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

June 7, 2000

FSIS Docket Clerk
Docket No. 00-016N
US Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

00-016N
00-016N-2
Caroline Smith DeWaal
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Re: Notice of Public Meeting: Revised Action Plan for the Control of *Listeria Monocytogenes* for the Prevention of the Foodborne Illness Listeriosis
Docket No. 00-016N
65 Fed.Reg. 26563 (May 8, 2000)

On behalf of the Center for Science in the Public Interest (CSPI) and the following members of the Safe Food Coalition: the American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, and Safe Tables Our Priority, we appreciate this opportunity to provide comments on the Food Safety and Inspection Service's (FSIS) plans to protect the public from foodborne illnesses associated with *Listeria monocytogenes.* CSPI is a nonprofit consumer group with over one million members that focuses primarily on nutrition and food-safety issues. 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.

CSPI is pleased that FSIS is stepping up its efforts to combat *L. monocytogenes* in ready-to-eat meat and poultry products and that the agency is considering whether to implement the regulatory changes we urged in our January 13, 2000 petition.[1] However, based on FSIS's statements and presentations at its May 15 public meeting on *L. monocytogenes*, we are very concerned that the agency is developing new microbial-testing regulations based not on what will best protect consumers, but rather on what the processed-meat industry considers acceptable. Specifically, CSPI strongly opposes FSIS's proposal to require the industry to conduct only environmental testing -- and not final-product testing -- for *Listeria* in processing plants. Consumers will continue to face an unnecessary risk from foodborne listeriosis, and President Clinton's stated objective of cutting the number of illnesses caused by *L. monocytogenes* in half by 2005 will remain unfulfilled, unless FSIS reverses its misguided position and instead proposes regulations requiring producers of ready-to-eat meat and poultry products to test both their plants and their products for the pathogen.

I. Background: The Bil Mar Outbreak and Rising Tide of *Listeria* Recalls

The 1998-1999 outbreak of listeriosis from contaminated hot dogs produced by Sara Lee's Bil Mar plant, which caused 21 deaths and 100 illnesses,[2] was a wake-up call for both FSIS and the processed-meat industry. It tragically demonstrated that FSIS's Hazard Analysis and Critical Control Point (HACCP) program was not working in processed-meat plants.

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[1] 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*, (January 13, 2000).

[2] 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/pressrel/r990114.htm>Internet

Since the outbreak, many in the industry have taken meaningful steps to improve their processes to control *L. monocytogenes* contamination. Industry trade associations have disseminated useful information about how plants can redesign their processes and interventions to reduce the likelihood of product contamination with the pathogen. And, according to a recent poll conducted by the National Food Processors Association, many plants have instituted microbial-testing regimes, systematically scrutinizing their plants and final products for the bacterium.

Unfortunately, despite those efforts, large recalls of *L. monocytogenes*-contaminated meat products continue to occur at an alarming rate. During 1999 alone, companies recalled products -- sometimes on a nationwide basis -- for *L. monocytogenes* contamination 55 times, with the amount of affected meat exceeding 32 million pounds.[3] Those numbers, which reflect the huge production and wide distribution of many processed-meat products, should send chills down the spines of federal regulators because they illustrate the enormous threat the pathogen poses to consumers. That threat is further magnified by the lack of information about the initial symptoms of listeriosis that would facilitate early detection and by the long time period between exposure and illness onset.

Clearly, more needs to be done to prevent the contamination of ready-to-eat meat and poultry products with *L. monocytogenes*. Systematic microbial testing for the pathogen by the processed-meat industry must play a prominent role in any effort to control the hazard, as President Clinton and virtually everyone involved in the issue agrees. The question that FSIS

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[3] 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>Internet.

now confronts is not whether such testing should be required in all processed-meat plants, but what form it should take.

As CSPI asserted in its petition to FSIS, the agency should mandate microbial testing by industry of *both* plant environments and final products. Because the two forms of testing serve different, but complementary functions, neither is sufficient by itself to protect consumers.

II. Why Companies Must Test Both Plants and Final Products for the Pathogen

The processed-meat industry has two primary weapons against *L. monocytogenes* contamination: (1) maintaining the best possible sanitary conditions in its plants, and (2) using the manufacturing processes and hazard-control systems that best prevent the pathogen from contaminating products. Continually improving those two weapons is essential for the industry to eliminate the hazard of *L. monocytogenes* in ready-to-eat products. But success also requires a reliable means for judging whether a given sanitation protocol, manufacturing process, or intervention is effective on an ongoing basis against the pathogen. Today, microbiological testing is the single most reliable and practical means of making that judgment in processed-meat plants.

