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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-2664
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Leslie G. Sarasin

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 American Frozen Food Institute (AFFI) appreciates the opportunity to provide comments on the Food Safety and Inspection Service's (FSIS or the agency) proposed rule to establish performance standards for the production of processed meat and poultry products.

AFFI is the national trade association that represents frozen food processors, as well as marketers and suppliers of goods and services to the industry. AFFI's more than 540 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally.

A. Introduction

AFFI member companies are dedicated to pro viding safe, high quality products for consumers. The industry has adopted and int grated into its operations a wide range of practices designed to address ar d control the risks associated with foodborne and environmental pathogens. These practices include Hazard Analysis and Critical Control Point (HACCP) syste ns, Good Manufacturing Practices (GMPs), Sanitation Standard Operating Procedu es (SSOPs), and related prerequisite programs. The resulting safety record for froz n processed meat and poultry products is exemplary. In fact, to AFFI's knowledg no frozen processed product containing fully cooked meat or poultry component s has ever been linked with a public health incident involving *Listeria monocytoge nes* (*Lm*).

AFFI supports science-based efforts to enhanc e the safety of all meat and poultry products. AFFI is concerned, however, that th proposed rule is too broad in scope. Applying the same regulatory strategy for *Listeria monocytogenes* testing to refrigerated ready-to-eat (RTE) products that su port growth, to shelf-stable or frozen products that do not, and to products that re to be cooked will dilute limited agency resources and is not consistent with t he results of the recent *Lm* risk assessment undertaken by FSIS in conjunction wi h the Food and Drug Administration (FDA).

A final rule governing pathogen testing must identify clearly the products affected by the rule by adopting a definition of rea dy-to-eat (RTE) products that is consistent with existing agency needs, compatible w ith the policies and practice of related federal and state agencies, and based or widely accepted scientific standards. A concise definition of that which con stitutes a RTE product, as compared to a not ready-to-eat (NRTE) product, will con municate more clearly to consumers how they should prepare/consume the produc t, facilitate industry compliance, foster improved relationships among companie s and inspectors and, ultimately, enhance food safety.

Furthermore, as regards a pathogen such as *L monocytogenes*, AFFI cannot overstate the importance of adopting sound scientifi : regulatory policy that encourages testing for and eradication of harborage sites of this ubiquitous organism. FSIS must recognize the commonality of an orga nism that studies have shown is present in 51 percent of soil in uncultivated fields, 1/ on 12 percent of office personnel and 77 percent of bacteriological workers,2/ and i n 14 percent of households.3/

FSIS's testing policy should be designed to enc ourage establishments to identify problems, take corrective action, and implement procedures to eradicate the problem once it is identified. The policy should be base d on safety objectives, not enforcement.

B. Creating Incentives that Encourage Com panies to Conduct Environmental Testing for *Lm* and other Pathogens is Critical to Enhancing the Safety of All Meat and P oultry Products.

The agency and the frozen food industry share the goal of enhancing product safety. AFFI fully endorses the adoption of proced ures deemed appropriate to assure the safety of RTE products, including testing for *Listeria* (species) and *Listeria monocytogenes*. In this regard, AFFI believes that all manufacturers of RTE products should implement programs to detect and er adicate harborage sites of the organism. Moreover, the Institute recognizes that w hile the food industry can develop programs to control *Lm*, and eradicate harborage s tes once they are found, it is unrealistic currently to consider total elimination of th e bacterium from the production environment. In that regard, the 1988 World H ealth Organization (WHO) expert consultation on foodborne listeriosis conclud ed that, "Elimination of *Lm* from all food is impracticable and may be impossible."

1/Weis and Seeliger, Appl. Microbiol. 30:29, 1975.

2/Doyle, *Listeria*, State of the Science Conference, Rome, 1995.

3/L.J. Cox et al., Food Micro. 6:49-61, 1989.

