



GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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Docket Clerk #97-013
United States Department of Agriculture
Food Safety and Inspection Service
Room 102 Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

97-013P-2715
97-013P
Sue Ference

2715

Re: Proposed Rule to Establish Performance Standards for the Production of
Processed Meat and Poultry Products, 66 Fed. Reg. 12589 (February 27, 2001)

Dear Sir or Madam:

The Grocery of Manufacturers of America (GMA) welcomes this opportunity to comment on the Food Safety and Inspection Service's (FSIS or the agency) above-referenced proposed rule to establish performance standards for the production of processed meat and poultry products. GMA is [GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

Introduction

GMA supports the agency's goal of reducing the incidence of listeriosis attributable to contamination of finished food products with *Listeria monocytogenes* (LM). GMA disagrees, however, with the methods the agency proposes to use to achieve that goal. Most significantly, the proposed environmental testing requirement for *Listeria* (species) is overly broad in scope and, as written, would discourage companies from looking aggressively for *Listeria* within the processing environment. GMA urges the agency to restructure its proposal in a manner that will encourage companies to take these actions and, thereby, further the common goal of enhancing food safety. GMA likewise encourages the agency to limit the scope of any final rule to those products that have been shown to present a bona fide risk of listeriosis. Failure to do so will only

products that have been shown to present a bona fide risk of listeriosis. Failure to do so will only deplete already scarce food safety resources with little or no return in terms of enhanced public health.

Discussion

A. Companies Must be Applauded Not Punished for Taking Steps to Find and Destroy *Listeria* in the Processing Environment

As a matter of good manufacturing practice, GMA believes that companies producing ready-to-eat (RTE) products that present a meaningful risk of listeriosis should have *Listeria* control programs in place that include an environmental testing component. GMA, therefore, supports the agency's intention to promote and expand the use of environmental testing for *Listeria*.

The ultimate goal of an environmental testing program, whether undertaken voluntarily or in response to regulation, should be to reduce the risk of LM contamination of finished products. To serve this goal, the program must focus on identifying sites within a processing environment where *Listeria* occurs. With that information, companies can take steps to protect the areas where *Listeria* is found from contamination in the future. Continued environmental testing validates the effectiveness of the companies' actions in this regard (i.e., in destroying the bacterium when found and protecting identified harborage sites from future contamination). A successful environmental testing program should also afford companies the flexibility to refine and improve the environmental testing methods and tools employed. Certainly, few subscribe to the view that the methods and tools available today are the most reliable and effective possible.

Although FSIS's proposed environmental testing requirement aims to enhance food safety by reducing the incidence of LM in finished foods, as written GMA believes it would undermine that goal. Under the proposal, a single positive environmental test result would force a company to detain and test large quantities of finished product to demonstrate the absence of LM. This draconian regulatory response bears no relationship to the public health risk presented and would only discourage companies from looking aggressively for *Listeria* within their plants.

A positive finding for *Listeria* species on a product contact surface indicates little if anything about the finished products produced by the establishment. It certainly does not mean that those finished products necessarily or even likely contain LM. Positive environmental results will occur from time to time in any plant because *Listeria* is a ubiquitous organism. Although steps can be taken to minimize the incidence of *Listeria* in processing environments, current knowledge and technology simply do not permit its total eradication. Given these factors, the goal of environmental testing should not and cannot be a *Listeria*-free processing environment.

Despite these fundamental facts about *Listeria*, the proposal seemingly equates a positive environmental test result with end product contamination. Thus, companies whose *Listeria* control programs function properly (i.e., they reveal harborage sites for *Listeria* within the plant

environment) would have to endure potentially harsh regulatory consequences, including disruption of processing operations. Faced with these consequences, it is only reasonable to expect that companies will look less aggressively for *Listeria* than they otherwise might, undermining rather than advancing FSIS's goal of protecting the public health.

In sum, the proposal as drafted would act as a substantial disincentive to companies' creation and implementation of aggressive, effective *Listeria* control programs. For this reason, GMA strongly urges the agency to reconsider all aspects of the proposal carefully. Companies that institute aggressive *Listeria* control programs should be recognized for their leadership not punished for their foresight. Any final rule based on the proposal should reflect this principle by encouraging companies to find and destroy *Listeria* within the processing environment.

B. Science Should Shape the Scope of Any Final Rule

In reshaping its proposal, it is critical that any regulatory requirements imposed by the agency be founded on sound science as to the incidence of *Listeria* species and LM, the infectious dose of LM, the specific serotypes of LM responsible for listeriosis, and other related factors. Close examination of the expanding range and quantity of epidemiological data would be particularly helpful in identifying those RTE foods that present a meaningful risk of listeriosis. GMA recommends that the agency examine the findings of the draft *Listeria monocytogenes* risk assessment in that regard as well. As the draft makes clear, all food products do not support or allow the growth of LM. To the extent RTE products fall within these categories, they should be excluded from the scope of the final rule. An overly broad rule would only divert valuable food safety resources from the areas that most warrant them, undermining FSIS's overall public health goal.

C. The Definition of RTE Products Should be Consistent Across Agencies

In addition to this major concern, GMA is troubled by other aspects of the proposal as well. Specifically, it appears that the proposal would define RTE products (and, thus, the products that would be subject to the proposed environmental testing requirement) in a manner that is inconsistent with prior FSIS statements as to what constitutes a RTE product, as well as other agencies' definitions of the RTE category. The final rule should include a definition of RTE products that is fully consistent with that used by other agencies. In that regard, GMA notes that FDA's Model Code defines a ready-to-eat food as "food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form." In the interests of standardization and uniformity across agencies, GMA urges FSIS to apply this definition to determine what constitutes a RTE product for purposes of any final rule.

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GMA is committed to enhancing the safety of America's food supply through cooperative, science-based efforts by industry and government. GMA looks forward to working

with the agency to develop and implement effective food safety strategies that will continue to lower the risk of listeriosis and other foodborne illnesses.

Sincerely,

A handwritten signature in black ink, starting with a large, stylized capital letter 'S' that loops around itself. The signature continues with a series of connected, fluid strokes that end in a horizontal line.

Sue Ference, D.V.M., Ph.D.
Vice President, Scientific and Regulatory Policy
Grocery Manufacturers of America, Inc.