European Chilled Food Federation
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PRINCIPLES OF AN ENVIRONMENTAL MONITORING PROGRAM FOR THE MANAGEMENT OF *LISTERIA MONOCYTOGENES*

Contents

1. Introduction and Context

Since *Listeria* (*L*.) *monocytogenes* (*Lm*) is an environmental contaminant occurring widely in both agricultural (soil, vegetation, silage, faecal material, sewage, water), aquacultural, and food processing environments, some foods are more likely to be contaminated e.g., raw vegetables, fish and meat.

Although frequently present in raw foods of both plant and animal origin, sporadic cases or outbreaks of listeriosis are generally associated with ready-to-eat (RTE), refrigerated foods, and often involves the post-processing recontamination of cooked foods.

Control of *Lm* for many RTE products will typically require a stringent application of Good Hygienic Practice and other supportive programs. These prerequisite programs, together with HACCP provide a successful framework for the control of *Lm*.

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

2. Microbiological Cross-Contamination

Microbiological cross-contamination is a major issue with respect to *Lm*. It can occur through direct contact with raw materials, personnel, aerosols and contaminated utensils, equipment, etc. Cross contamination can occur at any step where the product is exposed to the environment, including processing, transportation, retail, catering, and in the home.

An effective environmental monitoring program is an essential component of a *Listeria* control program, particularly in establishments that produce RTE foods that support growth and may contain *Lm*.[1]

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

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

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

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

1. **Product design.** Understand the structure, composition and characteristics of the product to establish the level of control required for its safe production and ensure potential growth of *Lm* is prevented or minimised.

2. **Raw material Risk Assessment**. To include water, air, ice, steam, packaging etc. and establish any potential risk of contamination from all incoming raw materials. Determine any further processing or controls required to minimise contamination of the manufacturing area and ensure a safe finished product. Good stock control systems must be in place.

3. **Premises design and layout.** Ensure processed materials are not re contaminated by people, equipment or manufacturing areas which have been in contact with unprocessed materials. Determine the barrier mechanisms (segregation) in place to prevent contamination and which require monitoring.

4. **Equipment.** Must be well designed to prevent harbourage and allow for easy cleaning. Where equipment is found to have harbourage areas, these must be eliminated by redesign or repair or the frequency and depth of machinery strip downs must be validated, verified and monitored to prevent harbourage of *Listeria*. Equipment which is infrequently used must be re-sanitised immediately prior to use.

5. **Building work / renovations / maintenance.** Work must be managed to prevent contamination of both food or the manufacturing environment by any debris, contamination or equipment used. A risk assessment must be carried out and controls in place prior to the work commencing. In addition to building work, this includes repairs to equipment, fabric, floors, blocked pipework and drains and installation of new equipment.

6. **Waste management.** Ensure the correct routes through the manufacturing area to prevent recontamination of processed foods by waste. Waste must not accumulate.

7. **Cleaning and disinfection.** The manufacturing areas and equipment must be cleaned and disinfected to eliminate *Listeria* from food contact surfaces and reduce levels on non-food contact surfaces e.g. floors to a minimum.

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

Cleaning methods must be validated, verified and monitored. Cleaning carried out during production must be risk assessed to ensure that product or ingredients are not cross contaminated. Niche environments should be eliminated. Hygiene and production schedules must be monitored to ensure adequate time and resources are available. A risk assessed and regularly reviewed environmental swabbing plan must be in place to enable continual monitoring of cleaning practices to ensure their continuing efficacy.

8. **Personal hygiene**. This includes hand washing, use of appropriate PPE dedicated to specific areas and according to the risk of cross contamination, and general good practices of the manufacturing staff to prevent cross contamination.

9. **Removal of water - humidity and ventilation.** Water and condensation provide moisture for bacteria including Lm to survive and potentially grow. Isolate wet areas and eliminate standing water. Remove hoses before production and eliminate aerosols. Adequate ventilation is required to prevent condensation and humid air must be exhausted. Where possible, heat air after cleaning to aid drying.

10. **Storage**. Storage areas must be temperature controlled with good air flow, designed to prevent cross contamination and condensation and allow for regular cleaning without risking cross contamination of processed food.

11. **Training.** All personnel must be appropriately trained for their duties with particular attention to food safety and the risk of cross contamination, including *Listeria*. Sources of contamination must be understood as well as the way *Listeria* can be transferred onto food contact surfaces and potentially onto processed food. Personnel should be encouraged to identify potential risk.