AFFI disagrees with the agency's tentative decision to require environmental testing for *Listeria,* unless and until it is understood by all stakeholders, including regulated facilities and inspectors, that positive test results should not serve as the basis for regulatory action. In the context of a *Listeria* control program, test results constitute data points that fit into a complex pattern of data. Data points should not be viewed in isolation, but instead should be considered in light of the exact composition of the sample that tested positive, the related equipment design and personnel practices, prior testing history and the conduct of the facility once a positive sample has been established.

Appropriate corrective action steps are not identical from situation to situation, product to product, production line to production line, or plant to plant. Imposing a rigid regulatory system around the finding of positive test results will undermine, rather than enhance, FSIS's food safety goals. A regulatory scheme that couples mandated testing with regulatory action inevitably undermines the value of at least some of such testing in enhancing product safety. Regulatory action, if any, should be the consequence of inaction on the part of the facility to control the problem once it is found.

The appropriate goal of environmental testing for *Listeria* is very simple. A company focuses on looking broadly and vigorously for *Listeria* and, when found, implements measures to eliminate its source in the environment. The intended effect of finding and eliminating the source of the bacteria is, of course, to reduce the likelihood of product contamination with *Lm.*

The introduction of a mandatory element with regulatory consequences complicates this dynamic. When testing is mandatory as contemplated in the proposal, a "positive" finding for *Listeria* presumably will have regulatory consequences. Numerous questions and concerns arise about the respective roles of companies and inspectors, and their obligations, in light of a "positive" result. AFFI urges the agency to consider carefully the impact of mandatory testing requirements on testing initiatives and to work toward the creation of a regulatory scheme that encourages rather than discourages the simple goals of finding *Listeria* and eliminating harborages from the processing environment.

C. Any Final Rule Governing Testing for *Listeria* Must Clearly Delineate the Products Affected.

For the reasons discussed above, and under the current regulatory scheme, AFFI views mandatory environmental testing for *Listeria* with corresponding regulatory consequences as counterproductive and therefore opposes it. If the agency nevertheless concludes that mandatory testing of some kind is warranted or necessary, AFFI believes it is critical that the agency clarify those products whose manufacturing environment would trigger testing. Although not entirely clear, it appears that the proposal would apply to all RTE products, a category defined as "a meat or poultry product that can be safely consumed without cooking or application of some other lethality treatment to destroy pathogens" and which, based on the agency's "examples of RTE products" (see pages 12591-92), would include frozen pizzas and entrees/frozen dinners, among others.

AFFI submits that the agency's examples are inconsistent with prior agency statements regarding that which constitutes RTE versus NRTE products, as well as with the Model Food Code's treatment of that issue. Frozen processed products containing a fully cooked meat or poultry component along with raw or partially cooked non-meat or poultry ingredients -- many of which function as "dinners/entrees" -- are among the products most commonly produced by AFFI members. FSIS has determined that it is appropriate to treat these products as NRTE for purposes of microbiological sampling under HACCP, as well as for HACCP plan reassessment to determine if *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur. 4/

In meetings and correspondence with agency officials regarding these multi-component products, AFFI explained that they are intended to be cooked by the consumer prior to consumption, and all bear explicit instructions directing the consumer to do so. 5/ FSIS acknowledged these points, recognizing that simply because products may contain components that have been cooked or thermally processed during manufacturing does not necessarily mean these products are RTE.

4/ FSIS Directive10.240.2, Attachment 2.

5/ AFFI further explained that the products contain raw or partially cooked non-meat or poultry ingredients because the finished "cooked" food would not be palatable to the consumer if the raw or partially cooked ingredients were cooked twice.

FSIS's classification of these multi-component products as NRTE is fully consistent with prevailing regulatory policy. In fact, the preamble to its final rule on safe handling instructions, the agency commented:

> Finally, as to whether safe handling instructions need to be on products that include a fully cooked meat filling but where the total product requires cooking, e.g., a fully cooked meat filling in uncooked dough; the rule does not require safe handling instructions on products where the meat or poultry portion is fully cooked or otherwise processed to render that portion ready-to-eat. However, while such products do not require safe handling instructions, they are not considered ready-to-eat. 6/

In addition, the agency has described RTE foods elsewhere as "products that may be consumed without any further cooking or other preparation." 7/ FDA's 1999 Model Food Code continues to define RTE 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." Many states and local regulatory programs have adopted this code.

