CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

2711

September 10, 2001

United States Department of Agriculture
FSIS Docket Room
Room 102, Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

97-013P-2711
97-013P
Karen L. Egbert
Charlotte A.
Christin

Re: Comment on Proposed Rule Establishing Performance Standards for the Production Of Processed Meat and Poultry Products, Docket # 97-013P, 66 Fed. Reg. 12,590 (Feb. 27, 2001)

Introduction

On behalf of the Center for Science in the Public Interest (CSPI) and the following members of the Safe Food Coalition -- American Public Health Association, Consumer Federation of America, National Consumers League, and Safe Tables Our Priority – we appreciate this opportunity to comment on the Food Safety and Inspection Service's (FSIS) proposed rule, "Performance Standards for the Production of Processed Meat and Poultry Products."[1] CSPI is a non-profit advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*. The Safe Food Coalition is an informal group of consumer, public health, whistle blower, senior citizen and labor organizations. It works to educate the public about the hazards of foodborne illness and seeks congressional and administrative action to improve meat, poultry, and seafood inspection.

[1] 66 Fed. Reg. 12,590 (Feb. 27, 2001).

In this comment, CSPI and the Safe Food Coalition address the proposed lethality and stability performance standards setting forth levels of reduction and limits on growth of *Salmonella, Esherichia coli* O157:H7, *Clostridium botulinum,* and *Clostridium perfringens* that official meat and poultry establishments must achieve in order to produce unadulterated ready-to-eat (RTE) meat and poultry products. In addition, CSPI and the Coalition provide more extensive comments with respect to FSIS's proposed adoption of testing requirements for the presence of *Listeria spp.* on product-contact surfaces and, where *Listeria spp.* is found, testing of final product for *Listeria monocytogenes* (*L. monocytogenes*).

L. monocytogenes remains one of the most serious foodborne pathogens. Listeriosis is associated with higher hospitalization rates than any other pathogen and had the highest case-fatality rate in 1999 of the FoodNet pathogens.[2] Fifteen percent of persons infected with *L. monocytogenes* died.[3] The Centers for Disease Control and Prevention (CDC) estimate that there are 2,493 cases, causing 2,298 hospitalizations and 499 deaths from food-borne listeriosis in the United States each year.[4] The estimated annual cost of illness caused by this pathogen is $2.3 billion.[5]

CSPI and the Safe Food Coalition are pleased that FSIS is stepping up its effort to combat contamination of ready-to-eat meat and poultry products by *L. monocytogenes.* Requiring

---

[2] Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 1999 (Final Report)*, Nov. 2000, at 5, 12 [hereinafter *FoodNet Surveillance Report for 1999*].

[3] *FoodNet Surveillance Report for 1999* at 12.

[4] Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 Emerging Infectious Diseases 600, 611 (Sept.-Oct. 1999) [hereinafter *Food-Related Illness and Death*].

[5] Stephen R. Crutchfield & Tanya Roberts, *Food Safety Efforts Accelerate in the 1990's*, 23 Food Review 49 (Sept.-Dec. 2000).

facilities to test their product-contact surfaces for the presence of *Listeria spp.* is an important first step in verifying the effectiveness of their overall plant sanitation. Although we support microbial testing of product-contact surfaces, we believe that FSIS should adopt an even broader testing regime such as that proposed by CSPI in its January 2000 citizen petition filed with FSIS.[6]

Specifically, FSIS also should require mandatory industry testing of both the plant environment and final products. Testing of the plant environment is an additional precaution to assure that establishments' sanitation practices are successfully preventing *L. monocytogenes* contamination. Testing of the final product is a necessary complement to environmental and product-contact surface testing since neither type of testing, standing alone, can detect problems in both plant sanitation and hazard-control systems. Final product testing is especially crucial given the high potential that RTE meat and poultry products may be re-contaminated after application of lethality treatment.

Indeed, in 2000, over 17 million pounds of frankfurters, sausage, sliced luncheon meats, chicken salad, beef jerky, beef bologna, and salami and other ready-to-eat products were recalled because of *L. monocytogenes* contamination.[7] So far in 2001, possible *L. monocytogenes* contamination has caused the recall of over 14 million pounds of ready-to-eat meat and poultry products.[8]

---

[6] Center for Science in the Public Interest, *Petition for Regulatory Action to Require Microbial Testing By Industry for Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products* (Jan. 13, 2000) [hereinafter "CSPI *Listeria* Petition"]. The USDA has not, to date, taken any action to either grant or deny CSPI's petition. We urge FSIS to act expeditiously to respond to the citizen petition.

[7] FSIS Recall Information Center, Recall Database, *2000 Recall Cases,* available at *http://www.fsis.usda.gov/OA/recalls/ recdb/rec2000.htm* [hereinafter *2000 Recall Cases*].

[8] FSIS, *Recall Notification Reports, Active Recall Cases*, available at *http://www.fsis.usda.gov/oa/recalls/rec_actv.htm.*The recalls affected a range of ready-to-eat products, including hot dogs, luncheon meats, sausages, bratwurst, turkey barbeque, dried duck breast, and salami.

Only by requiring a range of testing – environmental, product-contact surfaces and final product – can industry and government assure that RTE meat and poultry products minimize the threat of contamination by *L. monocytogenes*. Such testing facilitates early detection of problems before products become contaminated, thus avoiding the significant health costs incurred from foodborne illness, not to mention the industry expenses of product recalls. It also would assist the government in meeting its goal, stated in the Healthy People 2010 Objectives, of achieving an additional 50% reduction in listeriosis by 2010.[9] Indeed, unless FSIS adopts a regime of mandatory industry testing, with government testing as an additional verification measure, the public health cannot truly be protected.

In addition, FSIS should require RTE products to contain uniform expiration dating which makes it clear that for safety reasons, food should be used or frozen by a particular date and that the product should not be consumed "X" number of days after the package is opened. As an interim matter pending finalization of microbial-testing requirements, FSIS also should require that RTE product packages contain a safe handling statement. This statement should indicate that the product may be contaminated and therefore pose a potential health threat to infants, pregnant women, the elderly and those with weakened immune systems.

I. CSPI'S CITIZEN PETITION

On January 13, 2000, CSPI and the Safe Food Coalition petitioned FSIS to adopt a rule requiring establishments producing RTE meat and poultry products to conduct microbial testing after application of lethality treatment. More specifically, CSPI called for testing of both product-contact and non-product contact surfaces for the presence of *Listeria spp.* or other

---

[9] FDA & FSIS, *Healthy People 2010*, Chapter 10, Food Safety, at p. 8 [hereinafter *Healthy People 2010*].

indicator organisms and testing of final products for *L. monocytogenes*. CSPI explained that a positive finding of *Listeria spp.* should warrant immediate implementation of progressive corrective actions, including more focused testing of the plant environment and testing of potentially contaminated product. In addition, CSPI's citizen petition urged FSIS to require RTE meat and poultry products that have not been produced by a plant that incorporates microbial testing into its Hazard Analysis and Critical Control Point (HACCP) verification program to bear a label alerting consumers that the products may be contaminated and should not be eaten by at-risk consumers without reheating.

The petition emphasized that the current regulatory environment – which does not require establishments producing RTE meat and poultry to conduct any mandatory microbial testing either to verify the sanitation of their processing facilities or to detect direct contamination of their product – does not go far enough to address the serious public health consequences of listeriosis. The lack of mandatory industry microbial testing of RTE meat and poultry is of special concern because *L. monocytogenes* can grow under refrigeration. In addition, the infectious dose for healthy and at-risk consumers is not known. CSPI also urged FSIS to continue its program of random government sampling of final products for the presence of *L. monocytogenes* to provide an additional layer of protection and ensure that industry sanitation programs are working effectively to prevent post-lethality contamination.

In its petition, CSPI underscored the benefits that would result from mandatory microbial testing by RTE meat and poultry producers. Among other things, it would: 1) increase the likelihood that contamination problems at processing facilities can be uncovered and addressed before they cause consumer illnesses and death by significantly expanding the pool of products

subjected to microbial testing at the plant level; 2) help plants verify the efficacy of their process controls and identify when corrective actions are necessary; and 3) aid enforcement of the zero tolerance standard.[10]

While the FSIS's January 2001 rulemaking proposal does not fully adopt all elements of CSPI's approach for addressing the problem of contamination by *L. monocytogenes* in RTE meat and poultry products, the proposed rule's requirement for mandatory industry testing of product-contact surfaces for the presence of *Listeria spp.* does, nonetheless, make some progress toward assuring that plant sanitation problems will be detected before large volumes of tainted products are distributed to supermarkets and other retail establishments. However, as long as USDA cannot define a safe level of *L. monocytogenes* in RTE meats and poultry, a comprehensive testing regime that includes microbial sampling of plant environment, product-contact surfaces, and final product remains the most valuable tool to verify the efficacy of establishments' sanitation Standard Operating Procedures (SOPs) and HACCP plans. This regime is also needed to check that there is no direct product re-contamination after lethality treatment.

II. PERFORMANCE STANDARDS ARE NECESSARY TO MAINTAIN FOOD SAFETY

CSPI and fellow members of the Safe Food Coalition support science-based performance standards to ensure pathogen reduction. As FSIS experience since 1996 amply demonstrates, performance standards are a vital and necessary component of the broader HACCP/Pathogen Reduction system. Indeed, FSIS recognized in this rulemaking proposal that "[p]erformance standards can be usefully and seamlessly incorporated into HACCP systems . . . . HACCP

---

[10] CSPI *Listeria* Petition at 3, 12-14.

provides the framework for industry to set up science-based process controls."[11]

Performance standards serve another important function -- they level the playing field for industry by providing clear, consistent guidelines within which to operate. These standards give all processors the same targets and provide government inspectors with consistent inspection criteria. Thus, they help ensure that "bad actors" meet minimum food safety standards and do not put the public's health in jeopardy. Performance standards also encourage the development and use of pathogen-reduction technology since processing establishments must strive to reduce contamination levels in order to meet or exceed the standard. For these reasons, performance standards are an important step in meeting the government's food safety goals as announced in its *Healthy People 2010 Objectives.* By the year 2010, the government seeks to reduce outbreaks of infections caused by *E. coli* O157:H7 and *Salmonella* by 50% over 1997 baselines.[12]

We also endorse the use of microbial testing for pathogens to ensure that establishments' HACCP systems are functioning properly, in compliance with the regulations, and producing product that is safe, wholesome, and not adulterated. HACCP, performance standards, and microbial testing are not inconsistent, and in fact, are quite compatible. As the National Academy of Sciences has noted, it is appropriate to use both microbial testing for freshly processed carcasses, as well as on equipment and surfaces, and microbial guidelines (*e.g.*, performance standards) for ready-to-cook carcasses.[13]

---

[11] 66 Fed. Reg. at 12,592.

[12] *Healthy People 2010* , at 8.

