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CITIZEN PETITION

I. Introduction

The Center for Science in the Public Interest (CSPI) and fellow Safe Food Coalition members American Public Health Association, Consumer Federation of America, Government Accountability Project National Consumers League, and Safe Tables Our Priority urge the Food Safety and Inspection Service (FSIS) to require companies producing ready-to-eat meat and poultry products to test their plant environments and final products for the presence of *Listeria monocytogenes (L. monocytogenes).*

L. monocytogenes has become one of the most dangerous foodborne pathogens in the U.S. food supply. According to the Centers for Disease Control and Prevention's (CDC) most recent estimates, *L. monocytogenes* has the highest rate of hospitalization among foodborne pathogens and its case-fatality rate is second only to that of *Vibrio vulnificus*. CDC estimates that 92 percent or listeriosis cases require hospitalization and 20 percent result in death. Thus, although listeriosis is rare in comparison to infections caused by such pathogens is *Salmonella and Campylobacter*, it is a significantly more severe infection and far more likely to cause debilitating illness or death, especially in infants, pregnant women and their fetuses, the elderly, and people with compromised immune systems.

Unfortunately, *L. monocytogenes* contamination of ready-to-eat meat and poultry products has become all too common. Because such products may be widely distributed before the contamination is detected, they can cause large outbreaks of listeriosis. That tragic fact was brought to national attention once again in late 1998 and early 1999, when a multistate outbreak of listeriosis attributed to ready-to-eat meat products produced at Sara Lee Corporation's Bil Mar plant caused 21 known deaths and I 00 illnesses. In addition to that outbreak, there has been a rash of recalls of ready-to-eat meat and poultry products contaminated with *L. monocytogenes* in the past year. Clearly, the pathogen must be considered a significant public-health hazard.

The federal government has long been aware of the danger posed by *L. monocytogenes* in ready-to-eat products. Since 1989, FSIS has subjected such products to the most restrictive standard -- zero tolerance. In other words, any amount of *L. monocytogenes* in a ready-to-eat meat or poultry product renders it adulterated and subject to a voluntary recall. The zero tolerance standard reflects a still-valid policy decision, namely that the consequences of listeriosis are too severe, and the available data

regarding the pathogen's infectious dose and other characteristics are too limited, to define a safe level of contamination in foods that consumers need not further cook before consumption.

Unfortunately, FSIS's resources to enforce the zero-tolerance standard are insufficient to adequately safeguard public health. Currently, FSIS relies on a small-scale random-sampling program in which government inspectors annually test approximately 3,500 samples of domestic and imported ready-to-eat meat and poultry products for the presence of *L. monocytogenes.* When a positive sample is detected, the agency asks the producer to initiate a recall of the affected product.

Despite the fact that FSIS's sampling program tests only a small fraction of the ready-to-eat meat and poultry products produced in this country, there is no requirement that the producers of ready-to-eat products expand the effort to detect contamination by testing their own finished products for the presence of the pathogen. Nor are companies currently required to help prevent contamination of their products by testing their plant environments for *L. monocytogenes* or an appropriate indicator organism. The omission of such testing from FSIS's food-safety program for processed-meat products endangers consumers.

Mandatory microbial testing by the industry would improve the existing regulatory program in two important ways:

- It would broaden the safety net afforded by FSIS's limited random sampling program by significantly expanding the pool of products subjected to microbial testing and by extending testing to plant environments, where contamination could be detected even before it enters finished product. As a result, companies would be far more likely to uncover and address contamination problems before they cause consumer illnesses and deaths; and

- It would help plants to verify the efficacy of their required hazard analysis and critical control point (HACCP) plans and to identify when corrective actions are necessary.

As FSIS's experience with its meat and poultry HACCP/Pathogen reduction rule for slaughterhouses demonstrates, carefully conceived hazard-control plans combined with microbial testing for compliance with pathogen-reduction performance standards can reduce contamination in meat and poultry carcasses. Unfortunately, processed-meat plants are not subject to the microbial-testing requirement.

Now, especially in the wake of the recent outbreaks and recalls due to *L. monocytogenes* contamination, it is time for FSIS to move beyond the slaughterhouses and to extend mandatory microbial testing to plants that produce ready-to-eat meat and poultry products. Such testing should be a required component of the hazard-control programs of all plants for which *L. monocytogenes* is a hazard reasonably likely to Occur. Those plants should be required to verify the efficacy of their HACCP systems through scientifically valid microbial-testing regimens, as is currently required for meat and poultry slaughterhouses.

Until a mandatory microbial testing regulation is finalized, FSIS should require those plants that do not have an acceptable testing program (including both environmental and final- product testing) to label their products with a *L. monocytogenes* safe-handling statement that would alert especially vulnerable consumers to the risks posed by contaminated ready-to-eat meat and poultry products. That requirement would be consistent with FSIS's recent advice to such consumers in response to the Sara Lee outbreak

and the recalls that occurred in early 1999. Clearly, for at-risk consumers, foods labeled "ready to eat" may be anything but. Labeling, as an interim measure pending finalization of a microbial-testing rule, would better protect such consumers.

II. Action Requested

We request that FSIS require plants producing ready-to-eat meat and poultry products to conduct microbial testing for the presence of *Listeria* spp. or other indicator organisms in their plant environments and for *L. monocytogenes* in their final products. We also request that FSIS require ready-to-eat meat and poultry products that have not been produced by a plant that incorporates microbial testing into its 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. FSIS is authorized to take the proposed actions under the adulteration and misbranding provisions of the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Because of the potentially fatal effects of *L. monocytogenes* and to expedite development and implementation of the requested regulations, we ask FSIS to promulgate them as an interim final rule and to defer risk assessment and cost-benefit analysis until after publication of the rule. Such action is authorized under both the Administrative Procedure Act (APA) and the USDA Reorganization Act of 1994, Pub. L. 103-354. Alternatively, if FSIS decides that it cannot promulgate the requested regulations as an interim final rule, the agency should expedite rulemaking to the greatest extent possible in order to protect public health.

III. Statement of Grounds

A. Factual Grounds

1. Foodborne Listeriosis Poses a Grave Public-Health Threat *monocytogenes,* a gram-positive bacterium found in water, soil, silage, and other environmental settings, can contaminate a wide range of foods, including hot dogs, luncheon meats, and soft cheeses.' [1]Consumption of food containing *L. monocytogenes* can lead to listeriosis, a potentially deadly disease, in susceptible individuals.

Although listeriosis from contaminated food is less common than infections caused by such pathogens as *Salmonella and Campylobacter*, the consequences of listeriosis are far more severe than those of salmonellosis or campylobacteriosis. According to the latest CDC estimates, 92 percent of listeriosis cases require hospitalization (the highest among foodborne pathogens),[2] with an average

[1] U.S. Department of Agriculture, Food Safety and Inspection Service, "Listeria monocytogenes Contamination of Ready-to-Eat Products; Compliance with the HACCP System Regulation and Request for Comment," *Federal Register,* Vol. 64, No. 101 (1999), p. 28352 [hereinafter cited as *FSIS HACCP Reassessment Notice];* U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *"Listeria monocytogenes," Foodborne Pathogenic Microorganisms and Natural Toxins Handbook,* available at <http://vm.cfsan.fda.gov/~mow/chap6.html>lnternet.

[2] Centers for Disease Control and Prevention, National Center for Infectious Diseases, "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases,* Vol. 5, No. 5 (1999), available at <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>lntemet, Table 3 [hereinafter cited as *CDC Foodborne Illness Estimates*].

hospital stay of almost two weeks.[3] *L. monocytogenes* also has the second highest case-fatality rate among foodborne pathogens: approximately 20 percent of patients with listeriosis die.[4] Overall, 2,298 of the estimated 2,493 annual cases of foodborne listeriosis lead to hospitalization and 499 result in death.[5]

Although as many as one out of eight Americans may be exposed to *L. monocytogenes* each year,[6] most people with healthy immune systems can fight off the bacteria with few problems. Unfortunately, for those at greatest risk of contracting listeriosis, including the elderly, children, pregnant women, and people with compromised immune systems, the outcome can be dire.