The proposed rule ignores these well-established definitions, including the agency's own prior classification of multi-component products as NRTE, and categorizes them as RTE despite the fact that they require further cooking before consumption and that the package clearly directs consumers to cook them. AFFI urges the agency to address this inconsistency in any final rule by adopting a definition of RTE products which closely resembles that contained in the Model Food Code and which clearly excludes all frozen processed meat and poultry products that contain fully cooked meat or poultry components and are meant to be cooked by the consumer. FSIS already considers processed meat and poultry products with raw or partially cooked ingredients as NRTE for purposes of microbiological sampling and analysis. There is no reason to depart from that practice and AFFI believes, based on the evidence presented below, that all frozen processed meat and poultry products should be treated as NRTE for purposes of a final rule regarding pathogen performance standards.

6/ 59 Fed. Reg. at 14534.

7/ 64 Fed. Reg. at 28352.

D. Frozen Meat and Poultry Processed Foo ls are Safe.

The absence of any principled reason for trea ing any single or multi-component frozen processed meat and poultry products as RTE for purposes of this rulemaking is underscored by the inherent safety features of these products. Simply put, the fact that these products are frozen drastic ally lowers the likelihood that they may present a food safety hazard as a result of *l isteria monocytogenes* contamination.

Clear evidence of freezing's protective effects is available in the recently released FSIS/FDA *Listeria monocytogenes* draft isk assessment. That document confirms that freezing lowers the risk of illness due to *Lm* contamination by preventing organism growth, a precondition for infectic n. Not surprisingly, therefore, the risk assessment places ice cream, a product requiring no preparation by consumers, at the bottom of the risk continuum presen ed by the 20 food categories surveyed.

The protective effects of freezing against *Lm* are enhanced by several other important considerations with regard to single and nulti-component frozen processed meat and poultry products, including the follow ng:

1. The meat or poultry in the products is fully cooked, minimizing the potential for pathogens;
2. Finished product is frozen immediatel r after processing, and remains frozen during distribution an l storage, effectively managing the potential for temperatu e abuse during distribution;
3. Consumers prepare most of the produ ts directly from the freezer with little or no handling or de frosting, virtually eliminating the potential for consume abuse, and if thawing instructions are provided, they follow proper thawing procedures (e.g., "Thaw under refrigeration for a naximum of 48 hours, cook immediately after thawing."); an l
4. The cook step performed by the consu ner provides an additional protection against the presence or gro wth of pathogens.

All these factors contribute to making frozen dinners/entrees and other frozen items that consumers are directed to cook prior to consumption far less vulnerable to pathogen contamination than refrigerated RTE products. Thus, the science, as well as the agency's past policy determinations with regard to that which constitutes RTE products, both support excluding frozen processed meat and poultry products from the RTE category for purposes of any final rule imposing pathogen testing.

E. FSIS Should Encourage Implementation of Effective Testing Requirements.

Although AFFI is convinced that environmental testing for *Listeria* should not be mandatory as contemplated by the proposal, the Institute also recognizes that the agency might determine that testing should be required in facilities that manufacture true ready-to-eat products. Even in these circumstances, however, it is essential that FSIS encourage implementation of effective test and control programs by appreciating and acknowledging their objective. Put another way, the agency should not discourage companies from taking every reasonable measure to look for and find bacteria if present. Moreover, plants should not be penalized by inappropriate regulatory action simply because their program has been effective.

