Example Robust *Listeria monocytogenes* (LM) Control Program for We R Food Safety, Inc. (WRFS), clients.

Note: On November 18, 2024, I was asked by a group of our clients to share this document with non WRFS establishments. The request was very simple, the entire industry needs to get ahead of the LM issue, and now (there was another recall just prior to the request). I have agreed and am sharing this with our partner organizations, USDA FSIS, FDA, and those state programs we have contacts for, as well as having it moved to the public portion of our website.

Our legal advisors want me to remind anyone using this document, these are general recommendations, you must evaluate your specific environment and implement those controls that work for you, and we are not liable for any issues you may have utilizing this document. It is an example only. We R Food Safety, Inc., and the authors of this document accept no legal or other responsibility for how you implement your *Listeria monocytogenes* program or the results therein.

Background:

The recent LM outbreak has rocked the industry, and USDA FSIS extremely hard. So far, there have been over 10 deaths and 100 people sickened due to *Listeria monocytogenes* (LM) in their products. Then, on October 9th, another major recall of over 9 million pounds of product due to Listeria contamination. We are seeing a complete refocus of USDA FSIS and FDA to Listeria controls. These recommendations are based on our experience, USDA & FDA guidelines, other experts (noted at the end of the document), as well as data pulled from our database.

The number of "knee jerk" reactions by regulators was expected and is occurring. Our advice is to keep open and honest lines of communication with your local regulator. Do what you can; many of these recommendations are beyond what a very small operation implement; do what is applicable to your operation, if you are a produce operation you won't be able to implement a control around formulation, lettuce is lettuce.

We talk a lot about "after lethality", and that is a key focus of this program, having said that if you make a product that doesn't go through a lethality step these recommendation may be applicable. Review them and implement what you can.

Please remember that LM*[LM 3] doesn't produce gases, i.e., the packages won't blow up, your customer has no idea that it is there. It is VERY salt tolerant, and it survives in microaerobic conditions, i.e., oxygen free must be totally oxygen free.

You may not be able to implement all these recommendations. Collaborate with your consultant who can help you navigate what is feasible, and what is not feasible, for your facility. For example, if you can't test at the recommended frequencies, you may be able to do an increased intensified cleaning & sanitizing.

These recommendations are NOT all encompassing! You may be able to implement controls that are not listed in this example program, contact your consultant if you have other controls.

There are links in this example program to certain products used to help control LM. WRFS does not receive royalties from any of these firms, they are simply ones that have done an excellent job of taking care of our clients.

We realize that this is an extremely aggressive example plan that is designed to find and eradicate LM from your environment. This document exceeds regulatory guidance but based on the reaction from USDA FSIS & FDA in your establishments, it is our recommendation that you implement the controls you can to avoid regulatory actions.

We have one client that uses sodium cholorite as their base sanitizer. As they are the only client, we have using sodium cholorite, we can't make any conclusions (statistically a sample of one just isn't enough); however, the owner of the facility reports that after extensive testing they are not finding bio films or have had any positives.

I want to thank everyone who helped draft this document. Each of you brings a unique perspective to helping fight food borne outbreaks and helps enhance food safety. I also want to specifically thank the company's that allowed their experts to contribute; the fact that you recognize that food safety isn't a competitive advantage, and is in truth, advantageous to all of us speaks highly of your company. Again, thank you!

Drew Lorenz
Owner, We R Food Safety, Inc.

Example Robust *Listeria monocytogenes* control program.

Contents

Sanitation:

