the contamination of Zone 1.

Table A3.2. A guide for frequency of sampling

Type of products	Frequency
Foods that can support the growth of <i>L. monocytogenes</i>	Weekly
Foods than cannot support the growth of <i>L. monocytogenes</i>	Fortnightly

Method of sampling

Sampling should occur by swabbing sites using sterile moistened swabs or sponges. An overview of environmental swabbing can be found in the NSW Food Authority's publication '*Environmental swabbing: A guide to method selection and consistent technique*' (2013b).

Written procedures should be developed detailing how to conduct the swabbing and all staff should be trained in the procedures, ensuring swabs are not contaminated by the person conducting the swabbing or from other surfaces not swabbed.

Testing of samples

All samples need to be tested for *L. monocytogenes*. Testing for *Listeria* spp. could be considered as results will be available sooner, although this should be weighed up with the fact that *Listeria* spp. will be more frequently detected in the processing environment compared to *L. monocytogenes* resulting in corrective action being required more often.

Samples can be tested at a laboratory that has accreditation by the National Association of Testing Authorities (NATA) or ILAC equivalent for testing of *L. monocytogenes* in environmental samples. An alternative is the use of certified rapid test kits. These kits require minimal equipment outlay, are easy to use and are relatively cheap (approximately \$10 per test). Only kits that have been certified using International Standard Organisation (ISO) methodology or have approval by the Association of Analytical Communities (AOAC) should be used. Kit suppliers should be able to provide advice on the type of certification or approval their kits have. If rapid test kits are used, it is recommended that samples are sent to a NATA (or ILAC equivalent) accredited laboratory periodically for verification.

Actions due to positive results

When *L. monocytogenes* is detected in an environmental sample, corrective actions should commence immediately to eliminate it from the environment. The corrective actions taken due to a positive result should be documented as part of the HACCP/ food safety program and treated as a whole system approach.

Whenever there is a positive environmental sample for *L. monocytogenes* from either Zone 1 or Zone 2 surface, the business should increase the frequency of environmental testing to daily until three consecutive negative results are obtained. The purpose for increase testing is to monitor the effectiveness of the corrective action undertaken. Consideration should also be given to whether the frequency of environmental testing or the sites of testing need to be altered for the future.

Table A3.3. Actions to be taken due to positive results

Positive results	Actions to be taken
From zone 1 – food product contact surfaces	<ol style="list-style-type: none"> 1. Production should cease immediately. 2. The surrounding area and equipment are cleaned and sanitised. 3. All batches of product produced since the day of swabbing should be tested as per Standard 1.6.1 of the Code. If the products are positive for <i>L. monocytogenes</i>, depending on whether they can support the growth of <i>L. monocytogenes</i> or not, appropriate actions should be taken (see Figure A3.1) . 4. Prior to recommencing production, swabbing is repeated (Zone 1 and 2) <ol style="list-style-type: none"> a. Negative result – recommence production, increase environmental monitoring. b. Positive result – dismantles all equipment and conduct a deep clean of area and equipment. Reassemble equipment and sanitise. Repeat swabbing, cleaning and sanitising until negative result obtained. It may be necessary to test sites other than the normal environmental monitoring sites to determine the source of contamination with <i>L. monocytogenes</i>.
From zone 2 – non-food product contact surfaces	<ol style="list-style-type: none"> 1. The implicated areas are cleaned and sanitised. 2. Prior to recommencing production, swabbing is repeated (Zone 2) <ol style="list-style-type: none"> a. Negative results – increase environmental monitoring. b. Positive results – conduct a deep clean of area. Repeat swabbing, cleaning and sanitising until negative result obtained.

Review of results

The overall results should be reviewed at least monthly and quarterly to detect problems or trends over the period. This can be achieved by recording results on a map of the facility and examining to see if there are areas or equipment where contamination is re-occurring.

If problem areas or equipment are identified, a concentrated effort of monitoring around the area may assist with identifying the source of contamination. Further, a thorough cleaning of the area may be needed to eliminate any potential source. The environmental monitoring program may require modification to ensure that these problem areas are swabbed more frequently, especially if they are considered to be high-risk food contact sites.

