



2704

September 6, 2001

FSIS Docket No. 97-013P U.S. Department of Agriculture Food Safety and Inspection Service Room 102, Cotton Annex 300 12th Street, SW Washington, DC 20250 97-013P-2704 97-013P James A. McCarthy

Re: Performance Standards for the Production of Processed

Meat and Poultry Products; Proposed Rule [66 FR 12590,

February 27, 2001]

Dear Sir or Madam:

The Snack Food Association (SFA) welcomes this opportunity to comment on the FSIS (or the agency) proposed rule to establish performance standards and related requirements for processed meat ard poultry products. SFA is the international trade association of the snack food industry representing over 700 snack manufactures and suppliers. Members include manufactures and suppliers of potato chips, tortilla chips, cereal snacks, pretzels, popcorn, cheese snacks, snack crackers, meat snacks, pork rinds, snack nuts, party mix, corn snacks, pellet snacks, fruit snacks, snack bars, granola, snack cakes, cookies and other snack products. Retail sales of snack foods in the U.S. total more than \$21 billion. Because dried meat snacks are considered ready-to-eat (RTE), SFA meat snack producers would be directly and substantially affected by FSIS's proposed rule, including, in particular, the proposed environmental testing requirement for *Listeria* (species).

Introduction

SFA believes the agency's proposal is overbroad and would, if finalized, divert valuable food safety resources away from other efforts that promise meaningful enhancements in food safety. As the joint FDA/USDA risk assessment for Listeria monocytogenes (LM) illustrates, critical differences exist among food categories in terms of their ability to harbor LM and support its growth. The proposed rule, however, ignores these differences. It would subject producers of all RTE products to the same requirements, seemingly ignoring the substantial scientific evidence that demonstrates the safety of many product categories, including dried meat snacks.

For the reasons set forth below, SFA urges the agency to exclude dried meat snacks from any final rule mandating environmental testing for *Listeria* (species). Given dried meat snacks' long safety record, the inherent product characteristics that prevent the growth of LM, and the consistent, negative results of finished product testing, subjecting dried meat snack producers to mandatory environmental testing would only burden industry and the agency, with no offsetting benefit in terms of enhanced food safety.

Discussion

1. Mandatory Environmental Testing for *Listeria* in Establishments that Produce Dried Meat Snacks is Unwarranted Given the Inherent Safety of the Products Produced

The agency's proposed requirement for food contact surface testing for nonspecific *Listeria* poses the greatest concern for SFA. Dried meat snacks, including meat/poultry jerky, beef sticks, and pork rinds, have a long and virtually unblemished safety record. 1/. This record is attributable to fundamental characteristics of these products that prevent pathogen growth.

If the only reported foodborne illness outbreak on record attributed to "commercially prepared" meat snacks involved beef jerky purportedly contaminated with Salmonella. CDC-MMWR-October 27, 1995/44(42), ''85-788. Several factors about the incident, however, suggest that the product was not prepared in a manner typical of commercially prepared dried meat snacks. First, investigators found no records regarding water activity or process temperatures. Moreover, the so-called plant owner performed all of the work in the plant by himself. Finally, the reports suggested that the plant owner may have been the vector for the bacterium.

Specifically, shelf-stable dried meat snacks have a water activity level of 0.85 or less – a level that will not support the growth of LM. The critical role of water activity in suppressing and preventing the growth of toxic microorganisms is recognized in the Model Food Code. Section 1-201.10(61) of the 1999 edition of the Code specifically excludes from the definition of "potential y hazardous food" foods with a water activity value of 0.85 or less."

USDA's own Pathogen Models illustrate the resistance of products with a water activity level of 0.85 or less to microbial growth, including growth of LM. According to the Model, in dried meat snacks with a water activity of 0.85, a pH of 5.8, and sodium nitrite at 15 ppm, LM will decline by 1 log after seven days. The International Commission on Microbiological Specifications for Foods Handbook 5 validates the findings from USDA's Pathogen Model. The Handbook shows that LM will decline by 1 log over 3.5 days in brain heart infusion broth with a water activity of 0.87 and a pH of 7.4.

Practical experience in terms of finished product testing bears out what both the Model Food Code and the agency's pathogen models predict. One SFA member's jerky products are sampled approximately 30 times per year by FSIS at each of its three plants. Although all samples are tested for LM, no positive has ever been recorded. Another SFA member took eight samples of finished packaged product over the course of one week and tested those samples for *Listeria* (species) and variety of other pathogens. All results were negative.

Another, larger SFA member has sent in excess of 1400 finished product samples to an outside testing laboratory for LM analysis. It has never had a positive test result. This same SFA member conducted two challenge studies on fermented meat sticks. When those sticks are inoculated at low levels (<100 colony forming units/package) with LM, the LM does not grow. When inoculated at high levels (105 colony forming units/package), LM dies on the product surface.

