https://doi.org/10.4315/FPT-25-015

Listeria monocytogenes for Beginners: Hard Lessons Learned

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SUMMARY

If dealing with *Listeria monocytogenes* is new to you (and even if it is not), this article will provide you with useful background on the organism – what it is, how it grows, why it can be bad for public health, and its regulatory status around the world. Principles will be shared on how to find the organism, and resources described to assist in this endeavor. *Listeria monocytogenes* is a common concern in almost all food plants, so there is a wealth of knowledge available to help you.

INTRODUCTION

If you cannot pronounce "*Listeria monocytogenes*," (lih·steer'·ee- uh ma'·no·si·taa'·jin·eez) then this article is for you. If you are new to food manufacturing, then this article is for you. If you are new to a role in Food Safety and Quality Assurance (FSQA), then this article is for you.

Moving into a role in which *Listeria monocytogenes* (or "LM") may be your worst enemy is daunting and scary. The stress can affect your ability to make the right decisions, and to make them in a timely manner.

There is much written about LM and the body of knowledge can feel insurmountable, especially if there are active LM issues in your plant. This article is meant as a primer to deal with LM, providing enough background so that you can attack and control the pathogen with confidence. This confidence should also allow you to avoid some of the hard lessons that others have learned.

This article provides technical background about LM, including the regulatory rationale for FDA and USDA taking action in a food plant. It also provides some risk-based sampling and analysis principles to help guide your work. Finally, there are references from the experts who have saved the day many times with your colleagues from other companies.

By the end of this article, you may not be able to pronounce the name any better, but you certainly will know more about LM and might even look forward to the technical and aspirational challenges of keeping it at bay. Doing so is a very rewarding and essential way to protect public health. You can do this!

Listeria monocytogenes

"*Listeria*" is a family of bacteria, also known as a genus. Almost all members of that family get along well with each other, and do not cause any issues. *Listeria* species (*Listeria* spp.) are ubiquitous and are found everywhere – soil, groundwater, rotting vegetation, and animal feces. But at least one member of that family, *Listeria monocytogenes* ("LM"), is bad. It can cause illness and even death. As a pathogen, it is extremely unwanted and highly regulated. Almost all other members of the genus, such as *Listeria innocua* and *Listeria welshimeri*, are non-pathogenic.

Listeria was originally named "*Listerella*", in honor of the famed British surgeon, Sir Joseph Lister, who was an early proponent of using antiseptics during surgery. When it was discovered years later that the original name was already being used for a mold, the name was changed to *Listeria (21)*. "Monocytogenes" was chosen because the bacterium elicits monocytes (a white blood cell) in mammals as a response to their infection. The name was taken from the Latin, "*monocytus*" and "*genes*", meaning "monocyte producing."

LM is easily transported into a food facility through a variety of mechanisms, including personnel, equipment, air, water, and ingredients. LM is insidious: it is odorless, colorless, and tasteless. FDA explains LM in an easy-to-read overview document, "Get The Facts About *Listeria*" *(26)*.

From a microbiological point of view, LM is a Gram-positive, facultative anaerobe, meaning that LM can grow with reduced oxygen. This is one of many attributes which make LM adaptable to various foods (e.g., vacuum packaged). LM is one of the most virulent foodborne pathogens. Once it makes its way into food, it can infect a susceptible human and cause listeriosis, a very severe food-borne illness that can lead to sepsis, meningitis, encephalitis, or death.

LM is also a very hardy organism. It can survive pH ranges from approximately 4 to around 9 and temperatures from very cold refrigeration (near 0°C/32°F) to high heat (45°C/113°F), which also are ranges in which the bacterium can grow. Since LM is hardy, it can survive freezing temperatures and dry conditions, waiting for the opportunity when the organism can find itself in warmer temperatures with adequate energy sources and moisture to begin to grow again. LM may also form biofilms, or protective slime layers, that make the organism much more difficult to detect and eradicate and make it more resistant to disinfectants and sanitizing agents *(14, 19)*.

