

Alternative 3

9 CFR 430.4(b)(3) Use of sanitation measures only

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 3, seek answers to the following questions.

Does the establishment that produces post-lethality exposed product and that selects this alternative have on-going verification testing procedures that are designed to:

1. have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program?
2. test 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?
3. 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?
4. state the frequency with which testing will be done?
5. identify the size and location of the sites that will be sampled?
6. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

Also, does an establishment producing a **deli product or a hot dog product**:

1. verify that the implemented corrective actions (with respect to sanitation after an initial positive result on a food contact surface in the post-lethality processing environment) are effective by follow-up testing that includes targeted testing of the specific site on the food contact surface area and other sites as necessary to ensure effectiveness of the corrective actions?

2. hold lots of product (that may have become contaminated by contact with the food contact surface when the establishment obtains a second positive test for *L. monocytogenes*, or an indicator organism, during this follow-up testing) until the establishment corrects the problem as indicated by follow-up test (negative) results,
3. sample and test the lots for *L. monocytogenes* or an indicator organism, using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*, in order to be able to release into commerce the lots of product that may have been contaminated with *L. monocytogenes*?
4. document the results of the testing?
5. rework the held product using a process that is destructive of *L. monocytogenes*?

Assess the information

To answer these questions you should:

- Review the HACCP plan, Sanitation SOP, and/or prerequisite programs associated with the testing program for verification of effectiveness of sanitation procedures.
- Review HACCP records, SSOP records, or the records associated with the prerequisite program

Alternative 3 Examples

Example 1: As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the plant's hazard analysis for fully cooked breakfast type products such as bacon, sausage patties, sausage links, etc., packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in a prerequisite program to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. You review the establishment's prerequisite program 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. It also has identified the conditions under which it 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 testing frequency. The establishment 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)(3).

Example 2: As part of the 03G01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the plant's hazard analysis for fully cooked deli and hot dog type products such as franks, sliced ham, sliced bologna, sliced roast beef, sliced turkey breast, etc., packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and are incorporated into the HACCP plan. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. 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 it 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. You find that the establishment verifies the effectiveness of the corrective actions it takes with respect to sanitation after an initial positive test on a food contact surface in the post-lethality processing environment through follow-up testing, including a targeted test of the specific site that is the most likely source of contamination by the organism, and other additional tests in the surrounding food contact surface area. When the establishment obtains a second positive test during this follow-up testing, it holds the lots of product that may have become contaminated by contact with the food contact surface until a test result indicates that the sanitation problem is corrected. The establishment only releases into commerce the lots of product that may have become contaminated with *Lm* from the food contact surface after it has sampled and tested the lots for *Lm* using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*. The establishment considers sampled product lots that test positive for *Lm* as adulterated and withholds them from entering commerce. The establishment destroys the held product, or reworks the held product using a process that is destructive of *Lm*. The establishment documents the test results and the disposition of the product. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(3).

Determine compliance

After you have gathered and assessed all available information pertaining to

Alternative 3, 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)(3) and, depending where the use of the sanitation measures are 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 to determine whether the decisions made in the hazard analysis regarding the use of the prerequisite program remain valid, and the establishment’s choice of another alternative. You will receive more information about making compliance determinations in a later section.

Noncompliance with Alternative 3

The following are examples of noncompliance with Alternative 3.

1. The establishment does not have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program. (Cite 430.4(b)(3), and 417.5(a)1&2.)
2. The written sanitation procedures the establishment is using to meet the requirements of this alternative 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)(3), and 417.5(a)(1) and (2).)
3. An establishment that produces deli and hot dog products does not conduct follow-up testing of target sites on the food contact surface area that is the most likely source of contamination after an initial positive test for *Lm*, or its indicator organisms, to verify the effectiveness of its sanitation corrective actions. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)
4. An establishment that produces deli and hot dog products does not hold-and-test lots of product for *Lm*, or an indicator organism, that may have become contaminated by contact with the food contact surface when it obtains a second positive test for *Lm*, or an indicator organism, during its follow-up testing. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)

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