Chapter 4

FSIS *Listeria* Guideline: Enhanced Sampling Program

This chapter provides information on developing an **Enhanced Sampling Program** as part of the *Listeria* Control Program. The Enhanced Sampling Program includes **follow-up** and **intensified sampling** performed in response to a food-contact surface (FCS) result from the routine-sampling program. Sections on developing **Hold and Test** Programs and determining ***Listeria* trends** are also included in this chapter.

4.1 Follow-up Sampling

According to the *Listeria* Rule, establishments in Alt. 3 (deli and hotdog producers) are required to conduct follow-up testing (sampling) in response to FCS positive sampling results (9 CFR 430.4(b)(3)(ii)(A)). If follow-up testing (sampling) yields a second FCS positive result, then products must be held and tested using a sampling plan that will ensure that products are not adulterated with *Lm* before they are released into commerce (9 CFR 430.4(b)(3)(ii)(B)).

In response to a positive FCS result, establishments in Alt.1, 2, and 3 (non-deli or hotdog producers) are required to perform **corrective actions** (9 CFR 416.15(a) and (b) and 417.3(a) and (b)). FSIS recommends that they also perform follow-up sampling in response to a positive FCS result. By making efforts to find and address the source of contamination in the environment, establishments can take proactive steps to avoid *Lm* contamination of products. Appendix 4.1

Question: An establishment produces hotdog and deli products using Alt.3 and has 3 production lines in the post-lethality processing area. The establishment receives a positive result for *Lm* or indicator organism on line 1 FCS. Does the establishment need to sample FCSs only from line 1 or from all the 3 lines for the follow-up testing?

Answer: The follow-up sampling is verification that the corrective actions taken by the establishment are effective. If the establishment can support that line 1 is using equipment, personnel and processing area that is separate and independent of the other lines (i.e., not used by other lines) and has supporting documentation that there is no history of cross-contamination among the three lines, then follow-up testing and corrective actions should be conducted on line 1.

provides step-by-step guidance for sampling in each Alternative. The establishment's follow-up testing program can be included as part of its *Listeria* Control Program in its Enhanced Sampling Program.

In the *Listeria* Control Program, the establishment should specify the number of samples it will collect during follow-up sampling. FSIS recommends that **3-5 samples** are collected from the site of the original FCS positive and the surrounding area. According to the *Listeria* Rule, establishments in Alt.3 deli and hotdog producers must conduct **follow-up sampling that includes the specific FCS site that tested positive, as well as such additional tests in the FCS area as are necessary to ensure the effectiveness of the corrective actions.** These may include other FCSs that are upstream from the original positive. It would be useful for the establishment to record the rationale for selecting follow-up sampling sites. For example, if a slicer tests positive, the establishment may choose to sample the conveyor or other equipment leading up to the slicer. Follow-up sampling could also include other FCSs on the same piece of equipment that were not previously tested (e.g., slicer blade or plate) or employees' gloves that come in contact with the product as it is placed on the slicer.

The establishment should also include a brief description of corrective and preventative actions that will be taken in response to positive results (details can be included in the Sanitation SOP) and response to positive results (next steps). As stated previously, establishments in Alt. 3 (deli and hotdog producers) are required to hold and test product in response to a second positive test (obtained during follow-up testing) for *Lm* or an indicator organism. After the 2nd consecutive positive, the establishment should also enter into intensified sampling mode to find the source of positives (see Section 4.2). It is also recommended that establishments in the other alternatives enter into intensified sampling mode after the 2nd positive (although hold and test is not required at this point). Recommendations for follow-up testing, intensified testing, and hold and test are provided in Table 4.1. Sampling scenarios by alternative can also be found in Appendix 4.1.

Table 4.1 Timeframe for Follow-up Sampling, Intensified Sampling, and Hold and Test Performed in Response to Positive Food Contact Surface Results

<table>
<tr><th>Alternative</th><th>After the 1st positive</th><th>After the 2nd positive</th><th>After the 3rd Positive</th><th>After Multiple Positives</th></tr>
<tr><td>Alternative 1</td><td>Follow-up sampling</td><td colspan="2">Intensified sampling</td><td>Hold and test recommended</td></tr>
<tr><td>Alternative 2 , Choice 1 (2a)</td><td>Follow-up sampling</td><td colspan="2">Intensified sampling</td><td>Hold and test recommended</td></tr>
<tr><td>Alternative 2, Choice 2 (2b)</td><td>Follow-up sampling</td><td>Intensified sampling</td><td colspan="2">Hold and test required* (recommended after 3rd positive)</td></tr>
<tr><td>Alternative 3</td><td>Follow-up sampling</td><td>Intensified sampling</td><td colspan="2">Hold and test required* (recommended after 3rd positive)</td></tr>
<tr><td>Alternative 3 (deli or hotdog)</td><td>Follow-up sampling required</td><td colspan="3">Intensified sampling

Hold and test required after 2nd positive.</td></tr>
</table>

*Establishments in Alt. 2b and 3 (non-deli or hotdog producers) are **required** to identify when they will hold and test product. FSIS recommends that they do so after the **3rd** consecutive

positive. Establishments in Alt 3 (deli and hotdog producers) are **required** to hold and test product after the **2nd** consecutive positive.

4.2 Intensified Sampling

FSIS recommends that all establishments enter into **intensified sampling mode** after a 2nd FCS positive. Intensified sampling mode includes:

- Intensified samples collected from FCSs, indirect and NFCSs, and product, and
- Escalated intensified cleaning and sanitation (details included in the establishment's Sanitation SOP).

Intensified sampling may include the collection of FCS, NFCS, and product samples, and is performed to find sources of harborage and **cross contamination** in the post-lethality processing environment. **Harborage** is defined as the persistence of *Lm* in the establishment over time. Once a harborage point is formed, *Lm* may transfer through cross contamination onto FCSs or the product. Examples of conditions that may lead to cross contamination include condensation dripping onto product or FCSs, aerosolization from the drains, splashing from the floors, or product brushing against doors, walls, or pallets. For more examples of cross contamination and harborage, see Appendix 2.2).

Procedures for intensified sampling can be included in the establishment's *Listeria* Control Program. During intensified sampling, at least 3-5 samples should be collected per site that was found positive during follow-up sampling. Efforts should also be taken to find and address sources of harborage, track cross contamination in the establishment, and to find and address *Listeria* trends (for more information on *Listeria* trends, see Section 4.5).

Intensified sanitation efforts should be used in conjunction with intensified sampling to address sources of contamination. Intensified sanitation includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Intensified sanitation can include increasing the frequency of cleaning and sanitizing for certain pieces of equipment, breaking down the equipment into its parts for further cleaning, repairing or replacing broken equipment, and construction, if needed. For more descriptions of intensified sanitation, see Appendix 2.2.

As part of its *Listeria* control program, the establishment should also include a response to positive results found during intensified testing. **The finding of three consecutive positive samples for *Listeria* spp. from the same sampling site indicates a serious contamination issue, and increases the risk that product could be contaminated with *Lm*.** The establishment should be taking preventative steps such as:

- Increasing its routine sampling for *Listeria,*
- Collecting intensified samples to find sources of harborage and cross contamination,
- Holding and testing product (Alt. 2b and 3 non-deli or hotdog producers),
- Reassessing its **Sanitation SOPs** to determine if sanitation issues could be leading to positive results,

- Assessing the effectiveness of its PLT or AMAs or AMPs to address the increased likelihood of positives,
- Determining whether *Listeria* trends exist (see Section 4.5), and
- Reassessing its **HACCP plan,**[8] to determine if the actions it is taking are effective in controlling *Listeria*.