L. monocytogenes appears to be highly prevalent in raw meat. Researchers have detected the pathogen in up to 77 percent of ground beef and 95 percent of ground pork.[7] *L. monocytogenes* also occurs less frequently in processed meat and poultry products considered "ready-to-eat," which are typically consumed without further cooking. In its sampling program for ready-to-eat meat and poultry products, FSIS has detected significant amounts of *L. monocytogenes* in a broad range of products. Since 1989, FSIS testing has yielded positives in 5.7 percent of sliced ham/luncheon meats, 4.4 percent of small-diameter sausages, 3.4 percent of salads and spreads, 3.1 percent of roast/corned/cooked beef, 2.4 percent of cooked uncured poultry, 1.6 percent of large-diameter sausages, and 0.7 percent of jerky.[8]

2. The Sara Lee Outbreak and Recent Large-Scale Recalls Demonstrate That More Must be Done to Protect Consumers

The prevalence of *L. monocytogenes* in ready-to-eat meat products also is reflected in the both the number and the magnitude of recent recalls of contaminated products. Since January 1999, companies have recalled over 32 million pounds of ready-to-eat meat products.[9] Single recalls have involved 30 million pounds of various ready-to-eat meat products (distributed nationwide),[10] over two

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[3] Council for Agricultural Scienceand Technology, *Foodborne Pathogens: Risks and Consequences*, Task Force Report, No. 122 (1994), p. 45 [hereinafter cited as *CAST Report*].

[4] Jordan W. Tappero, *et al.*, "Reduction in the Incidence of Human Listeriosis in the United States: Effectiveness of Prevention Efforts?" *Journal of the American Medical Association*, Vol. 273, No. 14 (1995), p. 1118 [hereinafter cited as *Listeria Prevention Efforts]; CDC Foodborne Illness Estimates*, Table 3.

[5] *CDC Foodborne Illness Estimates*, Table 3.

[6] *CAST Report*, p. 44

[7] *CAST Report*, p. 34 (citing Jeffrey M. Farber, *et al*., "Microbiological Quality of Fresh and Frozen Breakfast-type Sausage Sold in Canada," *Journal of Food Protection*, Vol. 51 (1988), pp. 397-401.

[8] U.S. Department of Agriculture, Food Safety and Inspection Service, *Listeria Guidelines for Industry* (May 1999) (unpublished), p. 4 [hereinafter cited as *FSIS Guidelines* for Industry].

[9] U.S. Department of Agriculture, Food Safety and Inspection Service," 1999 Recall Reports," available at <http://www.fsis.usda.gov/OA/recalls/recdb/rec1999.htm>lnternet. A list of recalls of FSIS-regulated ready-to-eat foods is provided in the Appendix to this petition.

[10] Food Safety and Inspection Service, USDA, "Thorn Apple Valley Listeria Recall--Update and Amended List," January 28, 1999, available at <http://www.fsis-gov/OA/news/99-rc-05.htm>lnternet.

million pounds of beef franks,[11] over 126,000 pounds of bacon chips (distributed in nine -states),[12] 78,000 pounds of chicken burritos (distributed by a national airline),[13] over 33,000 pounds of turkey franks (distributed in six states),[14] and over 28,000 pounds of luncheon meat (distributed nationally).[15]

Unfortunately, *L.* monocytogenes-contaminated products have caused large outbreaks. The most recent example, a nationwide outbreak of listeriosis caused by ready-to-eat meat products manufactured by Sara Lee Corporation, resulted in 21 deaths (including six miscarriages/stillbirths) and 100 illnesses in 22 states. [16] The Sara Lee outbreak shows just how widespread and devastating a single outbreak can be. It also demonstrates that in the absence of microbial sampling of ready-to-eat products, vast quantities of contaminated product can escape detection and make their way to stores all around the country.

The products implicated in the Sara Lee outbreak were all produced in the company's Bil Mar plant located near Zeeland, Michigan.[17] Although the specific source of the contamination has not been conclusively identified, CDC has tentatively concluded that the bacteria were spread by contaminated dust particles stiffed up during replacement of a refrigeration unit in the plant over the Fourth of July weekend.[18] Contaminated hot dogs from the plant apparently caused the illnesses and deaths, although deli meats also may have been involved.[19] Illness onset dates for the outbreak were reported from August 2, 1998 to February 8, 1999.[20]

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[11] Food Safety and Inspection Service, USDA, " 1999 Recall Reports," October 13, 1999, available at <http://www.fsis.usda.gov/OA/recalls/recdb/rec1999.htm>lnternet

[12] Food Safety and Inspection Service, USDA, " 1999 Recall Reports**,"** July 26, 1999, available at <http://www.fsis.usda.gov/OA/recallls/recdb/rec1999.htm>Internet.

[13] "Chicken Burritos Recalled for Listeria," *Food Safety Net*, February 6, 1999. Culinary Foods, a subsidiary of Tyson Foods, recalled about 78,000 pounds of chicken burritos.

[14] Food Safety and Inspection Service, USDA, " 1999 Recall Reports," August 27, 1999, available at <http://www.fsis.usda.gov/OA/recalls/recdb/rec1999.htm>lnternet.

[15] Food Safety and Inspection Service, USDA, "1999 Recall Reports," January 15, 1999, available at <http://www.fsis.usda.gov/OA/recalls/recdb/rec1999.htm>lnternet.

[16] Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Listeriosis," *Press Release* (March 17, 1999), available at <http://www.cdc.gov/od/oc/media/pressre1/r990114.htm>lnternet [hereinafter cited *as Sara Lee Outbreak Press Release].*

[17] *Sara Lee Outbreak Press Release.*

[18] "CDC Finds Listeria Caused Outbreak Caused by Airborne Particles in Processing Plant," *Food Chemical News,* Vol. 1, No. 25 (July 14, 1999), p. 704; Alison Young, Jeff Taylor, and Janet L. Fix, "A Killer in Our Food: Special Report," *Detroit Free Press,* (August 26, 1999), p. 12 [hereinafter cited as *Detroit Free Press Report].*

[19] *Sara Lee Outbreak Press Release.*

[20] *Ibid.*

On December 22, 1998, Sara Lee initiated a voluntary recall of hot dogs and other ready-to-eat meat products produced at the Bil Mar plant.[21] During its investigation of the outbreak, CDC isolated the outbreak strain of *L. monocytogenes* from an opened and a previously unopened package of hot dogs manufactured at the Bil Mar Plant.[22]

Remarkably, the government's investigation revealed that the plant should have been alerted -- several weeks before the outbreak was first detected -- to a possible contamination problem on the very line that produced the tainted products. According to the CDC official in charge of the investigation, during the first six weeks after construction in the plant the positive rate for *Listeria*-like indicator organisms on hot dog production equipment climbed from 25 percent to 92 percent.[23] Unfortunately, the plant apparently did not respond to that clear indication of a potential hazard by testing its final products for the presence of *L monocytogenes*.[24] Under current regulations such testing is not mandatory.

Though the Sara Lee outbreak was notable both for the number of illnesses and deaths involved and for its broad geographic scope, neither of those characteristics should surprise those familiar with *L. monocytogenes* and the processed-meat industry. Many factors contribute to the potentially enormous magnitude of listeriosis outbreaks from contaminated ready-to-eat products: the lack of information about initial symptoms that would facilitate early detection, the long time period between exposure and illness onset, and the huge production and wide distribution of many processed-meat products.

The last factor has been made evident again and again by the numerous recent recalls of products contaminated with *L. monocytogenes.* Many of those recalls involved tens of thousands or more pounds of processed products that had been distributed to broad regions of the country. Although the recalled products are not associated with any broad-scale listeriosis outbreaks, it is possible, given the volume and wide distribution of the affected products, that they have caused illnesses and miscarriages that went unrecognized.

FSIS can take concrete steps to prevent future outbreaks by requiring producers of ready-to-eat products to test their products and plant environments for the presence of *L. monocytogenes,* so that problems are more likely to be detected before contaminated products reach consumers. FSIS's current sampling program for *L. monocytogenes* in ready-to-eat meat and poultry products is too limited to avert future outbreaks of listeriosis.