Food scientists, regulators, and auditing bodies often make different risk judgements between RTE (ready-to-eat) foods and cooked foods because the latter have "kill steps" which reduce the risk for bacterial growth. They also may assign a lower risk to foods with additional factors ("hurdles") such as low pH or use of preservatives. However, do not assume

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that cooked foods and/or foods with preservatives are free from LM, given how hardy the organism is. Assume LM can be present, even in "low risk" foods, and sample and test to confirm the absence of the organism (in the food, in the immediate processing environment, etc.).

Do not be fooled into thinking that LM is not in your plant environment, incoming ingredients, or end product just because interventions, such as freezing temperatures, acidification, high salt, or low water activity are employed. Measure, verify, and validate your way into an actionable risk assessment for the pathogen.

REGULATORY BACKGROUND

Public health notices, safety alerts, market withdrawals, and recalls due to LM can happen to the smallest and to the largest of food companies. No food company is immune from these actions should something go awry with practices, procedures, processing, or personnel.

It is unfortunate that despite hard lessons already learned, history still repeats itself: major recalls due to LM occur, no matter how costly the previous recall was, or how many people were affected. To wit, look at the examples of recalls provided in the *Appendix*. Note the wide variety in the type of food product and size of the implicated company.

For regulatory enforcement, FDA and USDA have instituted a "zero tolerance" position regarding LM in certain foods – the organism cannot be present in a 25 gram sample. From FDA's "Compliance Policy Guide" *(23)*: "… criteria for recommending legal action to CFSAN/Office of Compliance: *L. monocytogenes* is detected in one or more subsamples of a RTE (ready-to-eat) food that supports the growth of *L. monocytogenes*." Although this guide is still a "Nonbinding Recommendation", if LM is detected in your plant, then you could be at risk of legal action by FDA.

In contrast, the Canada *Listeria* Policy *(8)* says the following: "…the *Listeria* policy separates RTE foods that support the growth of *L. monocytogenes* … to levels not exceeding 100 CFU/g," and emphasizes the importance of environmental sampling in areas where RTE foods are exposed before packaging. Similar guidelines are presented in Australia, from their Food Standards Australia New Zealand *(7)*:

- for RTE foods in which growth of *L. monocytogenes* will not occur, the limit is less than 100 CFU/g.
- for RTE foods in which growth of *L. monocytogenes* will occur, *L. monocytogenes* must be undetectable in 25g.

Whether one agrees with a zero-tolerance policy or not, finding and eradicating LM in a food plant is essential work. Not doing so can be a huge cost to a company in recall expenses, public relations, and/or brand damage – along with the costs to public health and having to settle lawsuits.

TO LOOK FOR LM OR NOT

A strategic and ethical question must be answered by those with the important responsibility for safe food production: Do you want to know where *Listeria* spp. are hiding in your plant, and if you find it, do you want to know if any of them are LM?

Whole genome sequencing (WGS) is like testing for one's ancestry. Bacteria can be typed and categorized based on their genetic or deoxyribonucleic acid (DNA) makeup. With an extensive database, such as the national laboratory network PulseNet *(20)*, FDA may be able to link the DNA from a LM environmental sample in a plant with the DNA from a sample from someone who has been hospitalized with listeriosis. If also linked by epidemiology (e.g., the food was purchased in the same state as the plant is located; the consumers say they ate that specific food), then FDA may have a cause-effect relationship that supports regulatory action.

With a zero-tolerance policy in the USA, the finding of LM in a food can provide technical, ethical, and legal challenges. Consider the following comments as published by the UK-based Chilled Foods Association, "*Listeria* and Zero Tolerance" *(4)*:

"For the average healthy person the risk of becoming ill with listeriosis from food is very small and scientific evidence has shown that *Listeria* are consumed commonly with no ill effects. Because of this, EU legislation supports a risk-based policy allowing up to 100 colony-forming units of LM/g (with certain exceptions) present in food at the end of its shelf life. In contrast, the US, traditionally, has favored a zero tolerance approach for LM for all foods. This means that the presence of any amount of the bacteria is not permitted.

