

Summary of *Listeria monocytogenes* Compliance Guideline for Small and Very Small Meat and Poultry plants that Produce Ready-To-Eat Products

A. Purpose

This document is intended to assist small and very small meat and poultry plants that manufacture ready-to-eat (RTE) products to understand the regulatory requirements associated with the production of these products. 9 CFR Part 430 sets out the regulatory requirements for RTE products that have been exposed to the environment after the lethality treatment (e.g., cooking, drying, etc.). Appendix A contains useful recommendations for plants based on deficiencies commonly found in RTE plants.

B. Background

For humans, *Listeria monocytogenes* (*Lm*) is a pathogen/biological hazard that can cause serious health consequences including death. Consumers expect that RTE products do not contain any pathogens of human health concern and therefore can consume these products directly from the package without fully cooking. If plants do not effectively implement their HACCP plans, SSOP's, or prerequisite programs, post-lethality exposed RTE products may become contaminated with *Lm*, rendering the product adulterated. The Agency has made it clear that:

- Contamination with *Lm* is a hazard reasonably likely to occur in **all** RTE meat and poultry products that are exposed to the post-lethality processing environment.
- All RTE products contaminated with *Lm* and post-lethality exposed products that come into direct contact with a food contact surface that is contaminated with *Lm* **are** adulterated.

Therefore, the Agency determined that establishments that produce post-lethality exposed RTE products must control *Lm* either through their HACCP plan, or prevent through Sanitation SOPs, **or** other prerequisite programs (9 CFR Part 430).

Note: The establishment is not required to comply with 9 CFR Part 430 if the RTE products produced in the establishment are not post-lethality exposed to the environment. Examples of products that are NOT include:

- products that are fully cooked in a cook-in-bag that leave the official establishment in the intact cooking bag, or
- products receiving a lethality treatment and hot-filled as long as the lethality temperature and sanitary handling are maintained during the period of time in which the product moves from the point of lethality to the point of packaging, or
- thermally processed, commercially sterile (canned) products.

C. Definitions:

These and other word definitions can also be reviewed at 9 CFR 430.1.

Antimicrobial agent: A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process: An operation, such as freezing or drying and fermenting, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Post-lethality processing environment: The area of an establishment into which product is routed after having been subjected to a full lethality treatment. The RTE product may be exposed to the environment in this area as a result of slicing, peeling, dicing, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment: A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Ready-to-eat (RTE) product: A meat or poultry product that in its final form is edible without additional preparation to achieve food safety.

D. Alternatives 1, 2, and 3:

In order to maintain the sanitary conditions necessary to meet the requirements of 9 CFR Part 430, an establishment producing post-lethality exposed RTE product must comply with the requirements provided in one of the three following alternatives and complete FSIS Form 10,240-1:

Alternative 1: The components required under Alternative 1 would be: A **and** B,

Alternative 2: The components required under Alternative 2 would be: A **or** B **and** C.

Alternative 3: The components required under Alternative 3 would be: C.

The following information contains the requirements of each Alternative component:

A) A post-lethality treatment, must:

- Identify *Lm* as a Hazard reasonably likely to occur in the hazard analysis
- Be included in a HACCP plan with the point of treatment as a CCP
- Be validated as effective in reducing or eliminating *Lm*

B) The anti-microbial agent or process:

- May not reduce *Lm* but is still effective through **limiting the outgrowth** of organisms that survive the post-lethality process
- May be in the SSOP, or
- May be in a prerequisite program, or
- A validated HACCP plan

C-1) a sanitation program must:

- Provide testing of food contact surfaces (FCS) and a record keeping system to match samples to test results
- Identifies conditions under which hold and test procedures will be implemented following a positive test for *Lm* or an indicator organism such as *L. spp.*
- State a frequency of test sampling, and
- Identify the size and all FCS sampling sites that could contaminate product
- Include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm* or of indicator organisms is maintained

C-2) an establishment producing a Hotdog or Deli-type Product, must:

- Verify corrective actions after first *L. spp.* positive sample of a FCS by conducting follow-up sampling
- If there is a follow-up positive, hold product until problem is corrected
- Test affected product lots with a sampling procedure that ensures the lot is not adulterated with *Lm*

E. FCS Sampling Requirements

FSIS provided the recommended minimum frequencies for FCS sampling to be met by the establishment, which is provided below and on page 42 in the “Updated Compliance Guidelines”, dated May 2006. An establishment may elect to conduct FCS sampling at a higher frequency than the recommended minimum. The advantage of an increased FCS sampling frequency is the establishment would accumulate supportable data faster which validates that the establishment’s sanitation program is effective and appropriate to keep *Lm* out of its production environment. The extra data would further support that a plant is not producing an adulterated product. In addition, the extra accumulated in-house information, may support a plant’s decision to reduce its FCS testing frequency at some point in the future.