Just as there are two primary weapons against *L. monocytogenes*, there are two corresponding types of microbial testing that must be employed to monitor the weapons' ongoing effectiveness. To assess whether a plant's sanitation measures are effectively preventing *L. monocytogenes* contamination, a company must test the plant environment for the presence of the pathogen or appropriate indicator organisms. By contrast, to assess whether a plant's overall hazard-control system is working, a company must conduct random, statistically valid final-product testing. Neither type of testing, standing alone, can detect problems in both plant

sanitation and hazard-control systems. Therefore, both types of testing should be required in all plants producing ready-to-eat meat and poultry products.

III. Environmental Testing

Environmental testing is necessary to accomplish the following: (1) indicate when sanitation measures and other controls have broken down; (2) provide an early-warning signal for contamination problems; (3) serve as a trigger for immediate and aggressive corrective action; and (4) serve as a trigger for increased final-product testing.

In addition, over time accumulated data from environmental testing will reveal trends in *L. monocytogenes* contamination in plants and will enable the industry and government to identify the factors that contribute to contamination. This will lead to better regulations and improved public-health protection.

To achieve all of those important goals, FSIS should include the following elements in its proposed regulations for mandatory environmental testing by industry:

- Sampling should be for *Listeria* spp., to ease detection and accelerate test results. Companies should be required to fully validate their environmental-testing protocols.

- Both product-contact and non-product-contact surfaces should be sampled, with special emphasis on areas where cooked but unpackaged product could become contaminated.

- Sampling should be done regularly, but on a random, statistically valid basis. Companies should validate their sampling schemes to demonstrate statistical soundness.

- Companies should develop and adhere to specific corrective actions for when positives are detected. Corrective actions should be progressive: positives should lead to more focused testing and eventually to increased final-product testing, especially where positives are found on certain product-contact surfaces.

- Positives on product-contact surfaces should trigger shut down, dismantling, cleaning, and re-sanitization of all affected equipment. Also, additional microbial testing should be conducted to verify decontamination.

- Environmental test results should be fully documented, including the reason for contamination and the steps taken to correct the problem and prevent future incidents.

As part of its new regulations, FSIS should require all plants to describe their environmental-testing program, including corrective action and documentation requirements, in their prerequisites/Sanitation Standard Operating Procedures documents. The agency also should include specific standards for the environmental-testing program in the new regulations and provide concrete guidance to the industry about how to comply with the new standards. The guidelines should include a description of industry "best practices."

IV. Final-Product Testing

While environmental testing for *Listeria* indicator organisms provides vital information about the efficacy of sanitation measures and indicates when corrective actions are necessary to prevent product contamination, final-product testing plays a pivotal role in detecting other problems in the manufacturing process. Specifically, final-product testing serves at least three functions:

(1) *HACCP validation*: final-product testing enables plants to validate their hazard-control systems as achieving the requisite degree of pathogen reduction.

(2) *HACCP verification*: final-product testing enables plants to verify that their HACCP plans are effectively controlling for *L. monocytogenes* contamination on an ongoing basis.

(3) *Detection of contaminated products:* final-product testing by industry also would greatly expand the pool of products sampled for *L. monocytogenes*

and help ensure that contamination problems are detected before tainted products reach the market.

All three functions are essential in the government and industry's efforts to reduce the public-health threat of listeriosis in processed meats. And, as explained below, final-product testing is the best means of ensuring that plants carry out all three functions on an ongoing basis.

A. HACCP validation

The importance of process validation in preventing contamination of ready-to-eat meat and poultry products cannot be overstated. A company that produces such products without first validating its processes for their ability to kill *L. monocytogenes* is irresponsible in the extreme.

Microbial testing, using challenge studies or equivalent means of determining whether a plant's processes are achieving the requisite degree of pathogen reduction, is an essential tool for validation under a HACCP program. The preamble to the meat and poultry HACCP rule emphasized the importance of pathogen-specific testing in effectively validating HACCP plans, as well as the need for data from in-plant tests.[4]

B. HACCP verification

Microbial testing of final products plays an equally important role in HACCP verification. Such testing is a highly effective way to verify that plants' HACCP systems are functioning properly on an ongoing basis. Final-product testing offers a unique and unequaled opportunity to assess the efficacy of *all* steps in the manufacturing process in eliminating *L. monocytogenes*. FSIS has long recognized this role of final-product testing, including in the