But this target is impossible to achieve consistently as LM is ubiquitous in the environment. In addition, the US chilled food market is very different from the UK where manufacturers apply shorter shelf lives than elsewhere in the world. In the US, as a result of the zero tolerance policy, there is relatively little testing for LM in foods."

Related, that same organization has published the following statements in "Consequences of LM Zero Tolerance" *(3)*:

"The 100/g limit specified in EC 2073/2005 allows the manufacturer to actively search for *Listeria* species in the manufacturing environment, in components, in raw materials and verify the control of LM by testing finished product.

A zero tolerance/Not Detected (ND) approach is an unrealistic expectation and will not remove the fact that *Listeria* is ubiquitous in the environment and therefore will occasionally be present in minimally processed foods and chilled wet manufacturing environments."

For further background, there is a publication on WGS that addresses the strategic difficulty of testing to find LM versus the risk regulatory action *(13)*.

TO TEST FOR LM, OR NOT

Many US food manufacturers test for *Listeria* spp. (the genus) and not LM specifically; or they test for a "marker organism" such as *Listeria innocua*. Both approaches allow for the identification of "*Listeria*-prone" locations without having to identify LM specifically.

It is important to note that an organism such as *L. innocua* might out-compete LM in the environment and/or in some microbiological tests. This finding could lead to a false conclusion that LM is not present *(16)*.

Given the above issues, it is better to assume that if a non-pathogenic *Listeria* species can grow or be harbored in an equipment niche, then conditions may be right for LM to grow also. One can then take appropriate corrective actions. With this approach, the company is not getting direct confirmation of LM, so it does not fall into the "zero tolerance" conundrum. However, if this approach is used, and the company takes no or minimal corrective actions, then there is a high risk of potential problems. The better approach is to assume that LM may be present and to take appropriate corrective actions. An even better approach may be to sample and test for LM, find it, get the WGS results to assist in mapping its persistence or spread, and take an aggressive approach to eradicate it. However, this methodology takes a lot of corporate courage in navigating the finding of LM in a regulatory environment of zero tolerance. And it takes time, money, and resources.

FINDING LM

Companies with robust Preventive Controls, Hazard Analysis and Critical Control Point (HACCP), or food safety plans also have an active "Environmental Monitoring Program" (EMP) in place. The EMP is critical – it is a program centered on finding pathogens in the plant. The EMP includes finding niches and harborage sites, transfer points, and use of "zones" to identify how close potential contamination could be to food. Cornell University and 3M put together a helpful overview of these types of programs, "Environmental Monitoring Handbook for the Food and Beverage Industries" *(6)*. Their review covers topics such as sampling for pathogens, spoilage organisms, and allergens, and how to use an EMP to drive food safety culture change.

The Institute of Food Technologists has also published a review on design elements for EMPs *(27)*.

In addition, several scientists paved the way for the rest of us by understanding and sharing the hard lessons they learned. Dr. Bruce Tompkin developed the initial guidance for controlling LM in the plant environment *(19)*. Dr. Jeff Kornacki has extensive experience across a wide diversity of plants and product types *(12)*. Dr. John Butts developed a "seek out and destroy" method that is highly applicable to the control of LM in a plant *(1)*. Dr. Peter Taormina has brought awareness to the types of sanitizers used and the bacteria they are effective against *(18)*. Dr. Joseph Frank has published data *(5)* on LM biofilms on stainless steel. And Dr. Brigitte Carpentier has published a review *(2)* on LM persistence on food equipment.

Below are some of the hard lessons learned by others regarding EMPs.

LM is hard to find. It is even harder to figure out where it came from. You cannot see it (it is not purple!), and so the only way to discover it is by robust microbial testing. In parallel, one needs to consider where it might be. Some zones are clearly easier to assess than others, e.g., a flat dry surface away from production, as opposed to water moving from a piece of equipment to a drain.