[13] National Academy of Sciences, *An Evaluation of the Role of Microbial Criteria for Foods and Food Ingredients*, at 228 (1985)(discussing poultry in particular), available at *http://books.nap.edu/books/0309034973/html/228.html.*

A. Pathogens In RTE Meat And Poultry Have Significant Public Health Impacts.

Ready-to-eat meat and poultry products have been associated with human illness caused by a range of pathogens, including *E. coli* O157:H7, *Salmonella spp.*, *Clostridium botulinum*, and *Clostridium spp.*, in addition to *L. monocytogenes.*

1. *E. coli* O157:H7 and other Shiga-toxin producing *E. coli*

Estimates from the CDC suggest that *E. coli* O157:H7 and other Shiga-toxin producing *E. coli* cause approximately 110,220 cases of illness, 3,252 hospitalizations, and 915 deaths in the United States each year, with 85% of the infections caused by eating contaminated foods.[14] Infections are commonly associated with raw or undercooked ground beef and certain types of produce. However, since 1990, six documented *E. coli* O157:H7 outbreaks, comprising over 80 cases, have occurred from beef products other than ground or roast beef, including ready-to-eat salami.[15]

E. coli O157:H7 is of particular public health concern because experts believe it has a low infectious dose. The medical and societal costs of *E. coli* O157:H7 and other Shiga-toxin producing *E. coli* infections are substantial, given fatalities among young children and the high cost of chronic conditions such as kidney failure in survivors. USDA's Economic Research Service estimates that, each year in the United States, foodborne *E. coli* O157:H7 disease costs $659.1 million to society and foodborne *E. coli* non-O157:H7 costs $329.7 million, for a

---

[14] *Food-Related Illness and Death*, at 610.

[15] Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net*, pp. 40-43, 47 (rev'd 2000) [hereinafter cited as *Outbreak Alert!*]. *See also Escherichia coli O157:H7 Outbreak Linked to Commercially Distributed Dry-Cured Salami - Washington and California, 1994*, 44 Morbidity and Mortality Weekly Report 157 (Mar. 10, 1995), available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/00036467.htm.*

combined total societal cost of $988.8 million.[16]

Few, if any, recalls of fermented beef products for possible *E. coli* O157:H7 contamination have been issued because FSIS inspectors currently do not sample fermented or other non-intact beef products for this pathogen.[17]

2. Nontyphoidal *Salmonella*

The CDC estimates that nontyphoidal *Salmonella* infections cause 1.4 million cases of illness, 16,430 hospitalizations, and 582 deaths in the United States each year, with 95% of infections caused by eating contaminated foods.[18] CSPI's list of foodborne illnesses, *Outbreak Alert!*, documents *Salmonella* outbreaks from a range of RTE products, including beef jerky, ham, and bologna.[19] In the United Kingdom, pork sausages have been associated with *Salmonella* Typhimurium DT104 infection, a strain of *Salmonella* resistant to multiple antibiotics.[20] While USDA currently tests raw products for *Salmonella*, no testing of ready-to-eat products is required.

---

[16] Economic Research Service Briefing Room, *E. coli* (May 2001), available at *http://www.ers.usda.gov/briefing/FoodborneDisease/ecoli/index.htm.*

[17] By contrast, in calendar year 2000, FSIS analyzed approximately 6,300 samples of raw ground beef products for its *E. coli* O157:H7 program. *See* FSIS, *Microbiological Results of Raw Ground Beef Products Analyzed for Eschericha coli O157:H7, in* Electronic Reading Room: Microbiological Testing Program, available at *http://www.fsis.usda.gov/OPHS/ecoltest/tables1.htm.*

[18] *Food-Related Illness and Death,* at 611.

[19] *Outbreak Alert!,* at 40-47.

[20] P.G. Wall, et al., *A Case-Control Study of Infection with a Multiresistant Strain of Salmonella Typhimurium DT104 in England and Wales*, 4 Communicable Disease Report R130 (1994), available at http://www.phls.col.uk/publications/CDRreview/1994/cdrr1194.pdf.

3. Botulism

Botulism, a paralytic condition resulting from ingestion of a potent neurotoxin produced in foods by *Clostridium botulinum* bacteria, is estimated by CDC to cause 58 cases of illness, 46 hospitalizations and 4 deaths in the United States each year, with 100% of infections caused by eating contaminated foods.[21] The Food and Drug Administration reports that "sausages, meat products, canned vegetables and seafood products have been the most frequent vehicles for human botulism."[22] Commercial meat pot pies have been implicated in a number of separate outbreaks.[23] As a life-threatening illness, botulism poisoning always triggers a Class I recall of implicated food vehicles. Just last week, on September 3, 2001, a Texas firm recalled 15,000 pounds of frozen chili for possible contamination with botulinum toxins.[24]

4. *Clostridium perfringens*

C. perfringens is a bacterium that grows in anaerobic conditions in improperly cooked or stored foods. Ingestion of contaminated foods can result in severe cramps and diarrhea when the organisms form a toxin in the intestines. Infections from *C. perfringens* are estimated by CDC to cause 248,520 cases of illness, 41 hospitalizations and 7 deaths in the United States each year,

---

[21] *Food-Related Illness and Death*, at 611.

[22] Food and Drug Administration, *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook* (1992).

[23] *Botulism and Commercial Pot Pie – California*, 32 MMWR 39 (Jan. 1983), available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/00001230.htm.*

[24] FSIS, Recall Release FSIS-RC-01-048, *Texas Firm Recalls Chili for Possible Contamination with Botulinum Toxins* (Sept. 3, 2001), available at *http://www.fsis.usda.gov/OA/recalls/prelease/pro48-2001.htm.*

with 100% of infections caused by eating contaminated foods.[25] Outbreaks have been associated with a number of pre-cooked, ready-to-eat meats including ham, roast beef, and corned beef.[26]

B. FSIS Should Set Pathogen-Specific Performance Standards For Lethality.

Under the proposed rule, all RTE meat and poultry products, except for thermally-processed, commercially sterile products, would be required to achieve a lethality performance standard that reflects the destruction of a "reference" organism. FSIS chose *Salmonella* as a reference organism for most RTE meat and poultry products because it is prevalent in raw poultry, beef, and pork, causes a high incidence of foodborne illness, and these illnesses are severe.[27]

However, recognizing that the destruction of reference organisms may not eliminate or bring about the reduction of other pathogens of concern, FSIS also proposed to clarify in its regulations that establishments additionally must reduce other pathogens and their toxins to the levels necessary to prevent product adulteration. FSIS added that if it "were to find certain viable pathogens in a RTE product at levels considered dangerous, even in product otherwise free of the reference pathogen, it would consider that product to be adulterated."[28]

Rather than using *Salmonella* as a reference organism and "clarifying" its regulations to make it plain that RTE products containing pathogens would be considered adulterated, the

---

[25] *Food-Related Illness and Death*, at 611.

[26] FDA, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (1992). See also *Clostridium perfringens Gastroenteritis Associated with Corned Beef Served at St. Patrick's Day Meals – Ohio and Virginia, 1993*, 43 MMWR 137-38, 143-44 (Mar. 1994), available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/00025191.htm.*

[27] 66 Fed. Reg. at 12,593.

[28] 66 Fed. Reg. at 12,593.

agency should establish pathogen-specific lethality standards. While using *Salmonella* as a reference organism is a practical way to test on a broader scale, FSIS should require companies to check for actual contamination by a specific pathogen in or on their products. Certain pathogens are more resistant to lethality treatments than their "reference" organisms. Thus, establishing a performance standard for an organism that is easier to destroy may not fully eliminate the risk posed by the pathogens of concern, which means that the product may not be completely safe for human consumption. Therefore, to ensure that RTE products are truly ready-to-eat, FSIS should set pathogen-specific lethality performance standards for RTE meat and poultry products. Setting performance standards for pathogens of concern also would assist in building databases on the prevalence of specific pathogens and stimulate development of pathogen-specific testing technologies.[29]

Therefore, we request that FSIS develop specific lethality performance standards for *Campylobacter* in all RTE poulty products and *E. coli* O157:H7 in all RTE beef products, in addition to the general *Salmonella* standard that already exists for raw beef, pork, and poultry products.

Campylobacter is the most prevalent foodborne pathogen in poultry, responsible for more bacterial foodborne illnesses than any other pathogen.[30] Typical symptoms of campylobacterosis include diarrhea, cramps, vomiting, fever and headache. Foodborne campylobacteriosis is estimated to cause almost two million illnesses, 10,500 hospitalizations, and 100 deaths per

---

[29] CSPI, *Comments on Proposed Rule on Pathogen Reduction; HACCP Systems*, Docket No. 93-016P (July 15, 1995), at p. 24.

[30] 65 Fed. Reg. 75,187, 75,190 (Dec. 1, 2000).

year.[31] A performance standard requiring a minimum 5-log reduction therefore should be established for *Campylobacter* on RTE poultry products to ensure that these products are safe.

FSIS has proposed to establish an *E. coli* O157:H7 lethality performance standard for all fermented RTE products that include any amount of beef, except thermally-processed commercially sterile products. Because the infectious dose of *E. coli* O157:H7 is thought to be low,[32] it must be eliminated from **all** RTE beef products, not just those that are fermented. Therefore, FSIS should require a minimum of a 5-log reduction of *E. coli* in all RTE products containing beef that do not require further cooking at the retail or consumer level.

FSIS should establish clear performance standards by regulation, yet allow industry the flexibility to develop lethality processes that may go beyond the government standards. We are concerned, however, that codifying acceptable probabilities of remaining reference organisms in finished product may allow industry establishments to become lax in their processes, resulting in higher than acceptable levels of both the reference organisms and pathogenic organisms. Allowing an establishment to develop alternative lethality treatments and performance standards with different underlying assumptions (*i.e.*, worst case scenarios) could reduce current safety standards and open the door to a Pandora's Box of potential troubles -- from lawsuits and other legal challenges based on varying statistical models to challenges to performance standards themselves.

---

[31] *Food-Related Illness and Death*, at 611.

[32] 60 Fed. Reg. 6773, 6826 (Feb. 3, 1995).

C. The Stabilization Standard Is Necessary to Protect The Public Health.

We support FSIS's proposal to require a no (zero) multiplication performance standard for the spore-forming microorganisms *Clostridium botulinum* (*C. botulinum*) and *Clostridium perfringens (C. perfringens)* for RTE products and partially-cooked poultry and meat patties. Because the primary purpose for the zero-growth standard is to ensure that harmful toxins are not created in cooked product during cooling, "ensuring no growth of *C. botulinum* provides for the safety of the product with the greatest amount of confidence."[33]

C. botulinum and *C. perfringens* are very hardy and can survive the lethality processes. Indeed, partial cooking and cooling may even create a favorable environment for growth of spore-forming toxigenic bacteria. In fact, FSIS has recognized that "[c]ooking by consumer, retailer, or other end-user may not eliminate these bacteria or the toxins that they create in these products. Therefore, it is important that bacterial growth be controlled in these products to the extent possible before they reach the end consumer."[34]

We recognize that the current predictive models for outgrowth are insufficient and do not afford a high level of confidence to demonstrate zero growth, and that current testing requirements to meet such a standard may be expensive. However, until more accurate, less restrictive, and cheaper validation methods can be developed, we strongly urge FSIS to retain the zero-growth standard (no more than 1-log10 growth) for *C. botulinum* and *C. perfringens*. The cost of foodborne illnesses to the public health, including illness, hospitalizations, miscarriages, and death, far outweigh the costs to industry for adequate testing.

