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Via Hand Delivery

FSIS Docket #97-013P
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th St., S.W.
Washington, D.C. 20250-3700

2709

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John B. Dubeck

Re: Docket Number 97-013P; Proposed Rule; Performance Standards for the Production of Processed Meat and Poultry Products; Our File No. TE10413

On behalf of Tetra Pak Inc. (Tetra Pak), we hereby respectfully submit these comments on the above-referenced proposal to amend the Federal meat and poultry inspection regulations by establishing food safety performance standards for all ready-to-eat and all partially heat-treated meat and poultry products (66 *Fed. Reg.* 12589 (February 27 2001)).[1] These comments are limited solely to the portion of this compound proposal that relates to Thermally Processed, Commercially Sterile Products. Our comments initially discuss our strong support of the existing regulations and process authority system. We then comment on the provisions of the Proposed Rule itself, focusing on the importance of the U.S. Department of Agriculture (USDA) articulating a transition period for the Final Rule, clarifying the specific level of pathogen reduction required for thermally processed, commercially sterile products set forth in proposed Section 430.5(a) of Title 9 of the Code of Federal Regulations (C.F.R.), and allowing surrogate organisms to be used when developing data on *C. botulinum* risk levels.

[1] Tetra Pak develops, manufactures and markets systems for processing, packaging and distribution of liquid food. We produce packaging material at 68 plants and have 77 marketing companies around the world. Every day more than 200 million Tetra Pak packages are distributed in more than 165 countries. Tetra Pak's net sales amounted in 2000 to approximately $7 billion and 18,600 persons were employed.

Tetra Pak Supports the Current Regulations Governing Thermally Processed, Commercially Sterile Products

As an initial matter, Tetra Pak opposes any changes to the current regulations of the Food Safety Inspection Service (FSIS) of USDA with respect to thermally processed, commercially sterile products. FSIS has not provided a public health justification for the changes, and, by its proposal, risks disrupting an industry-supported system that has proven over the years to effectively promote the safety of thermally processed, commercially sterile products. We find the explanation offered in the Proposed Rule for replacing the current regulations with performance standards, namely that maintaining the current prescriptive requirements only for a single category of meat and poultry products would be "inconsistent' with FSIS' regulatory initiatives imposed on other meat and poultry products, to be an insufficient basis for superceding a regulatory framework that was initially developed in a non-meat context twenty-five years ago and has been successfully implemented more recently by FSIS and the processed meat industry.

Both industry and government agencies have long recognized that thermally processed, commercially sterile products are associated with specific safety concerns, and thus require a certain scientific approach to processing procedures. That is reflected in the fact that the USDA regulations are virtually identical to the FDA regulations for canned foods, which is of great importance to the many manufacturers who produce canned products regulated by both USDA and FDA. The proposed performance standards, therefore, not only trigger significant costs and disruptions without concomitant safety benefit, but they pose an unreasonable regulatory burden to many manufacturers simply because they are different from FDA's regulations for canned food for no good reason.[2] Further, the proposed performance standards differ widely from the Codex *Alimentarius* Commission recommendations at a time where there is widespread support for international harmonization.

In addition, we believe that the interest in granting greater processing flexibility to industry, as stated in the proposal, can be best achieved through modifications of the current system, particularly given the FSIS acknowledgment that the intent of the proposed performance standards is to provide the same level of food safety as currently exists. *See* 66 *Fed. Reg.* at 12611.

Finally, we are particularly concerned with the proposed elimination of the regulations that pertain to process authorities and process development. Process authorities, sanctioned by FSIS regulations, serve as accountable and informed sources of information for the industry on safe and effective processing. Elimination of the process authority concept may prompt

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[2] USDA's analysis for compliance with Executive Order 12866 is seriously flawed in assuming that Group IV establishments will incur no costs associated with the proposed rule.

establishments with less experience and fewer resources to use thermal processing practices that could provide inadequate public health protection. Moreover, the proposal does not specify the degree of information necessary to document compliance with the safety conditions.

USDA Should Provide a Sufficient Implementation Schedule for the Proposed Rule

The Proposed Rule does not specify an implementation schedule were it to become final. It is our position that, there is a significant economic impact associated with the proposed changes, and in the absence of an urgent public health basis, an extended transition period for industry to adopt these changes is appropriate. The absence of any discussion of an implementation schedule (other than briefly with respect to small businesses) is understandable given USDA's inexplicable view that there will be no cost to industry associated with abandoning an installed regulatory system in favor of an alternate system with an entirely new set of required documentation.