3. The Zero-Tolerance Standard for Listeria Monocytogenes in Ready-To-Eat Meat and Poultry Products is Necessary to Protect Consumers

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[21] *Ibid.*

[22] *Ibid*; Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Listeriosis -- United States, 1998-1999," *Morbidity and Mortality Weekly Review*, Vol. 47, No. 51, (1999), p. 1117.

[23] Remarks of Dr. Paul S. Mead, Centers for Disease Control and Prevention, at the 1999 Meeting of the International Association of Milk, Food, and Environmental Sanitarians (August 23, 1999); *Detroit Free Press Report* (August 23, 1999), p. 2.

[24] Detroit Free Press Report (August 23, 1999), p. 2.

In response to a 1989 CDC report linking listeriosis to turkey franks, FSIS introduced its zero-tolerance standard for *L. monocytogenes* in ready-to-eat processed meats.[25] By opting for the most stringent standard possible, the agency ensured that products containing any amount of the pathogen would be deemed adulterated and subject to immediate recall. Under the zero tolerance standard, there is no acceptable level of *L. monocytogenes* contamination for ready-to-eat meat and poultry products.

The zero-tolerance standard, which also was adopted by the U.S. Food and Drug Administration (FDA) for soft cheeses and other ready-to-eat products, proved to be highly successful in its first few years of implementation.[26] Between 1987 and March 1992, FDA and FSIS initiated voluntary recalls for 543 products from 132 firms because of contamination with L. *monocytogenes*. [27] In 1992, after a CDC case-control study linked sporadic listeriosis with consumption of delicatessen-counter foods and soft cheeses, recommendations for avoiding exposure to *L. monocytogenes* were distributed, and the food industry strengthened its efforts to minimize contamination of food with the pathogen. A study examining listeriosis rates between 1989 and 1993 concluded that the zero-tolerance policy, along with various reforms initiated by the food industry to respond to it, had succeeded in reducing illness by 44 percent and deaths by 48 percent.[28]

The zero-tolerance standard should remain in effect. The considerations that led the government to implement the standard in the first place are no less valid today than they were in 1989. Specifically, all of the following still apply:

- Listeriosis is a severe illness that has the highest hospitalization rate and the second-highest case-fatality rate among foodborne pathogens;

- Once in food products, *L. monocytogenes,* unlike many other foodborne pathogens, can multiply while stored at refrigeration temperatures;

- Ready-to-eat products subject to the zero-tolerance standard, such as deli and luncheon meats, are usually consumed without further cooking; even hot dogs are sometimes consumed without reheating;

- The infectious dose for *L. monocytogenes* is not known, either for healthy consumers or for those who are at increased risk; and

[25] *Listeria Prevention Efforts, p*. 1118.

[26] Remarks of Thomas J. Billy, Administrator, Food Safety and Inspection Service, before the World Congress on Meat and Poultry Inspection (June 10, 1997), available at <www.fsis.usda.gov/oa/speeches/1997/world.htm>lntemet.

[27] United States Department of Agriculture, Food Safety and Inspection Service, and United States Department of Health and Human Services, Food and Drug Administration, *Preventing Foodborne Listeriosis* (992), p. 5.

[28] *Listeria Prevention Efforts*, p.1121.

- Detection of the disease can be delayed because a long time can pass after exposure to the pathogen before the illness becomes apparent and because there is little information available about early symptoms.[29]

Those considerations should lead FSIS to reject arguments by meat-industry representatives that zero-tolerance policy should be abandoned. Given the severity of listeriosis, current gaps in our understanding of the pathogen's infectious dose, and its ability to multiply during refrigerated storage, setting a "safe" tolerance level in ready-to-eat meat and poultry products would be tantamount to gambling with consumers' lives. Instead, FSIS should continue to enforce the zero-tolerance policy until reliable scientific evidence shows that a less stringent standard would be equally protective of human health. Such evidence currently does not exist.

4. FSIS Should Require that Plants Producing Ready-To-Eat Meat and Poultry Products Conduct Microbial Testing of Their Plant Environment and Final Products

The Sara Lee outbreak and the recent recalls of *L.* monocytogenes-contaminated ready-to-eat meat and poultry products make it clear that FSIS must take further action to safeguard consumers. The existing system, which relies heavily on limited random sampling of final products by FSIS, has not kept contaminated products off supermarket shelves. As things currently stand, the HACCP program for ready-to-eat products is not truly preventive; all too often it takes the detection of human illnesses to signal a flaw or breakdown in a producer's *L. monocytogenes-control* systems.

FSIS could easily transform the HACCP program for ready-to-eat products into a preventive food-safety system by mandating that meat-processing plants conduct microbial testing for *L. monocytogenes* in both the plant environment and in final products. Mandatory microbial testing by the industry would serve three critical purposes: (1) it would enable companies to verify that their HACCP systems effectively control *L. monocytogenes* contamination in their products; (2) it would add teeth to, and facilitate 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; and (3) environmental testing would facilitate early detection of problems before products become contaminated. FSIS should require microbial testing by companies without further delay.

a. Verification of HACCP Systems

It is universally recognized that adequate verification is a core HACCP principle.[30] As FSIS explained in the preamble to its meat and Poultry HACCP/pathogen reduction rule, "[v]erification

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[29] "U.S. *Listeria* 'Zero Tolerance' Policy is Being Reviewed: Vanderveen," *Food Regulation Weekly*, Vol. 1, No. 30 (1998), p. 12 (quoting John Vanderveen, U.S. Food and Drug Administration, who described the factors that contributed to the zero-tolerance standard).

[30] *See, e.g.*, U.S. Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," *Federal Register*, Vol. 61, No. 144, (1996), p. 3 8817 (citing HACCP Principle No. 7: "HACCP systems must be systematically verified") [hereinafter cited as M*eat and Poultry HACCP Final Rule*]; Food and Drug Administration, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule," *Federal Register*, Vol. 60, No. 242, (1995), p. 65129 ("Verification is one of the seven commonly recognized HACCP principles."); National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point System* (March 20, 1992); "Hazard Analysis and Critical Control Point Principles and Application Guidelines, *J. Food Protect.*, Vol. 61, No. 6, (1998), pp. 762-775; Food and Agriculture Organization of the United Nations,

of HACCP plans by establishments is designed to demonstrate that the HACCP plan is accomplishing process control and resulting in the production of safe food on a continuing basis".[31] Because safe food is the bottom-line demand of consumers, verification plays a crucial role in any HACCP program.

FSIS took an important step in May 1999 when it confirmed that, absent scientific evidence to the contrary, *L. monocytogenes* specifically must be controlled for by plants' HACCP plans because it is a hazard reasonably likely to occur in ready-to-eat meat and poultry products.[32] CSPI welcomed FSIS's demand that plants reassess their HACCP plans to ensure that they effectively address *L. monocytogenes* contamination. Unfortunately, however, FSIS's action fell short because the agency did not prescribe any meaningful verification mechanism for assessing whether the plants' HACCP plans, reassessed or not, are successfully controlling *L. monocytogenes* contamination on a continuing basis. Without thorough and ongoing verification, it is impossible to determine whether plants' interventions against the pathogen actually are working, leaving consumers without any assurance that products are free from *L. monocytogenes.*

Microbial testing is the missing verification mechanism. Such testing is a cornerstone of FSIS's HACCP/pathogen reduction rule for slaughterhouses, which requires the industry to test carcasses for generic *E. coli* while government inspectors conduct *Salmonella* testing to determine whether the applicable pathogen-reduction performance standards are being satisfied.[33] According to FSIS data, that program of mandatory microbial testing -- with its built-in incentives for plants to implement the most effective intervention measures possible -- seems to have contributed to a dramatic reduction in *Salmonella* contamination levels in raw meat and poultry carcasses, as well as a corresponding decrease in salmonellosis among consumers.[34]

Unfortunately, under the existing meat and poultry HACCP regulations, microbial testing to gauge the efficacy of hazard-control programs is mandated for slaughterhouses only. Manufacturers of ready-to-eat meat and poultry products are not obliged to do so. As a result, there is no meaningful way for the government to verify that plants' HACCP plans are effectively preventing *L. monocytogenes* contamination. Instead, as the Sara Lee outbreak shows, problems come to light under the most tragic of circumstances: illnesses and deaths among the consumers of a manufacturer's products. Thus, without

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Food Safety Through HACCP -- The FAO Approach, *Food, Nutrition Agriculture*, Vol. 15, available at <http://www.fao.org/docrep/v9723t/v9723t0e.htm#haccp principles>Internet.