---

[33] 66 Fed. Reg. at 12,601.

[34] 66 Fed. Reg. at 12,601.

III. Mandatory Industry *Listeria* Testing Is Necessary To Assure Adequate Plant Sanitation And That RTE Products Are Not Re-Contaminated

A. The Zero Tolerance Policy Remains An Effective Tool For Decreasing The Risk Of Illness From *L. monocytogenes.*

L. monocytogenes is a particularly insidious organism, one that is hard to eliminate at the plant level and easily reintroduced through the environment.[35] It survives cold temperatures and grows out to dangerous levels in RTE products before they may reach their expiration dates at the retail level. Most importantly, however, foodborne illness caused by *L. monocytogenes* has a very high case-fatality rate across the whole population – 20 deaths per 100 cases of illness[36] – and is particularly dangerous to vulnerable populations such as the elderly, newborns and small children, and pregnant women and their fetuses.

Adoption of mandatory industry testing will help strengthen the zero tolerance policy for *L. monocytogenes.* Science has not, to date, identified a "safe" level of *L. monocytogenes* in ready-to-eat foods. And the potential for consumer exposure to *L. monocytogenes* has likely increased as demand for ready-to-eat foods has increased.[37] In addition, *L. monocytogenes* is widespread in the general environment, which increases the likelihood that foods will be re-contaminated after lethality treatment. Indeed, the recent draft risk assessment for *L. monocytogenes* noted that "[o]ver 15 years of scientific investigation have indicated that the

---

[35] *See* R. Bruce Tompkin, et al., *Guidelines to Prevent Post-Processing Contamination from Listeria monocytogenes,* 19 Dairy, Food and Environmental Sanitation 551, 552 (Aug. 1999) [hereinafter *Guidelines to Prevent Post-Processing Contamination from Listeria monocytogenes*].

[37] FDA/Center for Food Safety and Applied Nutrition, USDA/Food Safety and Inspection Service & Centers for Disease Control and Prevention, *Draft Assessment of the Relative Risk to Public Health from Foodborne* Listeria monocytogenes *Among Selected Categories of Ready-to-Eat Foods* [hereinafter *Draft Risk Assessment*], Interpretative Summary (May 23, 2001), p. 2, available at *http://www.foodsafety.gov/~dms/lmrisksu.html.*

primary determining factor affecting the presence of *L. monocytogenes* . . . is the likelihood that [products] will be recontaminated."[38]

Despite industry advances in implementing control strategies to minimize the presence of *L. monocyogenes* in foods, product contamination remains a problem. Currently, FSIS tests approximately 3,500 ready-to-eat meat samples for *L. monocytogenes* each year, including beef jerky, cooked beef, sliced ham and luncheon meat, sausages, cooked poultry, meat or poultry salads, and spreads.[39] In 1998, approximately 2.5% of the samples tested positive for *L. monocytogenes*.[40] Some products have even higher contamination rates. Nearly 6 percent of the sliced ham and luncheon meats sampled by FSIS from 1989 to 1999 were positive for *L. monocytogenes*.[41]

These high contamination rates also lead to a high rate of recall for RTE meat and poultry products. For example, over 17 million pounds of ready-to-eat frankfurters, sausage, sliced luncheon meats, chicken salad, beef jerky, beef bologna, and salami and other RTE products were recalled in 2000 because of *L. monocytogenes* contamination.[42] So far in 2001, *L. monocytogenes* contamination has caused the recall of over 14 million pounds of ready-to-eat

---

[38] *Draft Risk Assessment*, Executive Summary, at xiii.

[39] U.S. Department of Agriculture, Backgrounders, *FSIS Action Plan for Addressing Listeria monocytogenes* (May 1999) (Resources/Contact information revised May 2000), p. 2 [hereinafter *FSIS Action Plan*], available at *http://www.fsis.usda.gov/OA/background/Implan.htm.*

[40] *FSIS Action Plan,* at 2.

[41] USDA, Food Safety and Inspection Service, *Listeria Guidelines for Industry* (May 1999), p. 4, available at *http://www.fsis.usda.gov/oa/topics/lmguide.htm.*

[42] FSIS, *2000 Recall Cases.*

meat and poultry products.[43] Thus, the zero tolerance policy remains an important last line of defense if process controls and sanitation fail to eliminate this hazard from consumers' food.

Although FSIS's *L. monocytogenes* sampling program has resulted in numerous voluntary recalls, the 1998 Sara Lee Bil-mar outbreak, which resulted in 21 deaths and approximately 100 illnesses in 22 states,[44] demonstrated that a zero-tolerance policy, enforced by only minimal government sampling, cannot identify all hazardous products. Indeed, FSIS has admitted that "its current testing programs serve a useful purpose but are not adequate by themselves to protect consumers. Microbial testing by companies to verify process control and demonstrate progress toward pathogen reduction is an integral part of FSIS's food safety strategy."[45]

To ensure that an establishment producing ready-to-eat products is pathogen-free, all equipment in the plant that could harbor *L. monocytogenes* should be subject to thorough cleaning checked by regular microbial sampling. While the proposed requirement – testing of food-contact surfaces for *Listeria spp.*, with product testing for *L. monocytogenes* where a positive is found -- is an important step in improving food safety, a broader testing regime is needed. In fact, sampling the plant environment and the final product is the most effective -- indeed the only -- way to verify that establishments are producing products under sanitary conditions and that they are meeting FSIS's pathogen reduction goals.

Therefore, the FSIS should strengthen its oversight of RTE meat and poultry products by requiring mandatory industry testing of both plant environments and product-contact surfaces for

---

[43] FSIS, *Active Recall Cases.* The recalls affected a range of ready-to-eat products, including hot dogs, luncheon meats, sausages, bratwurst, turkey barbeque, dried duck breast, and salami.

[44] CDC, *Update: Multistate Outbreak of Listeriois*, Press Release (Mar. 17, 1999).

[45] 60 Fed. Reg. at 6798.

Listeria spp., as well as final product testing for *L. monocytogenes.* It is imperative that microbial testing be employed at the processor level since the public will consume RTE products without additional "kill steps" such as cooking. Requiring microbial testing will help keep industry attention focused on improving their Sanitation Standard Operating Procedures, good manufacturing practices, and process-verification systems that prevent the re-contamination of RTE foods, particularly those that support the growth of *L. monocytogenes* at refrigerator temperatures. As CSPI has previously explained, "without mandatory microbial testing in processing plants, HACCP is not an adequate hazard-prevention system for ready-to-eat meat and poultry products."[44] At the same time, FSIS should maintain its own random testing program to assure effective oversight.

B. There Is Adequate Legal Authority for Requiring Mandatory Industry Microbial Testing of RTE Meat And Poultry.

In enacting both the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), Congress gave USDA broad power to prevent the introduction of adulterated meat and poultry into commerce.[45] The FMIA is premised on a congressional finding, among other things, that "[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are

---

[44] CSPI *Listeria* Petition, at 17.

[45] 21 U.S.C. § 601 *et seq.*; 21 U.S.C. § 451 *et seq.* Section 453(f)(4) of the PPIA applies to all "poultry" products, which are defined to include "any product which is made wholly or in part from any poultry carcass or part thereof." 21 U.S.C. § 453(f). Similarly, FMIA section 601(m)(4) applies to all "meat food products," which are defined in section 601(j) as "any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats." 21 U.S.C. § 601(m)(4). Thus, both PPIA section 453(g)(4) and FMIA section 601(m)(4) apply to ready-to-eat products.

wholesome, not adulterated, and properly marked, labeled, and packaged."[46] The courts have agreed that the purpose of these statutes is to insure a high level of cleanliness and safety of meat products.[47]

Consistent with this purpose, neither meat and meat products nor poultry and poultry products that are "rendered adulterated" can be labeled, marked, stamped, or tagged as "inspected and passed."[48] Both the FMIA and PPIA define as "adulterated" any product that has been "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it **may have been** rendered injurious to health."[49] Thus, actual contamination of the finished product need not be shown for the agency to find legal "adulteration."[50]

---

[46] 21 U.S.C. § 602. *See also* PPIA section 451 (parallel finding with respect to poultry products). According to the District of Columbia Circuit, the FMIA and the PPIA should be construed as far as possible to have the same meaning. *Original Honey Baked Ham v. Glickman*, 172 F.3d 885, 887 (D.C. Cir. 1991).

[47] *See, e.g.*, *Original Honey Baked Ham v. Glickman*, 172 F.3d at 887 (stating that the FMIA and PPIA share common purpose of ensuring that "meat and poultry products are 'wholesome [and] not adulterated,' all to the end of protecting the 'health and welfare of consumers' and the market for wholesome and unadulterated products"); *United States v. Jorgensen*, 144 F.3d 550, 559 (8th Cir. 1998) (noting public policy underlying FMIA is that Congress has determined that the companies and people engaged in the food business have an affirmative duty to insure the food they sell to the public is safe). *See also National Pork Producers Council v. Bergland*, 631 F.2d 1353, 1361 (8th Cir. 1980) (Act authorizes USDA to ensure that products desired by consumers are made available to them "in a form and manner consistent with the public health and welfare").

[48] 21 U.S.C. § 608. *See also* 21 U.S.C. § 456(b).

[49] 21 U.S.C. §§ 601(m)(4); 453(g)(4) (emphasis added).

[50] *See United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409 (1914) (interpreting analogue of 21 U.S.C. § 601(m)(1) in Pure Food and Drug Act of 1906 and concluding that if food "may possibly" injure consumers, it is adulterated); *United States v. General Foods Corp.*, 446 F. Supp. 740, 752 (N.D.N.Y. 1978) (construing comparable "adulteration" standard under the Federal Food, Drug and Cosmetic Act) (citation omitted). *See also Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952) ("the statute is designed to prevent adulterations 'in their incipiency' by condemning insanitary conditions which *may* result in contamination") (citation omitted).

In order to reduce the potential for product adulteration, Congress has provided USDA with broad authority to establish the sanitation requirements under which meat and poultry products are produced. Section 608 of the FMIA explicitly authorizes the Secretary of Agriculture to "prescribe the rules and regulations of sanitation under which [meat slaughtering and packing] establishments shall be maintained . . . ."[51] Likewise, section 456 of the PPIA provides that each official establishment slaughtering poultry or processing poultry products otherwise subject to inspection under the Act "shall, among other things, be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce . . . of poultry products which are adulterated."[52]

This statutory language represents an express delegation by Congress to USDA of the power to determine the specific requirements that are necessary to assure that an establishment's sanitation practices and conditions do not create a health risk to the human food supply. Where Congress has delegated to an agency the principal role in implementing a statute, the agency "is entitled to some leeway in choosing . . . which regulatory tools will be most effective in advancing the Congressional objective."[53]

With the advancement of science, USDA now has new tools and techniques available to

---

[51] 21 U.S.C. § 608. *See also* 21 U.S.C. § 621(stating that the Secretary "shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter," including rules on sanitation).

[52] 21 U.S.C. § 456(a). The PPIA also provides that "[n]o establishment processing poultry or poultry products for commerce or otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter." 21 U.S.C. § 459.

