

Health Consequences. The baseline for comparing human health benefits associated with the rule is established by the "Draft FSIS Risk Assessment for *Listeria Monocytogenes* in Ready-to-eat Deli Meat Products"³ (*Lm* Risk Assessment). The *Lm* Risk Assessment concludes that 320 deaths are attributable to RTE deli meats. It is not possible at this time to identify the number or deaths attributable to RTE MPPs, which in addition to deli meats includes hotdogs, fermented sausages, and related products.

The FDA/FSIS risk ranking model⁴ estimates that there are about 340 billion servings of all RTE products consumed per year. RTE MPPs are contained within the following classes: reheated franks, non-reheated franks, deli meats, fermented sausages, pâté, and deli-salads. These classes comprise about 43 billions servings. The deli meat class is responsible for 49 percent of the 43 billion servings of RTE MPP. The two hotdog classes are together responsible for 15 percent of the servings of RTE MPP. Based on these estimates, there could be as many 375 annual fatalities associated with RTE MPPs.

The *Lm* Risk Assessment, because of its focus on deli meats, is only able to estimate the human health benefits associated with the rule as it affects this category of products. For purposes of establishing a baseline for potential human health benefits, deli meats are divided into two categories: Products sliced and packaged at the establishment; and retail sliced product. Pre-packed products are post-lethality exposed and the focus of the regulation. Retail-sliced products are not post-lethality exposed until prepared for use or sale at a retail location. The human health exposure to each type of product is a function of its share of total RTE deli meats consumed and the level of contamination in each type of product. Actions by FSIS can reduce the exposure to some, but not all RTE deli meat.

The Economic Research Service estimates that pre-packaged product accounts for 46 percent (\$11.6 billion) of total sales of RTE deli meats (\$25.2 billion) and retail sliced product the remaining 54 percent (\$13.6 billion).⁵ Volume of product in the categories

would provide a more suitable basis for establishing a baseline level.

There is considerable uncertainty about the level of contamination in each type of product when purchased. A recent study by Gombas, Chen, Clavero, and Scott⁶ finds that there is a 0.4 percent prevalence rate for *Lm* in pre-packaged product and a 2.7 percent prevalence rate for *Lm* in retail sliced product at the retail level. If 0.4 percent of pre-packaged product was found to be contaminated at the processing plant, it follows that 0.4 percent of the 2.7 percent prevalence rate at retail might be due to contamination at the processing site. That means that the prevalence of product solely contaminated during retail slicing is 2.3 percent (the observed 2.7 percent minus the 0.4 percent that was contaminated at the processor site). Using this information and the relative market share weights for pre-packaged and retail sliced deli meats from ERS provides a weighted average exposure rate for deli meats: $.004(0.46) + 0.004(0.54) + .027(.54) = .0164$ or $.004 + .01242 = .01642$

The pre-packaged product share of the weighted average exposure rate is 24.4 percent ($.004/.01642 = 0.2436$) and the retail sliced product share is the remaining 75.6 percent. Therefore, the human health baseline risk which the FSIS can affect at federally inspected establishments is a potential maximum 78 deaths (24.4×320).

The Agency has several concerns about this approach to establish a baseline level of human health risk. The prevalence levels estimated by Gombas, *et al.* and based on National Food Processing Association (NFPA) Survey data, taken at retail establishments, are significantly lower than those found by FSIS and reported in the *Lm* Risk Assessment Model. Levine, *et al.*⁷ reported 1999 prevalence levels of *Lm* at 2.71 percent for cooked, roast, and corned beef and 4.58 percent in sliced ham and other pork luncheon meats. All samples were collected at production facilities, not at retail. The prevalence levels from the NFPA and FSIS studies are not entirely comparable, but they do seem to be inconsistent, even after taking into account basic limitations in the data used in both studies. The NFPA survey data describe the difference in prevalence between product contaminated at processing and product contaminated at retail. It is important to recognize that some of the product found contaminated at retail was contaminated at the processor but was only detected at retail. It is difficult to reconcile FSIS product sampling which finds 2.7–4.6 percent of RTE meats positive for *Lm*, with the finding based on the NFPA survey data

that only 0.4 percent of packaged RTE meats are positive at retail outlets. Some net growth, not dying off, of *Lm* within contaminated packages between processor and retail is expected. The Agency concludes that there is much uncertainty about the true proportion of products contaminated at the processor and at the retail facility and among products affected by the rule and not affected by the rule.

All things considered, the Agency concludes that it is appropriate to make at least a 50-percent reduction in the potential deaths and illnesses averted due to *Lm* control measures taken by RTE MPP establishments as a result of this rule (versus the 24.4 percent based on the estimate presented). This percentage takes into account the study by Gombas, *et al.*, and discussions with FSIS industry experts, risk assessors, and microbiologists. Consequently, the maximum potential reduction in fatalities achieved through Agency measures for RTE deli meat products is $180 (320 \times .5)$. This level would be somewhat higher if hotdogs, fermented sausage, and related products were included in the *Lm* Risk Assessment.

Expected Movement Among Establishment Groups

There are six major industry cost impacts that are expected with the final rule. Most of these impacts arise because some establishments are expected to shift into establishment groups that entail different technologies than they currently employ. These shifts are attributed to compliance with requirements of the rule. Costs are estimated on the basis of such shifts among the establishment groups. The movements among establishment groups are based on the experience and judgment of FSIS personnel which were pooled together to produce certain guidelines to estimate the expected movement of establishments across establishment groups, depending on their establishment size. For large establishments, it is expected that, based on this collective judgment, 20 percent of the establishments in EG 2 (that were already applying a PL treatment and referred to as EG 2A) would move into EG 1 (Table 8). These seven establishments already had the necessary equipment for these treatments, but simply had not validated their use. Therefore, only very little additional cost was involved for these establishments to move into EG 1 (along with the adoption of applying a *Lm* inhibiting agent or process). A 10-percent shift in establishments in EG 2B and EG 4 is expected because these establishments have not incurred the high initial costs of the post lethality equipment, resulting in a shift of seven establishments from EG 2B and two from EG 4. No establishment shifts in EG 3 are anticipated. In total, the application of these guidelines produced an increase of 16 establishments in EG 1 (Table 9).

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³ 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.

⁴ 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.

⁵ The estimate is based on information from the A.C. Nielson Co. 2001 Consumer Expenditures Study as reported in *Progressive Grocer*, September, 2002. The data sources are: supermarket checkout scanner data from a representative sample of 10,000 U.S. supermarkets, a representative consumer panel consisting of 55,000 households, and *Progressive Grocer* estimates.

⁶ "Survey of *Listeria monocytogenes* in Ready-to-Eat Foods", *Journal of Food Protection* 66 (H): 559–569.

⁷ Levine P, Rose B, Green S, Ransom G, and Hill W (2001). Pathogen testing of ready-to-eat meat and poultry products collected at federally-inspected establishments in the United States, 1990 to 1999. *Journal of Food Protection* 64(8):188–1193.