NOTE: The finding of three consecutive positive samples from the same sampling site indicates a serious contamination issue, and increases the risk that product could be contaminated with *Lm.*

4.3 Hold and Test

According to the *Listeria* Rule, establishments in Alt. 3 (deli and hotdog producers) are required to hold product after a 2nd consecutive positive for *Lm* or an indicator organism until the establishment corrects the problem indicated by the test result (9 CFR 430.4(b)(3)(ii)(B)). Further, in order to release product into commerce, the establishment must sample and test the lots of product using a method that will provide a level of statistical confidence that the product is not adulterated (for more information see International Commission on Microbiological Specifications for Foods (ICMSF) Sampling Plans for *Lm* below). Alternatively, the establishment may rework or condemn the product (9 CFR 430.4(b)(3)(ii)(C)). Establishments in Alt. 3 (non-deli or hotdog producers) and Alt. 2b are required to identify when they will hold and test product ((9 CFR 430.4(b)(2)(iii)(B) and (3)(i)(B)) and FSIS recommends that they do so after the **3rd positive** (see Table 4.1). It is also recommended that establishments in Alt. 1 and 2a hold and test product after multiple positives for *Lm* or an indicator organism.

Establishments can include their hold and test procedures in their *Listeria* Control program. Products can be tested for either *Lm* or *Listeria* spp.; however, if a product tests positive for *Listeria* spp. an establishment may be asked to provide further evidence (such as confirmatory testing results) to demonstrate that the product is not contaminated with *Lm*.

Establishments should hold the entire product lot (and subsequent day's lots) until control is regained. For more information on defining product lots, see Section 3.5. Control is considered regained after 3 consecutive days of negative FCS results are obtained, and all other NFCS and product samples are negative. **If product tests positive for *Lm* during hold and test (see Appendix 4.2), then the product lot represented by the sample is considered adulterated.**

NOTE: Control is regained after **3 consecutive days of negative** FCS results are obtained, demonstrating that corrective actions are sufficient to address the contamination issue.

A hold and test scenario is provided in Appendix 4.2 that provides a day-by-day description of hold and test procedures. Establishments should also describe product disposition in response to positives (procedures for reworked or condemning the product).

Hold and test can only be used as a means to release product in situations where an FCS tests positive for *Listeria* spp. If FCSs or product tests positive for *Lm* the product is considered adulterated. In that case, holding and testing product would not be an appropriate

[8] Reassessment of the SSOP or HACCP plan is required in response to an FSIS *Lm* positive according to 9 CFR 417.3(b) and 416.15 (b) (see the Q&As in Appendix 3.1 for more information).

means of determining product safety, because even the best-designed testing program cannot detect all *Lm* that may be present. Therefore, product testing can not be used as a means for the establishment to release adulterated product into the marketplace.

NOTE: If a FCS or product tests positive for *Lm*, the product is considered adulterated. Product testing can't be used as a means to demonstrate that the product is safe. The product must be reworked or condemned, and FSIS would typically request that establishments recall such products if they have been released into the marketplace.

International Commission on Microbiological Specifications for Foods (ICMSF) Sampling Plans for *Lm*

According to the *Listeria* Rule, establishments in Alt. 3 producing deli or hotdog products must sample and test lots for *Lm* or an indicator organism using a sampling method and frequency that will provide a statistical level of confidence that ensures that each lot is not adulterated with *Lm* (9 CFR 430.4(b)(3)(ii)(C)). In order to meet this requirement, FSIS recommends that establishments use the International Commission on Microbiological Specifications for Foods (ICMSF) Tables. Additionally, FSIS recommends that establishments in other Alternatives use these tables if they hold and test product.

ICMSF categorizes microbial hazards according to risk:

1) Moderate
2) Serious
3) Severe

NOTE: ICMSF ranks *Lm* as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups e.g., hospital and nursing home patients).

ICMSF describes 15 different cases of sampling plans, with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11, and 12 would apply to the serious category and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to foods intended specifically for highly susceptible individuals (e.g. patients in hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible to foodborne illness; thus, increasing the stringency of the sampling plans is appropriate. **FSIS also considers product produced under the school lunch program to be intended specifically for high-risk populations.**

For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of *Lm* will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., the organism cannot grow), and for cases 12 and 15, conditions may increase the risk (e.g., foods in which *Lm*

Question: Should the ICMSF sampling plan be used for regular sampling or only for hold and test sampling?

Answer: For routine sampling, the establishment can use whatever sampling plan it justifies as appropriate to demonstrate that the product is safe. For hold and test sampling for *Lm*, a statistically-based sampling plan should be used. The ICMSF table provides examples of statistically-based sampling plans that are commonly used for demonstrating lot acceptance.

can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in the table below, where n is the number of samples and c=0 means that none of the "n" samples can be positive for *Lm*. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that *Lm* is present at <1 in the sample size. FSIS recommends analyzing a 25 g sample. **If the risk of the population is unknown, FSIS recommends that establishments use cases 13-15.**

NOTE: Product samples should be analyzed separately and not composited. However, if compositing is to be done, composites of 25-g portions should not exceed a total of 125 g in order to maintain the sensitivity of the method of analysis, and a validated method should be

Conditions reduce concern	**Conditions cause no change in concern**	**Conditions increase concern**
Case 10 n=5, c=0 Mean Concentration 1 cfu/32g	Case 11 n=10, c=0 Mean Concentration 1 cfu/83g	Case 12 n=20, c=0 Mean Concentration 1 cfu/185g
Case 13 n=15, c=0 Mean Concentration 1 cfu/135g	Case 14 n=30, c=0 Mean Concentration 1 cfu/278g	Case 15 n=60, c=0 Mean Concentration 1 cfu/526g

When RTE products must be sampled (hold and test) under the *Listeria* Rule, the number of samples (randomly selected) would be as specified for these cases based on the risk of the product and the intended consumers. Since deli and hotdog products are ranked as the top causes of foodborne illness, the establishment producing these products should select these products to be sampled first. Sampling starts after the establishment has conducted corrective actions that are specifically designed to find the most likely cause of the contamination and controls are put in place to prevent recurrence.

Case 10 n=5, c=0	Case 11 n=10, c=0	Case 12 n=20, c=0
Products with continued decline in population due to antimicrobial or other formulation considerations such as pH and A_w. Products in Alternative 1	Products that limit growth (< 1 log) due to antimicrobial or other formulation considerations such as pH and A_w. Products in Alternative 2	Products that support growth and that will be stored refrigerated for an extended period of time. Products in Alternative 3
Case 13 n=15, c=0	Case 14 n=30, c=0	Case 15 n=60, c=0
As for case 10, but where products are produced for a	As for case 11, but where products are produced for a	As for case 12, but where products are produced for a

hospital or nursing home or for another higher risk population Products in Alternative 1 intended for a hospital, nursing home or for another higher risk population	hospital or nursing home or for another higher risk population Products in Alternative 2 intended for a hospital, nursing home or for another higher risk population	hospital or nursing home or for another higher risk population Products in Alternative 3 intended for a hospital, nursing home or for another higher risk population.

The number of samples recommended should be collected in one day and all affected products should be held during the testing period. Testing can be for *Listeria* spp. or *Lm*. Any positive results from this follow-up testing (using the ICMSF approach) should lead to more significant investigations of the cause of the contamination. If samples test positive for *Listeria* spp., the establishment should confirm for *Lm* and if the samples are positive for *Lm*, the product is considered adulterated. The establishment should conduct rigorous corrective and preventative actions and other sanitation activities.