1. In all RTE areas use the hottest water that your systems can provide continuously, during cleaning.
2. Use a detergent that is good at removing grease and or adhering particles. The ingredients that you want in a good cleaner: Sodium Lauryl Sulfate, Sodium Lauretha Sulfate, C10-16 Alkyldime-Thylamine Oxide, PEI-14 PEG-24/PPG-16 Copolymer, C9-11 Pareth-8, Terpineol, PPG-26, Phenoxy-Isopropanol. This is not an all-encompassing list. You will note that these are found in Dawn® dishwashing products.
3. In all RTE areas use quaternary ammonia as your base sanitizer. Waltons.com sells Ultra-Quat, use it or a similar product. (https://waltons.com/ultra-quat/)
4. Quat blocks in all condenser/cooling unit drip pans.
5. Use alcohol vapor in hard-to-reach places, sensitive equipment, etc. Examples include bio-Mist: https://biomistinc.com.
6. Recommended basic cleaning regimen in RTE areas:
   a. Equipment should be disassembled first.
   b. Periodical breakdown of small parts that can form niches for L. monocytogenes harborage. This includes blades, emulsifier plates, condenser fins, etc.
   c. Start at the highest point in your cleaning process and clean down, using the hottest water your system can generate.
   d. After you have finished cleaning rinse thoroughly with potable water, again from the highest point in your cleaning process down, at the hottest water temperatures your system can generate.
   e. Inspect for residue, reclean and rinse as needed.
   f. Apply quaternary sanitizer. (Alcohol vapor to areas that you can't wet sanitize)
7. Recommended one time a week cleaning regimen in RTE areas:
   a. Equipment should be disassembled first.
   b. Start at the highest point in your cleaning process and clean down.
   c. After you have finished cleaning rinse thoroughly with potable water, again from the highest point in your cleaning process down at the highest water temperature your system can generate.
   d. Inspect for residue, reclean and rinse as needed.
   e. Apply peroxyacetic (PAA)[*LM 1] sanitizer. (Alcohol vapor to areas that you can't wet sanitize). Note due to cost and your environment it may be acceptable to use the PAA bi weekly or monthly. Again, discuss with your consultant.
8. Recommended biweekly cleaning regimen in RTE Areas:
   a. During the one-time weekly regimen include all overheads to include condensers/cooling units. These are critical areas that if LM gets in you will have an extremely hard time getting it out. LM can be an airborne pathogen!
   b. Heat treat all drains and floor cracks with water at +180F (Minimum of two gallons per drain if possible/thoroughly saturate cracks-get cracks and worn areas repaired ASAP!).

9. Recommended Monthly cleaning regimen in RTE Areas:
    a. Use aerosol vapor, alcohol, or Ozone vapor treatment during an overnight/weekend to "bomb" (Saturate) all RTE areas. If using ozone, ensure it is at least 1.5%!
    b. A member of senior management or owner physical verifies compliance.

Chlorine based sanitizers (Bleach) are not recommended in RTE areas as they are not as effective as other sanitizers.

Note: While science indicates that ozone is effective in controlling LM our database indicates that those that rely solely on ozone have a higher positive rate of LM than those that use quaternary ammonia, peracetic acid, or alcohol. While this is not a scientific study the empirical evidence is that ozone is less effective at eliminating LM from food production environments. This may be due to the age of the production units, a loss of emphasis on actual ozone concentrations, or some unknown factor. If Ozone is your primary control, we strongly recommend that emphasis be placed on assuring you are getting adequate ozone production and application.

Intensified cleaning and sanitizing:

Intensified cleaning can be used following a positive test result, or at a defined frequency as a preventive measure. If used as part of a corrective action following a positive result, intensified cleaning and sanitizing are conducted prior to any further RTE production.

1. Notify your consultant that you are in intensified cleaning and sanitizing. They may request pictures or videos to help advise you.
2. Repair any damaged walls, ceilings, and floors, doors, etc.
3. Remove equipment that can't be sanitized due to damage, for example rusty compressors, rusty buggy wheels, etc. and repair or replace. Do a full cleaning & sanitizing prior to returning them to RTE areas.
4. Equipment to include condensing/cooling units should be disassembled first.
5. Start at the highest point in your cleaning process and clean down using the hottest water your system can generate.
6. After you have finished cleaning rinse thoroughly with potable water, again from the highest point in your cleaning process down at the highest water temperature your system can generate.
7. Inspect for residue, reclean and rinse as needed.
8. Apply peroxyacetic (PAA)[*LM 1] sanitizer. (Alcohol vapor to areas that you can't wet sanitize)
9. Heat-treat all drains with water at +180F (Minimum of two gallons per drain if possible!).
10. Use aerosol vapor, (alcohol, hydrogen peroxide, Ozone, or other approved vapor sanitizer) vapor treatment for the recommended time per said product.

General sanitation recommendations:

- Limiting, or if possible, prohibiting, employee traffic from raw areas to RTE areas.
- Positive air pressure in RTE areas so that air moves away from the RTE areas. Proper filtration and air handling must be installed.

- Remove pitted, grooved, or warn equipment & fixtures on a routine basis. We recommend a focused inspection weekly.
- Remove or repair rusted or damaged equipment.
- Use quat rings in drains, below the ring is the sewer, above it is your production area.
- Increased focus on basic sanitation protocols:
    - Handwashing
    - Washing gloves
    - Separate clothing for RTE areas
    - Dedicated boots for RTE areas
    - Floor fomers or walk through sanitizers at entrances to RTE areas
    - Quat crystals on all RTE floors
    - Minimizing nonfood items in RTE areas
    - Examples:
        - Tape
        - Cardboard
        - cloth washcloths
    - Remove standing water
    - Control and remove condensation
    - Routine inspections of condensing units

Product Formulation:

We strongly recommend the addition of anti-microbial agents in product formulation whenever possible. Be very cognizant that many products with standards of identity cannot have an anti-microbial added unless renamed, contact your consultant if you have any questions.

