農林水産省補助事業

米国食品安全強化法

「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかるリステリア環境プログラム例

＜英語原文＞

2018 年 6 月

日本貿易振興機構（ジェトロ）

農林水産・食品部　農林水産・食品課

シカゴ事務所

本資料は、2015 年 9 月 17 日に公表された米国食品安全強化法「ヒトが摂取する食品に関する予防管理についての最終規則」に関して、米国の弁護士事務所 Olsson Frank Weeda Terman Matz PC(OFW)が作成した「リステリア環境プログラム例」です。

＜Olsson Frank Weeda Terman Matz PC(OFW)＞

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ジェトロでは、米国食品安全強化法（FSMA）への対応の参考とすることを目的に本調査報告書を実施しました。ぜひお役立ち度アンケートにご協力をお願いいたします。

◆本報告書のお役立ち度　（必須）

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本アンケートはインターネットでもご回答頂けます

（ https://www.jetro.go.jp/form5/pub/afa/fsma ）

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【報告書名：「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかるリステリア環境プログラム例＜英語原文＞】

はじめに

本調査報告書は、2015 年 9 月 17 日に公表された米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」（PCHF）規則に関して、食品安全計画の策定のための参考資料として「リステリア環境プログラム」の例を作成したものである。

*リステリア・モノサイトゲネス*は、食品を汚染し、軽度で非侵襲性の病気（リステリア性胃腸炎）または重度の侵襲性の疾病（リステリア症）を引き起こす可能性のある環境病原体である。リステリア症は、他の多くの食品媒介病原体（サルモネラ菌または大腸菌 O157）と比較して死亡率が比較的高いことが特徴である。*リステリア・モノサイトゲネス*で汚染された食品の摂取によりリステリア症を発症する危険性が最も高い人は、妊婦と胎児、高齢者、免疫系の弱い人である。過去にアウトブレークを引き起こした食品は、通常、製造／加工または梱包中に環境から汚染されている。

米国では、リステリア症は主に Ready-To-Eat 食品（そのまま食べられる食品、RTE 食品）に関連しているとされ、その pH や水分活性などの内因性特性を適正に管理・組成し、*リステリア・モノサイトゲネス*の増殖を抑制することが、リステリア症のリスクを低減させるために重要だとしている。

リステリア環境プログラムの様式は、PCHF 規則では規定されていない。またそれぞれの施設によって設備や製品、製造工程などは個々に異なるため、本報告書に記載された内容はあくまで一例である。実際の事業者のリステリア環境プログラムは、この例に施設固有の管理すべき危害や予防管理手順を修正・追加することによって、適切なものとなる点に留意いただきたい。

なお、FDA は 2017 年 1 月に、リステリア・モノサイトゲネスの管理に関する産業界向けガイダンス案を発行しているので、あわせてご参照のこと。

○Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods
https://www.fda.gov/RegulatoryInformation/Guidances/ucm073110.htm

○Ready-To-Eat（そのまま食べられる）食品におけるリステリア・モノサイトゲネスの管理：産業界向けガイダンス 案（ジェトロ仮訳）
https://www.jetro.go.jp/ext_images/world/n_america/us/foods/fsma/readytoeat.pdf

本調査報告書が米国食品安全強化法（FSMA）への対応の参考となれば幸いである。

2018 年 6 月

日本貿易振興機構（ジェトロ）
農林水産・食品部　農林水産・食品課
シカゴ事務所

Generic Listeria Environmental Program

Contents

Generic Listeria Environmental Program

1. Purpose: Listeria monitoring is not a mandatory sampling requirements under the US Food and Drug Administration's (FDA) Preventive Controls for Human Foods, FDA would expect a facility to have a program if its hazard analysis identifies that a preventive control is needed.[1] Moreover, the FDA's Food Advisory Committee (FAC) has recommended that FDA adopt the United States Departments of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) policy as its approach to Listeria sampling.

2. Reference: Our program is based on the requirements specified in the January 2014 FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post Lethality Exposed Ready to Eat Meat and Poultry Products, hereafter referred to as the "Compliance Guideline." All program specifics are based on the Compliance Guideline and will have references to same when necessary.