[53] *Philadelphia Television Broadcasting Co. v. FCC*, 359 F.2d 282, 284 (D.C. Cir. 1966).

assist in its regulation of the sanitation conditions at the facilities under its supervision, including microbiological testing. Nothing in the language of either the FMIA or PPIA limits USDA's ability to rely upon these advancements in fulfilling its mandate to assure that food products are not adulterated. Indeed, "[r]egulatory or enforcement authority generally carries with it all the modes of inquiry and investigation traditionally employed or *useful* to execute the authority granted."[54] Accordingly, requiring RTE meat and poultry establishments to verify, through microbiological testing and otherwise, that their sanitation processes are working effectively to prevent product adulteration and, where problems exist, to correct those problems is well within USDA's delegated authority under both the FMIA and PPIA.

The requirement that facilities conduct microbiological testing of their product-contact surfaces for the presence of *Listeria spp.* also represents a reasonable exercise of this delegated rulemaking authority. It is well settled that a statute is to be read in a "manner which effectuates rather than frustrates the major purpose of the legislative draftsmen."[55] The overall goals of both the FMIA and PPIA are to assure the safety of meat and poultry products. The proposed testing requirement is wholly consistent with this purpose since it helps assure that RTE products are not being processed under sanitary conditions that could lead to product adulteration.[56]

---

[54] *Dow Chemical Co. v. United States*, 476 U.S. 227, 233 (1986) (emphasis added).

[55] *Shapiro v. United States*, 335 U.S. 1, 31 (1948). *See also Mourning v. Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973) (regulations are to be sustained so long as they are "'reasonably related to the purposes of the enabling legislation'") (citation omitted).

[56] The fact that there may be alternative approaches to address the problem of *L. monocytogenes* contamination of RTE foods does not means that the approach selected by FSIS is irrational. *See Loyola University v. FCC*, 670 F.2d 1222, 1227 (D.C. Cir. 1982).

In the proposed rule, FSIS noted that the presence of *Listeria spp.* on food-contact surfaces may be indicative that sanitation measures are not working effectively, especially if positive findings recur.[57] The FSIS further explained that "*Listeria spp.* positives on food contact surfaces indicate a potential for product adulteration by *L. monocytogenes.*"[58] Requiring industry to test their product-contact surfaces for the presence of *Listeria spp.* therefore serves as an important tool to verify the adequacy of an establishment's sanitation procedures without waiting for an outbreak of illness.

The district court's ruling in *Supreme Beef Processors, Inc. v. United States Dep't of Agriculture* does not undermine FSIS's authority to require mandatory industry testing of food-contact surfaces.[59] In *Supreme Beef*, the plaintiff challenged USDA's action withdrawing inspectors based on government tests finding that the final products were contaminated with *Salmonella* in violation of the applicable performance standard. The district court found that USDA has the authority under the FMIA to withdraw inspectors from meat processing plants if the meat processed at the plant is adulterated, and that meat can be adulterated if the conditions of a plant are insanitary. However, the court concluded that government testing of a processor's finished product to draw any conclusions about the sanitary conditions in its plant was unreliable and therefore could not serve as the basis for finding a plant's meat adulterated under FMIA section 601(m)(4).[60]

---

[57] 66 Fed. Reg. at 12,604.

[58] 66 Fed. Reg. at 12,604.

[59] 113 F. Supp.2d 1048 (N.D. Tex. 2000), *appeal pending*, No. 00-11008 (5th Cir.).

[60] 113 F. Supp.2d at 1052-53.

Unlike *Supreme Beef*, where the court expressed concern that the beef may have been contaminated before it entered the plant, the product-contact testing here is targeted at the equipment and other surfaces with which products come in contact *after* lethality treatment, thus minimizing the likelihood that any contamination may have come from outside the facility. Requiring establishments to conduct microbiological testing of their product-contact surfaces for *Listeria spp.* provides a direct measure of the effectiveness of an establishments' sanitation processes and procedures. A positive finding for *Listeria spp.* is evidence that the facility has sanitation and processing problems since an environment that will support the growth of *Listeria spp.* will also support the growth of *L. monocytogenes*. Thus, a positive finding for *Listeria spp.* indicates a potential for product adulteration. Microbiological testing therefore assists both plants and government alike in verifying that meat and poultry products are being processed under conditions that ensure a high level of cleanliness and safety.

Because the product-contact surface testing requirement is an important mechanism for verifying plant hygiene, it is well within the authority delegated by Congress to USDA to prescribe the rules and regulations of sanitation. As the district court judge in *Supreme Beef* explained, "[t]here is no reason to suppose that 601(m)(4) would not allow science-based tests, as long as those tests truly evaluate sanitary conditions in a processing plant."[61]

The additional requirement that establishments conduct product testing for *L. monocytogenes* where a product-contact surface has tested positive for *Listeria spp.* is equally within USDA's statutory authority. "Where the sanitary conditions of any such establish are such that the meat or meat food products are rendered adulterated, [the Secretary] shall refuse to

---

[61] 113 F. Supp.2d at 1053.

allow said meat or meat food products to be labeled, marked, stamped, or tagged as inspected and passed."[62] Congress defined an adulterated product as one that "bears or contains any . . . deleterious substance which may render it injurious to health." Congress did not, however, define exactly how USDA is to make the determination that a product is not adulterated, thus leaving it to the agency's discretion.

A positive finding for *Listeria spp.* is evidence that the potential exists for product contamination by *L. monocytogenes*. *L. monocytogenes* is clearly a "deleterious substance" which may render a RTE product "injurious to health." Because of its human health impact, there is zero tolerance for this pathogen – the presence of any amount of *L. monocytogenes* on food automatically causes it to be considered adulterated. Thus, where product-contact surfaces within a facility test positive for *Listeria spp.*, there is no assurance that products passing those contact surfaces are not contaminated with *L. monocotygenes*. As a result, the only means of determining that products are not adulterated is to require facilities to conduct microbial testing of the products themselves.[63]

Nothing in either the FMIA or the PPIA precludes USDA from relying upon new detection methods made possible by scientific progress as a means of verifying that a product is "not adulterated." Indeed, "[a]n agency must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances.'"[64] The consumer-protection mandates of

---

[62] 21 U.S.C. § 608.

[63] Microbial testing of product does not guarantee that a product is "safe" from *L. monocytogenes*. It does, however, increase the likelihood that such contamination will be found.

[64] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983), quoting *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968).

the FMIA and PPIA can be fully implemented only by using the best available means, including those provided by modern science, to protect the public from adulterated meat and poultry.

Avoidance or minimization of contamination at every stage of the process is a critical element in public health protection – particularly in the case of meat and poultry processing where microbiological pathogens, once present, can multiply and spread to uncontaminated meat or poultry.[65] Because a positive finding for *Listeria spp.* on a food-contact surface is indicative of a potential for product adulteration, it therefore is well within FSIS's authority to require processors to test their final products for the presence of *L. monocytogenes* under those circumstances.[66]

Finally, reading both FMIA section 608 and PPIA section 456(a) as authorizing regulations requiring establishments to test their product-contact surfaces for *Listeria spp.* and, upon a positive finding, to test products for *L. monocytogenes*, is consistent with the general rule that regulatory statutes intended to protect the public health should be construed broadly to effect their regulatory purpose.[67]

C. *Listeria Spp.* is An Appropriate Indicator for *L. monocytogenes.*

CSPI supports the use of a non-pathogenic indicator such as *Listeria spp.* as an indicator of the effectiveness of an establishment's processes and process controls. A positive finding of

---

[65] *See Lartique v. R.J. Reynolds Tobacco Co.*, 317 F.2d 19, 36 (5th Cir. 1963) ("When a manufacturer or a processor places food products in the channels of commerce for human consumption he assumes a special responsibility to the public.").

[66] *See, e.g., United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 247 (2nd Cir. 1977) (finding under analogous statute that failing to prevent the growth and spread of pathogens in product is an "insanitary condition" because "the manner of processing can surely give rise to the survival, with attendant toxic effects on humans, of spores which would not have survived under stricter 'sanitary' conditions").

[67] *United States v. Sellers*, 926 F.2d 410, 416 n.2 (5th Cir. 1991).

Listeria spp. is evidence that a facility's sanitation measures are not working effectively to eliminate the conditions that might support growth of *L. monoctyogenes* and that those measures and process controls need to be reviewed and corrective actions taken. In addition, testing for *Listeria spp.* is cheaper and less time-consuming than testing for *L. monocytogenes.*[68]

Testing product-contact surfaces for the presence of *Listeria spp.* therefore helps USDA-regulated plants to detect contamination before it affects products, and establishments are far more likely to uncover and address contamination problems before they cause consumer illnesses and deaths.

D. There Are Deficiencies In The Proposed Rule Which Should Be Corrected.

1. FSIS Should Not Exclude From The Mandatory Industry Testing Requirements Plants That Have Not Incorporated. A Comprehensive Testing Regime Into Their HACCP Plans

The testing requirements set forth in the proposed rule would apply only to those establishments producing RTE products that have not identified *L. monocotygenes* as a hazard reasonably likely to occur and, accordingly, have not incorporated into their HACCP systems one or more controls validated to eliminate it from their products.[69] Thus, certain facilities would be excluded from the mandatory product-contact surface testing requirements so long as they have incorporated minimal procedures for addressing *L. monocytogenes* in their HACCP plans. These procedures do not, however, necessarily include microbiological testing either of their product-contact surfaces, their plant environments, or their final products.

---

[68] However, FSIS has recently announced that it is planning to evaluate the HBAX method to screen RTE products for *L. monocytogenes*, a test that could reduce the reporting time for negative results by one day. *See* FSIS, *Backgrounders/Key Facts: HBAX* (Aug. 2001), available at *http://www.fsis.usda.gov/oa/background/hbax.htm.*

[69] 66 Fed. Reg. at 12,603.

Although HACCP receives broad support as a science-based framework to promote food safety, last year the USDA Office of Inspector General (OIG) criticized some aspects of FSIS's HACCP program implementation.[70] The OIG concluded that FSIS has "reduced its oversight beyond what was prudent and necessary for the protection of the consumer," in part because the agency allowed plants to operate without complete HACCP plans.[71] The OIG also concluded that FSIS needs to "[d]evelop and implement procedures that provide FSIS employees at the appropriate level with the authority to require HACCP plans to include pathogen testing of product environment, contact surfaces, and final products, particularly if a plant has a history of positive test results for microbes such as *Listeria*."[72] FSIS agreed that "HACCP is an effective preventative system and a properly designed system includes microbiological validation and verification by the establishment."[73] Yet, the proposed rule does not specifically require plants with *L. monocytogenes* Critical Control Points (CCPs) to perform microbiological verification testing -- indeed, it excludes them from those requirements.

We strongly urge FSIS not to abandon the use of mandatory industry microbial testing as a necessary part of its HACCP program. Such testing helps plants operating under HACCP systems to verify the efficacy of their process controls. The testing results also help FSIS inspectors ensure that plants are meeting their obligation to prevent and reduce microbial product

---

[70] U.S. Dept. Of Agriculture, Office of Inspector General, Food Safety Initiative: Meat and Poultry Proudcts, *Food Safety and Inspection Service: Implementation of the Hazard Analysis and Critical Control Point System*, Report No. 24001-3-At (June 2000) [hereinafter *OIG Report*], available at *http://www.usda.gov/oig/auditrpt/full*_fsis.pdf.

