Alternative 2

9 CFR 430.4(b)(2) *Use of either a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes.*

Under Alternative 2, an establishment may select **either** Choice 1 or Choice 2 as follows.

Choice 1 - An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent or process) that **reduces or eliminates** microorganisms on the product. Again, the use of a post-lethality treatment must be included in the establishment's HACCP plan because the use of a post-lethality treatment reflects a determination that the pathogen is a hazard reasonably likely to occur, controllable by a post-lethality treatment. Consequently, the plant must incorporate the post-lethality treatment in its HACCP plan as a CCP. As with any other CCP, the plant must validate the effectiveness of the post-lethality treatment. In addition, the effectiveness of the anti-microbial agent or process, as used, must be documented in the HACCP plan.

OR

Choice 2 - An establishment that produces post-lethality exposed product and that selects this alternative chooses to use an antimicrobial agent or process that **suppresses or limits growth** of *L. monocytogenes*.

The application of an antimicrobial agent or the growth suppressing or limiting process must be included in the establishment's HACCP plan, SSOP or other prerequisite program. Because establishments that do not incorporate a post-lethality treatment are placing greater reliance upon plant sanitation, they must also provide for the testing of food contact surfaces in the post-lethality processing environment to ensure surfaces are sanitary and free of *Lm* or an indicator organism in accordance with 430.4(b)(2)(iii).

Note: Processes used to produce shelf-stable products are fermentation, salt curing, and drying. These processes can result in lethal treatment of pathogens and suppression of growth during storage at ambient temperature. These processes can enable the establishment to choose Alternative 1 or 2 for their products depending on the validation and documentation provided. Sometimes, the establishment cannot provide validation or documentation to show growth suppression or bacterial reduction, and in this case the establishment may chose Alternative 3.

Alternative 2, Choice 2 inspection verification example: As part of the 03F01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 2. You review the plant's hazard analysis for beef jerky products and find that the cooking and drying steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. In addition to these CCPs, *Lm* was considered a potential hazard at the packaging step but was not likely to occur because the establishment has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You decide to request the supporting documentation for the decision made in the hazard analysis that *Lm* is not likely to occur in the post-lethality environment. The plant provides a scientific document that identifies that the dryness of the jerky product would inhibit *Lm* growth in the finished product throughout the shelf life of the product. The plant also provides the procedures (verification activities) and the associated records it uses to demonstrate that products are dried below the level which the scientific validation document establishes as preventing the growth of *Lm.* The records for the past several months show that the product is achieving the level of dryness needed to suppress the growth of *Lm*. You review the establishment's SSOP and records and find that the plant is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The plant has identified the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *L. monocytogenes,* or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(2).

Noncompliance with Alternative 2

The following are examples of noncompliance with Alternative 2.

1. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only address the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(2), 416, and 417.5(a)1&2.)