[31] *Meat and Poultry HACCP Final Rule,* p. 38827.

[32] U.S. Department of Agriculture, Food Safety and Inspection Service, "Listeria monocytogenes Contamination of Ready-to-Eat Products," *Federal Register*, Vol. 64, No. 101 (1999), pp. 28351-353.

[33] *Meat and Poultry HACCP Final Rule,* p. 38837-854.

[34] U.S. Department of Agriculture, Food Safety and Inspection Service, "Progress Report on Salmonella Testing of Raw Meat and Poultry Products," *FSIS Backgrounder,* (October 1999), available at <http://www.fsis.usda.gov/OA/background/saimtest4.htm>lnternet; U.S. Department of Agriculture, Food Safety and Inspection Service, "HACCP Implementation: First Year Salmonella Test Results: January 26, 1998 to January 25, 1999," *FSIS Backgrounder*, available at <http://www.fsis.usda.gov/OPHS/salmdata.htm>lnternet; Centers for Disease Control and Prevention, "Incidence of Foodborne Illnesses: Preliminary Data from the Foodborne Diseases Active Surveillance Network (FoodNet) – United States, 1998," *Morbidity and Mortality Weekly Report*, Vol. 48, No. 9 (1999), pp. 189-193.

mandatory in microbial testing in processing plants, HACCP is not an adequate hazard-prevention system for ready-to-eat meat and poultry products.

FSIS can address this shortcoming in the existing regulatory program by mandating *L. monocytogenes* testing as a HACCP-verification mechanism in all processed-meat plants. Such a requirement would better enable both the federal government and the industry to identify problems in plant HACCP plans ***before*** contaminated products ever enter the stream of commerce.[35]

b. Enforcement of the Zero-Tolerance Standard

While on paper the federal government's zero-tolerance standard for *L. monocytogenes* in ready-to-eat foods appears to be a strong response to a substantial public-health risk, FSIS enforcement of the standard is too weak to afford consumers much protection against contaminated products. As previously stated, FSIS enforces the standard by randomly testing approximately 3,500 samples each year of both domestic and imported ready-to-eat meat and poultry products for the presence of *L. monocytogenes*.[36] When a confirmed positive sample is found, the agency asks the company to initiate a recall of all affected products and publicizes the recall to inform consumers of the contamination problem.[37]

Obviously, that approach is extremely limited in scope. The 3,500 samples, not all of which are domestic products, account for only a tiny fraction of the total yearly production of FSIS-regulated ready-to-eat products that are subject to the zero-tolerance standard. While additional testing by state regulators increases the number of products sampled, absent a dramatic expansion in government sampling such programs alone will never afford consumers an adequate level of protection against contaminated retail products.

A truly effective enforcement scheme for the zero-tolerance standard would augment government sampling with ongoing, systematic testing of products from all processed-meat plants. The surest and most efficient way to achieve such an expansion in the *L. monocytogenes* sampling program would be to require that every plant test its own products, using statistically valid sampling methods, for the presence of the pathogen.

In addition to helping plants detect and correct contamination problems before they can cause human illness, such a program would create a documentary record of plants' abilities to control the pathogen over time. Evidence of repeated serious problems, as reflected in a plant's paperwork, would provide a basis for aggressive agency action, including plant closure where a serious threat to public health exists.

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[35] Contrary to the assertions of some in the industry, mandating microbial testing is not tantamount to dictating critical control points. Microbial testing serves as a means of verifying the efficacy of HACCP plans and a regulatory tool for enforcing the zero-tolerance standard; plants would remain free to design their own HACCP plans and sampling programs -- including the identification and management of critical control points -- to account for the unique features of their operations.

[36] U.S. Department of Agriculture, Food Safety and Inspection Service, "FSIS Action Plan for Addressing *Listeria monocytogenes*," *FSIS Backgrounder*, (May 1999), p. 2.

[37] Ibid., pp. 2-3

Mandatory testing by the industry also would greatly expand the pool of available data on *L. monocytogenes* contamination in ready-to-eat meat and poultry products. That information could help the government and industry better identify and track contamination trends based on product type, plant geographical location, seasonality, etc. The expanded information base could also help to fill some of the data gaps in the federal government's current quantitative risk assessment for *L. monocytogenes*.[38]

An additional important benefit of mandatory industry testing is that it would encourage the meat-processing industry to develop and implement effective interventions specifically aimed at eliminating *L. monocytogenes* contamination. Because industry testing would increase the likelihood of detecting contamination -- resulting in more frequent recalls and associated costs -companies would have a strong incentive to introduce innovative, more effective interventions (such as cooking packaged products a second time) or to redesign their post-cooking systems to eliminate environmental exposure to the pathogen. The net effect would be an industry-wide effort to improve the safety of ready-to-eat products.

Finally, by making industry testing mandatory, FSIS would address a disturbing development that has been reported in the press: the unwillingness of some companies to test their products for *L. monocytogenes* based upon advice from their lawyers.[39] Clearly, some in the industry prefer to remain willfully ignorant of a potentially deadly problem and will not conduct microbial testing unless required to do so by FSIS regulations. The agency should stop that unconscionable practice by mandating microbial testing by all producers of ready-to-eat meat and poultry products.

C. Early Detection of Potential Contamination Problems

In addition to mandatory microbial testing of final products, FSIS should require plants to test their environments for the presence of *L. monocytogenes* itself or, better yet, more prevalent indicator organisms.[40] As both FSIS and industry groups recognize, such testing is a critical component of contamination-prevention programs for ready-to-eat products.[41]

Environmental testing can serve as an early-warning system for contamination problems. Detection of *L. monocytogenes* or an appropriate indicator organism alerts manufacturers that a

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[38] The federal government's *L. monocytogenes* risk assessment is discussed in greater detail in Section III (A)(7) below.

[39] Marian Burros "Experts Concerned About Return of Deadly Bacteria in Cold Cuts," *New York Times*, (March 14, 1999), p. 23.

[40] Whether companies test for *Listeria* spp. or other organisms as an indicator for *L. monocytogenes* contamination, their test methodologies should be fully validated. *FSIS Listeria Guidelines*, p. 5. The indicator organisms and tests should be chosen carefully to ensure that false negatives do not occur.

[41] *FSIS Listeria Guidelines*, pp. 5-7, 9-11; National Food Processors Association, *Guidelines to Preventing Post Processing Contamination from* Listeria monocytogenes, *First Edition*, (unpublished), April 1999, pp. 13-16 [hereinafter cited as *NFPA Guidelines];* 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*, (unpublished), April 1999, pp. 13-20; ConAgra Refrigerated Prepared Foods, *ConAgra Refrigerated Prepared Foods' Current Strategy* for Listeria monocytogenes, (unpublished), Updated May 19, 1999, pp. 2-4 [hereinafter cited as *ConAgra Strategy*].

particular plant location or piece of equipment has become contaminated and may threaten to contaminate products if the problem remains uncorrected. Especially where the bacteria is found on surfaces that come into direct contact with foods -- or that may indirectly cause contamination to spread to food by means of dripping water, dust particles, or the like -- plants should take immediate and aggressive action to determine the source of the contamination and eliminate it. Unless comprehensive environmental sampling is being conducted, such problems may not be revealed until consumer illnesses are linked to contaminated products.

In Section 5(a) below, we describe what CSPI believes to be the essential components of an environmental sampling program for *L. monocytogenes*. FSIS should require that plants adopt programs that include all of those components, or alternatives that yield an equivalent degree of protection.