FSIS itself seems to agree that dried meat sracks pose no significant risk of listeriosis. In discussing the lethality performance standard for the category, FSIS concludes that "based on the epidemiological data and research studies on jerky, it does not appear that *E. coli 0157:H7* or *Listeria* represent serious hazards in commercially produced jerky." 2/ Given the intrinsic safety characteristics of dried meat snacks, and their recognized safety record, SFA urges the agency to exclude this category of products from any final rule many ating environmental testing for *Listeria*.

2. The Proposed Environmental Testing Requirement Would Involve Substantial Additional Costs with No Offsetting Benefit in Terms of Enhanced Product Safety

Despite the strong safety record of dried meat snacks and the agency's own apparent conclusion that *Listeria* does not present a hazard in dried meat snacks, the proposal, as written, would require dried mean snack producers to test food contact surfaces for nonspecific *Listeria*. Such tests, of course, would be expensive. One SFA member estimates that it would spend between \$12,500 and \$17,500 annually to carry out the proposed testing requirements. A second SFA member estimates \$16,000 in added costs. A third SFA n ember, with sales of \$250 million, estimates \$130,000 in costs for environmental testing and, if positive results occur, an added \$12,000 per year for finished product testing.

In addition to these direct costs, SFA members would incur far greater costs if the environmental tests return a positive result. In that event, a company would be forced to hold the relevant lot or lots of product 1 ending testing to demonstrate the absence of LM. One SFA member estimates the cost of warehouse space to store product "on hold" at \$200,000 per year. Other costs would include added labor, incremental product distress, and increased inventories.

All of these costs, however, would return no benefit in terms of enhanced product safety. Even if a positive test for *Lister a* in the processing environment indicated something about the integrity of the products being produced, the low water activity and other fundamental characteristics of dried meat snacks make it impossible for *Listeria* to grow, eliminating any meaningful risk of listeriosis attributable to these products.

^{2/ 66} Fed. Reg. at 12598.

3. Any Mandatory Environmental Testing Requirement Should Encourage Companies to Look Aggressively for *Listeria* Not Punish Them for Finding It

For the reasons set forth above, SFA strongly urges FSIS to remove dried meat snacks from the category of products that would trigger environmental testing for *Listeria* under the final rule. In addition to excluding dried meat snacks, SFA believes other, substantial changes to the proposed to sting program are warranted. It is critical that any mandatory testing program be crafted in a manner that encourages companies to look aggressively for *Listeria* in their processing environments. A program that fails in this regard will only work as a disincentive, undermining rather than enhancing food safety.

The ultimate goal of any environmental testing program should be to find *Listeria* in the processing environment and eliminate it. If a positive environmental test occurs, a company's testing program is working correctly, providing it with the information necessary to eliminate harborage sites for the bacterium. Consequently, a positive test result should no as the agency proposes, be treated as some sort of process failure, requiring holding and testing of large quantities of finished product. A positive result on an environmental swab test indicates nothing with respect to the contamination status of finished products. Indeed, with respect to dried products, it is wholly irrelevant.

SFA, therefore, strongly recommends that FSIS restructure its proposal to incorporate any environmental testing requirement under its SSOP regulations. In the event of a positive test result, additional environmental testing, not holding and testing of finished product for LM, should serve as verification of corrective actions.

4. Stabilization Performance Standards for Shelf Stable Products Are Unnecessary and Should be Eliminated from Any Final Rule

The proposal's overly broad approach extends beyond the environmental testing requirement for *Listeria*. It appears that the proposed stabilization standards for *Clostridium botulinum* and *C. verfringens* would apply to all RTE products, including shelf stable dried meat snacks. Because these products are shelf stable, by definition they pose no risk of pathogenic growth. Accordingly, FSIS should clarify in the final rule that shelf stable products such as dried meat snacks are excluded from the scope of the stabilization standards.

Summary

The FSIS proposal to subject all RTE produces to the same pathogen performance standards and testing requirements is grossly overbroad. SFA urges the agency to consider carefully the science with regard to individual product categories and adopt regulatory requirements concomitant with the risks posed. To do otherwise would only waste the resources of both FSIS and industry. The scientific evidence with regard to dried meat snacks clearly supports their intrinsic safety. Accordingly, SFA urges the agency to revise its proposal to exclude dried, RTE meat snacks, including meat/poultry jerky, beef sticks, and pork rinds, from its scope.

SFA appreciates the opportunity to comment on the proposed rule and looks forward to working with the agency to enhance the afety of all RTE meat and poultry products.

Since ely,

Jame : A. McCarthy President and CEO