

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) that **reduces or eliminates** microorganisms on the product.

OR

Choice 2 - An establishment that produces post-lethality exposed product and that selects this alternative and chooses to use an antimicrobial agent or process that **suppresses or limits 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 2, seek answers to the following questions. Alternative 2 is based on the same requirements as Alternative 1, **except** that the establishment can choose to **just** have a post-lethality treatment that meets the requirements of questions 1-3 (Choice 1), **or** to just use an antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product that meets the requirements of question 4 (Choice 2).

Choice 1

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?

Choice 2

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?

Also, if the establishment chooses Choice 2, you should seek answers to these additional questions, regarding the establishment's sanitation procedures.

Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:

1. provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?
2. identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism?
3. state the frequency with which testing will be done?
4. identify the size and location of the sites that will be sampled?
5. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

Assess the information

To answer these questions you should:

- Review the HACCP plan,
- Review validation data 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),
- Review the Sanitation SOP and/or prerequisite programs associated with the testing program for verification of effectiveness of sanitation procedures (as necessary), and

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

Alternative 2 Examples

Example 1: As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 1. You review the plant's hazard analysis for halved and sliced fully cooked deli-type products such as roast beef, turkey ham, ham, poultry rolls, etc., and find that the cooking, chilling and packaging steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis identifies a hot water pasteurization step after the product has been vacuum packaged as the treatment to reduce or eliminate post-lethality contamination by *Lm*. The post-lethality pasteurization CCP has critical limits for the exposure time and the temperature of the hot water. You decide to request the supporting documentation for the critical limit for the post-lethality CCP. The plant provides published research studies as reference for the effectiveness of hot water pasteurization processes in reducing or eliminating *Lm*. Since the establishment is using post-lethality pasteurization on different products and using different variables (exposure time and temperature) than that used in the studies, it provides the results of its own challenge studies to validate the use of the hot water pasteurization process to reduce or eliminate *Lm* for its specific products. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(2).

Example 2: As part of the 03G01 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 fully cooked frozen breaded chicken products and find that the cooking and chilling 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 the frozen temperature which 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 frozen 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 frozen temperature 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).

Determine compliance

After you have gathered and assessed all available information pertaining to Alternative 2, 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)(2) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 417 (for HACCP and prerequisite programs) or the appropriate section of 416 (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 2

The following are examples of noncompliance with Alternative 2.

1. 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)(2), 417.2, and 417.5(a)1&2.)
2. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only addresses 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.)
3. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the conditions under which or at what point hold-and-test procedures following a positive test of a food-contact

surface for *Lm* or an indicator organism will be initiated. (Cite 430.4(b)(2), and 417.5(a)1&2.)

4. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the size of the site to be sampled. (Cite 430.4(b)(2), and 417.5(a)1&2.)
5. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not articulate its explanation as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. (Cite 430.4(b)(2), and 417.5(a)1&2.)

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