

combinations of in-plant interventions, including FCS testing, with and without test and hold actions.

The final rule also differs from the proposal by requiring RTE MPP establishments to furnish FSIS with at-least-annual estimates of production volume by type of RTE MPP and by alternative *Lm* control program used. This change responds to comments on the proposed rule indicating opposition to the use of establishment size criteria in determining verification testing intensity and to information provided in the public comments indicating that there may not be a connection between establishment size and volume of production. These comments noted that production volume is dependent on factors other than establishment size, such as technology.

Finally, the rule allows labels on RTE MPPs to show that the products were processed in a manner to eliminate, reduce, or limit the growth of *Lm*, provided that the claim is validated. This provision is not a regulatory requirement in that it does not mandate such labeling, but is intended to encourage the industry to implement effective *Lm* controls and to provide useful information to consumers, especially vulnerable subpopulations.

Coverage

FSIS found that that the final rule will affect 2,930 federally inspected RTE MPP establishments and about 2,046 State-inspected establishments. About 144 of these establishments are considered large, 1,276 small and 3,556 very small, using the size criteria adopted by FSIS in implementing the HACCP regulations. FSIS was able to determine that the baseline numbers of federally and State-inspected establishments in the respective *Lm* control groups 1 through 4 are, respectively: 49; 2,297; 1,864; and 766. These numbers are expected to change as a result of this rule.

FSIS was further able to determine that, because of the intensity of verification testing that sanitation-and-testing establishments would have to implement to ensure that product contaminated with *Lm* is not shipped, a certain percentage of establishments in this group are likely to decide to put their *Lm* controls in their HACCP plans or to adopt *Lm* growth

suppressing or limiting methods. They would decide, therefore, to "move or migrate" into the grouping of establishments that take either the first or the second *Lm* control approach. The number of establishments in establishment groups 1 through 4 is expected to be 95, 2,363, 1,864, and 654, respectively, after the final rule goes into effect. The expected movement among establishment groups is discussed in detail in a later section.

The numbers of establishments in each of these *Lm* control groupings will determine the allocation of FSIS inspection resources for *Lm* control verification. FSIS will verify that establishments that produce RTE products are carrying out *Lm* control procedures in their post-lethality processing areas as described in their HACCP plans or their Sanitation SOPs or other prerequisite programs, and that they are complying with the requirements of this final rule. In addition to verifying establishment *Lm* controls, the Agency will verify that any label claims regarding *Lm* control have been validated. The frequency of FSIS verification testing of establishment *Lm* controls is expected to be higher for each successive *Lm* control alternative. In other words, the frequency will be lowest for establishments that use control Alternative 1 and highest for establishments that use control alternative 3 and that produce deli meats and hotdogs.

Establishment Groups

Grouping by Control Method. For the purposes of this analysis, four establishment groups can be identified in the final rule. The four groups are composed respectively of the establishments choosing *L. monocytogenes* control Alternatives 1 through 3, and the deli meat- and hotdog-producing establishments choosing Alternative 3 (9 CFR 430.4(b)(1), (b)(2), (b)(3)(i) and (b)(3)(ii)).

Establishment Group One (9 CFR 430.4(b)(1)): Establishments apply a post-lethality (PL) treatment to their products or process and use a *Lm* growth inhibiting agent or process. Products produced by establishments in EG 1 are expected to present the least risk of possible *Lm* contamination of products because they use a combination of intervention measures. EG 1's HACCP, Sanitation SOP or other prerequisite program controls and FSIS's

"normal" verification procedures are expected to provide information that is adequate to assure the establishment and FSIS inspection personnel that an adulterated product is not being produced.

Establishment Group Two (9 CFR 430.4(b)(2)): Establishments apply either a post-lethality treatment to their products or use a *Lm* growth inhibiting agent or process. Because establishments in EG 2 apply a PL treatment to their products or use a growth inhibiting agent or process, but not both, this group's products present a somewhat higher level of risk. They still would be considered "safe" with a high degree of certainty, but this final rule will provide additional assurance that the products are not adulterated by requiring EG 2 establishments to test food contact surfaces (FCSs) and make the test results available to FSIS.

Establishment Group Three (9 CFR 430.4(b)(3)(i)): Establishments use neither a PL treatment nor a growth inhibiting agent or process, but has Sanitation standard operating procedures (Sanitation SOP) or other prerequisite programs and produce a class of post-lethality exposed product that is not a deli product or a hotdog product.

Establishment Group Four (9 CFR 430.4(b)(3)(ii)): Establishments use neither PL treatments nor *Lm* growth inhibiting agents or processes in their RTE MPP production, but have Sanitation SOP or other prerequisite programs and produce a class of post-lethality exposed product that is a deli product or a hotdog product. Establishments in EG 4 produce RTE MPPs that have been identified in recent risk assessments as posing significant risk of *Lm* contamination in their post-processing environment and significantly contribute to illnesses and deaths. The *Lm* control measures for establishments in EG 4 are similar to those of EG 3, but FSIS feels that specific holding action requirements are justified to ensure that no adulterated product enters commerce when a second consecutive positive FCS test in the post-lethality processing environment of a EG 4 is found. A guide to the final rule requirements by establishment group is given in Table 1.

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