Some anti-microbials that are popular and that are supported by scientific studies:

Sodium lactate combined with Sodium diacetate.

Sodium lactate by itself

Sodium diacetate by itself

Potassium lactate

Sodium citrate

Lauric arginate

For brine chillers: Citric acid and salt (must use both). We are reviewing if lowering the pH will help, however there is little science available to support this.

In many cases combinations of anti-microbial substances have been more effective at controlling & reducing LM contamination. Work with your consultant to determine your best course of action.

To be a cured product you must have sodium nitrite & a cure accelerator such as sodium erythorbate. If you are using celery powders to be considered cured, you must have a certificate of

analysis demonstrating the amount of ingoing nitrite & use a cure accelerator such as cherry juice. While you may be able to demonstrate that sodium nitrite combined with time results in a cured product this can be expensive to prove.

Product Chemistry:

Producing a product that doesn't provide LM with the conditions it needs to grow isn't just an alternative, it can mean that you can take advantage of those growth parameters to stop LM from being viable in your product.

Examples include:

1. Products with a aW of less than .91 (Per USDA FSIS)
2. Products with a pH of less than 4.6.
3. Products with a range of combinations of less than aW of .93 AND a pH of less than 4.7. Note, these combinations may not be recognized by USDA FSIS or the FDA and are pushing the growth parameters of LM and while there are studies and predictors that approve such study's, others are contradicting them as such they are not recommended.
4. Some of the more recent scientific studies[*LM 2] indicate that the actual ranges are aW of less than .90 and pH of less than 4.6. This is concerning as most programs follow the USDA FSIS shelf stable requirements (for meat & poultry) of an aW of less than .91.
5. Temperature controls, to include freezing, are not effective at destroying the bacterium.
6. Based on the current scientific studies available we are recommending an aW of equal to or less than .90. Or a pH of equal to or less than 4.5. These are very drastic changes to regulatory guidelines, however with the number of outbreaks, positives, etc., these are the parameters where we don't see positives in product.

Testing for LM:

Notes: Initially test for *Listeria* spp. If you receive a positive, ask the lab to test out (or *confirm*). Samples should be random (see random sampling below); however, after a positive you will want to go after the areas where you had positives and those areas you suspect may be harborage points, i.e., focused testing.

1. Product Testing:

   Routine Testing

   Note: Typically conducted after the first third of scheduled production, i.e., after 3 hours of production when scheduled for an 8-hour day.

   1) Test one product run using statistically valid testing. This is the initial testing to establish product baseline.

a. Out of a microbial lot, immediately prior to packaging, pull 32 ounces of product from 32 different items. This is typically destructive sampling, but, if possible, you may be able to use ends and pieces or trim. See the statistical sampling section.
b. After initial testing: A single item of packaged product monthly (this is per HACCP Category, i.e., if you make both FCNSS & HTSS products you would sample one of each).
c. For both initial and monthly testing, all products in the microbial lot are held pending laboratory results.

2) Food Contact Surface Testing monthly:
   a. Per RTE post exposed production line, conduct 5 food contact surface tests for *Listeria* spp. Collect individual samples (i.e., not composited) until 3 sets of samples sets come back negative. After 3 sets of samples have been found to be negative, the samples may be composite sampled using individual sponges per location.
   b. All product that is in the microbial lot is held pending laboratory results.
3) Near food contact (also known as zone 2) testing. Note: these are areas directly over or within 3 feet of a food contact surface. The frequency is also monthly.
   a. Per RTE post exposed production line, follow the sampling plan found in **Figure 1. Listeria Sampling Plan** to determine the appropriate number of routine samples. Initial sampling is for *Listeria* spp. Do not composite until 3 sets of samples come back negative. After 3 sets of samples have been found to be negative, the samples may be composite sampled (per 5 samples) using individual sponges per location.
   b. Product is not held.
4) Far food contact testing (also known as zone 3) testing. *Note: these are areas that don't fall into zone 1 or 2, examples are drains, condensers that are not directly over production lines or paths, door handles, warehouse areas, maintenance areas, etc.* The frequency is also monthly.
   a. Per non-production area, follow the sampling plan found in **Figure 1. Listeria Sampling Plan** to determine the appropriate number of routine samples. Initial sampling is for *Listeria* spp. Samples may be composite sampled (per 5 samples) using individual sponges per location. If there are positives for Listeria spp have the samples tested out for LM.
   b. Product is not held.