5. Components of a Mandatory Microbial Testing Program for Plant Environments and Final Products

CSPI is not alone in emphasizing the importance of microbial testing in preventing ready-to-eat meat and poultry products from becoming contaminated with *L. monocytogenes.* In the wake of the Sara Lee outbreak, both the federal government and the processed-meat industry developed guidelines outlining effective measures that companies should implement to eliminate *L. monocytogenes* from their products. Those guidelines sounded a consistent theme: microbial testing of plant environments is necessary to alert companies to potential contamination problems in their plants, and final-product testing is a useful means of assuring that control measures in the plant are effective in eliminating *L. monocytogenes* from products.[42]

The government and industry guidelines provide a solid foundation upon which to build a set of mandatory regulations for environmental and final-product testing. The guidelines share a number of common elements that should be included in a mandatory microbial-testing program. Rather than discuss all of the elements in detail, below we briefly outline those that CSPI believes should be included in a mandatory program.

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[42] FSIS's own guidelines state, "Establishments with limited resources should establish end product sampling as their top priority, followed by product contact surface/non-product contact surface testing." *FSIS Listeria Guidelines. p.* 5. NFPA's guidelines explain the importance of environmental sampling as follows:

> An environmental monitoring program is necessary to assess the need for additional pathogen control measures for products that may be recontaminated by *L. monocytogenes*. Industry experience has shown that an ongoing monitoring and control program that uses *Listeria* species ... as an indicator of potential *L. monocytogenes* contamination not only reduces the possibility of finding *L. monocytogenes* in finished product but other pathogens as well. Industry experience also shows that reentry of *Listeria* spp. Into the production environment cannot be reliably prevented. Thus, ongoing monitoring to detect the organism in the environment is necessary.

NFTA Guidelines, p. 13. NFPA's guidelines also state that random final-product testing "may be used to verify that the *L. monocytogenes* control/monitoring program is effective in preventing product contamination." *Id.*, p.15.

a. Environmental Sampling

Environmental sampling would serve as an early-warning system to alert plants of a potential contamination problem. Accordingly, companies should be required to test for the presence of *Listeria* spp. or *Listeria*-like organisms, rather than *L. monocytogenes* itself, because the indicator organisms are more likely to be found in the plant environment and the test results are available more quickly.[43] Reliance on an appropriate indicator rather than the pathogen itself should afford a greater degree of protection because the broader scope of organisms detected by the test will minimize the likelihood of false negatives.

Regulations also should require that plants devise an environmental sampling scheme that includes both product-contact and non-product-contact surfaces. Although plant surfaces that do not come into direct contact with product are less likely to transfer pathogens to foods, transmission can occur by indirect means (e.g., by means of wheels on rolling bins or carts, dripping liquids, air-borne dust particles, etc.). In addition, a positive test result on non-product-contact surfaces can provide the earliest indication that substantial amounts of *Listeria* have infiltrated the plant environment, so that immediate measures can be taken to avert further distribution of the bacteria in the plant.

Under a mandatory environmental-sampling scheme, testing should be required to be done regularly, but on a random, statistically valid basis so that problems will not inadvertently be overlooked. Companies should be required to validate their microbial-testing programs to assure the statistical significance of the results.

As the missed opportunity in the weeks leading up to the Sara Lee outbreak shows, perhaps the most critical component of an environmental-sampling program is the set of corrective actions that must be followed when positives are detected. Companies should be required to specify in their HACCP plans exactly how findings of *Listeria* contamination in the plant environment will be dealt with. FSIS should require that corrective actions be progressive; that is, a positive result should trigger additional, more focused testing of the plant environment and potentially contaminated product. For instance, when non-product-contact surfaces test positive, regulations should require that plants step up their sanitation measures, product-contact-surface testing, and final-product testing.[44]

In addition, trends toward an increase in environmental contamination should be identified and subjected to further investigation. Where the initial positive is obtained from a composite sample (that is, a sample of multiple surfaces), additional, more localized sampling should be required.

Detection of *L. monocytogenes* or indicator organisms on surfaces that contact ready-to-eat foods should elicit a stronger response. At the very least, regulations should require shut down, dismantling, cleaning, and re-sanitization of all product-contact surfaces that test positive, as well as additional testing to verify that the surfaces are decontaminated. In addition, such a finding should trigger increased testing of final products from the affected line, with retention of product pending test results, until the situation is demonstrated to be under control.[45]

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[43] *NFPA Guidelines*, p. 13; *ConAgra Strategy*, p. 2.

[44] *FSIS Listeria Guidelines*, p. 6; *NFPA Guidelines*, p. 15

[45] *ConAgra Strategy*, p. 2.

Finally, as with all aspects of a plant's control plan for *L. monocytogenes,* the regulations should mandate that plants fully document any contamination findings, including the reason for contamination and steps taken to correct the problem and prevent future incidents.[46]

b. Final-Product Testing

Final-product testing for *L. monocytogenes* would serve two important purposes: it would facilitate enforcement of the zero-tolerance standard by greatly expanding the pool of products sampled, and it would enable plants to verify that their HACCP plans are effectively controlling for *L. monocytogenes* contamination. To achieve both objectives, regulations mandating final-product testing should include the following components:

- The regulations should require that sampling be systematic -- that is, performed regularly but on a random, statistically valid basis so that problems are less likely to escape detection;[47]

- The regulations should mandate that product be retained at the facility until negative results are obtained, to better protect consumers and to obviate the need for massive recalls. In addition, because even extensive sampling may not prevent all contaminated product from entering commerce, plants should be require to define lot sizes appropriately, so that all potentially contaminated product can be identified and recalled if positive product is detected;[48]

- To help companies develop their microbial testing regimes, FSIS should publish detailed guidelines in conjunction with its regulations. Based upon data from the agency's decade-old random sampling program, as well as any relevant data from the federal government's ongoing quantitative risk assessment for *L. monocytogenes,* FSIS should advise companies about how best to sample the different types of products they produce;

- Final-product testing should be stepped-up when positive environmental samples are detected, though such testing should be conducted on an ongoing basis even when environmental testing yields no positives. As FSIS's current guidelines recommend, plants should be required to increase the sampling intensity for products that are exposed to the plant environment after cooking but before final packaging.[49] In

[46] *FSIS Listeria Guidelines,* p. 6.

[47] CSPI recognizes that even a carefully conceived final-product testing program cannot guarantee that contamination problems will be detected before distribution of the affected product, due in part to limits in current detection methods and the pathogen's ability to grow even while refrigerated. However, mandatory final-product testing by the industry should significantly decrease the likelihood that contaminated products escape detection, as compared to the existing FSIS sampling scheme.

[48] *NFPA Guidelines,* p. 15 (stating that "[all sampled lots should be held until the laboratory results are available.").

[49] *FSIS Listeria Guidelines,* p. 7

addition, trends toward repeated or increasing product contamination should be identified and corrected without delay; and

- The results of final-product testing, like those of environmental sampling, should be subject to stringent documentation standards. Among other things, companies should be required to record all findings and include a reason for positive findings and the steps taken to correct the problem and prevent future incidents.[50]

6. FSIS Should Take Appropriate Enforcement Action Based On Industry Final-Product Testing

FSIS should develop a program for taking enforcement action based upon the results of industry testing for *L. monocytogenes.* Regulations should require that companies alert FSIS immediately upon detection of confirmed positives in finished-product samples. In response, the agency should ensure that all affected products in the company's possession are destroyed or otherwise treated to eliminate the pathogen, and that all affected products that have already entered commerce are immediately recalled.

Under that scheme, positive findings from industry testing would be treated in the same manner as positives from FSIS's own *L. monocytogenes* sampling program, as required under the zero-tolerance policy. Regardless of who is doing the testing, all affected products must be treated as adulterated and subjected to immediate recall.

In addition to an enforcement mechanism based upon the results of industry testing, FSIS should develop a plan to carefully monitor, on an ongoing basis, all environmental and final-product testing data from plants producing ready-to-eat meat and poultry products. Such data would provide a wealth of new information about the prevalence of the pathogen in various types of products and the effectiveness of different control measures used by processing plants. FSIS should regularly incorporate the new information into the agency's overall *L. monocytogenes* regulatory strategy.

