

than that for other products produced under the Alternative 3 approach.

Under Alternative 3, for establishments producing deli meats and hotdogs, FSIS is requiring specific procedures for holding and testing product to minimize the risk of contaminated product entering commerce. These procedures are to be followed if an establishment has had a positive test for an indicator organism, such as *Listeria* species, on a food contact surface in the post-lethality processing environment.

After the establishment takes corrective action to clean the food contact surface, the establishment must verify that the corrective action has been effective through follow-up testing in the post-lethality processing area. This testing is to include targeting the specific site on the food contact surface area that was the most likely source of contamination by the organism and must include such additional tests of the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective action. (If the initial positive test was for *L. monocytogenes*, the product is considered adulterated and must be withheld from commerce even before the results of further testing are available.)

If, during this follow-up testing, the establishment obtains a second positive test result for the indicator organism on a sample from the previously tested area, the establishment must hold lots of product produced between the second positive test result and completion of the corrective action until samples from the food contact surfaces in the same area test negative for *L. monocytogenes* or the indicator organism. The establishment may sample and test the held product, using a sampling method that will provide a level of statistical confidence that is sufficient to establish that the product is not adulterated with *L. monocytogenes*, and it can release the product into commerce if the results are negative.

For Alternative 3, 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 part 1.

Estimates of annual production volume. As previously stated in this document, some commenters observed that a large establishment may not necessarily produce more RTE product than a small establishment. FSIS agrees and regards production volume as a more important risk factor than establishment size. FSIS intends to target its inspection resources on the higher volume operations. To do this effectively, FSIS will need data on the annual production volume of post-lethality exposed RTE products produced, by product, and by *L. monocytogenes* control alternative (1, 2, or 3), and other related information (such as the establishment's own testing procedures). The affected establishments will have to provide FSIS with this information at least annually. The Agency expects to have an electronic form available for this purpose (9 CFR 430.4(f)).

Labeling Incentive

Finally, FSIS is allowing establishments that use post-lethality treatments or antimicrobial agents or processes that are effective in destroying *L. monocytogenes* or in limiting its growth to declare this fact on the labels of their products. The purpose of the labeling is to inform consumers about measures that have been taken to ensure the safety of the products and thus to enable the consumers to select such products in preference to others. This provision is entirely voluntary, but FSIS believes that labeling claims about treatments that eliminate, suppress, or limit the growth of *L. monocytogenes* can be of value to consumers, especially those in groups most vulnerable to foodborne infection.

For example, products with antimicrobial agents can be viewed as containing substances that reduce the presence of pathogens or the likelihood of foodborne illness, provided that the products are appropriately handled throughout the distribution chain and prepared safely by the consumer. Thus, a label statement should identify the presence of ingredients and their purpose of use but not claim that the product is somehow "safer than" other untreated products.

Examples of statements that can be made are: "Sprayed with a solution of sodium lactate to prevent the growth of *L. monocytogenes*" or "Contains sodium diacetate and sodium lactate to prevent the growth of *Listeria monocytogenes*."

New and Existing Regulatory Requirements

The regulations promulgated in this interim final rule include new

requirements and reiterate for clarity certain existing regulations. The definitions in § 430.1 are new, as are the provisions in § 430.4 specifying the three permissible alternatives for addressing *L. monocytogenes*. Similarly, the provisions in this interim final rule requiring that measures included in the establishment's Sanitation SOP or other prerequisite program are new. The provision requiring that RTE establishments report at least annually the volume of production by type of RTE product and by alternative for controlling or addressing *L. monocytogenes* is new. Also new are the sanitation procedure requirements that include hold-and-test provisions.

Although the use by industry and the Agency's acceptance of prerequisite programs is not new, the provisions on prerequisite programs in this interim final rule constitute explicit recognition, for the first time in the codified regulations, of such programs. The requirement that documentation of prerequisite programs and the results of such programs be available to the Agency also makes explicit an implied requirement in the HACCP regulations.

Also, the requirement that a post-lethality treatment be included in an establishment's HACCP plan is made explicit for the first time in this interim final rule. The requirement to maintain documentation on Sanitation SOPs or other prerequisite programs that are used to support a decision not to identify *L. monocytogenes* as a hazard reasonably likely to occur that must be controlled makes explicit a requirement in the HACCP regulations (9 CFR 417.5). The provision for validation of controls included in a HACCP plan just reiterates existing requirements of 9 CFR 417.4. Similarly, the requirement that Sanitation SOPs be evaluated routinely to ensure their effectiveness reiterates the requirements in 9 CFR 416.14.

The requirement to verify, that is, to evaluate routinely and maintain, the effectiveness of the Sanitation SOP, is already a regulation (at 9 CFR 416.14). Also, the requirement to follow existing sanitation requirements in the post-lethality processing environment simply reiterates the general sanitation regulations (9 CFR 416) that are applicable everywhere in an official establishment.

Finally, the provision for RTE product labeling that declares the fact of an *L. monocytogenes* control treatment or ingredient is new, but permissive. RTE product labeling may, under current regulations, bear such statements if the statements are valid.