

The Economic Research Service of USDA presented a method for estimating the human health benefits of reduced listeriosis at a public meeting on the proposed rule held in May 2001. To estimate the benefits, it was assumed that 5 percent of the cases were moderate, and that moderate cases resulted in hospital costs of \$10,300 per case. The remaining 95 percent of the illness were severe, resulting in hospital costs of \$28,300 per case.<sup>9</sup> Using these assumptions and excluding the loss in productivity of those affected and any pain and suffering, the benefits of the reduction in illness-related

losses due to the final rule are estimated to be \$3.7 million at the median ( $0.05 \times 136.7 \times \$10,300$ ) + ( $0.95 \times 136.7 \times \$28,300$ ) and \$1.2 million at the 5th and \$4.3 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 the implementation of the 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 output of the risk assessment dealing only with deli meats and as per the discussion found earlier concerning the estimates of health consequences, FSIS believes that this estimate may be overstated by as much as 50 percent. If so, the adjusted annual net benefits then become \$50.8 million, \$5.4 million and \$60.4 million at the median, 5th and 95th percentile levels, respectively (Table 25). It appears that a downward adjustment in total benefits of 85 percent would be necessary to lower net benefits to near zero.

Table 25. Summary of Annual Total and Net Benefits			
Item	No adjustment	Benefits reduced 50 percent	Benefits at Breakeven (15%)
	\$million		
Total Benefits			
Median	134.9	67.5	20.2
5 <sup>th</sup> percentile	44.0	22.0	6.6
95 <sup>th</sup> percentile	154.0	77.0	23.1
Net Benefits			
Median	118.3	50.8	3.6
5 <sup>th</sup> percentile	27.4	5.4	-10.0
95 <sup>th</sup> percentile	137.4	60.4	6.5
Net benefits hold industry-wide compliance cost of this regulation constant at \$16.6 million.			

#### Compliance With Regulatory Flexibility Act of 1996

The Administrator has determined that for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–612), this rule will have a significant economic impact on a substantial number of small entities. As discussed above, FSIS estimates that the *Lm* sanitation coupled with FCS verification testing provisions of this final rule may result in annual costs to small and very small producers of post-lethality exposed RTE MPPs of \$12.5 and \$0.6 million, respectively. These establishments incur about 79 percent of the total industry-wide costs of compliance with the sanitation coupled with FCS verification testing provisions of this final rule.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) requires, among other things, that for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of title 5, United States Code, the agency must publish one or more guides to assist small entities in complying with the

rule, and must designate such publications as “small entity compliance guides”. The guides must explain the actions a small entity is required to take to comply with a rule or group of rules. FSIS is developing guidance to assist small and very small establishments in fulfilling their responsibilities under the final rule. The guides will include instructions on how establishments that produce post-lethality exposed RTE MPPs can conduct sanitation coupled with FCS and product verification testing. Establishments that wish to use the guides may incorporate their features into their HACCP plans, Sanitation SOPs or other prerequisite programs. Because FSIS is basing its guidance on existing research and industry practices that are known to be effective, the Agency also will consider the processing instructions to be already validated. That is, an establishment may follow the guidance without contracting for or conducting additional validation of the content of the materials.

FSIS is examining other options to minimize the potential negative economic effects of these proposed regulations on small businesses, including encouraging research

that would facilitate validation of pathogen lethality in many products, especially those produced by traditional methods by small and very small establishments.

*Types of Entities and Production Affected by the Final Regulations.* The preliminary RIA found that small and very small establishments made up about 91 percent of the number of establishments in the U.S. RTE MPP industry and were expected to incur up to 69 percent of the cost of complying with the requirements of the proposed rule. The FRIA finds that small and very small establishments make up about 97 percent of the number of establishments in the industry and are expected to incur nearly 80 percent of total cost impact on the industry. As was also stated in the FRIA, the final rule only involves that part of the original proposal dealing with FCS verification testing for *Lm* or indicator organism and also uses a more accurate baseline for the number of establishments affected by the final rule.

An important note to consider throughout this analysis is that much of the projected impacts originate from expected movements of establishments from one establishment group to another. As was stated in the

<sup>9</sup> Stephen Crutchfield, “The Benefits of Reducing Listeria in Ready to Eat Products.” 2001. Presented at public meeting, “Performance Standards for the Production of processed Meat and Poultry

Products,” May 9–10, 2001. FSIS–USDA Washington, D.C. Roberts, Tanya, and Robert Pinner. Economic Impact of Disease Caused by *Listeria monocytogenes*.” In Miller, AJ, Smith JL,

and Somkuti GA, (Eds.) *Foodborne Listeriosis*. Amsterdam, the Netherlands: Elsevier Science Publishing Co., 1990, pp. 137–144.