The Performance Standard for Thermally Processed, Commercially Sterile Products is Unclear

Paragraph (a) of proposed 9 C.F.R. § 430.5 ("Thermally processed, commercially sterile products") reads as follows:

> For a low-acid product that receives thermal or other sporicidal lethality processing, that processing must be validated to achieve a probability of 10^{-9} that there are spores of *C. botulinum* in a container of the product that are capable of growing, or, a 12-$\log_{10}$ reduction of *C. botulinum*, assuming an initial load of ≤1000 spores per container.

Thus, FSIS is proposing two options by which a low-acid canned product may conform with the lethality performance standard: the establishment can either demonstrate that manufacture of the product results in a **10^{-9} probability that there are spores of *C. botulinum* in** a container of the product that are capable of growing, assuming an initial load of 1000 spores or less per container, or the establishment can demonstrate a 12-$\log_{10}$ reduction of *C. botulinum*. 66 *Fed. Reg.* at 12606.

We believe that the regulatory language establishing this performance standard does not clearly reflect the processing flexibility that is intended by FSIS and that the proposal attempts to achieve for other types of products.[3] For example, the Proposed Rule states that the lethality

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[3] The Proposed Rule indicates that, particularly with regard to thermally processed, commercially sterile meat and poultry products, FSIS is attempting by the proposal and its other regulatory initiatives "to grant industry maximum flexibility to innovate in processing, while

(continued ...)

performance standards for the pathogens *Salmonella* and *E. coli* 015' :H7 in ready-to-eat meat and poultry products were derived from the application of the propos ed performance standard to hypothetical "worst case" raw products. Those results were then con verted into probabilities of remaining pathogens in 100 grams of the finished product (expressed as "x-$\log_{10}$"). 66 *Fed. Reg.* at 12609. This standard, therefore, permits an establishment demons rating that its incoming raw product is less contaminated than the assumed "worst case," to apply a lower lethality than proposed, provided the corresponding probability of pathogen reduct on in the finished product is met.[4] 66 *Fed. Reg.* at 12610.

The worst case raw product for thermally processed, commer cially sterilized products is not defined. Rather, the pathogen load used to derive the standard is "≤1000 spores." The preamble discussion of the performance standard for thermally proce ssed, commercially sterile product in the Proposed Rule does not explicitly discuss whether an establishment can use a lower lethality reduction provided the 10^{-9} probability is satisfied. N onetheless, the language of proposed section 430.5, with its reference to an initial spore load of l ss than or equal to 1000 per container, cryptically allows that interpretation. We respectfully req est that if FSIS concludes that a performance standard should be substituted for the current pres criptive regulations, the preamble to the Final Rule should confirm this interpretation of "≤1000 spores."

The Final Rule Should Clarify that Surrogate Organisms May be Used to Demonstrate Compliance with the Lethality Standard for Thermally Proces sed, Commercially Sterile Products

Proposed Section 430.5 requires that a company's processing be validated to demonstrate that there exists a 10^{-9} probability of *C. botulinum* contamination in a container, or that there has been a 12-$\log_{10}$ reduction of *C. botulinum*, assuming an initial load of 1000 spores or less per container. The same factors that make *C. botulinum* a hazard in food make it undesirable to handle in a laboratory. Surrogate organisms are frequently used to develop data on pathogen reduction. We respectfully request that FSIS explicitly confirm in the Final Rule that it is appropriate to use surrogate organisms to establish compliance with the 10^{-9} risk standard set forth in proposed Section 430.5.

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clarifying industry's responsibility and accountability for the safety of meat and poultry products." 66 *Fed. Reg.* at 12606.

[4] In fact, the language of the proposed regulation at Section 430.2 appears to be inconsistent with this preamble discussion.

Tetra Pak appreciates the opportunity to comment on USDA's Proposed Rule to amend the Federal meat and poultry inspection regulations. Tetra Pak would be pleased to respond to requests from FSIS for additional information pertaining to these comments.

Respectfully submitted,

Tetra Pak

By: _____
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