

preliminary RIA, "mandatory *Listeria* testing is the most difficult provision in the proposed rule to analyze because of the uncertainty of current practices and how establishments will react to the proposed rule. Major uncertainties include: the degree to which firms will switch to a *Listeria*-related CCP in their HACCP plan, the degree to which firms will be able to resolve their *Listeria*-related problems if they present themselves, and the degree to which they must increase their testing." This problem is further compounded in this analysis because the final rule is not limited to whether establishments either elect to incorporate a *Lm*-related CCP in their HACCP plan or face mandatory testing. In this analysis, it is possible for establishments to address possible *Lm* contamination in their operations through a variety of methods.

A large share of the cost impact is on small establishments, which are expected to absorb nearly 75 percent of the total industry-wide cost impact (Tables 26 and 27). These establishments have the same incentives to move to new post-pasteurization technologies as do very small establishments, but their production volumes more easily justify the associated high capital and recurring expenditures. Very small establishments will likely have to increase sanitation coupled with FCS verification testing to comply with this final rule. Large establishments are likely to complete the process of adopting new technologies. The expected impacts on large, small, and very small establishments are discussed below.

#### Large Establishments

As discussed in the "Baseline" section of this analysis, most (131 out of 144 large establishments) already fall into either establishment group 1, 2 or 3. This number is expected to increase by 5 establishments as a result of the final rule, leaving only 8 establishments in the establishment group 4: those establishments required to conduct more intense sanitation coupled with FCS *L. spp.* verification testing than establishments producing product in the other establishment groups. Many of these firms already employ post-pasteurization technologies, but need them validated to comply with the final rule. In fact, six of the existing establishments in EG 1 and four of the establishments from EG 2 already employ the technology, but simply have not validated their processes. It is expected that total validation costs will run about \$749,000 in first-year costs for these establishments.

The remaining establishments are likely to have high enough product volume levels to justify the acquisition of new post-pasteurization technologies and/or to alter product formulations and packaging. The remaining eight establishments (seven of the 10 establishments from EG 2 (or 10 percent of the establishments in EG 2 that do not apply a post-pasteurization step)); and one from EG 4 (or 10 percent of the establishments in EG 4) all are expected to need post-pasteurization equipment and have their processes validated. The resulting large initial cost outlays plus the estimated recurring annual operating costs are expected to total \$14.3 million in first-year costs. This cost represents about 90 percent of all the costs that are expected to be incurred by large establishments as a result of this final rule. The remaining costs are incurred by those establishments electing to add an inhibiting agent or process in their production or to a lesser degree, as a result of sanitation coupled with FCS verification testing and possible subsequent actions related to hold and test and finding remedies to possible persistent *Lm* contamination problems.

#### Small Establishments

It is estimated that there are 1,276 small establishments producing RTE MPPs. FSIS estimates that 108 small establishments will migrate to other establishment categories as a result of the final rule. This is a costly undertaking, especially for those establishments that elect to migrate into EG 1. Due to the high cost of both technologies (post-lethality processing and adding an agent or process to the product) and because their products must conform to both process adjustments, it is expected that only 31 establishments (or 10 percent of the small establishments that were formally in EG 4) migrate to EG 1 as a result of the final rule. All movement involves the purchase and use of new technology which is expected to cost these establishments over \$42 million. About twice the number of establishments that is expected to migrate to EG 1 is expected to migrate to EG 2. This move is less costly and it is expected that more RTE MPPs lead themselves to the addition of an inhibiting agent or process. These 77 establishments are expected to incur \$10.6 million in first-year, total direct and recurring costs. All of the 108 establishments are expected to migrate from EG 4.

#### Very Small Establishments

It is estimated that there are 3,556 very small establishments producing RTE MPPs.

The preliminary RIA had an estimate of only 524 establishments, acknowledging that that estimate severely underestimated the true number of very small establishments. Due to the combination of high costs and technical difficulties faced by very small establishments, FSIS projects that no very small establishments will shift into a different establishment group. Consequently, FSIS does not expect that very small establishments will incur any costs associated with the adoption of post lethality treatment methods or by incorporating an inhibiting agent or process in their production. Instead, most of the entire cost impact of this final rule on very small establishments is expected to originate from sanitation coupled with FCS verification testing and the possible production adjustments and additional handling and storage associated with increased testing and the higher likelihood of incurring *Listeria* species positive FCS test results. A small amount of costs are expected to be incurred by those very small establishments that currently employ un-validated post-lethality processing technologies.

#### Summary

Small establishments make up 26 percent of the establishments, yet are expected to incur up to 75 percent of the aggregate cost burden. Much of these expected costs are in large capital expenditures in post lethality processing equipment and in changing their production process to incorporate *Lm* growth inhibiting agents or processes. This cost impact would be reduced to the extent that these cost estimates over-estimate the actual costs of acquiring these technologies or over-estimate the establishment movements. It is unlikely that actual cost impacts would exceed those estimated in this analysis. Very small establishments make up 71 percent of the number of establishments in the industry and yet are expected to incur only 4 percent of the total costs of this final rule. This estimate may under-estimate their exposure to cost increases related to FCS testing. Thus, it is unlikely that actual cost impacts would be lower than those estimated in this analysis. The estimates for large establishments are highly contingent on their movement into EG1 and EG2. To the degree that actual movements into these establishment groups occur, the estimates in this analysis should reflect these expected cost outlays.

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