



May 28, 2002

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10235
725 17th Street, N.W.
Washington, DC. 20503

Re: Request for Comment on Draft Report to Congress on the Costs and Benefits of Federal Regulation, 67 Fed. Reg. 15,013 (Mar. 28,2001).

Dear Mr. Morrall:

The draft report to Congress on the costs and benefits of federal regulation, among other things, discusses the use of “prompt letters” by OMB’s Office of Information and Regulatory Affairs. The Center for Science in the Public Interest (CSPI) supports the use of prompt letters as a valuable mechanism by which OIRA can help agencies identify their priorities for regulatory action.

CSPI urges OIRA to issue a prompt letter to the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) identifying as a FSIS priority final action on food safety performance standards for all ready-to-eat (RTE) and all partially heat treated meat and poultry products, published at 66 Fed. Reg. 12,590 (Feb. 27,2001). The proposed rule, published 15 months ago, would require establishments that produce RTE meat and poultry products to test food contact surfaces for *Listeria spp.* to verify that they are controlling the presence of *Listeria monocytogenes* – one of the most dangerous foodborne pathogens – within their processing environments.

In late 1998 and early 1999, a multi-state outbreak of listeriosis – the illness caused by *L. monocytogenes* – attributed to RTE meat products at Sara Lee Corporation’s Bil Mar plant caused 21 known deaths, including six miscarriages, and 100 illnesses. Between May and December 2000, 29 illnesses caused by a strain of *L. monocytogenes* were linked to consumption of deli turkey meat produced at Cargill Turkey Products, Inc. in Waco, Texas. The 29 cases were associated with four deaths and three miscarriages and stillbirths. In addition to these outbreaks,

there have been numerous recalls of RTE meat and poultry products contaminated with *L. monocytogenes* within the past two years.

According to the Centers for Disease Control and Prevention, listeriosis has the highest rate of hospitalization among foodborne pathogens and the second highest case-fatality rate. CDC estimates that 20 percent of listeriosis cases result in death. Those at greatest risk of contracting listeriosis are infants, pregnant women and their fetuses, the elderly, and people with compromised immune systems.

The federal government has long been aware of the danger posed by *L. monocytogenes* in ready-to-eat products, particularly since they are consumed without further treatment, such as cooking. Since 1989, FSIS has subjected such products to the most restrictive standard – zero tolerance. In other words, any amount of *L. monocytogenes* in a RTE meat or poultry product renders it adulterated and subject to a voluntary recall. FSIS currently relies on a small scale random sampling program in which government inspectors annually test approximately 3500 samples of domestic and imported ready-to-eat meat and poultry products for the presence of this dangerous pathogen. There is no requirement that the producers of RTE products expand the effort to detect contamination by testing their own finished products for the presence of the pathogen. For these reasons, we believe that FSIS should act expeditiously to take final action on the proposed rule.

There are numerous monetary benefits that would result from promulgation of this rule as well. In its Preliminary Regulatory Impact Analysis, FSIS did not monetize the benefits associated with reducing listeriosis cases and deaths. However, USDA's Economic Research Service (ERS) has estimated that the average annual death reduction would be 5 to 50 cases (over a 10-year period) and would result in a range of benefits of \$55.1 million to \$755.5 million (\$36.5 million to \$500.1 million in present dollars). Even then, these estimates understate the value of death and illness reduction. Neither FSIS nor ERS placed any value on reducing maternal listeriosis illnesses or saving the lives of fetuses as a part of the benefits calculation for the proposed rule, even though it is well established that pregnant women and their fetuses are among those who are most susceptible to severe listeriosis infections. ERS's benefits estimates also do not include the significant costs avoided by industry, including the avoided costs of recalls and litigation, reduced consumer demand resulting from publicity from an outbreak or recall, investigating the source of contamination, cleaning up or even closing a plant, changes in production to reduce future contamination, product spoilage, and disrupted schedules because of employee illness due to handling of contaminated products.

A prompt letter from OIRA would assist FSIS in identifying the RTE rule as an agency priority and address serious shortcomings in the existing regulatory program before another outbreak of listeriosis causes more illnesses and claims more lives.

Sincerely,

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