FSIS’ expected minimum verification testing frequency of a food contact surface under Alternatives 1, 2, or 3.

	Food Contact Surface Testing	
	Higher Frequency	Lower Frequency
Alternative 1	> 2/year/line	2/year/line
Alternative 2	> 4/year/line	4/year/line
Alternative 3		
Non-deli, non-hotdogs	> 1/month/line	1/month/line
Deli, hotdogs:		
Very Small volume plant	> 1/month/line	1/month/line
Small volume plant	> 2/month/line	2/month/line
Large volume plant	> 4/month/line	4/month/line

F. Hold and Test Methodology:

“Hold and test” is a written procedure that is incorporated into the sanitation program. This written procedure identifies the conditions under which the establishment will hold product pending test results following an *Lm* or an indicator organism positive FCS test result. If there is a FCS positive for ***L.spp***, the establishment may conduct an aggressive non-biased sampling method, that the establishment has established in advance of the suspect product that was in direct contact with this FCS, to determine whether it is *Lm* or not. If the sample returns a negative for *Lm*, the lot may be released into commerce. Always keep in mind, once it has been determined product is *Lm* positive, the establishment may **either** destroy the product **or** rework the product using a validated lethality process that will kill the *Lm* pathogen.

There are no other options.

The establishment would also develop a sanitation procedure, a FCS testing procedure, and a hold and test procedure. Each of these procedures should be designed to aggressively identify, control, and eliminate *Lm* in the RTE environment. All together, these written procedures should ensure that:

- Future RTE lots are held until a negative lab result is returned
- The plant can demonstrate it has eliminated the *Lm* pathogen on the affected FCS
- The plant can demonstrate that its SSOP program is effective to control *Lm* on FCS and in the surrounding RTE environment, and
- The plant continues to assess its control of *Lm* in its establishment

In order to release into commerce any lot of product on hold for ***L. spp.*** positive that **may** be contaminated with *Lm*, the establishment may choose to test the lot for *Lm*, using an aggressive non-biased sampling method that should provide a level of statistical confidence to ensure the lot is not adulterated. If the samples are negative for

Lm, the lot may be released into commerce. The establishment **must** document the results of this testing. Alternatively, the establishment may destroy or rework the held product using a validated process that is destructive of *Lm* or *L. spp.*

Do keep in mind an establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. In addition, an establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

Appendix A. Recommendations for RTE Establishments

A. Sanitation Procedures

Cooling units, Air handling equipment, Condensation and Standing Water

- *L. monocytogenes* is an environmental pathogen and may be present in cooling units, air handling equipment, standing/dripping water, or condensation. The moist environment is conducive to *Lm* growth.
- Immediately address and correct problems of dripping, condensation and standing water.
- Clean cooling units and air handling units at some specific frequency.
- Production of RTE products should be stopped during repairs and corrective actions for these problems.
- The equipment and processing area should be cleaned and sanitized after all the repairs and corrective actions are finished.
- Equipment and processing area environment should be tested for *Lm* or *Listeria spp.* before resuming RTE production.

Personnel Hygiene

- Wash hands before putting gloves on.
- Wash hands before resuming duties after breaks.
- Train personnel on hygienic practices in an RTE processing environment on a regular basis.
- Monitor employee hygiene practices.

Separation of RTE and Non-RTE Areas

- If processing both RTE and raw products, completely separate the processing areas, by time or space, such as scheduling RTE processing on different days. If not possible, schedule RTE processing first, then raw processing. Have a complete wash down and sanitizing after each production process.
- Use separate equipment for RTE and raw processing. If not possible, schedule to use equipment for RTE processing first, then for raw processing.
- Assign different personnel for RTE and raw processing, especially if both are

- conducted on the same day. If not possible, have personnel clean hands very well, and use new, clean coats, new gloves, hairnets, and sanitized boots for RTE processing.
- Restrict travel of personnel from and to NRTE area during RTE processing. If necessary, use footbath, wash hands, and use new gloves, clean, unused coats and hairnets when returning to a RTE production area.
 - Locate coat racks for coats used in RTE processing in an identified RTE area.
 - Use color coded coats for use in RTE processing area, in raw processing area, and in other areas.
 - Maintain procedures so that personnel coming from any area common to RTE and raw processing are not transferring contamination to RTE areas.
 - Establish procedures for moving equipment from a non-processing area to a RTE processing area to prevent *Listeria* contamination from the equipment and during the moving operation.
 - Avoid passing raw product through RTE areas and RTE product through raw production areas.
 - Do not allow RTE product to come in contact with surfaces or raw products in coolers.