Product testing

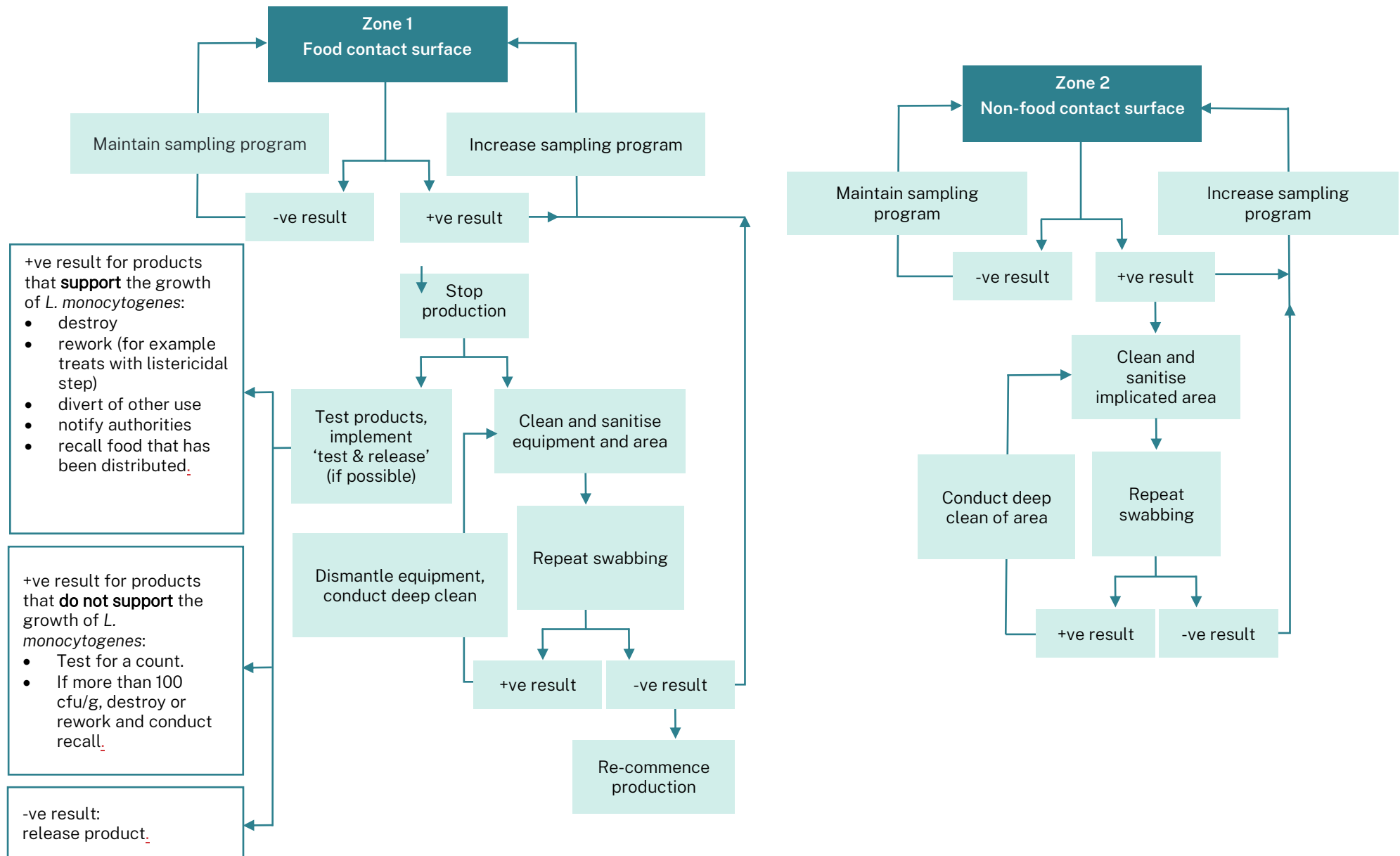
End product testing for *Listeria* is a useful activity that forms part of the verification of the control measures. Product testing alone is not sufficient to demonstrate the safety of food because it has a high probability of not identifying contaminated product even when large sample numbers are tested. Keep in mind that if product contaminated with a low level of *Listeria*, not all units in the batch may be contaminated.

Food should be tested according to Standard 1.6.1 of the Code. The Standard specifies the microbiological safety criteria for certain foods, including the sampling plans and limits. Foods that fail to meet those limits may pose a risk to human health and must not be offered for sale.

Conclusion

The adoption of a testing program that encourages frequent and targeted testing of *L. monocytogenes* in the environment, followed by appropriate corrective actions for positive results will result in a better consumer protection. It may also provide a financial benefit due to reduction in product losses, or loss of confidence in the brand and subsequent financial loss following a product recall.

Figure A3.1 Flowchart for environmental swabbing program



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- Visit foodauthority.nsw.gov.au
 - Email food.contact@dpird.nsw.gov.au
 - Phone 1300 552 406
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