Environmental testing for *Listeria* is an effective tool that helps eliminate *Lm* harborages from a food processing facility. In this regard, an effective environmental testing program should be designed to detect sources of *Listeria* so that corrective and preventive actions – primarily, enhanced and focused sanitation, GMPs, and employee behavior – can be employed to reduce the presence of the bacterium and ultimately eradicate harborage sites.

Positive environmental sampling results, even on food contact surfaces, however, do not necessarily indicate that products produced in such an establishment are or may be contaminated. Moreover, effective actions to find and eliminate *Listeria* require that the food processing operation continue unimpeded. Industry experience has shown that elimination of the source of *Lm* contamination requires observation. Observing personnel practices and equipment during normal operations is a precursor to pinpointing the source of *Listeria monocytogenes* contamination.

Accordingly, inspectors must understand that they s ıould not suspend inspection, effectively stopping a plant from operating, sim ›ly because *Listeria* has been detected in the environment. So long as the plant is f ›llowing the procedures set forth in its test and control program for addressing posi ;ive results, taking prescribed corrective and preventive action, the plant's ope :ations should continue uninterrupted.

Similarly, because a good environmental testi ıg program should look comprehensively and broadly for and find the bacterium so steps can be taken to eliminate it, and because positive environmental test resul ;s do not necessarily implicate product integrity, inspectors need only to be able to confirm that a plant is conducting testing and taking appropriate action as set for ;h by its testing plan. Inspectors typically are accustomed to instituting regulato ·y action on the basis of any kind of positive test result under the assumption that ›ositive results mean either that a plant's SSOP or HACCP plan is inadequate o · that the plant is violating its plan. This not only discourages a responsible ›lant from doing the right thing, but also prevents the program from achieving ts goals.

AFFI recognizes that, to the extent environm ·ntal testing may be required in a particular facility, inspectors have an obligat .on to ensure the testing is being done as prescribed. In the absence of evidence tha t adulterated product has been shipped in interstate commerce, however, actual test results are not meaningful and may even be inherently misleading when ·:onsidered individually rather than in the context of the results for the relevant a ıea of the plant over time. Therefore, to facilitate inspector oversight, perhaps a simp le record should be developed on which a plant affirms it has conducted testin ; in accordance with its plan, and that appropriate corrective and preventive actio ı has been taken in response to positive test results.

F. Conclusion

AFFI recognizes the importance of a sound re gulatory framework for managing the public health risks posed by the presence of high levels of *Listeria monocytogenes* in food. Moreover, the Institute understan ds that FSIS must focus limited resources on addressing those meat and poultry pı oduct contamination issues that pose significant risk. Therefore, AFFI believes that agency policy should not require the same level of *Listeria monocytogenes* contr ›l for those products that support growth and those that prevent and/or reduce or el iminate the organism through processes such as freezing and cooking.

FSIS should recognize that all meat and poul ry products are not alike. Single and multi-component frozen processed meat and po ultry products categories which include but are not limited to pizzas, chicken nugge s, burritos, lasagna, pot pies, breakfast and dinner entrees and casseroles, provide an arsenal of weapons which mitigate the public health risk of listeriosis from th se products. These weapons include freezing which eliminates growth of the p athogen, minimal consumer handling which limits contamination, and cooki ng from a frozen or cold state which greatly reduces or eliminates residual contam nation.

AFFI members fully endorse identification a d control of *Listeria monocytogenes* in the frozen food environment. Companie s must be permitted freely to test, find and eradicate this organism. Moreover, the In stitute recognizes that frozen processed meat and poultry products are not ready-to-eat, although they may contain fully cooked meat or poultry. Importantly, the pr cessing, handling, and preparation of these products present a minimal risk to th e health of consumers. AFFI therefore recommends that FSIS classify all frozen p rocessed meat and poultry products as not ready-to-eat.

AFFI appreciates the opportunity to share it s views on the pathogen performance standard proposed rule and looks forward to working with the agency to develop flexible, science-based policies that enhance th e overall safety of the food supply.

Sincerely,

Leslie G. Sa asin
President a d
Chief Execu ive Officer