

included as a CCP in the HACCP plan, it must be validated as effective in suppressing or limiting growth of the pathogen. The establishment must also verify the effectiveness of the control measures in accordance with 9 CFR 417.4. If the agent or process is included in the establishment's sanitation program, it must be in compliance with the general sanitation regulations and the Sanitation SOP requirements in 9 CFR part 416. The control measures, if included in the HACCP plan, must be validated as effective. The establishment's regular monitoring of its operation must be verified. Sanitation procedures must be in compliance with the general sanitation regulations and the Sanitation SOP requirements, as applicable.

In addition, the establishment is required to make the results of its verification measures, under whichever program—HACCP, Sanitation SOP, or other prerequisite program—available upon request to FSIS inspection personnel.

FSIS has concluded, and this conclusion is informed by the FSIS risk assessment, that Alternative 1, which involves a combination of interventions that includes a post-lethality treatment and the application of an antimicrobial agent or process, is likely to be among the most effective means of reducing the risk of *L. monocytogenes* contamination and hence of listeriosis mortality among vulnerable populations.

Alternative 2. An establishment may choose to address *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that suppresses or limits the growth of the pathogen. As with Alternative 1, the post-lethality treatment, if used, must be included as a CCP in the establishment's HACCP plan. The application of the antimicrobial agent or the growth suppressing or limiting process must be included in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. Whichever program includes the application of the antimicrobial agent or the growth suppressing or limiting process, the establishment must have documentation to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting the growth of *L. monocytogenes*.

In addition, FSIS is providing that if the establishment chooses Alternative 2 and chooses to use only a post-lethality treatment of product, it would likely be subject to more frequent verification testing than if it chose Alternative 1. FSIS has concluded that multiple steps are more likely to reduce the risk of *L. monocytogenes* contamination of RTE

products and subsequent adverse public health effects. Without an antimicrobial to suppress or limit the growth of *L. monocytogenes* that may survive the post-lethality treatment, it becomes more important to verify the effectiveness of that treatment.

The establishment may choose not to rely on a post-lethality treatment to reduce or eliminate *L. monocytogenes*, but to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If so, it becomes extremely important to minimize any possibility of post-lethality contamination. The establishment's sanitation program must, therefore, provide for the testing of food contact surfaces in the post-lethality processing environment to ensure that the establishment's sanitation program is effective in keeping those surfaces sanitary and free of *L. monocytogenes* or of indicator organisms that would reflect the presence of *L. monocytogenes*. The program must delineate the frequency with which testing will be done, state the size and location of the sample sites (so that the area represented by a sample can be known), and provide an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or the indicator organism is being maintained. The program also must identify the conditions under which the establishment will implement hold-and-test procedures after a positive test for *L. monocytogenes* or indicator organisms.

As under the Alternative 1, the establishment must make the verification results of the effectiveness of its controls from its HACCP, Sanitation SOP, or other prerequisite program available upon request to FSIS inspection personnel.

For Alternative 2, if the measures for addressing *L. monocytogenes* are in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment's documentation of its program and of its results and its implementation of the program must be sufficient to support a finding, during validation or reassessment, under 9 CFR 417.4, that the HACCP plan is adequate and that the HACCP plan in operation is not inadequate within the meaning of 9 CFR 417.

Alternative 3. An establishment that processes RTE products may control *L. monocytogenes* in the post-lethality processing environment through sanitation procedures only. If

incorporated in the HACCP plan, the sanitation procedures followed in this alternative must be validated and verified in accordance with 9 CFR 417.4. Also, sanitation in the post-lethality processing area must be maintained in accordance with 9 CFR 416.

As in Alternative 2, FSIS is requiring that the sanitation procedures in the post-lethality processing environment include testing of food contact surfaces to ensure that the surfaces are sanitary and free of *L. monocytogenes* or an indicator organism. The procedures must delineate the frequency of testing; state the size and location of sample sites; and provide an explanation of why the testing is sufficient to ensure that the establishment's sanitation procedures are effectively keeping *L. monocytogenes* or indicator organisms from contaminating product. The establishment must identify in its procedures the conditions under which it will implement hold-and-test procedures to ensure that *L. monocytogenes* or indicator organisms are not contaminating product.

Establishments that adopt Alternative 3 will need to address in their decisionmaking documents why the sanitation procedures they employ, the frequency of testing they carry out, and the circumstances in which they test the product and hold it pending receipt of test results are appropriate and adequate to prevent the contamination of their product by *L. monocytogenes* and to ensure that contamination is discovered if it has occurred.

Because establishments using Alternative 3 are relying only on sanitation procedures and because verification activities are so important to ensuring the on-going effectiveness of such measures, FSIS has concluded that establishments electing to adopt Alternative 3 are likely to be subject to a higher frequency of testing by FSIS than establishments using Alternative 1 or 2. As is the case with establishments adopting the other alternatives, an establishment that has adopted Alternative 3 must make the verification results obtained from its own food contact surface testing available on request to FSIS inspection personnel.

Under Alternative 3, more stringent requirements apply to an establishment that processes deli meats or hotdogs. These products were shown in the FDA/FSIS risk ranking to pose a relatively high risk of listeriosis, in terms of cases per annum. Thus, in order to provide the assurance that comes from increased verification, FSIS expects the frequency of its own testing, as well as the establishment's testing, to be higher