Establishments may send a letter or certification when they ship tested products to nursing homes, hospital, and other institutions with susceptible populations. Such a letter would indicate that product has been sampled and tested according to ICMSF recommendations. Establishments supplying nursing homes, hospitals and other institutions with susceptible populations are expected to implement whatever additional controls and verification procedures are necessary to ensure that product is not adulterated.

4.4 Reprocessing *Lm* Contaminated Product

Product that tests positive for *Lm* or an indicator organism, or passes over an FCS that tests positive for *Lm*, or is suspected to be positive because of sanitation or processing issues at the establishment, may be reprocessed. A process that has been validated to achieve at least a 5-log *Lm* reduction would be accepted by FSIS to reprocess the product. In order to reprocess the product, the establishment may use a processing treatment such as re-cooking and re-cooling the product (see below), applying a PLT (as described in Section 2.1), or other supportable process. An example of a PLT which has been found to achieve a 5-log *Lm* reduction is HPP. If an establishment chooses to use HPP to reprocess *Lm*-positive product, then the establishment should have scientific support that demonstrates that the process achieves at least a 5-log reduction of Lm in their particular product (see Appendix 2.1 for more information on validation).

> **NOTE**: FSIS will consider PLTs achieving at least a 5-log reduction of *Lm* sufficient for reprocessing contaminated product.

In addition, establishments may use both Appendix A and Appendix B of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products," FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, or other supportable processes to reprocess *Lm*-positive product. When using these guidance documents, establishments should ensure that adequate humidity is maintained during heating according to Appendix A and that *C. perfringens* and *C. botulinum* growth is controlled according to Appendix B, or other scientific support. Although Appendix A and B, the FSIS Guidance on Safe Cooking of Non-intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-

to-Eat Poultry Products, are designed to achieve reductions in *Salmonella*, establishments are not expected to validate that these processes also achieve reductions in *Lm* because *Salmonella* is considered an indicator of lethality for *Lm* (see Appendix 2.1).

4.5 Determining *Listeria* Trends

As described previously, establishments are expected to take corrective and preventative actions in response to positives based on their alternative. One way that establishments can ensure that their corrective actions are effective is to track sampling results. Repeated *Listeria* spp. positives on FCSs, NFCSs, or product indicate positive ***Listeria* trends** in the establishment. The finding of *Listeria* trends could indicate that the establishment's *Listeria* Control Program is not effective in controlling the presence of *Lm* in the establishment's post-lethality processing environment. In response to a finding of *Listeria* trends, the establishment should perform intensified testing and sanitation, and conduct a comprehensive investigation to determine the source and the cause of the contamination (the steps in a comprehensive investigation can be found below the section on identifying and addressing *Listeria* trends). One way to track and address *Listeria* trends is through a sentinel site program.

> **NOTE:** Repeated *Listeria* spp. positives on FCS, NFCS, or product (***Listeria* trends**) could indicate that the establishment's *Listeria* control program is not effective in controlling the presence of *Lm* in the establishment's processing environment.

Identifying and Addressing *Listeria* Trends

Establishments should track their sampling results over time, to identify *Listeria* trends. *Listeria* trends can consist of increases in positive samples over a particular time period (e.g., weekly, biweekly, monthly, quarterly, or 6 months) or increases in positives in particular sites or areas (see Appendix 4.3 for specific examples). By tracking their percent positive sampling results, establishments can determine if the percentage of positives in the establishments is increasing, indicating that changes in their cleaning protocols or sanitation procedures should be made.

Listeria trends may also exist if positives are seen in a particular area over time. In the example provided in the tracking sheet in Appendix 4.3, positives were found on a freezer fan, wall, floor, and conveyor belt over a six month period. Although the establishment addressed each individual positive by routine cleaning and sanitizing (and the sampling site subsequently tested negative), positives still continued to occur in other areas of the freezer. The *Listeria* trend was not addressed until cleaning and sanitizing were escalated and repairs made to the freezer. Although every finding of *Listeria* trends may not require extreme steps such as equipment repairs or replacement, it is important for establishments to track their results in order to address harborage points. For more information on cleaning and sanitizing steps that can be taken to address positive results, see Appendix 2.2.

Positive product results for either *Listeria* spp. or *Lm* over time could also indicate a *Listeria* trend. FSIS uses results from its product and RLm and IVT sampling to track trends over time, by comparing pulsed-field gel electrophoresis (PFGE) patterns. These results can be used to demonstrate possible harborage and cross contamination in the establishment (see Appendix 3.3). FSIS may use this data to take regulatory action against the establishment. By monitoring and addressing *Listeria* trends, establishments can take a proactive role in demonstrating that they have controlled contamination in their processing environment.

When *Listeria* trends are identified, establishments should take corrective actions to address the trend. Corrective actions should include **intensified sampling** (as described in Section 4.2) and **intensified sanitation**. Along with intensified sampling and sanitation, establishments should perform a **comprehensive investigation** to find the source of the problem (see explanation below). **Preventative actions**, such as increasing sanitation frequency, intensified sanitation in particular areas or equipment, repairing or replacing equipment, increasing testing frequency, and reassessing the Sanitation SOP and HACCP program, should be taken.

NOTE: Continued findings of *Lm* in an establishment's products or contact surfaces could lead to foodborne illness and regulatory action (including suspension of inspection by FSIS). Therefore, it is important to ensure that trends are addressed ***before*** the product becomes contaminated.

Parts of a Comprehensive Investigation

In response to findings of *Listeria* trends, establishments should conduct a comprehensive investigation into the source of positives, which includes:

a. Review the cleaning and sanitizing procedures, including the types of cleaning agents.

b. Review traffic control patterns, equipment layout and adherence to employee hygiene procedures.

c. Locate possible niches that may represent harborages.

   i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for *Lm.*

   ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination.

   iii. Test up stream in the production area from the initial positives to find the source of contamination

   iv. Collect at least 3-5 samples per sampling event until negatives are found.

In conjunction with the comprehensive investigation, the establishment should take preventative actions, including examining and reviewing the HACCP plan, Sanitation SOP, or prerequisite program where the sanitation and testing programs are included. As part of this review, the establishment should evaluate these programs to determine if there are any design or execution flaws, and modify them as necessary.

4.6 Glossary

Comprehensive Investigation: An investigation performed by the establishment to address *Listeria* trends. As part of this investigation, the establishment should review cleaning and sanitizing procedures, traffic control patterns, and identify sources of harborage.

Corrective Actions: Procedures to be followed when a deviation occurs. These include actions the establishment will take to ensure that the cause of the deviation is identified and eliminated, the critical control point (CCP) will be under control after the corrective action is taken, measures to prevent recurrence are established; and no product that is injurious to health or otherwise adulterated enters commerce (9 CFR 417.3(a)).

Cross Contamination: Movement of a microorganism (e.g., *Lm*) from one site to another. Cross contamination may occur in the post-lethality processing area when *Lm* moves from a harborage area, such as a drain, onto equipment and product.

Enhanced Sampling Program: Includes follow-up and intensified sampling, performed in response to a positive FCS result from routine sampling program. Samples should be collected in addition to those collected as part of the routine sampling program.

Follow-up Sampling: Collection of a 2nd FCS sample performed in response to a 1st FCS positive result. Follow-up samples should be collected from the specific site of the original positive sample, as well as additional samples of the surrounding FCS areas as necessary to ensure the effectiveness of corrective actions (required for Alt. 3 deli and hotdog processors).

Harborage: Persistence of *Lm* in a processing establishment over time. Harborage areas are areas where bacteria may survive and multiply, and are often NFCSs that may be cleaned less frequently than FCSs.

Hold and test: Product samples that are held and tested by the establishment in response to a 2nd FCS positive result (required for Alt. 3 deli and hotdog producers).