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

3. Core Principles

An effective environmental monitoring program is essential to control Lm in RTE manufacturing facilities as it can be used to monitor the effectiveness of control of e.g. premises, equipment, building work / renovations, waste management, cleaning and disinfection, personal hygiene, ventilation and storage areas.

"Occasional positive results (i.e. for *Listeria* species) should not be seen in isolation as a failure of control but as verification that the monitoring program is effective. An environmental program which is not capable of detecting contamination may be misleading as the business believes that the environment is under control when in fact it may not be so." [2]

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

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

The necessity for an environmental monitoring program is highest for RTE foods that support *Lm* growth and that are not given a post-packaging listericidal treatment[3]. Recontamination from the environment has led to many of the

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

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

recognised outbreaks of listeriosis. One effective element of managing this risk is to implement a monitoring program to assess control of the environment in which RTE foods are exposed prior to final packaging.

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

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

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

4. Developing an Environmental Sampling Program

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

a) Type of product and process/operation

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

b) Type of samples

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

c) Target organisms

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

d) Sampling locations and number of samples

The number of samples will vary with the complexity of the process and the food being produced. Locations should be considered a risk that are chilled, damp / wet, undisturbed e.g. difficult to clean or access or damaged and are in the proximity of food. Guidance on potential risk locations can be taken from section 8, published literature, and based on process experience, expertise or in plant surveys. Sampling locations should be reviewed on a regular basis (minimum annually). Additional locations may need to be sampled depending on special situations such as major maintenance or construction or when new or modified equipment has been installed or when changes in working shift patterns are required.

e) Frequency of sampling

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

f) Sampling tools and techniques

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

Fig 1

Fig 2

Fig 3

Fig 4

g) <u>Taking environmental samples</u>

All personal taking environmental samples must be appropriately trained.

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

Prior to taking samples hands must be washed and dried.

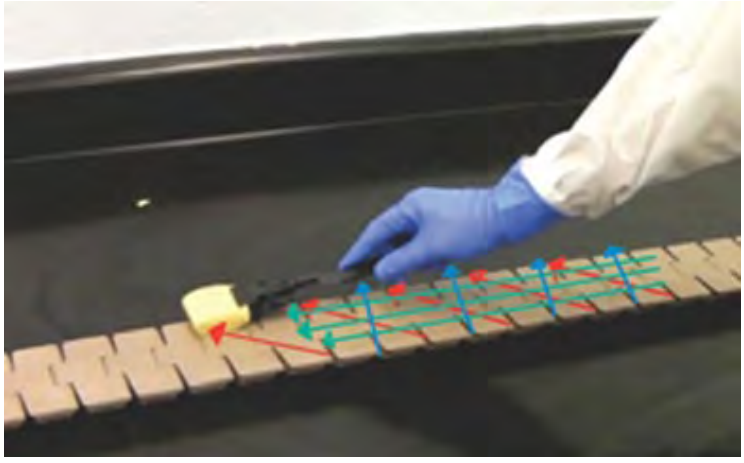
All swabs and sponges must be pre-moistened with either:

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

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

A surface area of approx. 30x30cm is recommended where possible (templates should not be used as they can transfer contamination), however if this is not possible the trained personnel should swab areas in a consistent way for each location to enable results to be compared and trended. Swabs must be taken by swabbing or wiping the sponge over the surface vertically and horizontally, if a swab is being used it should be turned whilst wiping the surface (Fig 5). Sponges must be held through a sterile plastic bag or sterile disposable gloves.

Fig 5



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

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

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

Samples must be stored at 5°C +/- 3°C[4] and ideally tested within 24 hours of the sample being taken. Label the samples with enough detail to enable trends to be monitored, e.g. date, time, **exact** location, pre/ post clean, during production etc.

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

h) Analytical methods

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

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

i) Data management

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

These could include:

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

Factory mapping should only be used for stationary swab locations, and mapping should restart if actions have been taken to eliminate sources.