3. Organism To Be Sampled: For routine testing, Listeria species is tested as an indicator organism (note that genus Listeria includes a subset of at least 18 different species thereby increasing the odds of finding an organism of interest.) If under Intensified Sampling a product Hold and Test is triggered, product testing will be directly *for Listeria monocytogenes*. Reference page 116, Table 4.1 (below) of the Compliance Guideline.

(**NOTE**: While the table below discusses follow-up sampling and intensified sampling, the **key** to a rigorous Listeria control program is the investigation done to determine the root cause of the positive. This root cause investigation should be done for every positive received and should begin immediately after notification of positive sample (even if the sample is never confirmed as *Lm)*. The purpose of the investigation is to determine how the Listeria got to the positive site. While corrective action – cleaning – will eliminate the positive site – the key is to determine how the site became positive to prevent it from occurring again. **This is also the main documentation on which both regulatory agencies will concentrate when reviewing actions taken as a result of a positive sample**.

Table 1

Type of Product Produced	**After 1st Positive**	**After 2nd Positive**	**After 3rd Positive**	**After Multiple Positives**
Product produced using a post-lethality treatment (PLT) to reduce or eliminate Lm in the product and an antimicrobial agent or process (AMAP) to limit or suppress growth of Lm in the product.	Follow-up sampling	Intensified sampling		Hold and Test recommended
Product produced using a PLT to reduce or eliminate Lm in the product.	Follow-up sampling	Intensified sampling		Hold and Test recommended
Product produced using an AMAP to limit or suppress growth of Lm in the product.	Follow-up sampling	Intensified sampling	Hold and test required (recommended after 3rd positive)	

[1] Most RTE foods' hazard analysis would identify that a preventive control for Listeria was needed.

The facility relies on sanitation alone to control Lm in the processing environment and on the product.	Follow-up sampling	Intensified sampling (Hold and test required after 2nd positive)

Keep in mind that this should be done for not only food contact surfaces (FCS), but also for positives found in drains or elsewhere. Listeria does not magically appear in a drain, it generally is washed there from another site. It is the route to the drain that you are trying to determine. An investigation would look at water flow during production to try to determine if Listeria was introduced to the drain from equipment, personnel movement, etc. While it is not always possible to determine the exact root cause, many times issues that could have resulted in the positive are identified and are able to be addressed. If the site then remains negative, this supports that your investigation likely corrected the issue.)

4. Types of Products Produced: All products covered by this plan are in the (list the types of products by HACCP category or preventive controls plan). There are several published challenge studies that cover these types of items including the following that were conducted at (add information here as necessary). The following Table summarizes the results of these published studies and shows the efficacy of (brief explanation of what studies are being used to demonstrate or support, if appropriate):

(Below is an example of summarizing several studies demonstrating a reduction of Lm after packaging using a wide variety of packaging options and various dried products. This may not be necessary depending on what alternative(s) and support you are using for specific decisions/controls.)

Effect of Packaging and Storage Time on Survival of Listeria monocytogenes on Kippered Beef Steak and Turkey Tenders: Kamaldeep K. Uppal, Kelly J.K. Getty, Elizabeth A.E. Boyle, Nigel M. Harper, April Shayne S. Lobaton-Sulabo, Bruce Barry (Journal of Food Science Article first published online: 2 DEC 2011)

Package systems and storage times serve as post lethality controls for Listeria monocytogenes on whole-muscle beef jerky and pork and beef smoked sausage sticks. by April Shayne S Lobaton-Sulabo, Tyler J Axman, Kelly J K Getty, Elizabeth A E Boyle, Nigel M Harper, Kamaldeep K Uppal, Bruce Barry, James J Higgins Journal of Food Protection 2011: Vol 74, 188-192.