Records of Sanitation Procedures

- Keep records of sanitation procedures to be used for processing of RTE products that are covered by the *Listeria* rule.
- Maintain monitoring records of sanitation procedures.
- Maintain records of corrective actions taken if adulterated product or a direct FCS noncompliance occurs, such as ensure appropriate disposition of products, restore sanitary conditions to prevent recurrence, and record the date of the noncompliance and the initials of the plant employee conducting the corrective action.

Room Temperature

- Maintain temperature in processing areas, and packaging rooms as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs.
- Maintain cold temperature (<50° F) in packaging room for products that are to be refrigerated or frozen, as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs to prevent *Lm* growth in the RTE processing environment.
- Monitor temperatures as stated in the HACCP plan, Sanitation SOPs, or Prerequisite Programs.

Miscellaneous

- For establishments processing deli type products, establish procedures to ensure that other non-meat or non-poultry RTE ingredients do not cause cross-contamination with *Listeria*.

- Maintain an effective rodent and insect infestation preventive and control program. Rats, mice, and insects are sources of *Listeria* and other microbial contamination.
- Develop and maintain procedures to ensure that sanitizer concentrations in footbaths are adequately maintained. .
- Maintain records and verify the correct procedures for the concentrations and mixing of sanitizers.
- Discard products that touch environmental surfaces, such as products falling on the floor, if the product cannot be properly re-conditioned.
- During cleaning and sanitizing, make sure there is no food residues left on the equipment.
- Maintain procedures for routine cleaning and develop procedures for intensified cleaning.
- When adding ingredients to a second container, do not to bang or contact the container against the interior of the other container.

B. Listeria program

- Maintain a record of all FCS and environmental surfaces in the processing area that are to be tested. Make sure all of the identified surfaces are actively sampled and have an equal opportunity of being sampled during each sampling event.
- Include the supporting documentation of the testing frequency in your *Lm* sanitation program.
- Include testing and monitoring of drains after an *Lm* positive finding.
- Do not use the *Lm* testing program to support that *Lm* is not reasonably likely to occur. The *Lm* testing program is a verification of the effectiveness of the establishment's food safety program to control *Lm*.
- Include supporting documentation in the prerequisite program to support your claim that *Lm* is a hazard not reasonably likely to occur in your RTE processing.
- Include supporting documentation for the alternative chosen for the product.
- When there is a repeated *Lm* positive finding, suspend RTE operations to determine the cause or origin of the contamination, develop measures for removal of contamination and prevention of recurrence, and verify that there is no remaining contamination.

C. Maintenance of Facilities and Equipment

- Immediately fix leaky roofs, broken and cracked equipment, floors, doors, windows, etc. Suspend operations during leakage and during repairs. It is recommended to test the environment for *Listeria spp.* after repairs are finished.
- Throw away rusty, pitted, peeling tools or parts of equipment and replace with new, smooth-surfaced ones. These rusty, pitted tools and equipment parts serve as ideal harborage places for *Lm* to grow and multiply.
- Have an equipment maintenance record and monitoring program to check for

broken, pitted, rusty, peeling, or dirty equipment that need replacing, repair, cleaning, etc.

D. Dual Jurisdiction Establishments

Because FSIS regulated products are susceptible to *Lm* outgrowth:

- It is advisable due to the food safety nature of FSIS regulated product to separate processing areas for FSIS regulated products and FDA regulated products by time or space, such as scheduling processing on different days. If that is not possible, schedule FSIS product processing first, then FDA product processing. If FDA product is produced first, a complete clean-up and sanitizing, and plant pre-operational testing of equipment and processing environment before starting FSIS product processing, is required.
- Because of the food safety nature of FSIS regulated product, it may be advisable to use separate equipment for processing FSIS and FDA product. If not possible, consider scheduling the equipment for FSIS product processing first, then followed by FDA product processing.
- Because of the risk for cross contamination, consider assigning different personnel for FSIS product and FDA processing areas, if possible, especially if both are conducted on the same day. If not possible, have personnel clean hands thoroughly, and use unused, clean coats, new gloves and hairnets, and sanitized boots for FSIS and FDA processing.