Zone 1	Zone 2	Zone 3
		
Food Contact	Near Food Contact *Directly over or within 3 feet of food contact surface*	Far From Food Contact

2. Corrective Actions in the Event of a Positive (Product or Food Contact Surface:

   A) Product Testing:

      1. Product positive *Listeria monocytogenes*:
         a. Product is either re-processed or destroyed.
         b. Intensified cleaning and sanitizing are conducted prior to any further RTE production.
         c. Product that has been produced between sample pull and sample results is reviewed for potential contamination, these products are on hold, as such there should be no recall. Note that there must be a clear break in microbial lot!
         d. After intensified cleaning, product, food contact surfaces, and near & far Surfaces are tested per paragraph 1 A) prior to production.
         e. Intensified cleaning is conducted after testing.
         f. All products produced after *B) 1. d.* is on hold pending test results.
         g. If product, food contact surfaces, and near & far test results are negative, resume routine product testing, release product.
         h. If there is a positive for any test protocol go into the emergency sanitation procedure found below. Do not release any product on hold.

   B) Food Contact Surface Testing:

      1. Food Contact Surface Positive.
         a. Product that is implicated is either re-processed or destroyed.
         b. Intensified cleaning and sanitizing are conducted. Product that has been produced between sample pull and sample results is reviewed for potential contamination, these products are on hold, as such there should be no recall. Note that there must be a clear break in microbial lot!
         c. Product produced after the initial intensified cleaning and sanitizing and while additional test results are pending is placed on hold.
         d. Perform second cleaning.

e. Per RTE post exposed production line, conduct 10 food contact surface tests (5 targeted to the test sites that were positive, 5 additional random sites) for Listeria spp.
f. Do not composite samples.
g. All products that are in the microbial lot are held.
h. Intensified cleaning is conducted after testing. {for a third time?}
i. If product, food contact surfaces, and near & far test results are negative, resume routine product testing.
j. If there is a positive for any test protocol go into the emergency sanitation procedure found below.

C) Near Food Contact Positive (also known as zone 2):

Note: these are areas directly over or within 3 feet of a food contact surface.

1. Follow the "Tightened Samples" protocol in **Figure 1. Listeria Sampling Plan** to determine the appropriate number of samples to test. Use one sponge per sample location, may composite up to 5 sponges.
2. Product is not held.

D) Far Food Contact Positive (also known as zone 3):

Note: these are areas that don't fall into zone 1 or 2, examples are drains, condensers that are not directly over production lines or paths, door handles, warehouse areas, maintenance areas, etc.

1. The number of samples to test can be found in **Figure 1. Listeria Sampling Plan** (using tightened sampling) Use one sponge per sample location, may composite up to 5 sponges.

2. Product is not held.

Emergency Protocol:

If the emergency protocol is triggered the following actions are taken:

E) Product or Food Contact Surface Positive:

1. All production of RTE products is stopped.
2. Prior to any intensified cleaning we will test:
3. All food contact surfaces, do not composite.
4. Randomly near surfaces per **Figure 1. Listeria Sampling Plan**, emergency samples protocol, may be composited per 5 samples.

5. Randomly far surfaces per **Figure 1. Listeria Sampling Plan**, emergency samples, protocol, may be composited per 5 samples.
6. Perform intensified cleaning and sanitizing under senior management/owners' direction.
7. Retest all locations per 3, 4, & 5.
8. If all locations are negative, resume operations and perform testing the following week on 1 product, 5 food contact surfaces, 5 near surfaces, and 10 Far surfaces. If negative return to routine sampling. If a positive is noted on any sample re-initiate emergency sampling.

F) Near Contact Surface Positive:

1. Prior to any intensified cleanup we will test:
2. A single item.
3. Test 10 randomly selected food contact surfaces; do not composite.
4. Test focused near food contact surfaces per **Figure 1. Listeria Sampling Plan** tightened samples protocol; do not composite.
5. Test randomly selected far surfaces per **Figure 1. Listeria Sampling Plan,** tightened samples protocol, may be composite per 5 samples.
6. Perform intensified cleaning and sanitizing under senior management/owners' direction.
7. Retest all locations per 2, 3, 4, & 5.
8. If all locations are negative, resume operations and perform testing the following week on 1 product, 5 food contact surfaces, 5 near surfaces, and 10 Far surfaces. If negative return to routine sampling. If a positive is noted on any sample re-initiate emergency sampling.