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[4] 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. 38826-27 [hereinafter cited as *Meat and Poultry HACCP Final Rule*]

preamble to the meat and poultry HACCP rule ("The end of production is the only point that reflects all steps in the production process and, ultimately, all elements of the HACCP system.")[5] and, most recently, in the comments of FSIS Administrator Thomas J. Billy after the May 15, 2000 public hearing on *L. monocytogenes* ("[End-product testing is] one way for industry, as required under the regulations, to continually verify that their HACCP program is working as intended.")[6]

The National Advisory Committee on Meat and Poultry Inspection (NACMPI) has also recognized the importance of product testing for *Listeria monocytogenes* in HACCP verification. At its latest meeting, the NACMPI specifically called upon FSIS to "[e]xpand testing through [an] FSIS mandated standard for adequate *Listeria monocytogenes* product testing as part of HACCP verification."[7]

The power of end-product testing as a verification tool is not merely theoretical: the dramatic improvements in *Salmonella* contamination levels in raw meat and poultry products after implementation of the HACCP rule attest to the ability of such testing to document real food-safety gains. Final-product testing helps deliver reduced microbial contamination in products because it provides such a strong incentive for companies to use the best available interventions and processes.

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[5] *Meat and Poultry HACCP Final Rule*, p. 38854.

[6] David Safford, "FSIS Will Not Require End-Product Tests But Will Encourage Them, USDA Official Says," *Bureau of National Affairs Food Safety Report*, Vol. 2, No. 20 (May 17, 2000), p. 609 [hereinafter cited as *BNA article*].

[7] National Advisory Committee on Meat and Poultry Inspection, Sub-Committee Number Three, *Listeria Developments*, (May 16, 2000).

For many ready-to-eat products, final-product testing is the only effective verification tool. As documented in the Bil Mar outbreak, products that are exposed to the plant environment after cooking but before final packaging can become contaminated with *L. monocytogenes* if interventions against the pathogen fail. For such products, microbial testing of final, packaged product is the best available method to verify that interventions against recontamination are in fact working on an ongoing basis.

Despite FSIS's recognition of the importance of final-product testing for HACCP verification, the agency apparently intends only to "continue to strongly encourage end-product testing as part of [FSIS's] HACCP system," rather than to require such testing in all processed-meat plants.[8] That strategy is misguided, especially when viewed against the backdrop of the Bil Mar outbreak and the growing number of recalls of processed-meat products due to *L. monocytogenes* contamination. Effective verification of HACCP systems should be mandatory, not voluntary. Absent systematic testing of final products to verify the efficacy of plants' hazard-control systems, there is every reason to expect that the HACCP program for ready-to-eat meat and poultry products will again fail to prevent large-scale outbreaks of listeriosis, with tragic consequences for consumers.[9]

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[8] *BNA article*, p. 609.

[9] It almost goes without saying that FSIS's random-sampling program for ready-to-eat meat and poultry products cannot serve as an adequate verification tool. The program is simply too limited and unsystematic to verify the ongoing efficacy of plants' control systems. As FSIS has explained, the program was designed to "encourage process *validation*," not verification. U.S. Department of Agriculture, Food Safety and Inspection Service, *Revised Action Plan for Control of* Listeria monocytogenes *for the Prevention of Foodborne Listeriosis*, (May 12, 2000), p. 7.

C. Detection of contaminated products

On paper, the zero-tolerance standard for *L. monocytogenes* in ready-to-eat meat and poultry products appears to be a strong response to a significant public-health hazard. Unfortunately, FSIS's random-sampling program for *L. monocytogenes*, though useful, is too limited to provide much of a safety net against the distribution of contaminated products. Mandatory industry testing of final products would greatly expand that safety net by dramatically increasing the pool of products subjected to *L. monocytogenes* testing.

FSIS should require as part of its new regulations that final-product testing be done on a "test and hold" basis; that is, lots should not be released until negative test results are obtained. That will prevent consumer illnesses and deaths and will obviate the need for massive recalls.

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.[10]

In addition, data from industry final-product testing 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 develop and install innovative, more effective interventions

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[10] FSIS should develop a means to verify that companies' documentation of product testing accurately reflects the laboratory results obtained. The agency should consider such means as performing some degree of parallel testing to confirm results or requiring companies to make full laboratory data available.

(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.

CSPI recognizes, of course, that even a well-designed, statistically-valid final-product testing scheme will not detect *every* contamination problem. But there is no question that expanding the testing program by requiring the industry to test products based on sound statistical-sampling methods will greatly decrease the likelihood of recalls and outbreaks from *L. monocytogenes*.