Intensified Sampling: Sampling performed in response to a 2nd FCS positive testing result. Intensified sampling may include the collection of FCS, NFCS, and product samples, and is performed in order to find sources of harborage and cross contamination in the post-lethality processing environment.

Intensified Sanitation: Intensified sanitation includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives.

***Listeria* Trends:** Repetitive positive FCS, NFCS, or product samples that are not addressed by routine cleaning and sanitation. *Listeria* trends should be addressed by intensified sanitation and investigative sampling to find sources of harborage and cross contamination.

Preventative Actions: Actions taken in response to positive results to prevent further positives from occurring. These may include increased sanitation in particular areas or equipment, increased testing frequency, and review and revision of the HACCP program and Sanitation SOPs.

4.7 References

International Commission on Microbiological Specifications for Foods (ICMSF). *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. Kluwer Academic/Plenum Publishers, NY. 2002).

Appendix 4.1: Sampling Scenarios by Alternative

The following sections provide steps that establishments can take, depending on their alternative, once a positive is found. For a description of requirements by alternative, see Attachment 1.1.

a) Alternative 1

i) **Recommended**: Conduct tests of food contact surfaces (FCS) for *Lm*, *Listeria* spp., or *Listeria*-like organisms (LLO) **at least twice a year**.
ii) Sample at least a 12"x12" area for each surface, if possible.
iii) Record the test results.
iv) If the test results are positive for *Lm*, *Listeria* spp. or LLO:
  (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include intensified cleaning and sanitizing.
  (2) If the FCS test is positive for *Lm*, the product is considered adulterated. If the FCS is positive for *Listeria* spp., or LLO, the product is not summarily considered adulterated, but corrective actions should be taken.
  (3) Record the corrective actions taken.
  (4) Collect follow-up samples from the FCS and surrounding areas **(recommended).**
  (5) Repeat corrective action and testing until samples are negative for *Lm*, *Listeria* spp., or LLO.
  (6) Initiate intensified sampling after the 2nd consecutive positive.
  (7) If FCSs continue to test positive, hold and test product (**recommended**).
v) If the product tests positive for *Lm*,
  (1) Recall the product, if already shipped, and
  (2) Destroy the product, or
  (3) Re-work the product with a process that is destructive of *Lm*

b) Alternative 2, choice 1 (Alt. 2a)

i) **Recommended**: Conduct tests of FCSs for *Lm*, *Listeria* spp., or LLO organisms **at least quarterly**.
ii) Sample at least a 12"x12" area for each surface, if possible.
iii) Record the test results.
iv) If the test results are positive for *Lm*, *Listeria* spp., or LLO:
  (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program)
  (2) If the FCS test is positive for *Lm*, the product would be considered adulterated. If the FCS is positive for *Listeria* spp. or LLO, the product is not summarily considered adulterated, but corrective actions should be taken.
  (3) Record the corrective actions taken.
  (4) Collect follow-up samples from the FCS and surrounding areas **(recommended).**
  (5) Repeat corrective action and testing until samples are negative for *Lm*, *Listeria* spp., or LLO.
  (6) Initiate intensified sampling after the 2nd consecutive positive.
  (7) If FCSs continue to test positive, hold and test product (**recommended).**
v) If the product tests positive for *Lm*,
  (1) Recall the product, if already shipped, and
  (2) Destroy the product, or
  (3) Re-work the product with a process that is destructive of *Lm*.

c) **Alternative 2, choice 2 (Alt. 2b)**
   i) **Required**: Conduct tests of FCSs for *Lm*, *Listeria* spp., or LLO **recommended frequency: at least quarterly**.
   ii) Sample at least a 12”x12” area, if possible.
   iii) Record the test results.
   iv) If the test results are positive for *Lm*, *Listeria* spp., or LLO:
      (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program).
      (2) If the FCS test is positive for *Lm*, the product is considered adulterated. If the FCS is positive for *Listeria* spp., or LLO, the product is not summarily considered adulterated, but corrective actions should be taken.
      (3) Record the corrective actions taken.
         (a) Collect follow-up samples from the FCS and surrounding areas **(recommended**).
      (4) Repeat corrective action and testing until samples are negative for *Lm*, *Listeria* spp., or LLO.
      (5) Initiate intensified sampling after the 2nd consecutive positive.
   v) Holding and testing of product is **required*** (recommended after the **3rd** positive).
   vi) If the product tests positive for *Lm*,
      (1) Recall the product, if already shipped, and
      (2) Destroy the product, or
      (3) Re-work the product with a process that is destructive of *Lm*.
      *The establishment is **required** to identify when they will hold and test product. FSIS recommends that it hold and test product after the third consecutive positive result.

d) Alternative 3 (non-deli or hotdog products)
   i) **Required**: Conduct tests of FCS for *Lm*, *Listeria* spp., or LLO. **Recommended frequency: once a month**
   ii) Sample at least a 12”x12” area for each surface, if possible.
   iii) Record the test results.
   iv) If the test results are positive for *Lm*, *Listeria* spp. or LLO:
      (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program).
      (2) If the FCS test is positive for *Lm*, the product is considered adulterated. If the FCS is positive for *Listeria* spp. or LLO, the product is not summarily considered adulterated, but corrective actions should be taken.
      (3) Record the corrective actions taken.
      (4) Collect follow-up samples from the FCS and surrounding areas (**recommended).**
      (5) Repeat corrective action and testing until samples are negative for *Lm*, *Listeria* spp. o*r* LLO.
   v) Initiate intensified sampling after the 2nd consecutive positive.
   vi) Hold and test of product is **required*** (recommended after the **3rd** positive).
   vii) If the product tests positive for *Lm*,
      (1) Recall the product, if already shipped, and
      (2) Destroy the product, or
      (3) Re-work the product with a process that is destructive of *Lm*.
      *The establishment is required to identify when they will hold and test product. FSIS recommends that it hold and test product after the **3rd consecutive positive result.**

e) Alternative 3 (deli and hotdog products)

i) **Required**: Conduct tests of FCSs for Lm, Listeria spp., or LLO. **Recommended frequency:**
   (1) Large Establishments: **four times per month per line**
   (2) Small Establishments: **two times per month per line**
   (3) Very Small Establishments: **once per month per line**

ii) Sample at least a 12"x12" area, if possible.

iii) Record the test results.

iv) If the test results are positive for *Lm*, *Listeria* spp., or LLO:
   (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include intensified cleaning and sanitizing. If the FCS test is positive for *Lm*, the product is considered adulterated. If the FCS is positive for *Listeria* spp. or LLO, the product is not summarily considered adulterated, but corrective actions should be taken.
   (2) Record the corrective actions taken.
   (3) Collect follow-up samples from the FCS and the surrounding area **(required).**
   (4) Repeat corrective action and testing until samples are negative for *Lm*, *Listeria* spp., or LLO.

v) Initiate intensified sampling after the 2nd consecutive positive.
   (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
   (2) If the FCS test is positive for *Lm*, the product in the sampled lot would be considered adulterated. If the FCS is positive for *Listeria* spp. or LLO, the product is not summarily considered adulterated, but corrective actions should be taken.
   (3) Record the corrective actions taken.
   (4) Hold the product (see hold-and-test scenario below in Appendix 4.2).
   (5) **Test** product for *Lm* at a rate that provides a level of **statistical confidence** that the product is not adulterated **(required after the 2nd consecutive positive result).**
   (6) Conduct follow-up testing of the FCS each day until there are 3 consecutive negative test results for *Lm*, *Listeria* spp., or LLO.
   (7) At the same time, continue to **hold** each day's production lot until the test results for the FCS are negative.
   (8) If the test results for the product are positive for *Lm*,
      (a) Destroy the product, or
      (b) Re-work the product with a process that is destructive to *Lm*.

