

September 6, 2001

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Docket Clerk
Docket #97-013P
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-2665
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Robert L. Garfield

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 National Frozen Pizza Institute (NFPI) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) proposed performance standards for ready-to-eat (RTE) products. In broadest terms, the proposal addresses three topics: lethality, stabilization, and testing of product contact surfaces for *Listeria species (L. spp.)*. NFPI's comments will focus on the issue of *L. spp.* testing exclusively.

NFPI is the national trade association that represents U.S. frozen pizza processors as well as suppliers to the industry. NFPI represents a significant majority of the frozen pizza market, valued at approximately \$3 billion. NFPI members are located throughout the country and are engaged in retail and food service sales.

As discussed below, NFPI was surprised and disappointed to find in the proposal repeated references in the preamble to frozen pizza as a RTE product (*see, e.g., 66 Fed. Reg. 12590, col. 3; 12611, col. 3; 12622 and n. 3*). Frozen pizza is *not* RTE according to existing agency policy and common sense. NFPI respectfully requests that FSIS expressly reaffirm that frozen pizza is **not** an RTE product and is not within the purview of the proposal so as to avoid any misunderstandings in the field.

A. Frozen Pizza is Not a RTE Product

On several occasions in the past, FSIS has found products, such as frozen pizza, not to be a RTE product.

For example, in the Safe Handling Label regulation's preamble, FSIS stated:

Finally, as to whether safe handling instructions need to be on products that require 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. . . . However, while such products do not require safe handling instructions, they are *not* considered ready to eat.¹

FSIS Directive 10, 240.2, Attachment 2 entitled Microbial Sampling of Ready-to-Eat (RTE) Products states:

"A product containing a meat/poultry component that **has** received a lethality treatment for pathogens in combination with non-meat/poultry components that **need** to receive a lethality treatment by the intended user," such as frozen entrees, is not an RTE product, though this fact must be clearly conveyed to the ultimate user. (Emphasis in original.)

Even in other FSIS contexts, frozen pizza does not meet the agency's definition of RTE. The Central Kitchen Exemption,² defines RTE when "no further cooking or other preparation is needed, except that they may be reheated if chilled during transportation". Moreover, frozen pizza is not a RTE food under other regulatory definitions. For example, under the Food and Drug Administration's (FDA) 1999 Model Food Code:

"Ready-to-eat food" means 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.

¹ 59 FR 14534 (emphasis added)

² 9 C.F.R. §303.1(d)(2)(iv)(c)

There should be no doubt that frozen pizza is not RTE. NFPI members have sold literally tens of millions of frozen pizzas, yet, we are unaware of any evidence which points to even a single occasion when an individual has consumed our product without thermal treatment of the product first. Accordingly, we disagree with the FSIS statement in the preamble that our products are "customarily cooked;" these products *always* are cooked and there simply is no evidence to the contrary.

B. Possible Post Lethality *Listeria* on Frozen Pizza Does Not Pose a Realistic Food Safety Concern

Beyond the above regulatory precedent, post lethality environmental contamination with *Listeria monocytogenes* (L.m) does not present a food safety concern in frozen pizza products. There are a number of reasons why the Institute offers this conclusion.

1. The meat/poultry component has been fully cooked.
2. Instances of random environmental contamination do not result in any appreciable level of *L. monocytogenes* on the product.
3. The product is frozen from time of production until placed in the oven by the consumer, so no grow-out occurs.
4. The product is labeled with clear cooking instructions (as required by FSIS Directive 10,240.2) that ensure lethality.

Not surprisingly, in the draft Risk Assessment prepared by FDA and FSIS,³ frozen products were identified as the lowest risk of any RTE product in the risk continuum. Moreover, the draft risk assessment also concluded that, on a per serving basis, the predictive relative risk for frankfurters decreased significantly when reheated before consumption. Since frozen processed products pose such a low risk, we respectfully submit frozen pizza poses far less of a risk given the cooking instructions and additional labeling on the package which ensures proper preparation before consumption.

³ FSIS Docket No. 00-048N, 66 FR 5515

As the agency is aware, *Listeria* is ubiquitous in the environment. The only way to control the pathogen is to seek and eradicate the organism. If the control method is based upon finding the organism, FSIS should not adopt a policy that imposes adverse regulatory consequences upon finding *Listeria*. Such proposed consequences include the holding and testing of product if there is even a single food contact positive for *L. spp.*

For large companies, test and hold policies have significant costs, especially if there is uncertainty as to the scope of product implicated, e.g., multiple lines. For smaller companies, who currently may not even be holding product after an FSIS finished product sample, this could mean recall. FSIS should encourage proactive actions on the part of establishments by clarifying in no uncertain terms that the regulatory event is not the finding of *Listeria* -- it is what the company does after finding it that is important.

On a related note, establishments should be given maximum flexibility in designing their *Listeria* testing programs. In this regard, NFPI believes FSIS should continue with the current Directive addressing establishment *Listeria* testing, Directive 10,240.2, rather than proceeding to finalize the instant proposal.

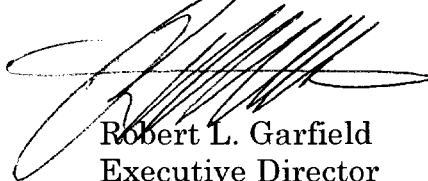
Finally, NFPI strongly encourage FSIS to provide its in-plant inspectors with the necessary assistance so they will be able to verify (and understand) testing and other programs conducted by establishments.

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In sum, NFPI respectfully request that FSIS reaffirm a previous decision that frozen pizza is not a ready-to-eat product. Moreover, the Institute suggests that FSIS proceed using risk analysis principles in adopting performance standards and other controls that have a true public health benefit.

NFPI appreciates the opportunity to comment on this proposal and look forward to working with FSIS on this and other initiatives.

Respectfully submitted,



Robert L. Garfield
Executive Director