D. Elements of an Effective Final-Product-Testing Program

To serve as an effective HACCP verification mechanism and to facilitate detection of contamination problems, FSIS should develop an industry final-product testing program containing all of the following:

- Regular testing on a random, statistically-valid basis with appropriate lot sizes;
- Holding of tested lots at the plant until negative results are obtained.
- Stepped-up final-product testing when positive environmental samples are obtained.
- Corrective-action plans for when trends toward repeated or increasing product contamination are identified.
- Stringent documentation standards; plants should be required to record all test results, the reason for any positive findings, and the steps taken to correct the problem and prevent future occurrences.

In addition, to help companies develop their microbial testing regimes, FSIS should publish detailed guidelines in conjunction with its regulations. The agency should use data from

its decade-old random sampling program to advise companies about how best to sample the different types of products they produce.

V. FSIS Enforcement of the Microbial-Testing Program

Even the most well-conceived testing program will fail to assure safe food on an ongoing basis if it lacks adequate government oversight. Therefore, FSIS should develop an enforcement strategy that will ensure industry compliance with all requirements, facilitate early detection and correction of contamination problems, and enable the industry and government to update the testing program in light of new data and technological improvements.

CSPI believes that FSIS should closely monitor both environmental and final-product testing by the industry, but that a different enforcement approach is appropriate for each type of testing. In general, FSIS should put more enforcement "muscle" behind the final-product testing regulations than those pertaining to environmental testing.

For environmental testing, FSIS should (1) review documentation of contamination findings; (2) monitor trends in contamination to ensure that plants are addressing potential problems; and (3) confirm that plants are taking the proper corrective actions where necessary. In general, environmental positives by themselves should not elicit an aggressive regulatory response from FSIS; however, the agency should take strong enforcement action upon evidence that a plant is repeatedly failing to address contamination problems or is neglecting to take the corrective actions necessary to assure product safety.

FSIS needs to be especially sensitive to trends of increasing environmental contamination when inspecting plant records. Some reports of the Bil Mar outbreak indicate that a dramatic

increase in environmental contamination rates leading up to the outbreak either were not identified or were ignored.[11]

For final-product testing, regulations should require companies to alert FSIS immediately upon detection of confirmed positives in final-product samples. Positives detected by industry should be treated in the same manner as positives from FSIS's own sampling program. That is, the agency should ensure that all affected products in the company's possession are destroyed or otherwise treated to eliminate the pathogen, and any affected products that have already entered commerce should be immediately recalled.

Regulations should authorize FSIS to close down a plant that repeatedly fails to produce *L. monocytogenes*-free product, until the plant can demonstrate that it has gained control over its processes. In addition, strong regulatory action should taken against companies that are discovered to have failed to inform the agency about positive test results in final products.

VI. Additional Benefits of Mandatory Industry Testing

FSIS should design the new regulations to ensure that the agency can take advantage of some additional benefits of systematic microbial testing by industry. Mandatory testing by the industry will 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,

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[11] 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); Alison Young, Jeff Taylor, and Janet L. Fix, "A Killer in Our Food: Special Report," *Detroit Free Press*, (August 26, 1999), p. 2.

seasonality, etc. It could also help identify interventions and processes that best prevent *L. monocytogenes* contamination.

FSIS should establish a system to collect and analyze data from the testing program, so that regulations could be revised as more is learned about the pathogen's ability to invade plants and products and about which hazard-control systems are most effective.

The data from industry testing will also help FSIS identify the products and plants that pose the greatest risk of *L. monocytogenes* contamination. That information will enable the agency to fine-tune its random-sampling program and ensure that limited resources are directed to the riskiest plants and products.

VII. FSIS Should Maintain Its Random-Sampling Program for Listeria

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.

VIII. 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. However, we urge the agency to develop new regulations based upon its mission to protect consumers from unsafe foods, rather than what may be palatable to most of the processed-meat industry. That means establishing microbiological testing requirements for *both* plants and final-products, as CSPI and other consumer groups called for in their petition to the agency this past January.

The Bil Mar outbreak and the increasingly common recalls of *Listeria monocytogenes*-contaminated products demonstrate just how much more needs to be done to protect consumers from foodborne listeriosis. The industry must step-up its efforts to develop and implement truly effective sanitation measures and hazard-control systems. The guidance from the trade associations is a good start, but it is up to each company to translate that guidance into concrete, effective controls in their plants. And it is up to the government to develop new testing requirements that ensure that industry efforts to combat the pathogen are successful.

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, both environmental and final-product testing are necessary to achieve those goals. Neither type of testing, standing alone, can get the job done.

Respectfully submitted,

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On behalf of:

American Public Health Association
Government Accountability Project
Safe Tables Our Priority

Consumer Federation of America
National Consumers League