[71] *OIG Report* at ii.

[72] *OIG Report* at 35.

[73] *OIG Report* at 36.

contamination. Just as FSIS requires slaughter establishments to test for generic *E. coli*,[74] so too FSIS should require RTE firms with *L. monocytogenes* CCPs to test for *Listeria* and to make those results available to agency inspectors. RTE plants that do not test, or fail to keep appropriate records, should be subject to withdrawal of inspection.[75]

Without thorough and ongoing verification through testing, particularly testing of plant environment as well as final products, it is impossible to determine whether plants' interventions against the pathogen actually are working to prevent product contamination. As FSIS explained in its guidelines for industry, data from environmental testing provides information about the sources and extent of *Listeria* contamination in the plant environment and enables plants to identify faulty equipment and probable post-process cross-contaminations sites.[76] Representatives of the meat industry also have recognized the importance of environmental microbial sampling for *Listeria spp.*, recommending that meat processors should "[l]ook once, look twice, and keep looking for it."[77]

Accordingly, FSIS should not exclude from the mandatory testing requirements facilities

---

[74] 61 Fed. Reg. 38,811, 38,837-54 (July 25, 1996).

[75] FSIS should consider issuing guidance to RTE processors regarding appropriate testing protocols to incorporate in their HACCP plans. Such guidance should ensure that the plant environment, including drains, walls, ceilings, overheads, cooling units, pipes, and boxes, are sampled on a weekly basis. Because workers also can carry *Listeria*, FSIS should ensure that HACCP plans provide for routine sampling of workers' personal protective equipment, including gloves, frocks, knives, hands, and boots. An adequate testing protocol also should include testing a representative sample of product from each lot for *L. monocytogenes* to confirm that process controls have been sufficient to lower the risk of product contamination.

[76] *Listeria Guidelines for Industry* at 3.

[77] North American Meat Processors, et al., *Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs), Ready-to-Eat (RTE) Products*, p. 15 (April 1999). *See also* R. Bruce Tompkin, et al., *Guidelines to Prevent Post-Processing Contamination from Listeria monocytogenes* at 551, 552.

that have identified *L. monocytogenes* as a hazard at their plants and have implemented controls for it. Performing multi-tiered sampling increases the chance that *L. monocytogenes* will be detected before the product reaches consumers. Such sampling not only protects consumer interests but is beneficial to producers as well. Final product testing would provide an incentive for plants to implement the most effective intervention methods available, thus boosting development and use of pathogen identification and more effective processing equipment.

2. Sampling Frequencies Should Be Increased And Testing Intervals Specified.

The testing frequencies set forth in the proposed rule are based on the number of employees that an establishment employs, with large plants (500 or more employees) conducting at least four tests per line of RTE product per month, small plants (between 10 and 499 employees) performing at least two tests per line of RTE per month, and very small plants (fewer than 10 employees or annual sales of RTE products of less than $2.5 million) conducting at least one test per line of RTE product per month.[78]

The underlying purpose of the testing requirement is, according to FSIS, to provide verification that establishments' Sanitation SOPs are preventing post-lethality direct product contamination by *L. monocytogenes*.[79] Testing product-contact surfaces at frequencies of once or even four times a month does little to help facilities identify conditions that may lead to post-lethality product adulteration.[80]

---

[78] 66 Fed. Reg. at 12,620.

[79] 66 Fed. Reg. at 12,603.

[80] While CSPI's January 13, 2000 petition does not identify any specific frequency for either environmental or final product testing, it urges that, at a minimum, environmental testing should be conducted on a regular but random, statistically valid basis so that contamination problems are not inadvertently overlooked.

Moreover, there appears to be no scientific justification for using plant size as the basis for determining testing frequency. Small plants are just as likely as large plants to experience conditions and problems conducive to the growth of *Listeria* and are just as likely to experience post-lethality product contamination.[81] One recent study has found that the "RTE products with the highest prevalences of *L. monocytogenes* were those that required a significant amount of postheat treatment handling (e.g., peeling, slicing, repackaging, etc.) or addition of other ingredients."[82] At a minimum, all establishments, regardless of plant size, should be required, at the outset, to test all of their post-lethality product-contact surfaces – such as conveyors, slicers, dicers, collators used for assembling product, containers and bins used for storing food before packaging -- at least once every five operating shifts (or the equivalent). A plant running one shift five days per week should conduct a minimum of four tests per food-contact surface per month.

Beyond that, testing frequency should be based on the amount of post-lethality handling performed on the products and the likelihood for product re-contamination. Process-flow diagrams designed for HACCP plans could be used to identify areas along the product flow

---

[81] Under current FSIS testing, plants are selected on a monthly basis from the database of all known establishments, regardless of size, producing a particular class of RTE products. *See* Priscilla Levine, et al., *Pathogen Testing of Ready-to-Eat Meat and Poultry Products Collected at Federally Inspected Establishments in the United States, 1990 to 1999,*" 64 Journal of Food Protection 1188-1193, at p. 1188 (2001) [hereinafter "P. Levine, *Pathogen Testing of Ready-to-Eat Meat and Poultry Products*"].

[82] P. Levine, *Pathogen Testing of Ready-to-Eat Meat and Poultry Products*, at 1193.

where exposed food is most likely to become re-contaminated after lethality treatment.[83] Procedures for assuring the random selection of sampling sites should be specified in the rule.

Not only should FSIS increase the required testing frequencies, it also should specify an appropriate interval between sampling times. Under the proposed rule, an establishment that is required to test four times a month could meet its testing obligation by conducting all required sampling in the same day, or even the same hour. As a result, a RTE processor could be producing product under contaminated conditions for a whole month before it is required to test again. Therefore, FSIS should specify the appropriate **intervals** at which testing must be performed.[84]

3. The Proposed Product-Testing Provisions Are Inadequate.

Under the proposed rule, "an establishment's corrective actions following a positive must include product testing and any other activities that it deems necessary to determine and demonstrate that the affected lot or lots of product are not adulterated with *L. monocytogenes*."[85] This statement indicates that FSIS is leaving it to each establishment's discretion to determine whether the product sampling and corrective actions it has conducted are sufficient to meet its burden of demonstrating that product is not contaminated with *L. monocytogenes*. The FSIS

---

[83] Establishments that have, over a specified period of time, demonstrated consistent negative test results for *Listeria spp.* could potentially be permitted to reduce the frequency of their required testing or the number of sampling locations, so long as a minimum sampling frequency were retained. However, if FSIS testing were to reveal a positive product sample for *L. monocytogenes,* the facility should then be required to increase the frequency of its product-contact surface testing.

[84] The industry's own guidelines recommend sampling of non-product contact locations in high potential areas at or during pre-operation time every week. North American Meat Processors, et al., *Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs), and Environmental Sampling/Testing Recommendations (ETSRs): Ready-to-Eat (RTE) Products,* p. 15 (Apr. 1999).

[85] 66 Fed. Reg. at 12,604.

should set sampling procedures by which companies are to demonstrate that they are testing a statistically significant amount of product for *L. monocytogenes*. Requiring a large sample size to be tested would increase confidence levels that the product meets the zero tolerance requirement.

Under the proposed rule, an establishment would be required to test and hold product where product-contact equipment tests positive for *Listeria spp.* The agency does not, however, require re-sampling of the affected equipment. Since a positive for *Listeria spp.* on product-contact surfaces is an indication that the facility's sanitation procedures are ineffective, establishments also should be required to re-sample the equipment following clean-up procedures and before more product comes in contact with it. This sampling will ensure that sanitation has been effective.[86]

4. FSIS Should Maintain Its Random-Sampling Program For Listeria As An Additional Layer Of Protection For Consumers And To Verify The Efficacy Of Industry Testing Programs.

Implementation of a mandatory industry testing program for *Listeria* should not spell the end of FSIS's existing random-sampling program. Companies must conduct the initial testing for contamination in their plant environments and final products because they are the only ones who can control what is going on in their own facilities. However, FSIS should continue to sample final products from plants on a random basis to verify that industry testing protocols are working to identify product contamination and its potential sources, help enforce the zero

[86] Equipment design should be taken into account when sampling. Equipment that is computerized or has multiple electrical connections may require special cleaning and sampling procedures. Older equipment may have gouges, rough spots or dents that hold bacteria. It is especially important to sample the items such as pusher arms, saw blades, cutting boards, and similar equipment that touch all product.

tolerance policy for *L. monocytogenes,* and provide an additional layer of protection to the public. Dual pathogen-monitoring systems would help to ensure that industry Sanitation SOPs and HACCP systems are working to eliminate microbial hazards.

FSIS should concentrate its limited resources on those plants (and products) that pose the greatest potential risk to consumers. The comprehensiveness of a plant's testing scheme can be one factor in determining whether FSIS should focus its attention on that plant or elsewhere,[87] but the government should conduct periodic testing in every plant.

5. Industry Alternatives Are Inadequate To Assure That An Establishment's Controls are Effectively Minimizing The Hazard Of *L. monocytogenes*.

Industry representatives have advanced several alternatives to the proposed rule for *Listeria* testing. Under one option, FSIS would merely retain revised Directive 10,240.2, "Microbial Sampling of Ready-to-Eat Products Produced by Establishments Operating Under a HACCP System."[88] The Directive exempts from the current government random testing regime establishments that either have incorporated a product-testing protocol into their validated HACCP plan or SSOPs and (1) at a minimum, test one RTE product per HAACP plan per month, or 2) conduct both "on-going" food-contact surface and nonfood-contact surface testing for *Listeria spp.* and "targeted" product testing for *L. monocytogenes* when there is a positive result of *Listeria spp.* on a food-contact surface and test one RTE product per HACCP plan for *L.*

---

[87] FSIS News Release, *FSIS Action Will Increase Microbiological Sampling Of Ready-To-Eat Meat and Poultry Products* (Nov. 2, 2000), available at *http://www.fsis.usda.gov/oa/news/2000/rte.htm.*

[88] FSIS Directive 10,240.2, Revision 1 (Dec. 1, 2000) [hereinafter *Directive*]. The Directive was subsequently amended to, among other things, clarify the meaning of the term ready-to-eat. FSIS, *Directive 10,240.2, Revision 1, Amendment 1* (Jan. 24, 2001), available at *http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.2Transsheet.htm.*

monocytogenes once every 3 months.[89]

Under a second industry option, FSIS would retain the Directive and require sampling of product-contact surfaces at the same time product samples are collected for analysis. Under this scenario, industry would be required to place product on hold pending test results. In the third industry alternative, the Directive would be retained as in the first and second options and FSIS would sample the environment and/or products from establishments that do not implement a sampling program.[90]

These proposed testing alternatives should be rejected. The Directive only defines the minimum testing frequencies by which establishments can avoid random government testing. These testing frequencies are even less than the minimum levels set forth in the proposed rule. Frequent and systematic testing of food-contact surfaces is necessary to assure that products are being produced under optimal sanitary conditions and that sanitation procedures are working effectively to prevent contamination. Testing on a quarterly or even monthly basis as the Directive requires simply is not designed to reveal defects in an establishment's sanitary procedures or provide early warning of contamination problems.[91] Moreover, under the Directive, even where testing reveals a positive product-contact surface for *Listeria spp.*, the

---

[89] *Directive* at 4-5.