G) Far Contact Surface Positive:

1. Perform intensified cleaning and sanitizing under senior management/owners' direction. Test far surfaces per **Figure 1. Listeria Sampling Plan** tightened samples protocol.
2. Prior to any intensified cleanup we will test:
    a. Random near surfaces per **Figure 1. Listeria Sampling Plan**, tightened samples protocol, may be composited per 5 samples.
    b. Focused Far surfaces per **Figure 1. Listeria Sampling Plan**, tightened samples protocol, not composited.
    c. Perform intensified cleaning and sanitizing under senior management/owners' direction.
    d. Retest all locations per 1 & 2.

e. If all locations are negative, resume operations and perform testing the following week on 1 product, 5 food contact surfaces, 5 near surfaces, and 10 Far surfaces. If negative return to routine sampling. If a positive is noted on any sample re-initiate emergency sampling.

Figure 1 Listeria Sampling Plan

Figure 1

Total Square Footage of Near & Far production rooms	Number of routine samples	Number of tightened samples	Number of emergency samples	Notes
1-10,000	8	20	32	AQL=.65, IL=S-4 Pass=0 positives Fail=any positives
10,001-35,000	13	32	50	AQL=.25, IL=S-4 Pass=0 positives Fail=any positives
Over 35,001	32	80	125	AQL=.15, IL=S-4 Pass=0 positives Fail=any positives

Note: When calculating the square footage of near contact surfaces, you will use the square footage of the production room. For example: If the production room is 2,000 square feet you will pull 8 samples of near contact surfaces. If you have two 2,000 square foot rooms you would pull 4 samples from each room, for a total of 8 samples. If your warehouse and other non-production space is a total of 20,000 square feet; you will pull 13 samples of far contact surfaces.

Recommended criteria to determine product disposition:

When product has been produced after to a positive sample but prior to sample results, you will want to review:

a. Was there a complete clean and sanitizing event after the sample was pulled?
b. Was it documented?
c. Did the documentation clearly identify the sanitizer used?
d. Are there any findings in the SSOP or other records that would indicate a cross-contamination event?
e. Was all potentially contaminated product held?
f. Is it viable to reprocess the implicated product? If not is the documentation concerning destruction clear and match production records?

Random Sampling:

When pulling samples that require random sampling, number the sample sites, then use a random number generator. For example, if you have 20 food contact surfaces, they should each be numbered, 1-20. Then run a random number generator (there are many free ones on the internet (https://www.random.org/integer-sets/). The key is that for random sampling to have the statistical validity, every potential sample must be available for sampling. This is how we find the needle in the haystack.

Product Example:

Each case is assigned a number. Each case has 5 one-pound summer sausages in it. Each position is given a number, for example, each position in the case, i.e., bottom right is number one, bottom middle is 2, bottom left is 3, top right is 4, and top left is 5 as viewed from the label. You then run the random number generator to generate 32 sets, 1 integer per set. Number This is what you get: Set 1= 5, Set 2= 3, Set 3= 3, Set 4= 3, Set 5= 1, Set 6= 2, Set 7= 1, Set 8= 2, Set 9= 3, Set 10= 1, Set 11= 5, Set 12= 2, Set 13= 2, Set 14= 1, Set 15= 1, Set 16= 2, Set 17= 1, Set 18= 3, Set 19= 5, Set 20= 2, Set 21= 2, Set 22= 2, Set 23= 3, Set 24= 2, Set 25= 3, Set 26= 5, Set 27= 3, Set 28= 1, Set 29= 5, Set 30= 5, Set 31= 3 & Set 32= 5.

The set is the case number, the equal to number is the position number to pull from. Yes, this is a lot of work, but assures you are statistically valid.

You can do the same thing with equipment, spaces, etc. Just make sure you are using logical sample sizes, for example a single sample of the floor may make sense, but if it is a 4,000 square foot floor, it might make more sense to break it into quadrants or smaller units.

Special thanks to:

My team: Artemese Dolliole, Faith Brown, Dan Robert, Ashley Scott, Matthew Bayer, Kerres USA-Dr. Jonathan Campbell, Link Snacks Incorporated-Mr. Frank Hendra, and all of the We R Food Safety, Inc. clients, and those that participated in the numerous teams' meetings and calls, there are too many too list, but again, thank you!

Drew Lorenz