

further preparation for safety, *i.e.*, “fully cooked,” “Ready-to-eat,” and “Heat and Serve.” Features that are used exclusively on non-RTE products to inform consumers that the products must be cooked to be safe for consumption include the Safe Handling Instructions, which indicate that the meat or poultry portion have not received an adequate lethality treatment and such phrases as, “Raw,” “Uncooked,” “Not Ready-to-Eat,” and “Ready-to-Cook.”

Cooking instructions alone, however, are not a reliable labeling feature for consumers to determine whether a product requires cooking for safety. Phrases such as “Cook and Serve,” “See cooking instructions,” and “Cook thoroughly” have been used interchangeably on both RTE and NRTE meat and poultry products.

FSIS will continue to consider frozen foods that provide clear instructions to consumers about safe handling and cooking requirements as not-RTE and therefore not subject to this regulation. Frozen products that do not meet these requirements will be considered RTE.

The Agency does not agree that either frozen foods or dried meat and fermented products should be excluded from the definition just because they pose a low risk for *L. monocytogenes*. In both cases, the products are lower in risk because they have undergone a process that is either lethal to or suppresses or limits the growth of pathogens, including *L. monocytogenes*. For this reason, FSIS believes that establishments producing these products should also be required to incorporate in their operations measures addressing *L. monocytogenes* to ensure that the products can be consumed safely without further preparation.

Tolerance for L. monocytogenes and Food Safety Objectives (FSO's)

Comments: Some commenters recommended that FSIS establish a tolerance for *L. monocytogenes* in certain products that do not support growth of the organism. The commenters suggested that a FSO would be consistent with the concepts favored by the Codex Alimentarius Commission and the standards applied by some of this Nation's trading partners. A more rigorous standard could be applied to product that is intended for vulnerable populations.

Response: Establishing a tolerance for *L. monocytogenes* is outside the scope of this rulemaking. The Agency is not in a position to set a regulatory tolerance for *L. monocytogenes* in RTE products, for a number of reasons, including the fact

that the Agency is unable routinely to identify the end users of the products.

Absent a conclusive demonstration to the contrary, the Agency must regard any amount of *L. monocytogenes* in a RTE product as an adulterant under the FMIA or PPIA (21 U.S.C. 601(m), 453(g)).

Labeling and Consumer Education

Comments: Some commenters said that development of meaningful “use-by” dating that reflects the safety of the product is a practical impossibility. They said that “use-by” dates would only be effective for products that are “refrigerated foods of extended shelf life (>10 days) that can support the growth of *L. monocytogenes* and that will be consumed without further listericidal treatment.”

Other commenters maintained that FSIS should require RTE products to have a uniform expiration dating system to identify product that should be frozen or not consumed after a specified number of days. Some commenters said that RTE products should carry warning labels if they are produced by a plant that does not conduct product testing for *L. monocytogenes* as a feature of its HACCP system. Also, they said, because of the possibility that RTE products might be contaminated with *L. monocytogenes*, the products should carry safe-handling labels until testing is required.

Response: FSIS proposed some revisions to the special-handling label requirements that are not addressed in this interim final rule. The Agency did not propose use-by labeling but requested comment on the feasibility of requiring such labeling, including the most effective way to implement it, the assumptions retailers and consumers should be expected to make in using it, scientific and economic data on the shelf-life and safety of RTE meat and poultry products, the kinds of post-lethality interventions that should be expected for products bearing use-by labeling, and the content of the labeling (66 FR 12635). FSIS notes that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is currently addressing safety-based use-by dates. FSIS will consider the NACMCF findings and other information of the kind requested in the proposal before any further rulemaking on the issue.

VII. The Interim Final Rule: Control of *L. monocytogenes*

FSIS has considered the information presented in comments on the proposal, public meetings, the FDA/FSIS risk ranking, and the FSIS risk assessment.

Given the pathogenicity of *L. monocytogenes*, the opportunity for it to contaminate RTE product in the post-lethality environment, and the significant consequences that this contamination can have, FSIS is amending its regulations. The Agency is adding provisions that require establishments that produce post-lethality exposed RTE product to include in their HACCP plans or in their Sanitation SOPs or other prerequisite programs measures that prevent product adulteration by *L. monocytogenes*.

FSIS is adding several definitions (9 CFR 430.1) to the regulations. FSIS is defining “deli product” and “hotdog product,” which are a particular focus of the regulations because of the risks they pose. The Agency is also adding several definitions relating to conditions affecting RTE products after the products have undergone a process that destroys *L. monocytogenes* (9 CFR 430.1).

The first definition in 9 CFR 430.1 is for “antimicrobial agent,” which FSIS is defining to mean a substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism or of suppressing or limiting its growth throughout the shelf life of the product. In the context of this regulation, an antimicrobial agent may be added to a post-lethality exposed product (also defined) after its initial lethality treatment. An antimicrobial agent, such as acid from fermentation, may also be an inherent component of the product or a result of its formulation. In any case, the effect of the use of the antimicrobial agent is to limit or suppress growth of *L. monocytogenes*.

“Antimicrobial process” is defined to mean an operation, such as freezing, that is applied to an RTE product and that has the effect of suppressing or limiting the growth of a microorganism. In the context of this regulation, the process is typically applied to a post-lethality exposed product after its initial lethality treatment, and the effect of the process in limiting or suppressing growth of *L. monocytogenes* continues throughout the shelf life of the product. If a product were frozen, the effect of freezing the product could only continue throughout the shelf life of the product if the product were maintained continuously in a frozen state.

The Agency is defining “post-lethality exposed product” as RTE product that comes into direct contact with a food contact surface after undergoing a lethality treatment that is a usual and necessary step in the production of the product, *e.g.*, the cooking step for a hotdog or other cooked sausage. A