[90] A fourth option involves establishing a food safety objective for *L. monocytogenes* of no greater than 100/g in RTE products at the time they are consumed.

[91] Under industry proposals, facilities would be allowed to conduct environmental and product testing at the same time, pointing out that such testing would generate additional data concerning the relationship between a positive product contact surface and the probability that a product will be contaminated without increasing the burden of hold and test. At a minimum, however, product-contact surface or regular environmental testing is more likely to reveal flaws in sanitation that would lead to conditions likely to harbor *L. monocytogenes*.

establishment is not necessarily required to conduct product sampling for *L. monocytogenes* as it would be required to do under the proposed rule.[92]

In addition, the Directive does not define what constitutes the "on-going" food contact surface and non-food contact surface testing or the "targeted" product testing for *L. monocytogenes* that would allow an establishment to escape government testing. As a result, the frequency of any testing that an establishment conducts beyond the monthly or quarterly minimum necessary to evade government testing is left solely to the facility's discretion. Indeed, the Directive specifically states that "FSIS is not prescribing the frequency of the on-going *Listeria spp.* testing or the targeted product testing" but that establishments will need to develop a scientifically-based frequency for this testing.[93]

Contrary to industry suggestions, it is imperative that FSIS require mandatory minimum industry microbial testing in order to verify that plants are operating under the sanitary conditions required under the federal meat and poultry inspection statutes and regulations. Mandatory industry testing also adds teeth to and facilitates enforcement of the existing zero-tolerance standard for the pathogen in ready-to-eat products by dramatically increasing the number and range of products sampled.

---

[92] *See* Olsson, Frank and Weeda, P.C., *Memorandum: FSIS Revised Directive On Microbial Sampling of RTE Products,* p. 3 (Nov. 3, 2000) (indicating that in an industry briefing, FSIS Administrator Billy and Deputy Administrative for Policy Derfler both stated that there is not a one-to-one requirement between a positive finding of *Listeria spp.* and testing for *L. monocytogenes*).

[93] *Directive* at 4-5.

E. Pending Adoption of a Mandatory Microbial Testing Program, Ready-to-Eat Meat and Poultry Should Be Required to Bear a *L. Monocytogenes* Safe-Handling Label.

In the wake of the Sara Lee Bil Mar outbreak, FSIS advised consumers that RTE meat and poultry products are not truly ready to-eat for people who are especially vulnerable to food - borne illness. According to FSIS:

> People at risk for listeriosis, their family members, and individuals preparing food for them should . . . [r]eheat until steaming hot the following types of ready-to-eat foods: hot dogs, luncheon meats, cold cuts, fermented and dry sausage, and other deli-style meat and poultry products. . . .*If you cannot reheat these foods, do not eat them.*[94]

Typically, deli-style and other products are perceived by consumers to be "ready- to-eat." This perception, coupled with a USDA shield on product packages, creates the mis-impression that they are safe to consume without further cooking.

Accordingly, RTE meat and poultry products that have not been pasteurized in the final package should be required to carry a safe-handling statement indicating that they could be contaminated with the pathogen and, therefore, pose a potential health threat to infants, pregnant women, the elderly and those with weakened immune systems. In addition, FSIS should require all RTE meat and poultry products to bear uniform expiration date labels, making it clear that for safety reasons, food should be used or frozen by a particular date.

1. "Use-By" Dating for Safety Should be Required to Protect Consumers.

Because *L. monocytogenes* grows under refrigeration, it can present a safety hazard when a lengthy time has elapsed even under cold storage conditions.[95] In notices warning consumers

---

[94] *FSIS Action Plan*, at 3 (emphasis added).

[95] R.A. LaBudde, *Durability indication: United States*, *in* Food Labelling 111, 120 (J. Ralph Blanchfield ed. 2000) [hereinafter LaBudde, *Durability indication*].

about the risk of listeriosis, both the USDA and the Food and Drug Administration (FDA) have advised consumers to check dates on labels for those products that have been associated with *Listeria.*[96] But the absence of a uniform federal dating regulation hinders consumers from following this advice.

State regulations have been inadequate to address this problem. Only 15 state governments require some form of date labeling. Five of those states follow the guidelines provided by the U.S. National Conference on Weights and Measures (NCWM), an organization that has developed model dating regulations.[97] The NCWM's model regulations call for date labeling of pre-packaged perishable foods and for optional date labeling of non-perishable pre-packaged foods. Ten of the states that have requirements, however, do not base them on the NCWM standard.[98]

The absence of uniform date labeling requirements has led to inconsistent date labels on ready-to-eat food products and consumer confusion.[99] For example, some products are labeled "sell by," which is designed to tell the store how long to display a product for sale, but provides

---

[96] *E.g.*, FSIS Recall Press Release, *New Jersey Firm Recalls Salami for Possible Listeria Contamination* (Feb. 28, 2001) (Directions for people at risk for listeriosis and persons preparing food for them: . . . . "Observe all expiration dates for perishable items that are pre-cooked or ready-to-eat. *See also* FDA, *Background: Preventing Foodborne Listeriosis* (Mar. 1992, rev. Apr. 1992) ("Recommendations for all Individuals . . . . Read and follow label instructions to 'keep refrigerated' and 'use by' a certain date"), available at *http://www.cfsan.fda.gov/~mow/fsislist.html.*

[97] National Conference on Weights and Measures, *Summary of State Laws and Regulations in Weights and Measures, in* Uniform Laws and Regulations (as of Sept. 2000) [hereinafter *Summary of State Laws*],available at *http://ts.nist.gov/ts/htdocs/230/235/stlaw.pdf.*

[98] *Summary of State Laws.*

[99] *See* Appendix I, attached hereto, which shows the multitude of ways in which dates are used for products which are virtually identical.

no information to consumers about appropriate home storage times. Some products contain a "Best If Used By" (or Before) date that refers only to product taste or quality. Other products contain a "use-by" date that has generally been considered the last date recommended for the use of the product while at peak quality."[100] Finally, some products may contain no date at all. Even the USDA has taken conflicting positions on the meaning of "use by." Although FSIS's *August 2000 Consumer Education and Information Focus on: Food Product Dating* states that "product dates aren't a guide for safe use of a product,"[101] standard USDA press releases announcing individual recalls tell at-risk consumers to "[o]bserve all expiration dates for perishable items that are precooked or ready to eat."[102]

In the notice of proposed rulemaking for this proceeding, FSIS states that "[i]f consumers *understood* 'use-by' dates and *changed their behavior* accordingly, 'use-by' labels could help to ensure food safety through proper handling of RTE meat and poultry products and thereby reduce the risk of listeriosis."[103] However, while acknowledging the potential usefulness of date labeling, FSIS also appears to question the value of this requirement in practice.

The fact that consumers may not understand "use-by" dates and change their behavior accordingly is a function of the inconsistent use of such "use-by" dates. The concept of "use-by" dates is confusing because it is unclear whether the date refers to safety or product quality.

---

[100] FSIS, *Focus On: Food Product Dating* (August 2000), available at *http://www.fsis.usda.gov/oa/pubs/dating.htm* [hereinafter *Focus On: Food Product Dating*]

[101] *Focus On: Food Product Dating.*

[102] *See, e.g.*, FSIS Recall Press Release, *New Jersey Firm Recalls Salami for Possible Listeria Contamination* (Feb. 28, 2001).

[103] 66 Fed. Reg. at 12,635 (emphasis added).

Rather than abandon the idea of date labeling, FSIS should require uniform and clear terminology. As one expert has stated: "In the future, the mandates for risk assessment and HAACP planning will inevitably result in a prescription for open and uniform durability indications for at least all potentially hazardous foods . . . ." [104]

The FDA faced an analogous problem in 1997. In its "Guidance on Labeling of Foods that Need Refrigeration by Consumers," the agency explained that:

> [c]urrent labeling of shelf-stable packaged foods is not adequate because the same label statements, e.g., 'keep refrigerated' or 'refrigerate after opening' appear both on foods that are potentially hazardous and on foods that do not pose a hazard but that are refrigerated to retard deterioration in quality.[105]

To maintain the distinction between refrigeration necessary to control product quality and refrigeration required to maintain product safety, the FDA divided foods into three categories and recommended the use of differing labeling requirements for each one.

Group A foods are "potentially hazardous foods, which, if subjected to temperature abuse, will support the growth of infection or toxigenic microorganisms that may be present." The appropriate label statement for such foods is "IMPORTANT Must Be Kept Refrigerated to Maintain Safety."[106] Group B includes "those foods that are shelf-stable as a result of processing, but once opened, the unused portion is potentially hazardous unless refrigerated." FDA recommended the following language for Group B foods: "IMPORTANT Must Be Refrigerated

---

[104] LaBudde, *Durability indication*, at 121.

[105] 62 Fed. Reg. 8248, 8249 (Feb. 24, 1997).

[106] 62 Fed. Reg. at 8251.

After Opening to Maintain Safety."[107] Group C foods "do not pose a safety hazard even after opening, but . . . may experience a more rapid deterioration in quality over time if not refrigerated." The suggested label statement for this group is: "Refrigerate for Quality."[108]

In its request for comments on the labeling issue, FSIS questioned whether language such as "For Safety, use-by * * * " would be more effective than language that did not contain a reference to safety. Given the degree of confusion over whether "use-by" relates to quality or safety, FSIS should follow the approach taken by the FDA and require products to state: " IMPORTANT for safety, use by or freeze by * * * . Do not consume products after "X" days of opening, regardless of expiration date." Manufacturers would be able to use statements such as "for best quality use by * * * " so long as that date does not extend beyond the safety expiration date.

2. The USDA's Policy Of Not Mandating Standardized "Use by" Dates Is Out Of Step With International Norms.

The European Union (EU) requires many types of foods to indicate the "date of minimum durability," which is usually expressed as "Best before . . ." or "best before end of . . ." followed by the date until which the food will keep its "specific properties when properly storied." Foods which "*from the microbiological point of view are highly perishable*must state "use before" followed by the date after which the food should not be used.[109]

---

[107] 62 Fed. Reg. at 8251.

[108] 62 Fed. Reg. at 8251.

[109] 1979 O.J. (L33) 9 (emphasis added).

Similarly, the World Health Organization (WHO) resolution on Food Safety urges member states "to ensure appropriate, full and accurate disclosure in label of food products, including warnings and best-before dates where relevant." This recommendation was based on the fact that the Fifth-third World Health Assembly is "deeply concerned that foodborne illnesses associated with microbial pathogens, biotoxins and chemical contaminants in food represents a serious threat to the health of millions of people in the world."[110]

3. USDA Has Authority Under Both The FMIA And PPIA To Require "Use-By" Dates on Ready-to-Eat Meat And Poultry Products.

Both the FMIA and PPIA authorize USDA to require label information "to assure that [products] will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition."[111] Thus, both the FMIA and the PPIA clearly give the agency discretion to require labeling in addition to the official stamp to ensure safe use of the product.[112]

In the early 1970's, USDA declined to invoke this authority to require a warning label on uncooked meat and poultry products, a decision that was upheld by a federal appellate court in *American Public Health Ass'n v. Butz*.[113] That case does not, however, undermine USDA's

---

[110] World Health Assembly, 53d Sess., WHA 53.15 (May 2000).

