

environment. The use of these technologies and documentation of records on the environment of these establishments, brought about by this final rule, will provide the kind of information, and needed food safety assurance, that is lacking for consumers.

#### Rationale for the Approach Taken

The economic rationale for the requirements of the final rule is that it recognizes that a combination of interventions have been shown to be more effective than a single intervention and builds this into the framework of regulation. Second, the requirements recognize that the level of risk varies by product and how it is produced. Third, the requirements provide incentives for the establishment to adopt sanitation and testing practices that are most suitable for its products and processes. And lastly, these incentives for establishments have been shown to be preferable over mandatory requirements.

The FDA/FSIS risk ranking<sup>1</sup> found that RTE MPPs posed a moderate to high human health risk, particularly among vulnerable populations. These products include deli meats, hotdogs, meat spreads, pâté, and deli salads that include RTE meat or poultry products as components. The risk ranking indicates that among the RTE MPPs, deli meats pose an especially high risk.

The FSIS Risk Assessment for *L. monocytogenes* in Ready-to-Eat Deli Meats<sup>2</sup> (FSIS *Lm* risk assessment) estimated the reduction in fatalities among vulnerable populations from consuming contaminated deli meats that might be achieved through in-plant sanitation with verification testing regimes of increasing intensity. These results were compared with estimates for similar fatality reductions that might be achieved by applying post-lethality treatments or growth inhibiting additives or processes. Based on the finding of the FSIS *Lm* risk assessment, the Agency concluded that a combination of interventions, including sanitation coupled with verification testing, and the use of growth inhibitors, appears to be more effective in controlling *Lm* than a single intervention in these operations.

FSIS considered the findings of the FDA/FSIS risk ranking and the Agency's *Lm* risk assessment and the public comments that had been submitted on the Agency's proposed rule regarding control of *Lm* in RTE products. Many of the comments expressed opposition to proposed mandatory testing frequencies—either the frequencies themselves or the fact that they would be mandated. Instead of mandatory testing requirements, the Agency is requiring that establishments incorporate appropriate verification methods into their HACCP plan, Sanitation SOP, or prerequisite program. This approach provides establishments with incentives to test for *Lm* and the flexibility

to implement control measures that are appropriate for the types of products produced and processing methods at the establishment.

The final rule sets out four alternative *Lm* control approaches. For the purposes of this analysis, FSIS has grouped the affected establishments according to their use of these *Lm* control approaches.

#### Changes Between the Proposed and the Final Rule

FSIS considered four regulatory options for this final rule that had been generated from comments on the proposed rule. The options were: (1) No action; (2) a sanitation performance standard for reduction of *Lm* in RTE MPPs; (3) mandatory testing frequencies for *Listeria* species on food contact surfaces different from the frequencies proposed; and (4) a warning label to inform consumers in vulnerable groups of the potential for *Lm* contamination.

FSIS determined that: (1) Comments supported a final rule; (2) scientific support for a sanitation performance standard was lacking; (3) mandatory testing frequencies were objectionable for reasons given in the comments; (4) a warning label would be inappropriate because, under the law, all RTE meat and poultry products must be not adulterated and thus safe for all consumers.

FSIS adopted a modification of the third option. It will require establishments to describe their testing programs in their HACCP plans or in their Sanitation SOPs or other prerequisite programs, as appropriate for products and processing technologies. It will also require establishments to set the frequency of their verification tests for *Lm* on food contact surfaces, but will not mandate a specific frequency. The *Lm* control alternative influences the frequency of verification testing at an establishment. Verification testing is expected to be most frequent for establishments that produce post-lethality exposed deli meats and hotdogs and rely exclusively on sanitation and verification testing to control *Lm*.

The final rule identifies four *Lm* control alternatives that are typical of industry practices. The purpose of these control alternatives is to link the usage of HACCP or sanitation procedures with the risk of *Lm* contamination based on the FDA/FSIS risk ranking and the FSIS *Lm* risk assessment. The control approaches are: (1) A HACCP-based post-lethality treatment plus *Lm* growth limiting measures; (2) a HACCP-based post-lethality treatment or *Lm* growth limiting measures; (3) solely sanitation and verification control measures in its post-lethality treatment and no *Lm* growth inhibiting measures—and producing a class of post-lethality exposed product that is not a deli product or a hotdog product; and (4) solely sanitation and verification control measures in its post-lethality treatment and no *Lm* growth inhibiting measures—and producing a class of post-lethality exposed product that is a deli product or a hotdog product. For the purposes of this analysis, FSIS has grouped all establishments producing RTE MPPs that are exposed post-lethality according to their current and expected use of these *Lm* control approaches

and this analysis will refer to these establishment groups as establishment group (EG) 1 through 4.

The proposed rule would have required RTE MPP establishments to control *Lm* either in their HACCP plans or their Sanitation SOPs. The final rule requires establishments to include post-lethality treatments in their HACCP plans and allows them to have other types of *Lm* contamination controls in their HACCP plans or in their Sanitation SOPs or other prerequisite programs. This modification of the proposal is based on the finding that the establishment's use of a post-lethality treatment represents a determination by the establishment that *Lm* is a hazard reasonably likely to occur.

The prerequisite program provisions in the final rule respond to comments that the Agency should provide establishments with greater flexibility in implementing *Lm* contamination controls. In particular, RTE MPP establishments usually do not control post-processing contamination through HACCP alone, but through a variety of prerequisite programs.

In response to public comments, the final rule also does not mandate food contact surface (FCS) testing frequencies. Instead, the final rule sets out specific requirements, for Alternatives 2 and 3 for sanitation procedures that are included in HACCP plans, or in Sanitation SOPs or other prerequisite programs. Establishments are allowed to choose their own testing methods and frequencies for verifying the effectiveness of their procedures.

The sanitation procedure requirements for Alternative 3 establishments that process hotdog and deli meat products and control for *Lm* using sanitation procedures only, include hold-and-test provisions. These procedures are invoked when follow-up testing to verify corrective actions in response to *Listeria*-positive FCS test results. A second positive FCS test for *L. monocytogenes* or an indicator organism entails withholding from commerce product that was in contact with the contaminated surface. Shipments can resume when subsequent tests in the same area of the plant are negative. The product can be tested under a sampling plan that provides sufficient confidence to enable the product to be released into commerce. The requirements for Alternative 3 establishments that process deli meats and hotdogs represent a modification of the hold-and-test procedures that the proposal would have required (proposed § 430.4(b)) but imposes this requirement only on establishments producing hotdog and deli-meat type products. This particular change from the proposal is responsive to comments opposing mandatory testing frequencies and the proposed hold-and-test requirements, which would have applied to all RTE MPPs. The requirements for Alternative 3 establishments that process deli meats and hotdogs are also responsive to the FDA/FSIS risk ranking which identified hot dog and deli-meat products as posing a moderate to high risk for listeriosis on a per annum basis (as opposed to a per serving basis), and the FSIS *Lm* risk assessment which evaluated the risk-reduction effectiveness of various

<sup>1</sup> FDA, FSIS, CDC. "Draft Assessment of the Relative Risk to public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods". The document is available at [www.foodsafety.gov](http://www.foodsafety.gov).

<sup>2</sup> USDA, FSIS. "Draft Risk Assessment for *Listeria Monocytogenes* in Ready-to-eat Deli Meat Products". FSIS. March 2003. The risk assessment is available at [www.fsis.usda.gov](http://www.fsis.usda.gov).