

The total number of establishments producing RTE MPP products is estimated to be 4,976: 59 percent federally inspected and 41 percent State-inspected. Of the total, 4.6 percent are associated with the O3E HACCP code; 20.2 percent with the O3F code; 71.1 percent with the O3G code; and, 4.1 percent with the O3I code (Table 4). Further analysis of HACCP size categories shows that 71.5 percent of all RTE MPP establishments are very small; 25.6 percent are small; and, 2.9 percent are large.

**Product groups.** The PRIA classified RTE MPP establishments by the expected range of potential cost impact on those establishments: Those likely to incur the greatest costs, moderate costs, minor costs, and no likely costs (Table 3 in **Federal Register**, Vol. 66, No. 39). This grouping was based on the likely impact from both the proposed testing programs as well as the proposed changes in lethality and stabilization performance standards. The final rule concerns only that section of the proposed rule dealing strictly with FSIS's desire to increase safeguards with respect to possible *Lm* contamination. Because of this and also because products and production processes vary across the same product classification, it is not feasible to disaggregate in the fashion of the PRIA. However, it appears that the largest impact will be on establishments producing cooked RTE MPP products—those products associated with HACCP process code O3G. There is little likelihood that there will be any cost impact on RTE MPP establishments producing products in the O3E, O3F and O3I HACCP process codes, except for costs attributable to a possible increase in FCS testing mandated by the rule. These costs are expected to be minor because many of the establishments in the HACCP process category codes already apply an agent or process that inhibits *Lm* growth so many of these establishments “qualify” to be classified in EG 2.

Establishments associated with the O3G HACCP process category code produce cooked RTE MPPs which may or may not be able to apply post-lethality treatment to products, apply antimicrobial agents, or include procedures in either Sanitation SOPs or prerequisite programs. In some cases, FCS testing and disclosure of those results to FSIS may result in minor cost increases similar to those for O3E, O3F, and O3I HACCP process category codes. For other products in the O3G HACCP process code, they could be produced under any of the four alternative post-lethality *Lm* control regimes identified in this final rule. In those cases, the costs could be significantly higher. Accordingly, the cost impact discussion is presented by each establishment group, type of products produced, and their associated establishment numbers and size distribution.

**Impacts according to establishment group.** The Agency anticipates that the measures taken by establishments will differ by establishment group. The following describes the major types of responses expected to be taken in response to the final rule for those establishments switching establishment groups and/or validating current *Lm* controls.

#### EG 1 EG 2 Impacts

(1) *Incorporation of post-lethality treatments and/or their validation for FSIS:* Many establishments are currently using post-lethality measures to address possible *Lm* contamination. These actions may have been taken in response to client requirements, the recent FSIS *Lm* intensified verification program, or in anticipation of further FSIS action. The costs of these actions taken by establishments are not attributed to the final rule. However, measures taken to satisfy this requirement or to validate these measures to FSIS are attributed to the final rule. These measures include: Post-lethality heating (may not be feasible for many products, especially those with a high fat content); high-pressure systems, which may be limited to a few specialty items and usually have a low throughput; and irradiation, which is not permitted to be applied to RTE MPPs at present. FSIS expects establishments using post-lethality treatments to verify that their treatments are effective and also to monitor FCSs to assure that the treatment is effective. This level of verification FCS testing for establishments in EG 1 is expected to be about twice yearly.

(2) *Use of agent in product formulation or change in processes to inhibit *Lm* growth in product:* FSIS has recently permitted the use of certain food additives that inhibit *Lm* growth (65 FR 17128, March 31, 2000). These additives include lactate and diacetates that have been applied increasingly to cooked and cured RTE MPPs such as hotdogs. The cost to establishments of taking measures involving the use of these additives is not attributable to the final rule. The Agency estimates that up to 70 percent of all hotdog manufacturers have recently changed their product formulations to incorporate one of the recently permitted food additives. Changes in a process that would help inhibit the *Lm* growth in the product include: lowering the pH or water activity levels and refrigerating or freezing the product following processing. Growth inhibiting processes uses antimicrobial agents to control growth in post-lethality exposed products such as many hotdogs and certain other kinds of sausages. Verification FCS testing for establishments in EG 2 would be expected at least once per quarter. This level of testing would be expected whether the establishment administered a PL treatment or applied a *Lm* growth inhibiting agent or included a process in either a Sanitation SOP or prerequisite program.

#### EG 3 and EG 4 Impacts

(1) *FCS testing frequencies:* For the purpose of this analysis, the minimum level of FCS testing expected for establishments in EG 3 is at least once per month: once a month for high, once a month for small, and once a month for very small establishments. Also, the minimal level of FCS testing for EG 4 is: at least weekly for high-volume establishments, semi-monthly for small volume establishments, and monthly for very small (or low volume) establishments (4–2–1). These testing frequencies are illustrative in that the actual testing frequencies incorporated into final compliance guidelines may differ.

A potential unintended impact of the rule for establishments in EG 4 might be the incentive to reduce their current level of FCS testing if results are to be shared with FSIS. An establishment in this group may conduct fewer tests if results could lead to costly hold-and-test actions. This potential unintended impact was not be quantified in this analysis.

#### EG 4 Impacts

(1) *Hold and Test:* EG 4 establishments may be unable to (1) apply a post-lethality treatment or (2) apply an agent or include a process in either the Sanitation SOP or prerequisite program for a variety of reasons. Product from these establishments can be held on the basis of FCS testing results shared with the Agency. Multiple episodes of holding product may be incurred in the case of two consecutive positive FCS test results.

#### Baseline

**Establishment Types.** The compliance cost impacts of the rule differ significantly among establishment groups and by HACCP size category. The current distribution of establishments by group and size serves as the baseline for determining the distribution of compliance cost and also the starting point for the expected establishment shifts among establishment groups discussed below.

Table 4 indicates that 1,440 establishments produced RTE MPPs in the O3E, O3F, and O3I HACCP process category codes. For purposes of this analysis, these establishments are distributed 90 percent in EG 2 and 10 percent in EG 3. The high proportion in EG 2 is a result of the use of growth inhibitors in most of these products which include cured and salted products. These products have not been associated with listeriosis outbreaks.

The remaining 3,536 establishments in O3G produce cooked RTE MPPs that may be produced by any of the four *Lm* control methods. These establishments were partitioned into the four establishment groups as follows:

(1) From a December 2002 FSIS hotdog and deli meat survey, we know that there are 1,712 operations producing hotdogs and/or deli meats. Given that 38 percent of these operations produce both hotdogs and deli meats, the actual number of unique establishments involved is 1,061  $((1 - .38) \times 1,712)$ .

(2) The number of establishments producing cooked products other than hotdogs and/or deli meats was estimated by subtracting the number of single establishments producing hotdogs and/or deli meats from the total number of establishments producing cooked products  $(3,536 - 1,061 = 2,475)$ .

(3) FSIS inspection program personnel were contacted to estimate the proportion of establishments producing hotdog/deli meat and other cooked products in each of the establishment groups. These estimates, provided in Tables 5 and 6, were used to partition the establishments producing hotdog and deli meats and the other cooked RTE MPPs by establishment group (Table 7).

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