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

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

5. Actions in the event of *Listeria* detections

The purpose of the monitoring program is to find *Lm* or other *Listeria spp* if present in the environment. Generally, manufacturers should expect to find them occasionally in the processing environment. There is no requirement to inform enforcement agencies but an appropriate action plan should be designed and established to adequately respond to *Listeria* detections. Investigations should initially confirm appropriate CCPs continue to be in place and monitoring data should be checked e.g. temperature monitoring, chemical concentrations followed by investigations into the hygiene procedures and controls. All data leading up to the positive result / trend should then be reviewed, rather than immediately collecting further samples without planning. This review will include microbiological results for finished product, component, raw material, hygiene (including ATP if used), including indicator organisms as well as any previous investigation sample results. Therefore, investigations can be planned and targeted to establish the contamination source or verify actions. Actions may include observing practices, auditing cleaning / production methods, dismantling equipment and taking swabs from inside, collecting component samples from different points of production. These results need to be received and reviewed before further action and samples are taken. The manufacturer should react to each positive result; however, the nature of the reaction will depend upon the level of contamination, likelihood of contaminating the products and their expected use. The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of recontamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices and testing of product. Particular attention must be paid to any increasing trends, in which case a multi-disciplinary team is needed to develop and effective action plan which is routinely monitored and actions verified. Molecular methods to further type isolates held by the laboratory, may identify common sources of contamination. (Examples of actions are given in section 9).

Both corrective and preventative actions must be considered.

All actions must be validated, monitored and verified.

6. Additional Samples to be Taken

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

- Raw material samples on intake and in high care manufacturing areas
- Component samples within the manufacturing area or from equipment after processing. This can allow the detection of *Listeria* that is not removed during cleaning, harbouring within equipment and is released while the equipment is used. Component samples can also be used to detect any cross contamination from the surrounding environment and practices.
- Finished packed product, as this sample incorporates all raw materials, processes, equipment, handling, storage. Samples must be routinely tested either at point of manufacture (if growth of *Listeria* is not supported) or end of the shelf life (if growth is supported OR if this is unknown). This is to build data to demonstrate compliance with EU Regulation 2073/2005. Any positive results must be enumerated to demonstrate the criterion of 100cfu/g has not been exceeded.
- Hand swabbing (or gloves if worn) to monitor hand hygiene, especially in high care / high risk areas where product is handled.

- Condensate samples e.g., from evaporators, this will monitor any *Listeria* in the evaporators or any dead legs in the pipework or extraction hoods to identify moisture trap points. Work in progress samples (components awaiting assembly) from the production lines or in storage, to assess any potential cross contamination.

- Rinse water taken from pipework or CIP systems to assess the effectiveness of the cleaning and any potential harbourage points or dead leg

- Water, ice, compressed air samples, air samples at the high care /low risk interface.

- Product debris i.e. particles of food that may accumulate under belts, on scrapers and at transfer points

7. Enforcement Aspects

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

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

8. Particular Risk Points

Materials
Raw materials, packaging, films

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

Periodically cleaned / in frequently used equipment. Lubricating oil (should include listericidal agent).

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

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

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

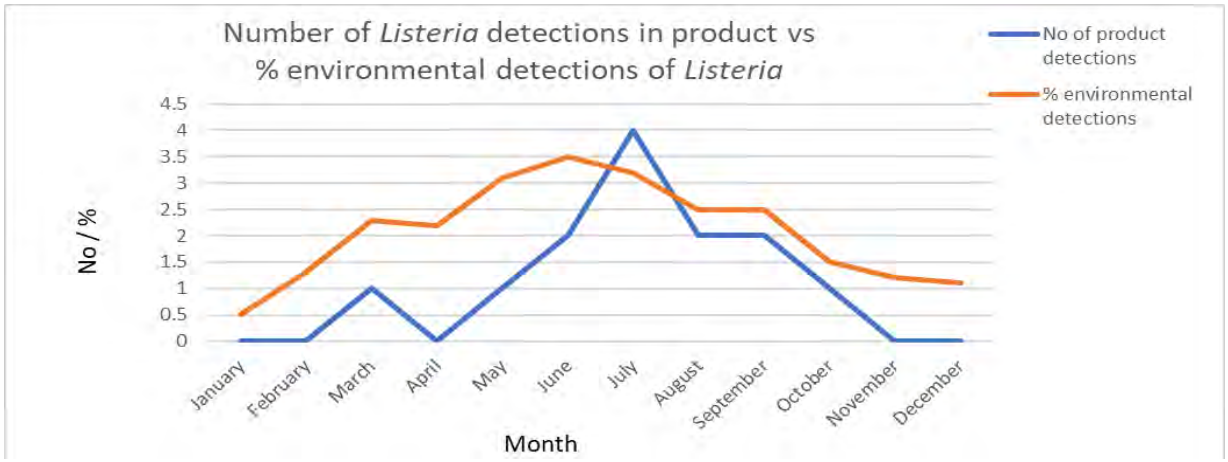
9. Examples of Actions

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

10. Examples of Trending

Keep trends simple and up to date

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



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