

definition of "lethality treatment" is provided. The "post-lethality processing environment" is defined as the area of an establishment into which product is routed after undergoing a lethality treatment.

"Post-lethality treatment" is defined as a lethality treatment applied to a product after post-lethality exposure. A post-lethality treatment might be an additional heat step or other pasteurization process, such as high-pressure processing. A "post-lethality treatment" to reduce or eliminate *L. monocytogenes* is to be distinguished from the use of an antimicrobial agent or process that suppresses or limits the growth of the pathogen. Antimicrobial agents include lactic acid in certain types of sausage products or ingredients of growth-limiting packaging (e.g., cellulose containing an antimicrobial substance). An example of a growth suppressing or limiting process is freezing.

FSIS is defining "prerequisite program" as a procedure or set of procedures designed to provide the basic environmental or operating conditions necessary for the production of safe, wholesome food. The definition is adapted from "Hazard Analysis and Critical Control Point Principles and Application Guidelines," which was adopted August 14, 1997, by the National Advisory Committee on Microbiological Criteria for Foods and has wide currency in the food industry. Prerequisite programs are a part of the decision-making documentation that is associated with the hazard identification and selection of CCPs in a HACCP plan. An establishment is required by 9 CFR 417.5 to maintain such documentation because the existence of an effective Sanitation SOP or other prerequisite program affects the outcome of an establishment's hazard analysis.

The definition of a "prerequisite program" is being provided, and the use of such a program in the new regulations is being permitted, in response to industry comments on the proposal emphasizing the importance of prerequisite programs in preventing *L. monocytogenes* contamination. One commenter stated that post-processing contamination by *L. monocytogenes* is best controlled through prerequisite programs.

Finally, FSIS is adopting the definition of a "ready-to-eat" product that, although similar to the one proposed, conforms with the 2001 Model Food Code. Thus, an RTE meat or poultry product is one that is "in a form that is edible without additional preparation to achieve food safety and

may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes."

In a new section on control of *L. monocytogenes* in post-lethality exposed RTE products, 9 CFR 430.4, FSIS first states its basic finding that *L. monocytogenes* is a hazard in such products, and that establishments must control this hazard through their HACCP plans or prevent it in the processing environment through Sanitation SOPs or other prerequisite programs. FSIS is making this finding, as it states in 9 CFR 430.4(a), based on the fact that RTE products that have been subjected to a lethality treatment but then exposed to the environment may be recontaminated with *L. monocytogenes*.

An establishment may determine that recontamination is not reasonably likely to occur in its post-lethality exposed RTE products because it has an effective Sanitation SOP or some other prerequisite program that effectively prevents *L. monocytogenes* contamination. If an establishment makes this determination, under 9 CFR 417.5(a)(2), the regulation requiring establishments to keep documentation supporting the selection of CCPs or critical limits, the basis for this determination must be documented and made available to the Agency. FSIS is aware that, in their hazard analyses, establishments have been taking their Sanitation SOPs and other prerequisite programs into consideration. Thus, an establishment that produces RTE products may not identify *L. monocytogenes* as such a hazard to be addressed in its HACCP plan, it must nonetheless effectively address this pathogen in its food safety system.

The Agency is requiring, in 9 CFR 430.4(b), that an establishment that produces post-lethality exposed RTE product must meet the specific requirements of one of three alternative programs for addressing *L. monocytogenes*. In the view of FSIS, any situation involving establishment measures to address post-lethality contamination of RTE products by *L. monocytogenes* is covered by one of the alternatives. Under this interim final rule, the first alternative relies largely on control through HACCP and an antimicrobial agent or process that suppresses or limits the growth of the pathogen. Each successive alternative places a greater reliance on the rigor of sanitation procedures, including verification testing, than on post-lethality treatments, to control *L. monocytogenes*. Consequently, the frequency and intensity of FSIS verification is likely to be greater for

Alternatives 2 and 3, as more reliance is placed on sanitation.

*Alternative 1.* In the first alternative, an establishment controls *L. monocytogenes* by using a post-lethality treatment of the product and an antimicrobial agent or process that suppresses or limits the growth of the pathogen. As mentioned previously, the use of the post-lethality treatment to reduce or eliminate *L. monocytogenes* reflects a determination that the pathogen may be present in the product—in other words, that it is a hazard reasonably likely to occur. Therefore, the establishment must include the post-lethality treatment in its HACCP plan. The point in the process at which the treatment is applied is, by definition, a "critical control point" under 9 CFR 417.1 in that it is a step in a process at which control is applied to prevent, eliminate, or reduce to acceptable levels a food safety hazard, *L. monocytogenes*. The post-lethality treatment incorporated in the HACCP plan must be validated in accordance with 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes*.

The use of an antimicrobial agent or growth suppressing or limiting process may not in practice have the *L. monocytogenes* reduction effect of a post-lethality treatment, but still be an effective measure because it inhibits growth of the pathogen, thus, limiting the possibility that any *L. monocytogenes* that survives the post-lethality treatment will grow out and presents a food safety hazard. In Alternative 1, FSIS is giving the establishment the choice of including the antimicrobial agent or process in its Sanitation SOP or other prerequisite program or as a CCP in its HACCP plan.

FSIS recognizes that an establishment electing to adopt Alternative 1 may employ an antimicrobial agent or process as part of its initial lethality treatment and that the agent or process may have a continuing bactericidal effect on *L. monocytogenes* that persists even through post-lethality exposure and distribution. In such a case, the antimicrobial agent or process could serve as both a post-lethality treatment and growth inhibitor. Thus, neither an additional post-lethality treatment nor an additional antimicrobial agent or process is necessary to qualify for Alternative 1. The establishment would need to have documentation on file to demonstrate that the conditions of Alternative 1 are being met through the application of the initial antimicrobial agent or process.

As with the post-lethality treatment, if the antimicrobial agent or process is