KSU Challenge Study Results for Lm Post Pack Log Reduction on Meat Snacks

Product	Packaging Treatment	Oxygen %	Log Redux 24 hrs	Log Redux 48 hrs	Log Redux 72 hrs	Aw	pH	Moisture	Protein	MPR	Fat	Salt	Cured
Kippered Beefsteak	Heat seal only	19	1	1	2.1	0.83	6.0	38.3	29.2	1.31	6.1	5.4	Yes
	Nitrogen Flush	<.2	1	1	2.1								
	Flush & Absorber	<.2	1	1	2.1								
	Vacuum	0	1	1	2.1								
Pork & Beef Dry Sausage	Heat seal only	19	2	2.3	2.5	0.82	5.0	22.0	23.4	0.94	48.0	4.3	Yes
	Nitrogen Flush	<.2	2	2.3	2.5								
	Flush & Absorber	<.2	2	2.3	2.5								
	Vacuum	0	2	2.3	2.5								
Turkey Tenders	Heat seal only	19	1.4	1.6	1.9	0.81	5.6	32.1	35.9	0.89	2.5	4.0	No
	Nitrogen Flush	<.2	1.6	1.5	2.2								
	Flush & Absorber	<.2	1	1.1	1.6								
	Vacuum	0	1.2	0.9	1.5								
Beef Jerky	Heat seal only	19	0.8	1.7	2.2	0.78	5.4	28.1	39.6	0.71	2.1	4.8	Yes
	Nitrogen Flush	<.2	1.1	1.6	2.4								
	Flush & Absorber	<.2	0.5	1.2	1.2								
	Vacuum	0	1.4	1.4	2.1								

5. Routine Sampling Program

Frequency and Sampling Sites (Please see pages 88-93 of the Compliance Guideline)

- Each RTE line in the facility will be swabbed for Listeria genus four times per year or approximately once per quarter. In rare situations where a line runs infrequently, it may be necessary to accept fewer sample sets.
- Line selection does not have to be random. Lines may be swabbed at any day or time of the week as long as the line has been in operation for at least three hours since a major clean up. (Though there is no mention of "random" selection, the expectation by FSIS is that the selections over time be "representative." as defined on page 92 of the compliance guideline, in the Sample Frequency Considerations box. However discussion on the same page indicates that at least initially, the samples **should be random** to ensure all FCS have an equal probability of being sampled. Best practice is that the last FCS on the line be sampled each time and 4 other sites (as an example) be randomly chosen using a random number generator program. The establishment should also have a plan so that all FCS will be sampled over a specified period of time –annually for example. Once data has been generated to demonstrate effective control of the system, then FSIS recommends a more "risk-based" sampling approach. Initial validation of a sampling program would suggest that sampling is done on a more frequent and aggressive basis and once validation is complete, the program moves to a routine or risk-based approach.)

- During each swabbing session, swab locations will be defined by Zones. These Zones are defined as follows:

  Zone One - *Direct product contact*. This includes all product contact equipment and utensils including wagons, rods, or screens as well as gloves and other protective coverings used by people that actually touch the product. (Establishments need to determine whether or not sites or even gloves are Zone 1 or not based on analysis of that specific site. Some employee gloves may not be food contact.)

  Zone Two - *Near product contact*. These areas would include equipment supports, the outside of product contact surfaces (for example, one side of an Ishida bucket touches product the other does not), control panels, small tools, clipboards, pallet jack handles, takeaway belts, lazy susans, etc. These areas could be touched by gloved hands which then could move on to product contact areas or have rare/brief product contact.

  Zone Three - *Non-product contact areas less adjacent to product*. These sites are still in the RTE area and may include sites such as telephones, hand jacks, forklifts, walls, drains, floors, waste containers, garbage carts, floor scales, supply shelves, floor mats.

  Zone Four - *Plant environment such as walls, floors, ceilings, material handling tools,*

and other equipment that are located outside the RTE area. (Samples in this area may be taken during an investigation but would not normally be part of routine sampling as an establishment's procedures should control the entrance of Lm into the RTE Area. If there is a high risk of Lm being carried into the RTE area due to the process, Zone 4 samples may be part of the routine sampling program.)