Be calm and patient. Finding the root source of LM contamination takes methodical work, and lots of time and effort. There are also typically a lot of dead ends when LM is found in one location, then never found there again. Or when LM is consistently found in one location, with no obvious root source (see case study below).

Do not over-sample. There is a tendency to sample everywhere, just to find *Listeria* spp. or LM. Sampling takes a lot of time and costs a lot of money – with no guarantee that a root source will be found. Rather, use sound judgment, and take a risk-based approach based on historical data. Such data can identify "hot spots" which have occurred from time to time, and, by contrast, areas in which LM has never been found.

Use risk-based sampling strategies. Take a hard look at the environment, speak with experts, and sample where you think the bacteria might be. Assess risk based on zones, employee behaviors, and sanitary (or not) equipment design. Also assess risk based on how effective sanitation programs are, how personnel and equipment move around the plant, and how well trained in HACCP and food safety practices the production personnel are. Below are some other possible risk factors to evaluate:

- fully-cooked vs. ready-to-eat foods
- hand-packed vs. machine-packed foods
- high-volume (seasonal) production vs. low-volume production
- no preservatives in the recipe vs. multiple preservatives
- high water activity vs. low-water activity foods
- higher pH vs. lower pH foods
- patterns of contamination vs. history of acceptable APC (aerobic plate count) and/or ATP (adenosine triphosphate) results
- high traffic area vs. low traffic area
- high water area vs. low water area
- second shift vs. first shift
- newer employees vs. experienced, well-trained employees
- USDA inspections vs. FDA inspections

Don't just sample indiscriminately all around the plant; instead, be systematic and thoughtful in sampling. Note that some third-party software programs that help with management of sampling tend to propose sampling "everywhere". So, if you use a program, do so smartly.

CASE STUDY: THE WALL

Through EMP sampling, LM was found across a very large section of a RTE food plant and in multiple locations. At first glance, the sample results appeared random. When sampling was repeated over several months, no discernable pattern led to the discovery of the "mother lode" which would help identify the root source of the pathogen.

LM was found in stainless steel troughs 10 feet above the kitchen hoods. LM also was found in drains 20 feet from those hoods. The kitchen was generally warm, with lots of steam due to the constant cooking of vegetables. LM also was found in the hallway outside the kitchen area, where water was pooling, even though a check of plumbing in the wall showed no leaks.

LM also was found in a refrigerated room next to the kitchen, where packaging of food items was occurring. Positive LM samples were found along the base of the shared wall and in the drains 10 feet away. Positive and negative LM samples were found in these locations over several months, yet with no obvious consistency in results.

Given the issues encountered, the food safety team hypothesized that since the shared wall had a large temperature gradient across it (warm kitchen on one side, cold packaging area on the other) then this gradient could result in constant internal condensation. As a result, holes were drilled into the wall from the packaging side (up to eight feet high), with lots of liquid pouring out of each hole meaning the wall was full of liquid. Subsequent microbiological testing confirmed that every sample taken from that wall was positive for LM. As a result, the production areas were taken out of service, and the wall was completely taken down – all two stories of it. The area was cordoned off and restricted since it was known that LM would flow from the wall.

Once the wall was removed, a concrete footer upon which the wall was placed was found to have many holes and drainage flaws. The holes were not visible in the intact wall and whoever inspected the initial concrete pour did not look carefully at this flaw. As such, water was trapped until it leaked through the concrete holes.

The wall was re-engineered and sealed on both sides. Further precautions were taken by moving packaging equipment away from the wall, as well as a nightly application of a sanitizer powder on the floor in that area and in the adjoining hallway (where the residual water was originally found). These areas also became part of the sampling program in the plant's EMP.

To date, LM has not re-appeared in that section of the plant and therefore, the plant personnel believe that they were successful. Seeking out LM root sources take far more than just a QA technician swabbing areas in a plant. Everyone owns this process. The entire project from start to finish took six months.