Ongoing monitoring of the data from industry environmental testing is necessary to avoid repeating a situation such as that which apparently occurred in the Bil Mar plant, where no additional scrutiny of the plant's processes was made despite a dramatic increase in environmental contamination rates during the weeks leading up to the outbreak. FSIS inspectors should be required to review environmental data to ensure that such problems are rapidly detected and aggressively investigated and corrected.

Moreover, the new regulations should authorize FSIS to take swift and aggressive regulatory action where trends in plant-testing data indicate a serious problem. If circumstances warrant -- for instance, where a plant repeatedly fails to produce *L. monocytogenes*-free product -- the agency should be able (and willing) to close down the plant until it demonstrates that it can gain control over its processes.

7. FSIS Should Not Await the Outcome of a *L. monocytogenes* Risk Assessment Before Mandating Microbial Testing

[50] *Ibid*., p.6.

Considering the risk to consumers, FSIS should take the regulatory action requested in this petition now, without awaiting the outcome of the federal government's ongoing *L. monocytogenes* risk assessment or undertaking its own risk assessment for the pathogen. To be sure, quantitative risk assessment eventually may yield insights into how best to address the public-health threat posed by the pathogen. However, given the abundance of data gaps and holes in our understanding of the factors that contribute to the pathogen's ability to cause illness,[51] risk assessments are not likely to provide reliable data to support rulemaking for quite some time.

Meanwhile, enough currently is known about the pathogen to enable FSIS to develop a meaningful regulatory response to the problem in the form of required microbial testing in processed-meat plants. For instance, there is no question that *L. monocytogenes* is capable of contaminating virtually all types of ready-to-eat meat and poultry products sold in the U.S. and that such foods can sicken or kill vulnerable consumers: the Sara Lee outbreak and the recent large-scale recalls of contaminated ready-to-eat products demonstrate that. In addition, available data show that the pathogen, once found in such products, can continue to multiply even at refrigeration temperatures, making it crucial to eliminate the organism at the processing plant. Finally, it is obvious from the large number of recent recalls of *L. monocytogenes*-contaminated products that FSIS's current random-sampling program is not comprehensive enough to keep huge volumes of potentially hazardous foods off the market.

Given all that is currently known about the public-health hazard posed by *L. monocytogenes* in ready-to-eat meat and poultry products, it is clear that a well-designed program of mandatory microbial testing in processing plants is necessary to better protect consumers from the pathogen. Regardless of the specific outcomes of the government's quantitative risk assessment, mandatory industry testing will remain a key component of a comprehensive strategy to prevent *L. monocytogenes*-contaminated products from reaching consumers, because such testing is the surest way to verify the efficacy of industry HACCP plans and to strengthen enforcement of the zero-tolerance standard. FSIS therefore should take immediate regulatory action to develop and implement a mandatory microbial-sampling program, without awaiting completion of the federal government's ongoing risk assessment or embarking upon its own risk assessment.

Of course, FSIS should be willing to refine the mandatory microbial-testing program to take into account any relevant data from the risk-assessment process. Requirements for industry sampling should be adjusted if scientifically justified by data obtained during risk assessment. Moreover, if analysis shows that particular intervention measures, plant designs, or other elements are particularly

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[51] During presentations at the September 23, 1999 meeting of the National Advisory Committee on Microbiological Criteria for Foods, various government personnel involved in the *L. monocytogenes* risk assessment noted the following data gaps, among others:

(1) very limited data on consumption levels of beef, pork, and poultry ready-to-eat products;
(2) difficulty in correlating *L. monocytogenes* serotypes with the magnitude of risk for listeriosis in susceptible populations;
(3) few human epidemiological studies of listeriosis outbreaks meeting quantitative requirements for the risk assessment;
(4) extremely limited dose-response data from relevant animal studies; and
(5) available host-susceptibility data is from studies that reflect extreme immunological scenarios (e.g., knockout mice).

effective in reducing the risk of *L. monocytogenes* contamination in ready-to-eat meat and poultry products, FSIS should take steps to encourage -- and perhaps even mandate -- adoption of such elements into plants' processes.

We emphasize that CSPI strongly supports the government's effort to conduct a quantitative risk assessment for *L. monocytogenes.* Especially in its early stages, that process will help to identify the important data gaps that currently exist, and we encourage the government and industry to sponsor and conduct additional research aimed at elucidating the bacterium's pathogenic characteristics. However, FSIS should not await completion of this lengthy process before taking the common-sense step of requiring the industry to test its plants and final products for the presence of the pathogen.

8. 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 *L. monocytogenes* should not spell the end of FSIS's existing random-sampling program. Rather, FSIS should continue to sample final products from plants on a random basis to ensure that industry programs are working and to provide an additional layer of protection.

FSIS should, however, direct its limited resources to those plants and products that pose the greatest risk to consumers. As data from both the industry sampling program and the government's *L. monocytogenes* risk assessment are analyzed, FSIS should revise its sampling program to concentrate on the plants and products posing the greatest risk of *L. monocytogenes* contamination.

FSIS has indicated that it intends to exempt from the government sampling program those plants that conduct their own tests, using as a model the agency's current *E. coli* O157:H7 sampling program under Directive 10,010.1. CSPI agrees that such an approach eventually may be appropriate, but we urge FSIS to refrain from exempting any plants from random government sampling until the industry testing program is well underway and the agency has had an opportunity to evaluate it. Rather than wholly exempting certain plants from FSIS sampling, the agency should instead 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.

9. Pending Final Adoption of a Mandatory Microbial Testing Program, Ready-To-Eat Meat and Poultry Products Should be Required to Bear a *L. monocytogenes* Safe-Handling Label

As FSIS advised consumers in the wake of the Sara Lee outbreak, ready-to-eat meat and poultry products are not truly ready-to-eat for people who are especially vulnerable to foodborne illness.[52]

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[52] That fact is reflected in FSIS's advice to especially vulnerable consumers:

> 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.*

Yet those products are both labeled as ready-to-eat and bear a USDA shield, creating the misimpression that they are safe to consume without further cooking.

To protect at-risk consumers until the entire industry is required to test for the presence of *L. monocytogenes* in plants and end products, all ready-to-eat meat and poultry products 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.

CSPI views such a labeling requirement merely as an interim measure pending adoption of a final rule requiring microbial testing in all processing plants, which, presumably, would lead to much safer food. In fact, FSIS could exempt from the label requirement those plants that voluntarily conduct microbial testing under a regime such as that proposed in this petition, provided that it proves effective at substantially lowering contamination rates.

B. Legal Authority

1. The FMIA and the PPIA Authorize FSIS to Mandate Microbial Testing of Plants Producing Ready-to-Eat Meat and Poultry Products and their End Products.

The same legal authority that supports *E. coli* and *Salmonella* testing in slaughterhouses under the HACCP/Pathogen Reduction rule authorizes FSIS to require plants producing processed meat and poultry products to conduct environmental and final-product testing for *L. monocytogenes*.

As FSIS explained in the preamble to the final HACCP/Pathogen Reduction rule, the FMIA and the PPIA give FSIS "ample statutory authority" to promulgate microbiological testing provisions.[53] The meat and poultry inspection statutes mandate federal regulatory oversight of "unusual intensity and comprehensiveness," and they provide the Secretary with broad rulemaking authorities to implement them.[54] As FSIS noted,

> [flrom their inception, the meat and poultry inspection laws have recognized that sanitary conditions in establishments are critical to the safety and wholesomeness of the products being produced. Any product found to have 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" is adulterated. No product will be granted inspection or marked "inspected and passed" unless the sanitary conditions and practices required by the Secretary are maintained.[55]

U.S. Department of Agriculture, Food Safety and Inspection Service, "FSIS Action Plan for Addressing *Listeria monocytogenes," FSIS Backgrounder*, (May 1999), p. 3 (emphasis added).

