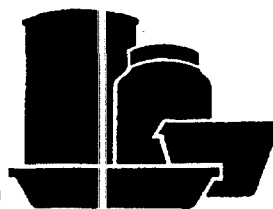


NATIONAL
MEAT CANNERS
ASSOCIATION

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September 10, 2001

FSIS Docket Clerk
Docket No. 97-013P
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102
Cotton Annex
300 12th Street, SW
Washington DC 20250-3700

97-013P-2655
97-013P
James H. Hodges

Re: Docket No. 97-013P: "Performance Standards for the Production of Processed Meat and Poultry Products"

To Whom It May Concern:

The National Meat Canners Association (NMCA) is the national trade association representing processors and suppliers of shelf stable meat and poultry products. NMCA was founded in 1923 to promote the interests of the canned meat industry in the United States. NMCA members include companies of all sizes, from regional processors to large multi-plant operations. Therefore, the Food Safety and Inspection Service's (FSIS or the agency) proposed rule on Performance Standards for the Production of Processed Meat and Poultry Products, specifically those parts pertaining to thermally-processed, commercially sterile products, directly affects our members. We have reviewed the proposed rule, and appreciate the opportunity to submit the following comments.

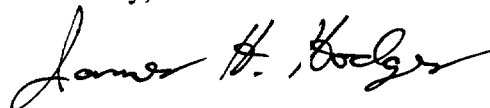
NMCA opposes the sections of the proposed rule that would significantly change the manner in which thermally-processed, commercially sterile products are regulated. Specifically, NMCA opposes inclusion of 9 CFR Part 430.5 and associated definitions contained in 9 CFR Part 430.1 in the proposed rule published in the *Federal Register* on February 27, 2001. These sections would replace the existing canning regulations contained in 9 CFR Part 318, Subpart G for meat and meat products and 9 CFR Part 381, Subpart X for poultry and poultry products.

1. NMCA sees no compelling rationale or need to make the wholesale changes described in the proposed rule. The existing rules and procedures for canned foods have been remarkably successful in protecting the public health against the threat of foodborne illnesses and deaths caused by *Clostridium botulinum*. The preamble to the proposed rule states that FSIS's action is "compelled by the recent outbreaks of foodborne illness related to the consumption of adulterated RTE meat and poultry products." However, none of the referenced foodborne illnesses involved thermally-processed, shelf stable foods which is a testimonial to the efficacy of the current regulations in assuring the safety of these products.
2. *Clostridium botulinum* toxin is one of the most lethal foodborne toxicants. The virulence of the *Clostridium botulinum* microorganism is unparalleled. Therefore, it is entirely appropriate and desirable that detailed regulatory requirements, such as those currently codified in the Code of Federal Regulations, are prescribed to control this significant public health threat. We applaud the agency's desire to provide the industry more regulatory flexibility, but the production of commercially sterile, shelf stable food products presents unique challenges that require specific procedures and controls to prevent a potential catastrophic outcome. FSIS cannot justify replacing the existing regulations simply on the belief that the current rules are inconsistent with FSIS's other regulatory initiatives. The existing canning regulations have been validated over time as effective in safeguarding public health. Replacing these proven regulatory standards with an untested regulatory approach based on performance standards cannot be justified.
3. Assuring the safety of meat and poultry products should be FSIS's first priority. Replacing the existing canning regulations with less prescriptive performance standards potentially threatens public health by creating unnecessary confusion and uncertainty in the industry. Section 430.5 of the proposed rule describes the performance standards an establishment must meet to achieve regulatory compliance, but the proposal is silent regarding the nature and scope of documentation a plant must have to demonstrate compliance with the performance standard. Presumably, FSIS will make the final determination regarding regulatory compliance based on the evidence that a company presents to the agency, but the company will not have the benefit of knowing the threshold of proof required by the FSIS. This regulatory approach that requires an establishment to prove that it is producing products that are not adulterated places the industry in an untenable and precarious position. Less industry guidance and more agency discretion is a prescription for creating, not solving problems.

4. The proposed rule adds new, burdensome requirements by mandating producers of thermally-processed, commercially sterile products address food safety hazards associated with microbial contamination in their HACCP plans. Presently, establishments producing canned meat and poultry products do not have to address microbiological hazards in their HACCP plan if the product is produced in accordance with the existing canning regulations. This exemption is permitted because sufficient microbial lethality is achieved to assure product safety. NMCA does not support the notion that performance standards should replace the existing canning regulations and requests the current exemption be retained.
5. The proposed rule is incompatible with regulations applicable to the production of thermally-processed, commercially sterile foods other than meat and poultry products. Several manufacturers produce products in the same plant that are regulated separately by both FSIS and FDA. FDA regulations codified in 21 CFR Part 113 govern the production of thermally-processed low-acid foods packaged in hermetically sealed containers other than meat and poultry products. These regulations are very similar to the existing regulations codified in 9 CFR Part 318 and Part 381 that govern meat and poultry products. The proposed rule would significantly alter the rules for producing meat and poultry products, thereby creating two vastly different regulatory regimes for foods that have virtually identical food safety hazards. FSIS has provided no rationale to justify this regulatory disparity.

In summary, the proposed rule to change the way thermally-processed, commercially sterile products are regulated is unnecessary, burdensome and not justified based on the exemplary safety record of the industry. NMCA believes the proposed wholesale changes to the existing regulations are unwarranted and respectfully requests FSIS withdraw sections of the proposed rule that pertain to thermally-processed, commercially sterile products. Thank you for the opportunity to comment on this important proposed rule.

Sincerely,



James H. Hodges
Executive Secretary

cc: Dave Morrison, President