Appendix 4.2: Hold and Test Scenario

Hold-and-Test Scenario for Deli and Hotdog Products in Alternative 3

Assuming it takes to 3 days to obtain a test result for *Listeria* spp. or LLO:

Day 1 – Take food contact surface (FCS) samples

Day 4 –If FCS samples (from Day 1) are **negative** for *Listeria* spp. or LLO.

- ✓ Continue production, as the corrective action appears to have resolved the problem and test FCSs as scheduled.

If the FCS samples are **positive** (from Day 1) for *Listeria* spp. or LLO.

- ✓ Take corrective action (as specified in the HACCP plan, Sanitation SOP, or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Collect follow-up samples of FCS—target the most likely source of contamination, and also perform additional tests in the surrounding FCS area.
- ✓ Continue production.

Day 7 – If the follow-up FCS sample (from Day 4) is **negative** for *Listeria* spp. or LLO.

- ✓ Continue production, as the corrective action appears to have resolved the problem and test the FCSs as scheduled.

If the follow-up FCS sample (from Day 4) is **positive** for *Listeria* spp., or LLO.

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test the FCS-- target most likely source of contamination, and also take additional tests in the surrounding FCS area.
- ✓ Collect intensified samples of FCS, NFCS, and product.
- ✓ Hold and test Day 7 product lot (for *Lm* or *Listeria* spp. or LLO).
- ✓ Continue production, hold product from the day's production.

Day 8 –

- ✓ Test the FCS— target the most likely source of contamination, and also perform additional tests in the surrounding FCS area.
- ✓ Continue intensified sampling of FCS, NFCS, and product.
- ✓ Hold product from this day's production.

Day 9 –

- ✓ Test the FCSs-- target the most likely source of contamination, and also perform additional tests in the surrounding FCS area.
- ✓ Continue intensified sampling of FCS, NFCS, and product.
- ✓ Hold product from this day's production.

Day 10 –If the FCS sample (day 7 sample) is **negative** for *Listeria* spp. or LLO.

- ✓ Continue production and hold product from days 7, 8, 9 and 10 until the results from Day 7 product testing and Days 8, 9, and10 FCS testing are available and found to be negative, unless there is compelling justification that affected products are not adulterated.
- ✓ Resume the FCS testing according to the frequency stated in the HACCP plan, Sanitation SOP, or prerequisite program.

If the FCS sample (day 7 sample) is **positive** for *Listeria* spp., or LLO:

- ✓ Hold and test product from day 10 production.
- ✓ Test product from days 7, 8, 9, and 10 for *Lm*, *Listeria* spp. or LLO.
- ✓ Take corrective action.
- ✓ Intensive cleaning and sanitizing.

- ✓ Take FCS sample-- target the most likely source of contamination, and also perform additional tests in the surrounding FCS area.

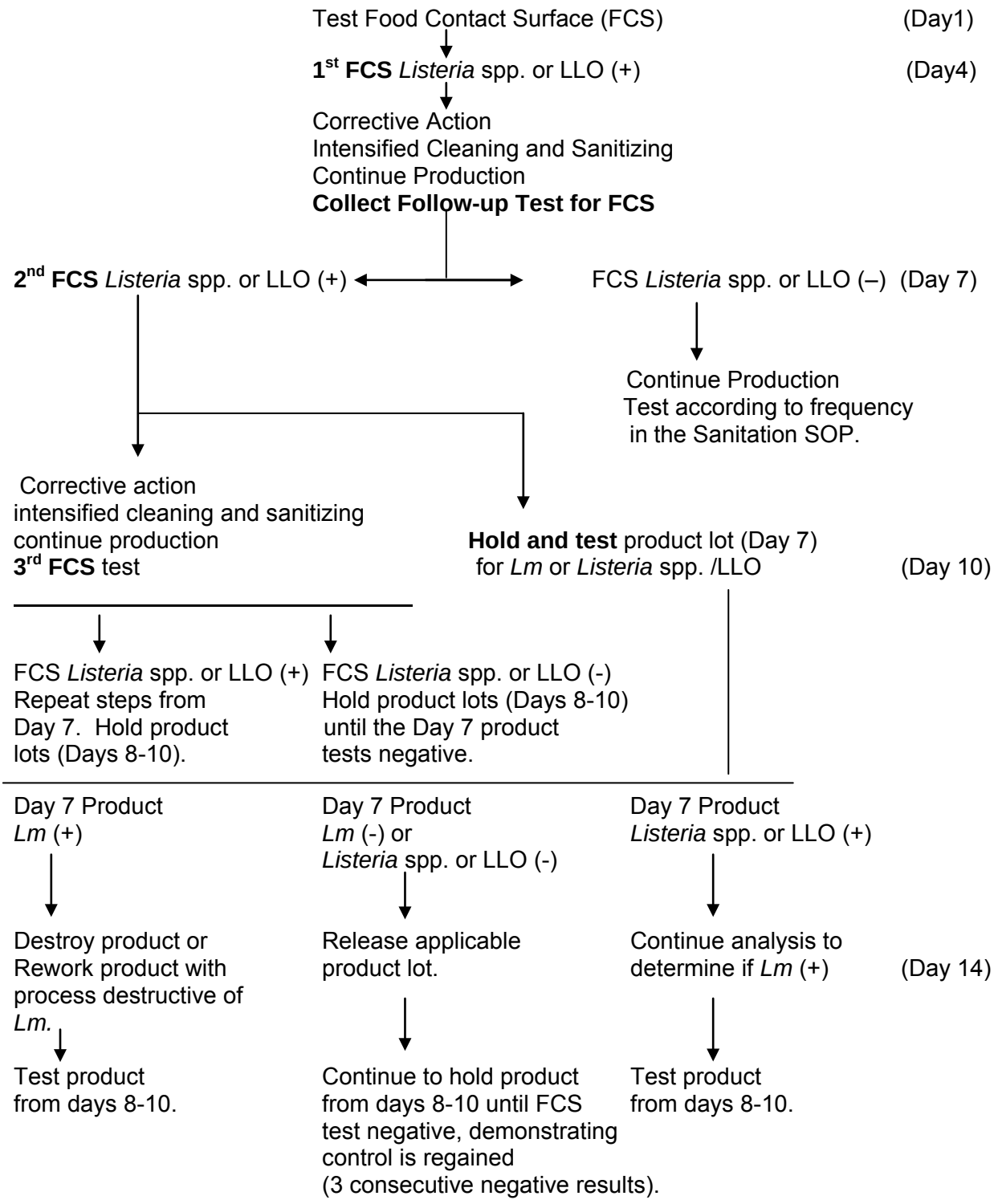
Day 14 – If the Day 7 product is **positive** for *Lm*, destroy product, or rework product with a process that is destructive of *Lm*. Recall product if already in commerce. If product is positive for *Listeria* spp., verify by testing that products (Days 7, 8, 9, 10), which may have been exposed to insanitary conditions are not adulterated

Question: An establishment that produces Alt. 3 deli and hotdog products tests FCSs on a Monday. The test comes back positive on Thursday. How would this affect the product produced on Monday, Tuesday, Wednesday, and Thursday?

Answer: If the test is positive for *Listeria* spp., the result would not affect product produced on Monday through Thursday. However, on Thursday, the establishment must initiate corrective actions, intensified cleaning and sanitizing, and verify the effectiveness of the corrective actions by follow-up testing of the FCSs.