- List of specific sampling sites – please see the Listeria Site List attached as Appendix 1 (Specify the form here which lists the sample sites. The list should be part of a regular review to ensure all sites have been identified. This may be in a spread sheet that allows for random sampling of site groups to identify which samples will be taken each sampling time.) for a detailed description of sampling sites for those sites on every machine and sampling area in the RTE area (Zones 1-3). (**Note**: Per the Q&A box on page 89 of the Compliance Guideline, each piece of equipment may have multiple sampling sites. Best practice is to generally have as complete a list as possible, meaning that all sites on a piece of equipment have been identified. Of course, your plan needs to recognize that such equipment may have both multiple FCS and non-FCS, and should be designed to sample these sites according to your program.)

- Frequency Summary - While each line is swabbed four times per year, the combination and frequency of certain zones will be based on the following schedule. (Example)

  Each machine/ line will be tested as follows (26 swabs annually per line):
  Zone One = 4 swabs / 4 times per year
  Zone Two = 1 swab / 4 times per year
  Zone Three = 1 swab / 2 times per year
  Any Zone at Preop = 2 swabs / 2 times per year

(Note: Refer to pages 90 - 93 of the Compliance Guideline for expectations for what should be considered when designing a sampling frequency.)

(Note: The minimum regulatory frequencies that USDA-FSIS provides are just that, the minimum. It is safe to say that FSIS and FDA would expect in most cases for establishments to **increase** their frequency in response to positives or Listeria trends over time. (See Chapter 4 (page 115) of the Compliance Guideline for sampling protocol guidance for "follow up" and "intensified" sampling.) An establishment must be able to validate that its program is adequate in preventing product adulteration and the minimum sampling is seldom adequate for the majority of establishments. All plans should include how the establishments will track and trend its sampling and results.)

Sampling and Testing Methods (Please see FSIS Expectations for Sampling Methods – 95, and Appendix 3.2, FSIS Sampling Procedure – Pages 107-108, and FSIS Expectations for Testing Methods – Page 3-11, and Appendix 3.3 Sample Collection and Testing Methods – Pages 3-24,25,26,27 of the Listeria Compliance Guideline.)

FSIS Expectations for Sampling Methods

Aseptic Technique: Sampling should be performed by a person trained in aseptic technique and samples should be collected using sterile sponges or other sampling devices.

Sample size: A 12"x12" area should be sampled, when possible, for FCS and NFCS surfaces. If the surface area is smaller than 12"x12", then the entire surface should be sampled.

NOTE: Cotton-tip swabs and other smaller sampling devices are not recommended for sampling large areas (12"x12") because they may become easily saturated with microorganisms. If these devices are used, FSIS recommends collecting a smaller sampling size according to the manufacturer's instructions to equal a 12"x12" area.

Sample collection: The sponge or sampling device should be hydrated with sterile neutralizing buffer, Dey Engley (DE) broth, or another sterile broth that contains components that can neutralize the effects of sanitizers that may be present in the sample.

When to collect samples: Some samples can be collected at pre op, but most samples should be collected at least 3 hours into operations, if possible, to allow *Lm* to work its way out of the equipment. If the establishment typically produces RTE product for less than 3 hours then the samples can be collected less than 3 hours into operations.

Sample integrity: Samples should be stored under refrigeration before analysis. Samples should be properly labeled to avoid confusion regarding testing results.

Brine sampling: Some establishments use brine to cool or inject into RTE product. Depending on whether the finished product surface is directly exposed to brine after the lethality step, the brine solutions could be considered either as food contact or environmental samples.

Sample compositing: FCS samples may be composited (combined) in order to conserve establishment's resources. If compositing is performed, FSIS recommends that no more than 5 samples be composited, and **separate** sponges (or other sampling device) be used to collect each sample, to avoid possible cross contamination. One laboratory test can then be performed on the 5 separate samples, decreasing the cost to the establishment.

In addition, individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing. **If a composited sample tests positive, the establishment should consider all the sites represented by the sample as positive and take corrective actions accordingly.** During follow-up sampling of FCSs, the sites should be **re-sampled individually,** along with additional swabs in the area. For more information on compositing, see Appendix 3.3.