[53] *Meat and Poultry HACCP Final Rule*, p. 38851.

[54] *Ibid.*

[55] *Ibid*. (quoting 21 U.S.C. §§ 453(g) and 601(m)).

In the HACCP/Pathogen Reduction rule, FSIS invoked that authority to require that slaughterhouses conduct and document tests for microbial contamination. Such tests are FSIS's chosen means to measure how well plant sanitation is working to prevent contamination of products.

The agency's authority to use microbial testing to evaluate plant sanitation is not limited to slaughterhouses, but extends to meat and poultry processing facilities as well. Section 45 3 (g)(4) of the PPIA and § 601 (m)(4) of the FMIA, which define as adulterated any poultry or meat product that has been prepared, packed, or held under insanitary conditions, apply to all processed products.[56] Likewise, § 456 of the PPIA and § 608 of the FMIA, which direct USDA to prescribe rules and regulations for plant sanitation and forbid inspectors from marking products as "inspected and passed" if they are prepared under insanitary conditions that render them adulterated, apply to plants producing ready-to-eat products.

In addition to the foregoing provisions of the FMIA and the PPIA, each statute contains a general provision that supports the actions requested in this petition. Both the FMIA and PPIA include provisions that grant the Secretary broad authority to promulgate rules and regulations "necessary to carry out the Act[s]."[57] F SIS relied upon these provisions when it promulgated its HACCP/Pathogen Reduction Rule and they are equally applicable here.

2. The FMIA and the PPIA Authorize FSIS to Mandate Safe-Handling Labels for Ready-to-Eat Meat and Poultry Products That May Be Contaminated with *L. monocytogenes*

FSIS's authority to require safe-handling labels on food products derives from § 601(n)(12) of the FMIA and § 453(h)(12) of the PPIA. Under those provisions, a food is misbranded if it does not bear, in addition to the official inspection legend, "such other information as the Secretary may require ... to assure that [the food] will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the product in a wholesome condition." Thus, both the FMIA and the PPIA give the agency discretion to require labeling in addition to the official inspection stamp *See American Public Health Ass'n v. Butz*, 511 F.2d 331, 335 (D.C. Cir. 1974).

In the early 1970s, USDA declined to invoke that authority to require a warning label on uncooked meat and poultry products, a decision that was upheld by a federal appellate court. *See Butz*, 511 F.2d at 331-335. However, it is important to recognize that in *Butz* 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; 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

[56] Section 453(g)(4) of the PPIA applies to all "poultry products," which are defined in § 453(f) as including "any product which is made wholly or in part from any poultry carcass or part thereof." Similarly, § 601 (m)(4) of the FMIA applies to all "meat food products," which are defined in § 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." Thus, both § 453(g)(4) of the PPIA and § 601(m)(4) of the FMIA apply to ready-to-eat products.

[57] 21 U.S.C. §§ 463,621.

revisited the question and, in 1994, promulgated a rule requiring raw meat and poultry products to bear safe-handling instructions.[58]

Given the serious health threat posed by *L.* monocytogenes-contaminated processed-meat products, especially to those consumers most susceptible to foodborne illness, FSIS should again exercise its discretion under the FMIA and PPIA to require labeling information in addition to the official inspection stamp. The agency has already issued a brochure alerting consumers to the risk of listeriosis from ready-to-eat products and has advised especially vulnerable consumers to avoid eating such products unless they can be reheated to steaming temperatures.[59] FSIS should, as an interim measure pending finalization of the microbial-testing regulations requested in this petition, require that the products themselves bear such a safe-handling statement, as authorized by § 601(n)(12) of the FMIA and § 453(h)(12) of the PPIA.

3. FSIS Should Promulgate the Requested Regulations as an Interim Final Rule Without First Completing Notice and Comment, Risk Assessment, and Cost-Benefit Analysis

Ready-to-eat meat and poultry products contaminated with *L. monocytogenes* pose a serious, immediate threat to human health. FSIS, the agency responsible for protecting consumers from hazardous meat and poultry products, has a duty to respond to that threat by taking *immediate* regulatory action, without pursuing an unnecessarily lengthy rulemaking process. Under ordinary circumstances, the agency must comply with procedural requirements under both the Administrative Procedures Act (APA) and the USDA Reorganization Act of 1994, including the use of notice-and-comment rulemaking and the completion of a risk assessment and cost-benefit analysis before issuance of a new rule. However, both acts provide for exceptions to those requirements for circumstances such as those present here, where the new regulations would address an imminent threat to public safety and any delay in rulemaking would be contrary to the public interest.

FSIS should avail itself of those statutory exceptions and promulgate the requested regulations without first providing the public with notice and an opportunity for comment and before completing a full risk assessment and cost-benefit analysis. The agency should first adopt the regulations as an "interim-final rule," which would become binding upon publication (or shortly thereafter), and subsequently provide for public comment and complete its risk assessment and cost-benefit analysis.[60] As explained below, FSIS is authorized to take such an approach under both the APA and the USDA Reorganization Act of 1994.

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[58] U.S. Department of Agriculture, Food Safety and Inspection Service, "Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products; Final Rule," *Federal Register*, Vol. 59, No. 59, (1994), pp. 14528-540.

[59] U.S. Department of Agriculture, Food Safety and Inspection Service, Listeriosis and Food Safety Tips (Brochure), May 1999.

[60] *See* Michael Asimow, "Interim-Final Rules: Making Haste Slowly," *Admin. L. Rev.*, Vol. 51, (Summer 1999), pp. 703-744 (describing numerous administrative agencies' use of interim-final rules as a pragmatic tool to “strike a compromise between a perceived need for immediate adoption of a rule and the values of public participation and regulatory analysis”).

a. The Requested Regulations Satisfy the "Good Cause" Exception to the Administrative Procedure Act's Requirement for Notice and Comment

The APA provides that full notice-and-comment rulemaking is not required when an agency "for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §553(b)(B). The good cause exception "is an important safety valve to be used where delay would do real harm." *United States Steel v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979). According to the legislative history of the provision, "'impracticable' means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." S. Rep. No. 752, 79th Cong., 1st Sess., at 16 (1945). As one court has held, determining "impracticality" requires "analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment." *American Transfer & Storage Company v. ICC*, 719 F.2d 1283, 1295 (5th Cir. 1983).

There are numerous instances in which courts have upheld an agency's decision to invoke the "good cause" exception and issue a rule without providing for notice and comment where a delay would threaten public safety or the environment. *See, e.g., Hawaii Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (good cause exception satisfied in view of "the threat to public safety reflected in an increasing number of helicopter accidents"); *Northern Arapahoe Tribe v. Hodel*, 808 F.2d 741, 750-52 (10th Cir. 1987) (good cause exception satisfied in view of urgent need for hunting regulations where herds were threatened with extinction); *Northwest Airlines-v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (good cause exception satisfied in view of urgent need to allocate landing slots at major airport).

The rationale underlying those decisions, that compliance with time-consuming procedural requirements would "do real harm" by delaying implementation of urgently needed regulations to safeguard public health, is equally applicable here. *L. monocytogenes*-contaminated meat and poultry products pose an imminent threat to public health, having very recently caused a major outbreak that resulted in 21 deaths and 100 illnesses. Repeated large-scale recalls of such products demonstrate that the problem is not under control, jeopardizing the health of consumers throughout the country. Under such circumstances, any delay in requiring the processed-meat industry to test its plants and final products for the presence of *L. monocytogenes* would pose a serious threat to public safety. Clearly, the exigent circumstances necessary to satisfy the APA's good cause exception are present.

b. The Requested Regulations Present a Situation In Which Regulatory Analysis is "Not Practicable Because of Compelling Circumstances" Under the U.S. Department of Agriculture Reorganization Act of 1994

Under § 2204e of the USDA Reorganization Act of 1994, USDA must complete a risk assessment and cost-benefit analysis for each proposed major regulation that relates to human health, safety, or the environment. 7 U.S.C. § 2204e. That section does provide an exception, however: when a risk assessment and cost-benefit analysis is "not practicable because of compelling circumstances," an explanation can be provided in lieu of a full analysis. *Id.* at § 2204e(b)(1).