If the test is positive for *Lm*, product that comes into direct contact with a FCS that tests positive for *Lm* is considered adulterated and FSIS would typically request that establishments recall such products if they have been released into the marketplace. That product must be destroyed or reworked with a process that is destructive of *Lm*. The establishment must have supporting documentation explaining why products produced on Tuesday, Wednesday and Thursday would not be contaminated with *Lm*. On Thursday, when it receives the positive result, the establishment must take corrective actions, conduct intensified cleaning and sanitizing, and test FCSs for *Lm* or indicator organisms to verify the effectiveness of the corrective actions.

Hold-And-Test Scenario Flowchart for Alt.3 (deli or hotdog producers)



FCS: food contact surface
Listeria spp. or LLO: *Listeria* spp. or *Listeria*-like organism (test results available after 2 or 3 days)
Lm: *Listeria monocytogenes* (test results available after 6 or 7 days)

Enforcement Strategy for Alternative 3 Deli and Hotdog Products

Under the *Listeria* Rule, an establishment with deli and hotdog products in Alternative 3 must provide for testing of FCSs. If a FCS tests positive for *Lm* or *Listeria* spp. or LLO, the establishment must conduct follow-up testing to verify that its corrective actions are effective. If during the follow-up testing another positive FCS occurs, the establishment must hold the applicable product lot if positive for *Listeria* spp. or LLO. If positive for *Lm*, destroy or rework with a process destructive of *Lm*, and test the FCS until the establishment corrects the problem as indicated by the test result. In addition, the establishment must test held product lots for *Lm* using a sampling plan that will provide a statistical level of confidence. The flowchart above shows a hold and test scenario that establishments under hold and test can use. The days described are approximate, depending on the typical amount of time needed to obtain a positive test result (see key at bottom of the flowchart). Establishments can adjust the flowchart based on their own process and time frame for sample results. The following section describes the likely action and reaction of inspection personnel during a hold and test situation.

Day 1 and 4

The testing program and the test results for FCSs and NFCSs should be made available to inspection program personnel (IPP). In case of an FCS testing positive for *Listeria* spp. or LLO, IPP will verify that the establishment is performing the corrective actions as specified in the HACCP plan, Sanitation SOP or prerequisite programs, including any intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, IPP will verify that the establishment is conducting follow-up testing for FCSs to determine the effectiveness of the corrective actions, targeting the most likely source of contamination, performing additional tests in surrounding FCS area, and recording the results of all these.

Day 7

Results of the follow-up FCS tests are available on this day. If the FCS tests are negative, then the establishment continues with its normal production and Sanitation SOP. If the follow-up FCS tests are positive for *Listeria* spp., or LLO, IPP will verify that the establishment is following its corrective action for a second FCS positive, including intensified cleaning and sanitizing. For deli and hotdog products in Alt. 3, inspection personnel will verify whether the establishment is holding the product produced that day and testing the product lot for *Listeria* spp. or *Lm*, and whether the establishment is conducting follow-up testing of FCS during each production day, and holding all products until a negative follow-up FCS test is obtained. Products produced on days 8, 9, and 10 are held until the follow-up FCS test available after about 3 days is found negative. The *Listeria* Rule states that products must be held until the problem is corrected, as indicated by testing. For establishments in Alt. 3 producing deli and hotdog products, inspection personnel can cite the establishment if these procedures are not followed.

Days 8, 9, and 10

The presence of *Listeria* spp. or LLO organisms on an FCS or on RTE product is associated with the potential for an insanitary condition to exist. FSIS expects an establishment to develop a compelling justification for concluding that product produced on days in which insanitary conditions may have existed is not adulterated. Thus, FSIS would further expect that the establishment, on days 8-10, would conduct verification testing on the FCSs to demonstrate that the potential insanitary condition was adequately redressed via the corrective and preventative actions. In addition, to further develop a compelling justification to support the establishment's decision, FSIS would expect a prudent establishment to also compile data on product testing to confirm and verify that the corrective and preventative actions were effective in preventing product from becoming adulterated.

Day 10

If Day 7 FCS Test is Positive, IPP will verify that if the follow-up FCS test taken on Day 7 is positive, then the day's production lots of deli and hotdog products in Alt. 3 are held and tested for *Lm* or *Listeria* spp, and the same procedures are followed as in the second FCS (+) test as in Day 7.

If FCS samples taken on day 7 are found positive for *Listeria* spp. on day 10, the establishment should hold and test product produced on days 8, 9, and 10 unless the establishment has supporting documentation to justify that product produced on days 8, 9, and 10 would not be contaminated with *Lm*. The sampling plan must provide a level of confidence that each product is not contaminated with *Lm*. Because of 3 consecutive positive FCS samples, the establishment should conduct intensive cleaning and sanitizing and reevaluate its Sanitation SOP.

If FCS sample is positive for *Lm*, affected product lots are considered adulterated. The establishment should also hold and test products produced on days 8, 9, and 10 because an FCS positive for *Lm* shows that the corrective action may not have been effective in removing the contamination and products produced on succeeding days may also be contaminated.

If Day 7 FCS Test is Negative
If FCS samples taken on day 7 are found negative for *Listeria* spp. or LLO on day 10, the establishment should wait for the results of the FCS tests conducted on days 8, 9, and 10 as detailed above, and results of the Day 7 product test before releasing these products. **Control is considered regained after 3 days of negative results.**

Day 14

If day 7 product was found positive for *Lm* on day 14, affected product lots produced on day 7 are considered adulterated. The establishment must destroy the product lots or rework them with a process destructive of *Lm*. The establishment should continue holding product lots produced on days 8, 9, and 10 until results of products tests are available, unless the establishment has supporting documentation for why product produced on days 8, 9, and 10 would not be contaminated with *Lm*. Establishment should also hold and test product produced before day 7 and recall them if already in commerce or provide compelling evidence that product produced before day 7 was not adulterated.

For a product sample that tests positive for *Lm*, inspection personnel will verify that the product lots affected are disposed properly, i.e., destroyed or reworked with a proces that is destructive to *Lm*. Establishments should have supporting documentation that products lots produced before Day 7 are not contaminated with *Lm,* so that these lots will not be included as adulterated.

A product that is positive for *Listeria*. spp. or LLO is not summarily determined to be adulterated, although it can lead to a determination that an insanitary condition exists and, without compelling documentation, the establishment may not be able to conclude that the product is not adulterated. This also indicates that corrective and preventative actions taken may not have been effective or that the Sanitation SOP is inadequate and ineffective and therefore, the establishment needs to take actions to prove otherwise. The establishment needs to have compelling documentation that the product is not adulterated and needs to determine that its sampling plan provides a level of confidence that each product is not contaminated with *Lm*.

If the establishment is using a post-lethality treatment or antimicrobial agent and the product tests positive for *Listeria* spp., LLO, or *Lm,* according to 417.6(e), the HACCP plan may be found inadequate. In determining whether the HACCP plan is inadequate, the Agency will take into account all available information and consider the entire situation. The cause and significance of a positive result varies from case to case depending on the circumstances of processing involve, and the pathogen found. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3.

Appendix 4.3: *Listeria* Trends Examples

The following are some scenarios describing how establishments can track and address *Listeria* trends.

Establishment A

Establishment A makes RTE salads, including potato salad, chicken salad, and ham salad for delicatessens in grocery stores. The establishment manufactures product in two 8-hour shifts, 6 days a week. The third shift is reserved for sanitation. It has identified three tiers in its sampling program: NFCS sampling, FCS sampling, and finished product testing.

