

Alternative 1

9 CFR 430.4(b)(1) Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*.

Alternative 1 is the use of **BOTH** a post-lethality treatment (which may also be the antimicrobial agent or process) that is capable of reducing or eliminating microorganisms on the product **AND** an antimicrobial agent or process. In some cases, the antimicrobial agent added to the RTE SS product or the antimicrobial process applied to the RTE SS product has **BOTH** a lethality effect (i.e., actually reduces or eliminates *Lm*) **and** suppresses or limits the growth of *Lm* during the shelf-life of the product.

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 by the establishment that the pathogen is a hazard that is reasonably likely to occur and is 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 accordance with 417.4. In addition, the effectiveness of the antimicrobial agent or process, as used, must be documented in the HACCP plan, SSOP or other prerequisite program.

Alternative 1 inspection verification example: As part of the 03E01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the plant's hazard analysis for not heat treated dry salami and find that the fermentation, drying, and packaging steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis identifies lowered acidity (pH) through the use of bacterial starter cultures and lowered water activity due to drying as measures to limit the growth of *L. monocytogenes* (*Lm*) in the finished product throughout the shelf-life of the product. A steam pasteurization process after the product has been vacuum packaged has been identified as the treatment to reduce or eliminate post-lethality contamination by *Lm*. There are critical limits at the respective steps in the plan for pH, water activity, and time and temperature exposure for the steam pasteurization process. You decide to request the supporting documentation for the decisions made in the hazard analysis. The plant provides scientific documents and the results of challenge studies conducted by a processing authority that show that the pH and water activity (achieved in the product) inhibits the growth of *Lm* during its shelf-life and that the surface steam pasteurization treatment is effective in reducing or eliminating the level of pathogens resulting from the contamination from post-lethality exposure. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(1).

Noncompliance with Alternative 1

The following are examples of noncompliance with Alternative 1.

1. The establishment has a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan, but does not have the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)1&2.)
2. The establishment is testing 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, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan OR the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)1&2.)
3. The establishment has included a post-lethality treatment to reduce or eliminate *Lm* in its HACCP plan, but has not validated the effectiveness of the treatment. (Cite 430.4(b)(1) and 417.4.)