

Analysis of Alternatives

For purposes of the analysis, the expected frequency of FCS verification testing for *Listeria* spp. for establishments in EG 2 is once per line per quarter; for EG 3, at least once per line per month; and for EG 4, once per line per month for very small establishments; semi-monthly for small producing establishments and weekly for high volume producing establishments (4–2–1). These testing frequencies are to be considered minimum expected levels for the purposes of estimating costs and benefits. Conditions may warrant a higher frequency of FCS verification testing to assure FSIS that establishments' sanitation or prerequisite plans are adequately addressing the risk of possible contamination in its products. As an additional precaution, FSIS is requiring that after a second positive *Listeria* spp. FCS test result in an EG 4 establishment, hold and test actions are taken until such time that FSIS is assured that this action is no longer needed.

The FSIS *Lm* Risk Assessment found an increase in median lives saved as FCS verification testing frequencies increase relative to the baseline. The minimum FCS verification testing frequency for EG 4 (4–2–1) results in 25 deaths averted if there is 100 percent adoption of this testing frequency by all establishments producing deli meats.

An alternative FCS verification testing frequency could be 40–20–10 for EG 4. In this case, the reduction in human health risk increases to 89 deaths averted, given 100 percent adoption. At an extremely high level of testing, such as 60–60–60 (for either FCS verification testing for *Listeria* spp. or product testing for *Lm*), 153 deaths are averted given 100 percent adoption. Also, at these high levels of FCS verification testing, hold and test protocols were shown to reduce the level of *Lm* contamination at retail.

Extremely high FCS verification testing levels may not be required to assure adequate sanitation. Nor are they necessarily effective from an economic perspective. Costly hold and test actions increase with FCS verification testing frequency. As such costs increase, establishments producing RTE MPPs, especially small and very small establishments, may eliminate product lines or cease production entirely. FSIS recognizes, however, that FCS verification testing frequencies higher than 4–2–1 may be

appropriate for establishments with a history of poor sanitation controls or evidence of producing adulterated product.

Another concern about high FCS verification testing frequencies is the likelihood that many establishments that produce RTE MPPs using traditional methods will no longer produce such products. To the extent that this reduces the amount of adulterated product, this rule and its emphasis on FCS verification testing is appropriate. It may be inappropriate for any product that FCS testing for *Listeria* species is not a reliable indicator for *Lm* product contamination. FSIS believes that its establishment categorization in this final rule will place only those products in EG 4 where intense sanitation and verification testing is most appropriate. However, extremely high verification testing frequencies in most cases may be unnecessary and burdensome.

The risk assessment clearly shows that a combination of post-lethality treatment or *Lm* growth inhibition along with sanitation and FCS verification testing and other measures is more effective than a "sanitation coupled with FCS verification testing only" strategy. This result also reinforces the observed industry practice of maintaining a series of adequate precautions throughout slaughter and processing, and of not exclusively relying on verification of sanitation through FCS testing alone to assure that products are not adulterated. FCS verification testing of sanitation procedures for *Listeria* species can complement these other measures, e.g. post processing pasteurization, the addition of *Lm* growth inhibiting packaging. To the extent that establishments take a series of steps to address their possible *Lm* contamination, the need for higher FCS verification testing frequencies, and its impact of inspection personnel to review these data, is reduced.

Summary of Direct Industry Costs

The PRIA identified three major possible industry-wide impacts from mandatory FCS verification testing: HACCP plan modification costs (\$1.28 million); direct testing costs (\$1.75 million); and, production adjustments (\$2.5 million). The total first-year cost of these impacts was \$5.53 million—\$3.8 million in one-time outlays and \$1.75 million in recurring annual costs associated with testing.

The Final Regulatory Impact Analysis (FRIA) reflects many comments received in

the public comment period. In addition to the impacts identified in the PRIA, the FRIA estimates (1) the cost of PL treatments (initial and annual operating); (2) the cost of using an agent or process to inhibit *Lm* growth (initial and annual operating); and, (3) the costs of holding product while awaiting confirmation of FCS verification testing.

The validation of PL treatments and related HACCP plan modifications results in a one-time cost of \$2.6 million. The estimated cost in the FRIA is higher than that in the PRIA due to an increase in the number of establishments affected. The FRIA estimate may be conservative as it does not take into account the use of validation studies conducted by PL equipment manufacturers. Direct testing costs are substantially lower than estimated in the PRIA (\$175,260 versus \$1.75 million) because the expected movement of establishments out of EG 4 and into the other establishment groups where higher FCS verification testing is not expected. Production adjustments are estimated at \$1.15 million in one-time costs in the FRIA compared to \$2.5 million in the PRIA. The difference is due mainly to fewer expected cases where establishments are not able to overcome their *Lm* contamination problem. More establishments adopt PL treatments and move into EG 1 or EG 2. The total of the two, one-time cost components (production adjustments and use of PL treatments) is the same as that estimated in the PRIA (\$3.8 million as opposed to \$3.75 million estimated in the PRIA). Verification testing costs, as noted above, are substantially lower than that estimated in the PRIA.

The additional costs associated with the installation of PL treatments and/or altering their production to incorporate an agent or process to inhibit *Lm* growth introduces potentially large cost outlays, especially for the initial, one-time investments in plant and equipment (Table 20). The initial industry-wide, one-time cost outlays for equipment associated with production adjustments and PL treatments are expected to be as high as \$51.6 and \$10.1 million, respectively. The annual operating (recurring) costs of \$5.2 and \$1 million, respectively, make first-year costs for these two technologies, \$56.7 and \$11.1 million, respectively.