

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*.

The thought process you should use when verifying regulatory requirements includes:

- Gathering information by asking questions
- Assessing the information, and
- Determining regulatory compliance.

Gather information by asking questions

When verifying compliance with the requirements in Alternative 1, seek answers to the following questions:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?
2. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?
3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?
4. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
5. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

Assess the information

To answer these questions you should:

- Review the HACCP plan,
- Review validation data (supporting documentation) for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as

- necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

Alternative 1 Examples

Example 1: As part of the 03I01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the plant's hazard analysis for sliced semi-dry sausage products such as Genoa salami, sandwich pepperoni, cervelat, thuringer, etc., and find that the fermentation, heating, 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 literature 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 refrigerated 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).

Example 2: As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the plant's hazard analysis for cooked sausage products such as hot dogs, wieners, bologna, franks, etc., and find that the non-meat ingredient receiving, non-meat ingredient storage, cooking, and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis identifies an antimicrobial coating (NOJAX[®] AL[™]) on the internal surfaces of cellulose casings that is transferred to the surface of the sausage product during thermal processing as a measure to reduce the level of *Lm* during the first days of storage (post-lethality impact) and inhibit the growth of *Lm* throughout the product's refrigerated shelf life. There are critical limits at the respective steps in the plan for supplier certification for the cellulose casings, casing shelf life, and casing storage temperature. The plant's hazard analysis identified growth of *Lm* as a potential hazard at the finished product storage step but determined that *Lm* growth was not a hazard reasonably likely to occur because it has control measures incorporated into a prerequisite program for the addition of sodium lactate and sodium diacetate (antimicrobial additives) in the formulation of the product. You decide to request the supporting documentation

for the decisions made in the hazard analysis. The plant provides scientific literature in which NOJAX[®] AL[™] coated casings applied to cooked hot dog type sausages effectively reduced *Lm* resulting from contamination from post-lethality exposure and suppressed the growth of *Lm* in the finished product throughout the shelf life of the product. It also provides several published research studies that show that sodium lactate and sodium diacetate inhibit the growth of *Lm* in commercial cured meat products throughout the shelf life of the product. The plant provides the procedures (verification activities) and the associated records it uses to ensure that sodium lactate and sodium diacetate are added at the concentration equivalent to those in the studies. The records for the past several months show that these ingredients have been added at the correct concentration. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(1).

Determine compliance

After you have gathered and assessed all available information pertaining to Alternative 1, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, i.e., the answer to any of the questions was “no”, there is noncompliance. You should issue an NR under the appropriate 01 or 03 procedure code as described in FSIS Directive 5000.1, Rev. 1, and reference 9 CFR 430.4(b)(1) and the appropriate section of 417 (for HACCP and prerequisite programs) or 416.14 (for Sanitation SOP). You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment’s choice of another alternative. You will receive more information about making compliance determinations in a later section.

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 has 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, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan. (Cite 430.4(b)(1) and 417.5(a)1&2.)

3. 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.)
4. 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.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.