USDA's Office of Risk Assessment and Cost-Benefit Analysis, which has been in operation for only five years, has yet to exempt a proposed rule from the regulatory-analysis requirement. Nevertheless, CSPI asserts that the rulemaking requested in this petition readily satisfies the exemption. The imminent public-health threat posed by *L. monocytogenes*-contaminated ready-to-eat meat and

poultry products presents the “compelling circumstance” needed to justify the promulgation of regulations without undertaking a full risk assessment and
cost-benefit analysis.

The Sara Lee outbreak demonstrates that many ready-to-eat meat and poultry products are widely distributed and, if contaminated with *L. monocytogenes*, can kill or sicken hundreds of consumers throughout the country. Ominously, the numerous recalls that have been undertaken since the Sara Lee outbreak -- some involving millions of pounds of *L. monocytogenes*-contaminated product -- show that the pathogen remains prevalent in processed-meat products and that many plants are not effectively addressing the problem under their HACCP plans. Luckily, so far the recalled products apparently have not sickened or killed any consumers. But it is reasonable to expect that, absent immediate adoption of the regulations requested in this petition, consumers' good fortune cannot continue indefinitely, and that a new deadly outbreak of listeriosis will produce another national tragedy.

CSPI contends that this imminent threat constitutes the "compelling circumstances" necessary to permit FSIS to adopt the requested regulation without first completing a full regulatory analysis. FSIS instead should publish the regulations as an interim final rule and provide an explanation for its rulemaking as contemplated under § 2204e(b)(1) of the USDA Reorganization Act.

c. If FSIS Believes That It Cannot Promulgate the Requested Regulations As an Interim Final Rule, It Should Take All Steps Necessary To Expedite Adoption of the Regulations

If FSIS concludes that it cannot promulgate the requested regulations without first pursuing notice-and-comment rulemaking and completing a risk assessment and cost-benefit analysis, the agency should commence the requisite rulemaking immediately and finalize the regulations as quickly as possible. Resources from other, less pressing regulatory activities should be reassigned to the development of the requested regulations, and all necessary components of the rulemaking process should be undertaken simultaneously, rather than sequentially, to eliminate any delay in the process. FSIS should also inform the Office of Management and Budget that exigent circumstances demand rapid review and approval of the rule.

In addition, if the agency does not publish the requested regulations as an interim final rule but instead undertakes a lengthy rulemaking process, it should take immediate action to require safe-handling labels on all ready-to-eat meat and poultry products as an interim measure to protect consumers.

III. Conclusion

The events of the past year make it clear that ready-to-eat meat and poultry products contaminated with *L. monocytogenes* pose a serious health threat, especially to older people, infants, pregnant women, and others who are most vulnerable to foodborne illness. The Sara Lee outbreak leaves little doubt that the pathogen is among the most hazardous in the food supply. And as the huge recalls of *L. monocytogenes*-contaminated products continue unabated, consumers are left to wonder not whether, but when and where, the next deadly outbreak will occur.

Unfortunately, the existing regulatory system fuels, rather than allays, that concern. Because the mandatory microbial-testing provisions of FSIS's highly touted HACCP program do not extend to processors of ready-to-eat products, it is unlikely that contamination problems will be detected

before large volumes of tainted products are distributed to supermarkets. Nor can consumers be sure under the existing system that the federal government is adequately verifying the continuing effectiveness of companies' *L. monocytogenes*-control processes.

FSIS can easily address those dangerous shortcomings in the existing regulatory program by developing a mandatory microbial-testing rule based upon the recommended practices in the agency's -- as well as the industry's -- guidance documents. By requiring companies to test both their plant environments and their final products, FSIS would transform the HACCP program for processed-meat products into a truly preventive food-safety system. CSPI urges the agency to take that step without further delay, before another outbreak of listeriosis claims more lives.

Appendix

FSIS 1999 Recall Listings:
Ready-to-Eat Meat Products Contaminated with *Listeria*

Date	Company/ Establishment	Location	Product	Amount (lbs.)	Distribution
1/15	Oscar Mayer Foods Corp.	Madison, WI	luncheon meat	28,313	Nationwide, Puerto Rico, Singapore, Bermuda, Aruba, St. Martin, Dominican Republic
1/22	Bosell Foods	Cleveland, OH	sliced ham	349	PR
1/22	Thorn Apple Valley	Forrest City, AR	various ready-to-eat meat products	30 million	Nationwide, International
2/2	Culinary Foods	Chicago, IL	chicken burritos	26,975	Nationwide
2/5	B.B. Meat & Sausage MFG, Inc.	Bellingham, WA	hot dogs, brockwurst	1,545	WA, OR, AK
2/17	Ba Le Meat Processing & Wholesale, Inc.	Chicago, IL	Head Cheese	2,600	NY, PA, IL, MN, NC, MD, MA, GA, CA, TX, FL
2/18	Lowell Packing Company	Fitzgerald, GA	franks, smoked sausages	4,460	GA,AL
3/2	Culinary Foods, Inc.	Chicago, IL	pasta with sausage	1,923	IL, NY
3/18	Philadelphia Foods, Inc.	Westville, NJ	franks	18	NJ
5/14	White Packing Company	Williamstown, NC	bologna, ham, salami, etc.	16,392	SC, NC, VA, NY, NJ
5/28	The Alpine Wurst & Meat House	Honesdale, PA	weisswurst	60	PA
6/1	Valley Meat Supply	Valley City, ND	weiners, frankfurters	150	ND
6/4	Real Sausage Company	Chicago, IL	skinless franks	1,285	IL
6/18	Redondo's Inc.	Waipahu, HI	frankfurters	9,620	HI
7/27-8/16	Marburger Packing Inc.	Peru, IN	bacon bits and bacon pieces	135,906	IA, MT, WA, NE, TN, TX, KY, OR, IL, OH, AL, OK, MI, WI, NC, FL, MN, UT, MS

7/29	Dearborn Sausage Co., Inc.	Dearborn, MI	ham	200	MI
7/30	Gerrity's Supermarket, Inc.	Kingston, PA	hot dogs	200	PA
7/30	Loeffer's Gourmet, Inc.	Trenton, NJ	roasting sausage	200	NJ
8/26	Medina & Medina	San Juan, PR	chiorzios	1,640	PR
8/27	Gaspar's Sausage Company, Inc.	Dartmouth, MA	sausage	3,720	RI, MA, CT
8/27	Foster Poultry Farms	Livingston, CA	turkey franks	33,710	CA, TX, UT, WA, NV, OR
9/9	Verl's Salads Inc.	Fredericksburg, PA	chicken salad	240	PA
10/13	Marathon Enterprises, Inc.	Bronx, NY	beef franks	2,100,000	Nationwide
11/11	Couch's Sausage	Garfield Heights, OH	hot souse meat	47	OH
11/12	Abe's Cajun Boudin, Inc.	Sulphur, LA	smoked sausage (pork and beef)	1,270	LA, TX
11/12	Uncle Louie Sausage Co	Kahului, HI	hot dogs	312	HI
11/12	Hy-Vee grocery store	Rochester, MN	lunchmeat	Unknown	MN
11/15	Sophie's Choice Meats	Cleveland, OH	cooked smokies	130	OH
11/17	Robbins Packing Co.	Statesboro, GA	hot dogs	1,020	GA
11/19	P.J.'s Inc.	Baltimore, MD	polish sausage	800	MD
12/2	J.L. Miller and Sons	York, PA	beef franks	4	PA
12/14	Foodarama Supermarkets, Inc.	Linden, NJ	sliced luncheon meats	900	NJ
12/29	Hannelore Gourmet Foods, Ltd.	Huntington, NY	Foie gras, other pate-type products	80,000	Nationwide, Canada

*Sources: Food Safety and Inspection Service, USDA, "1999 Recall Reports." (Available at http://www.fsis.usda.gov/OA/recalls/recdb/rec1999.htm>Internet)
Food Safety Net (Available at http://www.extension.iastate.edu/files/fscurrent/>Internet)