Handling and shipping of samples: If the samples will be analyzed by an in-house lab, testing should be initiated immediately after collection. If not tested by an in-house lab, the testing should be initiated within 2-3 days of collection. If this is not possible, the establishment should provide evidence that another strategy does not compromise the sensitivity of the method. The samples should be stored under refrigerated conditions (33 – 45 ˚F), and in no case be allowed to freeze, which could kill organisms captured on the sampling device. Samples should be placed into insulated shipping containers and sent refrigerated to the laboratory. Lastly, the identity of the sample should be maintained during testing to ensure that sites are correctly

NOTE: Direct plating methods (e.g., media that is added directly to an agar plate or dehydrated media) that do not include an 8-hour enrichment step would be unlikely to detect low levels of *Listeria* spp. or *Lm.*

NOTE: It is not sufficient for methods to be AOAC or ISO validated alone. To meet regulatory expectations for testing methods, the method should also include an enrichment step and analyze the entire sponge or sampling device.

Expectation for Testing Methods
Establishments may test for *Lm*, *Listeria* spp., or Listeria Like Organism (LLO). Testing can be performed either in-house or at a third-party laboratory (*see* Appendix 3.3). **However, if the testing is performed at a third-party laboratory, the establishment should be familiar with the method used by the lab, have the method on file at the establishment, and know whether it meets expectations for testing methods.**
If an establishment uses the testing results to support the decision made in its hazard analysis that *Lm* is not reasonably likely to occur in its product, then it is important that the results are reliable and accurate. Further information on testing methods can be found in Appendix 3.3 on page 110.

The following are FSIS's expectations for testing methods:

1) **An enrichment step is used** to allow for recovery of injured organisms and growth of *Listeria* to levels that can be detected by most testing methods. Many commonly used testing methods are unable to detect levels below 100 cells/sample. Therefore, it is important that the enrichment step be designed to allow low levels of cells that may be present in the sample to grow to detectable levels. It is also important to allow injured cells time to recover so that they can be detected by the testing method. In most cases, at least an 8-hour enrichment is needed to achieve adequate levels of *Lm* growth for detection. A one-hour resuscitation step is not an enrichment step, and would likely not be sufficient to detect low levels of *Listeria* spp. or *Lm*.

2) **The entire sponge or sampling device is analyzed.** Some methods involve testing just a small part of the broth or other diluent used to hydrate the sponge or sampling device. Studies have shown that bacteria are likely to be trapped on or in the interior of the sponge or other sampling device. Therefore, FSIS suggests that the whole sponge or sampling device be included in the enrichment step. Analyzing the entire sampling device will help ensure that cells that are present will be detected.

3) **The method has been validated**. All screening methods should either be used by a regulatory body (e.g., FDA Bacterial Analytical Manual (BAM)), or validated by a recognized independent body (*e.g.*, AOAC, AFNOR, ISO, NordVal, Microval). A validated method from a scientifically robust study using the FSIS *Lm* qualitative method as a reference method, or other validated cultural methods is also acceptable, but would be subject to FSIS review.[2] In addition to guidance provided by the recognized independent bodies mentioned above, FSIS has provided guidance on the design of validation studies for pathogen testing methods in the FSIS Guidance for Test Kit Manufacturers, Laboratories: Evaluating the Performance of Pathogen Test Kit Methods.

6. Enhanced Sampling Program

Follow Up Testing: Please see Chapter 4 Pages 115-118 of the *Listeria* Compliance Guideline.

- After a food contact surface positive the plant is required to make a comprehensive investigation into the source to try to determine the root cause of the positive sample. This could include but is not limited to the following:

[2]Submit request for review of methods to AskFSIS.

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.

- Written results of the investigation with corrective actions and preventative measures will be maintained on a Corrective Action Report.
- Testing should continue until 3 consecutive day sets of negative FCS tests are obtained.
- A move to Intensified Sampling does not happen on the second positive if there are intervening negative results, proof of this can be found at Appendix 4.2, Page 129 of the Compliance Guide.
- If a second **Consecutive** positive occurs, the plant then moves to Intensified Sampling.