It has identified 30 NFCS sampling sites, including the walls next to the preparation tables, the exterior of the mixing kettles, the mixer shaft, and the drains under the preparation tables. Each week it randomly picks 15 of the 30 sites for testing for *Listeria* spp.; these 15 sites are tested twice a week ("routine monitoring") before production. Results are tracked as total number of positives over time and also by site. When a positive is detected at any site, it is given extra attention during the next sanitation. If the number of positives exceeds 10% (e.g., if there are 3 positives out of 30) during the week (two test periods, rolling window) or if the same NFCS site comes up positive more than one time in a month, these sites are given extra attention during the next sanitation shift, and the areas are re-swabbed daily until there are three consecutive days of negatives. Once this has occurred, the establishment reverts to routine monitoring. If the problem is not corrected within 5 days, the establishment enters “trouble shooting" mode, which includes more stringent decontamination procedures, such as disassembly and sanitizing, fogging with sanitizers, changing sanitizers, double sanitizing, and heat treatments.

Establishment A also conducts routine random FCS testing and it has identified 20 FCSs, including tables, conveyor belts, and slicer blades. Each week, 10 of these are randomly selected and tested for *Listeria* spp., twice per week at the end of production and before cleaning. If a positive is detected, the site is given extra attention during the next sanitation shift and a follow-up sample is collected. The site is tested daily for 5 days. If the site is positive during this 5-day period, the line is shut down and, if appropriate, torn apart, taking trouble-shooting swabs during the disassembly. The product contact surface and surrounding areas receive extra sanitation and the line is re-assembled. FCS swabs are then taken every two hours during production and all products are placed on hold. If any swab tests positive, product from the 2-hour time period and from each period on either side is tested for *Lm*. Product that is negative is released. Product that tests positive is destroyed, since re-processing is not an option for this product.

The establishment conducts random product testing of one salad product each month by taking one package every two hours from an 8-hour shift and compositing product from two packages. The product is tested for *Lm*. Product found to be positive for *Lm* is destroyed and intensified sampling of FCSs for *Listeria* spp. is conducted daily for a week. If positive FCS results are found, the establishment undertakes investigations to determine the cause of the problem. The *Lm* control program is also reviewed and revised, as appropriate.

Establishment B

Establishment B produces fully cooked, breaded chicken products. The establishment manufactures product on three separate lines in two 8-hour shifts, 6 days a week. The third shift is reserved for sanitation. The establishment's NFCS monitoring component of its *Lm* control

program targets the area where product exits the fryer, is chilled, and then packaged. There are two parts to this establishment's program: product contact surface testing and non-product contact surface testing.

The establishment monitors 20 NFCSs on a weekly basis for *Listeria* spp. (routine monitoring). For each line, 5 swabs are composited, resulting in 4 tests per line for a shift. If a positive is detected, the establishment investigates by re-swabbing and testing the swabs individually, as well as by taking additional swabs in the area. If there are no additional positives, the establishment considers the initial positive to be an isolated incident and returns to routine monitoring. If additional positives are detected, the establishment institutes corrective actions, which may include a. review of the current *Lm* control program, revising GMPs, changing sanitizes, enhanced sanitation in clean areas, and employee retraining. The establishment then monitors twice a week (enhanced monitoring) until there are 4 consecutive negative periods, at which point the establishment returns to routine monitoring.

The establishment also monitors 15 FCSs on each line during each shift of production every other week. If the swabs are all negative, it continues routine monitoring. If there is a positive result, the establishment investigates by collecting a follow-up sample of the area, as well as by taking additional swabs in the surrounding area. In addition, it institutes corrective actions, which may include intensified cleaning and changing sanitizers. The establishment then takes swabs to confirm that the actions taken have been effective. If there are no positives, the establishment returns to routine monitoring. If there are any positives, the establishment escalates its corrective actions, which may include intensified testing, breaking down pieces of equipment and sanitizing, and heating pieces of equipment. It would also evaluate the need to conduct finished product testing based on all the existing evidence.

Example Table for Tracking Microbiological Sampling Trends

This table provides an example spread sheet that establishments may use to track testing results and corrective actions for *Listeria* spp. over time. Tracking this information will assist establishments in identifying trends and determining whether they are taking the appropriate corrective actions in response to positives and in reaction to trends. In the scenario below, a positive testing result was found on the freezer fan and addressed by the establishment. No trend was identified because it was the first positive found in that area. However, positives continued to be found in the same general area (Line 4 freezer) leading up to a food contact surface (FCS) positive on the belt exiting the freezer, despite progressively intensified corrective actions taken by the establishment. Negative results seen after the establishment identified a trend and took corrective action (including 3 negatives on the belt exiting the freezer) indicate that the trend was addressed. Corrective actions listed below are only examples and should not be considered the only methods to address *Listeria* spp. contamination. Regulatory testing for FCSs and non-regulatory testing of NFCS are shown within the table. **NOTE**: Establishments are **NOT** required to perform NFCS testing or follow-up testing in response to NFCS positives.

Sampling Results for *Listeria* spp. in an Alternative 3 Deli and Hotdog Small Volume Establishment

Date	Line #	FCS or NFCS	Surface Swabbed	Shift	Results	Follow-up Test Date	Follow-up Test Result	Intensified testing	Corrective Action	Trend Identified ?
9-Jan	4	FCS	QA utensil	2	neg.					
30-Jan	5	FCS	conveyor belt	pre-op	neg.					
9-Feb	1	FCS	conveyor belt	1	neg.					
12-Feb	3	FCS	eagle scale	pre-op	neg.					
19-Feb	1	FCS	plastic film	2	neg.					
19-Feb	5	NFCS	freezer structure	pre-op	neg.					
19-Feb	4	NFCS	Freezer fan	pre-op	positive	24-Feb	positive	3 days of Tests; (-) results	Removed product, recleaned Freezer and freezer fan	None
23-Feb	2	FCS	Freezer belt	2	neg.					
6-Mar	1	NFCS	Roller belts	pre-op	neg.					
6-Mar	4	NFCS	Hose	2	neg.					
10-Mar	4	FCS	product slide to freezer	pre-op	neg.					
10-Mar	4	NFCS	freezer air handler	pre-op	neg.					
18-Mar	5	FCS	return belt	1	neg					
18-Mar	3	NFCS	wall	1	neg.					
18-Mar	4	NFCS	stand	2	neg.					
23-Mar	2	NFCS	drain	2	neg					

Date	Line #	FCS or NFCS	Surface Swabbed	Shift	Results	Follow-up Test Date	Follow-up Result	Intensified testing	Corrective Action	Trend Identified ?
23-Mar	4	NFCS	freezer wall	1	positive	28-Mar	positive	3 days of tests; (-) results	Increase cleaning frequency for freezer, scrub freezer floors and walls.	Second positive in freezer area may indicate possible harborage , addressed by increased cleaning
3-Apr	6	FCS	tub	post-op	neg.					
3-Apr	4	NFCS	freezer floor	post-op	positive	8-Apr	positive	3 days of tests; (-) results	Intensified Cleaning of Freezer, consulted freezer manufacture r,	Third positive in area addressed by intensified cleaning.
3-Apr	1	NFCS	freezer structure	post-op	neg.					
6-Apr	4	NFCS	freezer floor	post-op	neg.					
21-Apr	3	FCS	conveyor belt	post-op	neg.					
21-Apr	4	NFCS	freezer wall	pre-op	neg.					
15-May	2	FCS	conveyor belt	1	neg.					
18-May	4	FCS	line personnel	pre-op	neg.					
15-Jun	1	FCS	product table	pre-op	neg.					
15-Jun	2	FCS	product scoop	1	neg.					
7-Jul	4	FCS	belt exciting the freezer	2	positive	13-Jul	positive	3 days of tests; (-) results; hold and test product (-) results	Stopped production. Repaired refrigerant leak. Intensified cleaning of freezer. Production resumed after repairs and cleaning.	Freezer is identified as a harborage point and addressed by repairs and cleaning.
14 Jul	1	NFCS	drain	1	neg.					
14 Jul	2	NFCS	wall	2	neg.					