[111] 21 U.S.C. §§ 601(n)(12), 453(h)(12).

[112] *American Public Health Ass'n v. Butz*, 511 F.2d 331, 335 (D.C. Cir. 1974). Two bills currently pending in the House of Representatives would require product dating. The National Uniform Food Safety Labeling Act would require labels to bear "the date upon which the food should no longer be sold because of diminution of quality, nutrient availability, *or safety.*" H.R. 1816, 107th Cong., 1st Sess. (emphasis added). The Food Freshness Disclosure Act of 2001 requires manufacturers to determine a date until which the product will "contain not less than the quantity of each nutrient set forth in the food label" and "otherwise be not *adulterated* and of an acceptable quality." H.R. 2611, 107th Cong., 1st Sess. (emphasis added).

[113] *American Public Health Ass'n v. Butz*, 511 F.2d at 335.

authority to require "use-by" date labeling since the court merely found that the agency is not *obligated* by statute to require a safe-handling label on meat products that may contain microbial contamination. Thus, the decision does not preclude the agency from reconsidering the safe-handling label issue and deciding to exercise its discretion differently in the future. In fact, FSIS has since revisited the question and, in 1994, promulgated a rule requiring raw meat and poultry products to bear safe-handling instructions.[114]

Given data demonstrating the serious health threat posed by *L. monocytogenes*-contaminated processed-meat products, FSIS should exercise its discretion under the FMIA and PPIA to require labeling information in addition to the official stamp.[115] Specifically, the agency should require that RTE products contain uniform expiration dating that makes it clear that for safety reasons, food should be used or frozen by a particular date and that it should not be consumed after "X" number of days after the package is opened. FSIS is clearly authorized to take those actions under section 601(n)(12) of the FMIA and section 453(h)(12) of the PPIA.

IV. The Preliminary Regulatory Impact Analysis Is Flawed Because It Underestimates The Benefits That Would Result From The Testing Requirements.

A. The Benefits of the Proposed Rule Should Be Monetized.

In its Preliminary Regulatory Impact Analysis (PRIA), FSIS did not monetize the values associated with reducing listeriosis cases and deaths because of perceived "uncertainties."[116] In addition, FSIS did not even attempt to quantify the benefits of the lethality and stabilization

---

[114] 59 Fed. Reg. 14,528 (Mar. 28, 1994).

[115] FSIS should require that RTE products that have not been pasteurized in the final package contain a safe handling statement indicating that the product could be contaminated with the pathogen and therefore pose a potential health threat to infants, pregnant women, the elderly, and those with weakened immune systems.

[116] 66 Fed. Reg. at 12,627.

performance standards, although it did calculate the costs of compliance. For years USDA and many other federal agencies have monetized the benefits of health and food-safety regulations, including, notably, in promulgating FSIS's HACCP rule. It is imperative for FSIS to provide monetized benefits for all of the various provisions of this rulemaking as well.

1. The Value of An Adult Life Can Be Monetized.

At the public meeting held to discuss the proposed rule, USDA's Economic Research Service (ERS) explained its estimates of the benefits of the proposal.[117] ERS stated that it valued the cost of an adult life lost to listeriosis at $4.8 million.[118] ERS applied this valuation to its estimate of the average annual death reduction of 5 to 50 cases (over a 10-year period) and calculated a range of benefits of $55.1 million to $755.5 million ($36.5 million to $500.1 million in present dollars).

The range of benefits that ERS calculated for adult lives saved significantly understates the value of death reduction because the "Value of Statistical Life," or VSL, the agency used is too low. ERS's VSL of $4.8 million is inconsistent with VSL estimates used by other federal agencies in evaluating the benefits of health regulations.[119] For instance, the Environmental Protection Agency (EPA) has established a VSL of $6.1 million, in 1999 dollars,[120] which is 21

---

[117] Although monetized benefits were not published in the proposed rule, ERS discussed its cost/benefit analysis of the proposal at the FSIS public meetings held in May 2001.

[118] Stephen Crutchfield/Felix Spinelli, Presentation at the Food Safety and Inspection Service Public Meetings (May 2001) (transcribed by Charlotte Christin, Center for Science in the Public Interest) [hereinafter *Crutchfield presentation*].

[119] Donald Kenkel, *Using Estimates of the Value of a Statistical Life in Evaluating Regulatory Effects, in* U.S. Department of Agriculture, Economic Research Service, Misc. Pub. No. 1570, Valuing the Health Benefits of Food Safety: A Proceedings 2-13 (Fred Kuchler, ed., Apr. 2001) [hereinafter *Kenkel*] (noting that USDA has been criticized before for using VSL estimates that are low compared to those used by other federal agencies).

[120] *See, e.g.*, 66 Fed. Reg. 6,975, 7,012 (2001) (stating that if the agency were to adjust the VSL to account for the growth in real income, the VSL would be approximately $6.77 million (assuming a 1.0 income elasticity)).

percent higher than the VSL used by ERS.

Although the proposed rule indicates the Department's concern about "uncertainties" in valuing the loss of life, such concerns are unwarranted with respect to the EPA's VSL. EPA derived its VSL from a statistical distribution of the values found in 26 wage-risk studies that were culled from a larger body of work on this issue.[121] Moreover, interagency proceedings on valuing the benefits of food-safety regulations have demonstrated the soundness of the EPA's VSL methodology.[122] Thus, we urge FSIS to adopt a VSL of $6.1 million when considering the value of adult lives saved as a result of FSIS's proposal.

2. The Value of A Fetus Can Be Monetized.

It is well-established that pregnant women and their fetuses are among those who are most susceptible to severe listeriosis infections. For example, a 1985 outbreak in southern California caused by Mexican-style soft cheese sickened 142 people and killed 46.[123] Eighty-five percent of the outbreak victims were pregnant women or their fetuses.[124] Similarly, in the Bil-Mar outbreak, ready-to-eat meat products sickened 100 people and killed 21, including six miscarriages. Nonetheless, neither FSIS nor ERS placed *any value on saving the lives of fetuses* as a part of the benefits calculation for the proposed rule. To the families who have suffered miscarriages as a result of *L. monocytogenes*-contaminated RTE meat and poultry products,

---

[121] 66 Fed. Reg. at 7,044.

[122] *Kenkel,* at 2-13.

[123] Center for Science in the Public Interest, *Unexpected Consequences: Miscarriage and Birth Defects From Tainted Food* 6 (Jan. 2000) [hereinafter *Unexpected Consequences*].

[124] *Unexpected Consequences*, at 6.

including those who belong to Safe Tables Our Priority (STOP) and other member-groups of the Safe Food Coalition, it is unconscionable for the FSIS to fail to acknowledge the value of their losses.

ERS and CDC officials have estimated the value of fetal life lost (as a measure of forgone lifetime earnings) due to listeriosis at $1.1 million (in 1990 dollars) per case.[125] This work continues to be cited by experts in the field.[126] The value of fetal life lost also should include the psychic costs suffered by parents and other caregivers. This would include pain, suffering, grief, and loss of companionship, as well as the costs of therapy, medications, and other related costs borne by the grieving families. STOP member Angela Babosh, who lost her first-born child to listeriosis, explained the suffering that she and her husband have endured:

> Our personal loss was great. . . [S]he would have been 4 years old now. I still think of her every day. I now have a 2 year old son, what do I tell him. How will I react the first time he spends the night at a friend's house who doesn't know what happened, what if they serve hot dogs? What if it happens again? I am scared every day that he might be exposed. . . It not only affects my husband and I, it affects my parents, my in-laws and all of our friends and family. They all lost a part of themselves that day.[127]

---

[125] Tanya Roberts & Robert Pinner, *Economic impact of disease caused by* Listeria monocytogenes, *in* Foodborne Listeriosis 137, 141 (A.J. Miller et al. eds., 1990) [hereinafter *Roberts & Pinner*].

[126] *Kenkel*, at 4.

[127] Angela Babosh, Member of Safe Tables Our Priority, Comment submitted to FSIS Docket No. 97-013P, (June 26, 2001) [hereinafter *Babosh comment*].

In addition, experts have argued that estimates of psychic costs to the fetus should be included in the valuation.[128] At least one expert has set the value of the psychic loss, in terms of the value of non-work time lost) to the fetus at $1.15 million (in 1990 dollars).[129] FSIS also should consider the psychic costs related to perinatal listeriosis. As STOP's Angela Babosh saw first-hand the suffering her daughter endured:

> I then delivered my daughter, who was rushed to the NICU. My daughter only lived for 40 hours but during that time she was poked, prodded, stuck, and evaluated by many physicians. She had tubes coming out of her arms and nose. She was on a machine to breathe for her and a pump to transfuse her blood.[130]

We believe FSIS should look to this comment for guidance in monetizing the pain, suffering, and other psychic costs of foodborne illnesses. We urge the agency to incorporate the monetized psychic costs, together with the value of a fetal life of *at least* $1.1 million (adjusted to current dollars), in calculating the benefits of its proposed rule.

3. The Costs of Maternal Listeriosis Can Be Monetized.

In examining the benefits of this proposal, ERS did not consider the value of reducing maternal listeriosis illnesses.[131] Earlier work by ERS and CDC officials indicates that maternal

---

[128] *Roberts & Pinner*, at 142.

[129] *Roberts & Pinner*, at 142.

[130] *Babosh comment.*

[131] *Crutchfield presentation.*

listeriosis could involve prolonged hospitalization, averaging approximately $7,000 per case in 1990 dollars.[132]

FSIS also should include the values of productivity losses and psychic costs associated with maternal listeriosis. For example, STOP member Angela Babosh documented that she lost approximately $2,000 in income during her infection, and she and her husband lost approximately $1,500 in income after their daughter's death.[133] STOP Board Member Dan Capriotti's wife gave birth 3 months prematurely and as a result their daughter had to spend 4 months in neonatal intensive care and has endured 6 surgeries for moderate but significant physical disabilities. As Capriotti has stated:

> It isn't only dollars and cents, there are real people with real lives unalterably and unspeakably changed. . . I believe that when the human impact is truly understood and accepted by all involved, it becomes much clearer why we have to do what is right, not what is easy.

Comments from the STOP families, as well as the work by Roberts and Pinner (copy attached), are instructive in monetizing these costs.

4. The Costs of Non-Maternal Listeriosis Illnesses Can Be Fully Monetized.

ERS has stated that it valued the medical costs of non-maternal listeriosis cases at $10,300 for mild cases and $28,300 for severe cases.[134] ERS applied these figures to its estimate of the average annual case reduction of 25 to 248 cases (over a 10-year period) and calculated a

---

[132] *Roberts & Pinner,* at 141.

[133] *Babosh comment.*

[134] *Crutchfield presentation.*

range of benefits of $4.4 million to $44.2 million ($2.9 million to $29.3 million in present dollars). However, ERS's calculations fail to account for the productivity losses and psychic costs associated with non-maternal listeriosis.