Intensified Sampling: Please see Section 4.2 Pages 117-118 and Appendix 2.2, Page 68 of the Compliance Guide

- Intensified sampling increases the sampling protocols to include environment as well as food contact surfaces.
- The investigation must move into a more global response and include tearing equipment down into component parts for further cleaning, replacing broken equipment, thorough evaluation of HACCP including the effectiveness of interventions, reassessing SSOP's and, if necessary, construction.

- As with Enhanced Sampling, written results of the investigation will be maintained on a Corrective Action Report.

- Intensified sampling protocols must be maintained until 3 consecutive days of negative FCS results are obtained demonstrating that corrective actions were sufficient to address the contamination issue (Section 4.3, Page118 Compliance Guideline.)

- The finding of a (refer to table on page one for guidance on triggering hold ant test, based on alternative chosen) **consecutive** positive from the same site indicates a serious contamination issue and the plant must move into Hold and Test.

Hold and Test: Please see Section 4.3 Pages 118-121of the Compliance Guide

- Lot by lot product testing is initiated in this phase. A Production Lot is defined by FSIS as follows (Section 3.6; Page 100 Compliance Guide):

Production lot

A production lot is the amount of product that may be impacted by a product or FCS positive test result. As previously stated, establishments are required to hold or maintain control of RTE products that FSIS has tested for *Lm* or RTE products that have passed over food contact surfaces that FSIS is testing for *Lm.* Establishments may move such products offsite provided that they maintain control of them (e.g., through company seals). A production lot is typically defined as all product produced from clean-up to clean-up unless the establishment can support a smaller lot size. If the establishment performs a complete cleaning and sanitizing (following the procedures in its Sanitation SOP) between lots, the lot size could be reduced. Factors that should be taken into account when determining lot size include RTE source materials used, frequency of cleaning and sanitizing, and processing steps.

NOTE: An establishment may reduce its lot size on a day when FSIS collects a sample, in order to facilitate holding the product, as long as the change does not interfere with FSIS's ability to collect a representative sample.

Products produced in the same room could be considered part of the same or different processing lots, depending on how the lots are separated. If the processing lines can be considered microbiologically and physically independent of one another (i.e. equipment, personnel, utensils, and RTE source materials are not shared among the lines), then they can be considered different lots. An example of a common source material could be chicken in a chicken salad that is taken from the same package over multiple lots. If a FCS tests positive on one line, and the establishment has supporting documentation that there is not cross contamination among the lines, then lots produced on the other lines may not be implicated.

Likewise, products produced on the same line could be considered different processing lots, if they are separated by a complete cleaning and sanitization, as well as the other factors described above.

NOTE: Products stored in a common cooler would not necessarily be considered part of the same lot. However, the establishment's Sanitation SOP should address possible cross contamination, especially if RTE and raw products are held in the same cooler.

- 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.

- Product will be tested for *Listeria monocytogenes*.

NOTE: For guidance on selecting an appropriate ICMSF Case sampling protocol, see section 4.3, pages 119-121 of the Compliance Guideline. As a default, if the risk of the population is unknown, FSIS recommends that establishments use cases 13 – 15.

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

- 25 gram samples should be collected aseptically with instructions not to composite.
- Company will maintain third party lab methodology on file including the enrichment step.
- Lm positive results for product will mean that the product must be reprocessed with either a PLT validated for a 5 log reduction of Lm or recooked with a heat treatment validated for a 5 log reduction of Salmonella (Section 4.4, Pages 121-122 of the Compliance Guideline.)
- The plant will hold the entire production lot as well as subsequent lots until control is regained as demonstrated by 3 consecutive days of negative FCS and product results (Section 4.3, Page 118 Compliance Guideline.)

7. Listeria Control Program Summary - Appendix 4.1: Sampling Scenarios by Alternative (Pages 126-128, Compliance Guideline)

As an example, based on Appendix 4.1 (Sampling Scenarios by Alternative) of the Compliance Guideline:

c) **Alternative 2, choice 2 (Alt. 2b)**
   i) **Required**: Conduct tests of FCSs for *Lm* or *Listeria* spp. **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* or *Listeria* spp:
      (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., 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* or *Listeria* spp.

(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 (Refer to the table on page 1 for test and hold triggering criteria).

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2018 年 6 月作成

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