REFERENCES FOR LM

There are innumerable technical publications over the past twenty years addressing LM. Some of the more seminal papers were listed previously *(1, 12, 19)*. These papers were written by scientists who learned their LM lessons the hard way–through a lot of trial and error. Given their work, the pathogen is much better understood and public health is much better off because of them.

A good all-around reference book is "Modern Food Microbiology" *(10)*. Chapter 3 covers intrinsic characteristics of foods which affect pathogen growth (many of which are mentioned in this article) and Chapter 25 covers foodborne listeriosis.

It is also worth noting that to find, contain, and eradicate LM, there are also publications available which offer a different paradigm to attacking the pathogen. For example, Dr. Bob Powitz *(17)* advocates a sanitarian's approach. Sanitarians focus on controls, hygienic zones, traffic patterns, timing of sanitation, and personal hygiene – to minimize use of sanitizing chemicals as the main control measure. Conversely, Dr. Lone Jespersen *(11)* advocates for the study of a company's food safety culture to identify practices and procedures that may help or hinder food safety risks. Dr. Jespersen also suggests that a company's psychosocial risks (such as job conditions and work organization) may strongly affect how an employee behaves relative to their attitude toward food safety.

Additionally, both FDA and USDA have published excellent resources that address LM in food processing facilities. The USDA document is entitled "FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products" *(22)* and the FDA document is entitled "Draft Guidance for Industry: Control of *Listeria monocytogenes* in Ready-to-Eat Foods" *(24)*. Both of these documents describe how these regulatory agencies view LM and food safety, and also provide excellent background on LM microbiology, identification, and risk assessment.

If the reader would like a more in-depth technical discussion of LM microbiological limits, "Microorganisms in Foods" has a section worth studying *(9)*. There are also tables in a book published by FDA *(25)*, "Fish and Fishery Products", which provide technical support for times and temperatures of relevance to *Listeria* and other pathogens. Related to RTE seafood products, the National Fisheries Institute has a manual on pathogen control including for LM *(15)*.

CONCLUSIONS

Whether you can pronounce *Listeria monocytogenes*, and whether or not you have found the pathogen in your plant: you can do this. It is important to have a positive and can-do attitude. The attack needs to be team-based (not just the "quality and food safety team") and needs to be founded on scientific principles (not guesses), quantitative data, and thorough risk assessments.

Many lessons have been learned by numerous people. Study history and reach out to experts. Develop your own expertise, one sample at a time. Most importantly, understand LM risks – "be the bug." To that end, consider this quote from Shawn Stevens, Food Industry Counsel, LLC: "Everyone has a *Listeria* problem – the real issue is that most companies don't even know it!"

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APPENDIX

Historical Examples of *Listeria* Recalls
(company name provides hyperlink to more information)

Sara Lee (December 1998) – 15M lb of hot dogs recalled; 21 deaths and miscarriages; company paid $4.4M to settle civil and criminal charges; company spent $25M to renovate plant.

Blue Bell (February 2015) – 8M gallons of ice cream recalled; 3 deaths; one-third of workforce laid off; $19.3M in fines; 7 felony counts against president of company.

Alexander & Hornung (December 2021) – Perdue Premium Meat Company; 200K lb cooked ham and pepperoni.

Old Europe Cheese (September 2022) – Brie and Camembert cheeses; 5 hospitalizations.

Daniele International (January 2023) – 53K lb ready to eat sausage products.

Rizo Lopez Foods (February 2024) – 50 different cheese products; 23 hospitalizations and 2 deaths.

Boars Head (August 2024) – 7.2M lb sliced deli meats; 10 deaths; Virginia Plant closed.

Bruce Pack (October 2024) – 12M lb pre-cooked meat and poultry.

FGF Brands (January 2025) – 2M cases of doughnuts and pastries.

Lyons ReadyCare and Sysco (February 2025) – frozen supplemental shakes (volume unknown, as investigation is currently ongoing); 38 people infected across 21 states, and 12 deaths to-date.