Moreover, ERS only calculated costs associated with non-maternal listeriosis hospitalizations. It did not account for milder cases of non-maternal listeriosis, such as abscesses, local infections, and intestinal disease, even though the costs associated with these types of cases have been calculated with respect to other pathogens and other regulatory proposals.[135] Although the costs per case of these milder manifestations may be minimal, if there are a sufficient number of cases, then these costs could be significant.[136]

We suggest that FSIS look to the STOP comments and the Roberts and Pinner article in calculating the productivity losses and psychic costs associated with severe listeriosis cases. FSIS should further look to the estimates prepared for the HACCP rulemaking in determining the benefits of reducing illnesses that manifest with a range of severity.

B. The Second Baseline Significantly Underestimates the Number of Listeriosis Cases and Deaths and Should Be Revised.

The second baseline of listeriosis cases and deaths, developed by FSIS from studies conducted by Olsen and Mead,[137] significantly underestimates the number of listeriosis illnesses and deaths caused by meat and poultry products. The second baseline is fatally flawed because the outbreak data reported in the Olsen study are no longer accurate and the outbreak data

---

[135] *See, e.g.*, U.S. Department of Agriculture, Economic Research Service, Ag. Econ. Report No. 791, Tracing the Costs and Benefits of Improvements in Food Safety: The Case of the Hazard Analysis and Critical Control Point Program for Meat and Poultry, (Oct. 2000) [hereinafter *Tracing the Costs*].

[136] *Roberts & Pinner*, at 138.

[137] 66 Fed. Reg. at 12,627.

generally fail to account for most listeriosis cases. For these reasons, we strongly urge FSIS to revise the second baseline estimates as outlined below.

1. The Olsen Study Does Not Contain Updated Foodborne-Illness Outbreak Data.

FSIS, in calculating the benefits of the proposed rule, relied upon a study by Olsen *et al.*, reporting data on foodborne illness outbreaks occurring in the U.S. between 1993 and 1997.[138] Based on the Olsen data, FSIS estimated the percentage of listeriosis illnesses attributable to meat and poultry products to be 8 percent.[139] However, FSIS's estimate is based on data that are no longer accurate. In June 2001, CDC published updated information on foodborne illnesses occurring during the period covered by the Olsen study.[140]

CSPI has reviewed the updated information, together with the data published by Olsen, and generated its own compilation of the reported foodborne illness outbreaks occurring in the United States. In addition to the Olsen data and other CDC outbreak data, CSPI's inventory of foodborne-illness outbreaks contains information gathered by contacting state health officials and reviewing medical journals and similar sources. All told CSPI has documented a total of 1,628 reported outbreaks with known or suspected food vehicles during the period of 1990 to 2001, representing 73,640 cases. Of those, 284 outbreaks (comprising 13,674 cases) were linked to meat and poultry products. (A copy of CSPI's summary of outbreak totals and the listing of meat

---

[138] Sonja Olsen *et al.*, "Surveillance for Foodborne-Disease Outbreaks—United States, 1993-1997," *Morbidity and Mortality Weekly Report*, Vol. 49, No. SS-1, (Mar. 17, 2001) [hereinafter *Olsen study*].

[139] 66 Fed. Reg. at 12,627.

[140] See *http://www.cdc.gov/ncidod/dbmd/outbreak/us_outb.htm*. These listings "include information received by CDC after publication of 'Surveillance for Foodborne-Disease Outbreaks—United States, 1993-1997,' (CDC Surveillance Summaries, March 17, 2000; 49/Ss-1)." The CDC published updated information from 1990-1992 as well.

and poultry outbreaks is attached.) The updated outbreak data show that meat and poultry products were responsible for 19 percent (13,674/73,640) of the illnesses (or "cases") associated with foodborne-illness outbreaks, or more than double the 8 percent derived from the Olsen data set.[141]

It is imperative that any baseline estimates generated by FSIS use the most up-to-date and accurate outbreak data. To that end, we recommend that the table, "ESTIMATED NUMBER OF U.S. FOOD BORNE DISEASE CASES AND DEATHS: TOTAL FROM ALL PATHOGENS, TOTAL FROM LM, TOTAL FROM LM IN MEAT AND POULTRY PRODUCTS (MPP'S) FOOD PRODUCTS AS DERIVED FROM A COMBINATION OF THE MEAD-OLSEN STUDIES" (Table 9 in the proposed rule), be revised using the more up-to-date data set prepared by CSPI. Our analysis shows that a revised estimate based on updated outbreak data would be 397 listeriosis cases and 82 deaths. While this is likely more accurate than the Olsen/Mead data, even these estimates are too conservative.

2. The Second Baseline Should Be Adjusted Because Most of the *L. monocytogenes*-related Outbreaks Are Linked to Meat Products.

A careful analysis of the outbreak data reveals that of the six *L. monocytogenes*-related outbreaks documented by CSPI, 50 percent were linked to ready-to-eat meat and poultry products. Furthermore, many of these outbreaks have been large, multi-state outbreaks that resulted in both lost lives and severe illnesses. The Sara Lee Bil-Mar outbreak, that was linked to contaminated hot dogs and possibly deli meats, sickened 100 and killed 21 people in 22 states.

---

[141] While the Olsen study also provided information on the number of deaths associated with these outbreaks, for the purposes of its analysis, FSIS used only the illness rate (8 percent) and not the death rate (20 percent) that it calculated based on CDC data.

Last year, ready-to-eat poultry and turkey products were linked to 29 illnesses, including 4 deaths and 3 miscarriages/stillbirths in 10 states.[142]

3. The Second Baseline Should Be Adjusted Because Outbreak Data Fail to Account For Most Listeriosis Cases.

Even though the largest listeriosis outbreaks have been associated with meat and poultry products, most listeriosis cases are sporadic and are not associated with outbreaks such as those reported by Olsen[143] or by CSPI. As the agency explained in the draft risk assessment for *L. monocytogenes,* "[i]llnesses attributed to documented outbreaks are a small proportion of the total estimated annual cases of listeriosis."[144] Although the proposed rule acknowledges the sporadic nature of most *L. monocytogenes*-related illnesses and deaths, the agency failed to adjust accordingly the estimates derived from Olsen's outbreak data.[145] Even the updated foodborne illness outbreak data that CSPI has compiled should be multiplied by an adjustment factor to reflect the fact that outbreak data do not capture most listeriosis cases. Therefore, we recommend that FSIS develop an adjustment factor and apply it to the revised estimates of listeriosis illnesses from ready-to-eat meat and poultry products of 397 listeriosis cases and 82 deaths.

Unless FSIS recalculates its second baseline estimates accordingly, its analysis will not account for the full range of benefits offered by the proposed rule.

---

[142] S. Hurd et al., *Multistate Outbreak of Listeriosis-United States, 2000,* 49 Morbidity & Mortality Weekly Report 1129-30 (2000).

[143] Laurence Slutsker and Anne Schuchat, *Listeriosis in Humans, in LISTERIA,* LISTERIOSIS, AND FOOD SAFETY 75, 86 (Elliot T. Ryser and Elmer H. Marth, eds., 1999).

[144] *Draft Assessment,* Interpretative Summary, at 22.

[145] 66 Fed. Reg. at 12,627.

C. The Industry's Avoided Costs Should Be Included in the Benefits Estimates.

While the PRIA included the costs to industry that would result from the testing requirements, it fails to take into consideration a host of other costs that industry would have incurred had there been an outbreak of listeriosis.

1. The Costs of Avoided Recalls Should Be Calculated.

The costs associated with recalls of ready-to-eat meat and poultry products can be quite expensive, in part because typically these products are produced in high volumes and are distributed widely. So, for example, the largest meat recall in history – 30 million pounds – involved hot dogs. Similarly, this past winter Cargill recalled about 17 million pounds of turkey and poultry product due to potential *L. monocytogenes* contamination. The costs to producers of large-scale recalls can be crushing. After Hudson Beef was forced to recall 25 million pounds of tainted ground beef, the company went out of business.

2. The Costs of Avoided Litigation Should Be Calculated.

Information pertaining to litigation for foodborne illnesses is limited; however, a recent ERS report documented that the mean compensation for a premature death case from 1988-1997 was $274,580 in 1998 dollars and the mean compensation for a foodborne-illness-related hospitalization was $141,199 in 1998 dollars.[146] Of course, these awards do not include the fees paid to attorneys, experts, and other costs associated with litigation. Nor do they include the costs of foodborne illness cases that have settled, since those awards are not public.

---

[146] U.S. Department of Agriculture, Economic Research Service, Ag. Econ. Report No. 799, Product Liability and Microbial Foodborne Illness 16 (Apr. 2001).

3. Other Avoided Costs Should Be Included.

Other avoided costs to industry should be included in the benefits estimate, such as the following: reduced consumer demand resulting from publicity from an outbreak or recall; costs of investigating the source of contamination, cleaning up or even closing a plant; changes in production to reduce future contamination; product spoilage; and disrupted work schedules because of employee illness due to handling of contaminated product.[147]

In its PRIA, FSIS acknowledges that there are benefits to the private sector that it has not included.[148] We believe that any PRIA is incomplete without consideration of the avoided costs.

D. The Benefits of the Proposed Rule Should Be Calculated Over a 20-Year Period.

ERS calculated the benefits of the proposal by estimating its effectiveness in preventing listeriosis cases over a 10-year period.[149] However, in a study of the benefits of the HACCP rule, ERS examined benefits over a 20-year period.[150] ERS is aware that in the later years, the economic benefits of this proposal rise more rapidly than the costs do.[151]

V. CONCLUSION

We applaud FSIS for its efforts to address the serious public-health threat posed by *L. monocytogenes* in ready-to-eat meat and poultry products. CSPI and the Safe Food Coalition view the proposed rule as a significant step forward in improving safety of ready-to-eat meat and poultry products. Mandatory microbial testing by industry of product contact surfaces for

---

[147] *Roberts & Pinner*, at 137-138.

[148] 66 Fed. Reg. at 12,635.

[149] *Crutchfield presentation.*

[150] *Tracing the Costs*, at 4.

[151] *Crutchfield presentation.*

Listeria spp., with a positive result requiring product testing for *L. monocytogenes*, is the minimal testing necessary to assure protection of the food supply against this dangerous pathogen. The industry must step-up its efforts to develop and implement truly effective sanitation measures and hazard control systems. The government also must remain involved in active oversight of industry efforts by conducting its own testing to verify the efficacy of industry sampling. Everyone involved – companies, the government, and consumers – needs a way to evaluate whether plants' sanitation measures and hazard-control systems are truly effective against *L. monocytogenes* contamination on an ongoing basis. We need a dependable mechanism to identify and address weaknesses in a plant's systems and to detect contamination problems *before* tainted products reach consumers. As explained above, environmental, product-contact, and final product testing are necessary to achieve those goals.

Respectfully submitted,

Karen L. Egbert

Karen L. Egbert
Senior Food Safety Attorney

Charlotte A. Christin

Charlotte A. Christin
Senior Food Safety Attorney

Caroline Smith DeWaal
Director, Food Safety Project

On Behalf Of:

American Public Health Association
Consumer Federation of America
National Consumers League
Safe Tables Our Priority