Date	**Line #**	**FCS or NFCS**	**Surface Swabbed**	**Shift**	**Results**	**Follow-up Test Date**	**Follow-up Test Result**	**Intensified testing**	**Corrective Action**	**Trend Identified ?**
30-Jul	4	FCS	knife blade	1	neg.					
3-Aug	1	FCS	spiral slide	2	neg.					
14-Aug	4	NFCS	freezer wall	pre-op	neg.					
14-Aug	4	NFCS	product entrance facing freezer	pre-op	neg.					
20-Aug	4	FCS	belt exiting the freezer	2	neg.					
26-Aug	10	FCS	product rack	1	neg.					
26-Aug	4	NFCS	freezer floor	post-op	neg.					
12-Sep	2	FCS	line personnel	2	neg.					
26-Sep	9	NFCS	condemn tub	pre-op	neg.					
26-Sep	7	FCS	product tray	pre-op	neg.					
28-Sep	4	FCS	belt exciting the freezer	2	neg.					
1-Oct	4	NFCS	freezer air handler	1	neg					
1-Oct	4	NFCS	freezer wall	pre-op	neg					
1-Oct	6	FCS	employee gloves	1	neg					
12-Oct	4	NFCS	freezer floor	2	neg					
12-Oct	4	FCS	belt exciting the freezer	1	neg					

Key
FCS = Food contact surface
NFCS = Non food contact surface

Appendix 4.4: Findings from Food Safety Assessments (FSA)

In 2009, FSIS began performing routine Food Safety Assessments (FSAs) in RTE establishments at a frequency of once every 4 years. These FSAs are performed along with routine risk-based *Lm* (RLm) sampling. FSIS also performs "for cause" FSAs along with Intensified Verification Testing (IVT). The purpose of the FSA is to evaluate the food safety systems (including the HACCP plan and Sanitation SOP) at the establishment to determine if they are effective in controlling the safety of the product. FSAs are performed according to FSIS Directive 5100.1 "Enforcement, Investigations, and Analysis Officer (EIAO) Food Safety Assessment Methodology," found at: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5100.1Rev3.pdf.

FSIS reviews the findings from "for cause" FSAs performed in response to IVTs on a quarterly basis. The findings from these reviews are used to help develop new policy and revise current policy to ensure that establishments are meeting the requirements of the *Listeria* Rule. By summarizing the findings FSA reports, FSIS can provide information to RTE establishments so that they can focus their attention on areas where further improvements in their food-safety systems may be needed. During the FSA review, it was found that several of the establishments had deficiencies in their Sanitation and HACCP design and record keeping systems.

These problems included the following:

- **The establishment failed to follow written *Listeria* programs.**

  According the *Listeria* Rule, establishments in Alt. 2b and 3 are required to indicate their sampling frequency and explain why the frequency they have identified is sufficient to control *Lm* or an indicator organism. As described in the *Listeria* Guideline, establishments can document the sampling frequency they have identified as part of the *Listeria* Control Program (Section 3.1). Once the establishment has established a frequency as part of its program, it would need to follow the sampling frequency. If an establishment does not follow the sampling frequency by not collecting a sample during the timeframe specified in their program, it would be found to be non-compliant, unless it can provide other supporting documentation demonstrating that its process is safe.

- **The establishment did not perform monitoring at frequencies specified in the HACCP plan.**

  In some cases, establishments identified a certain frequency for monitoring the CCPs associated with RTE products (e.g., measuring lethality temperatures) and did not monitor the temperature at the specified frequency. By failing to monitor the CCPs at the specified frequency, the establishment could miss processing deviations that could occur, leading to under processing or other safety issues in the product.

- **The establishments did not document corrective actions sufficiently.**

  If a deviation occurs from a critical limit, establishments are required to take corrective actions to bring the process under control (9 CFR 417.3). These corrective actions must include measures to prevent recurrence of the deviations. In some cases, the corrective actions written by the establishments did not provide sufficient explanation to demonstrate how future deviations would be prevented.

- **The establishment did not provide supporting documentation for their post-lethality treatments (PLT) and antimicrobial agents (AMA).**

  In some cases, establishments did not support that their PLTs achieved at least a 1-log reduction of *Lm* in the product or that the AMA allowed no more than 2-logs growth of *Lm* over the shelf-life of the product. The *Listeria* Guideline provides specific guidance establishments can use to ensure that the supporting documentation for the PLT and AMA is sufficient and reflects the critical operational parameters of their process (see Appendix 2.1).

- **The establishment failed to maintain sanitary operations and failed to maintain equipment and utensils in a sanitary manner.**

  In some cases, positive results were found during the RLm or IVT, indicating that sanitary operations were not maintained or that equipment and utensils were not maintained in a sanitary manner. In one case, condensation was dripping directly on exposed-RTE product. The *Listeria* Guideline provide information establishments can use to ensure that sanitary operations are maintained (see Appendix 2.2). In addition, establishments can use verification testing to ensure that their food-contact surfaces are sanitary and free of *Lm.* By collecting samples of non food contact surfaces, establishments can find potential harborage points and address them before the product becomes contaminated. Establishments are required, according to 9 CFR 416.2 (b), to ensure that the facility and the equipment are sanitary and in good repair, so that potential sources of cross contamination, such as condensation, are minimized.

- **The establishment did not identify the location and the sites that will be sampled for testing of food contact surfaces in the post-lethality processing environment and provide an explanation of why the testing frequency was sufficient to ensure that effective control of *Lm* or of indicator organisms is maintained.**

  If an establishment chooses either Alt. 2b or 3, it must test FCSs in the post-lethality processing environment, identify the frequency for testing, and provide an explanation of why the testing frequency is sufficient to ensure the effective control of *Lm* or indicator organisms (9 CFR 430.4(b)(2)(iii)(A), (C), and (E) and 430.4(b)(3)(i)(A), (C), and (E)). The FSIS expectation is that establishments in Alt. 2b or 3 will identify all possible FCS for testing. The *Listeria* Guideline provide information on site selection and a list of possible FCSs and NFCSs the establishment could sample (see Appendix 3.1).

  Recommended minimum testing frequencies are also provided in the *Listeria* Guideline (see Section 3.3). Establishments can use the recommended frequencies or select their own frequency; however they would need to provide support that the level of testing is sufficient to demonstrate that *Lm* is controlled in the product. Establishments should increase their sampling frequency due to repeated positive results, construction, or sanitation issues.

- **The establishment did not address hazards reasonably likely to occur in the production process.**

  Some establishments did not list all of the steps in the processing of their product in their flow chart, as required by 9 CFR 417.2(a)(2). In some cases, the establishment did not

consider possible hazards from ingredients (such as spices) added after the lethality treatment. In other cases, the establishment did not have supporting documentation on file, such as letters of guarantee or certificates of analysis (COA) demonstrating that the ingredients it added to product were safe and would not cause the product to become adulterated. Information on ensuring the safety of ingredients in RTE product can be found in the FSIS RTE *Salmonella* Guideline, available at: http://www.fsis.usda.gov/PDF/Salmonella_Comp_Guide_042211.pdf. Information on avoiding sources of environmental contamination can be found in the *Listeria* Guideline (see Appendix 2.2).

By reviewing the examples provided above and addressing deficiencies in their food-safety programs, establishments can help ensure that they meet the requirements of the *Listeria* Rule. In addition, by reviewing their programs to ensure that possible weaknesses are addressed, establishments can produce safe products and help protect public health.