

their healthcare providers. The Spanish version will be printed in spring 2003. In addition, FSIS is completing a low literacy flyer aimed at pregnant women entitled, "Protect Your Baby and Yourself from Listeriosis" with input from WIC nutritionists, public health nurses, and extension food safety specialists. To reach other vulnerable groups, discussions are underway with transplant organizations, community health clinics, geriatric organizations, dialysis centers, and AIDS/HIV care organizations to determine how best to reach these individuals. Through the newly launched Food Safety Education Mobile, informational materials will be distributed as the vehicle travels throughout the country.

In addition to providing education on safe food handling, FSIS will provide information to consumers regarding new labels that processors may voluntarily use under this regulation to inform consumers of interventions used to reduce contamination.

#### X. Executive Order 12866 and Effect on Small Entities

This interim final rule has been reviewed by the Office of Management and Budget under E.O. 12866 and has been determined to be economically significant. FSIS is amending the Federal meat and poultry inspection regulations by adding requirements for establishments that produce certain RTE meat and poultry products to take measures to prevent product adulteration by the pathogen *L. monocytogenes*. Establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments must include in their HACCP plans or their Sanitation SOPs or other prerequisite programs measures designed to prevent product adulteration by *L. monocytogenes*. The establishments also must share with FSIS all data relevant to the validation, operation, and verification of their controls for *L. monocytogenes*.

This action is compelled by outbreaks of foodborne illness in which RTE meat and poultry products contaminated with *L. monocytogenes* were implicated, coupled with information on the pathogenicity of the organism and the findings of the risk assessment and risk ranking conducted by FDA and FSIS. Although FSIS now routinely conducts food contact surface and environmental sampling in select establishments that produce such products, and performs product testing in nearly all RTE establishments for the presence of this pathogen before the products are distributed, until now there have been no specific regulatory requirements for

controlling the pathogen. Appendix A, published at the end of this interim final rule in this issue of the **Federal Register**, contains the final regulatory analysis required by E.O. 12866 and the Regulatory Flexibility Act (at 5 U.S.C. 604), including a discussion of the need for the regulations, regulatory alternatives considered by FSIS, and a cost-benefit analysis. This interim final rule provides affected small and very small establishments with the flexibility to minimize the costs associated with this rule by implementing Sanitation SOPs or other prerequisite programs. FSIS is providing compliance guidance for these establishments in accordance with the Small Business Regulatory Enforcement Fairness Act. In addition, in verifying compliance with this interim final rule, the Agency plans to conduct testing at modulated frequencies, taking into account all relevant factors, including the alternative employed to address *L. monocytogenes*, production volume by type of RTE product produced, and the establishment's compliance history.

#### Summary of Final Regulatory Impact Analysis (FRIA)

##### Benefits

FSIS has estimated the benefits of this interim final rule in terms of averted deaths and illnesses resulting from actions taken by establishments that produce RTE meat and poultry products so far with respect to only one product group: Deli meats. FSIS has concentrated on this product group for several reasons: The FDA/FSIS risk ranking identified deli meats as posing the most overall risk to public health. The FSIS in-plant risk assessment tied risk mitigation actions to possible reductions in deaths and illnesses from listeriosis when the FSIS risk assessment model was calibrated with the FDA/FSIS risk ranking model, and when containment strategies for *Listeria* contamination of RTE meat and poultry products were simulated. The FSIS risk assessment model has been presented to the public, along with estimates of reduced listeriosis mortality resulting from actions taken by establishments that prepare or process the products.

The FRIA relies on results from the FSIS in-plant risk assessment model and considers the adoption by large, small, and very small deli-meat producing establishments of stratagems of varying rigor for controlling *L. monocytogenes*. The analysis shows that adoption of *L. monocytogenes* mitigation measures induced by this interim final rule results in a total median reduction of deaths from listeriosis of 27.3; with 8.9 deaths

averted at the 5th percentile and 31.2 at the 95th percentile. These gains are attributable to an expected shift—discussed in detail in Appendix A—of establishments from sanitation-only to "Alternative 1" and "Alternative 2" methods of addressing *L.*

*monocytogenes*. The corresponding reductions in illnesses are 136.7 at the median, with 44.6 at the 5th percentile, and 156.0 at the 95th percentile.

Using a method used by USDA's Economic Research Service (ERS) for estimating the human health benefits of reduced listeriosis, the benefits of the reduction in illness-related losses due to the interim final rule are estimated to be \$3.7 million at the median ( $(.05 \times 136.7 \times \$10,300) + (.95 \times 136.7 \times \$28,300)$ ) and \$1.3 million at the 5th and \$4.4 million at the 95th percentile.

ERS estimated the value of statistical life at \$4.8 million<sup>7</sup> as a proxy for the cost of one fatality. Based on this estimate, the annual human health benefits from implementation of the interim final rule are \$134.9 million at the median (the \$3.7 million above plus  $27.3 \times \$4.8$  million) and \$44.0 million at the 5th percentile and \$154.0 million at the 95th percentile.

Given the limitations in data and the fact that the risk assessment addresses only deli meats, FSIS believes that this estimate may be overstated by at least 50 percent. If so, the adjusted annual net benefits then become \$50.8 million at the median, \$5.4 million at the 5th percentile, and \$60.4 million at the 95th percentile. FSIS performed a sensitivity analysis on the benefits estimates. Given the cost estimates, the total benefits of this rule would have to be 85 percent lower than estimated for the net benefits to lower to zero.

##### Cost Impacts

FSIS estimated the cost impacts of this interim final rule on all affected establishments. The FRIA adds several cost impacts in addition to those considered in the preliminary regulatory impact analysis (PRIA). The PRIA identified major cost impacts from mandatory food contact surface testing, HACCP plan modification, and production adjustments. In addition to these and in response to comments, the FRIA considers the costs, both fixed and recurring, associated with the installation by establishments of post-lethality treatments; the costs, both fixed and recurring, associated with product formulation or process changes to include antimicrobial agents or processes that limit the growth of *L. monocytogenes*; and the costs to establishments required to hold and test products pending confirmation of