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Testimony of James H. Hodges, Executive Secretary

National Meat Canners Association

FSIS Public Meeting

Proposed Rule (Docket No. 97-013P)

97-013P-2663
97-013P
National Meat
Canners
Association

Performance Standards for the Production of Processed Meat and Poultry Products

May 10, 2001

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 proposed rule on Performance Standards for the Production of Processed Meat and Poultry Products and specifically those parts pertaining to thermally processed, commercially sterile products directly affects our members.

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 including 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.

NMCA sees no compelling rationale or need to make the wholesale cl anges described in the proposed rule. The existing rules and procedures for canned foods ha ve been remarkably successful in protecting the public health against the threat of foodbor ne 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 r eferenced foodborne illnesses involved thermally-processed, shelf stable foods which is a t stimonial to the efficacy of the current regulations in assuring the safety of these products.

Furthermore, *Clostridium botulinum* toxin is one of the most lethal fo odborne toxicants. The virulence of the *Clostridium botulinum* microorganism is unparallelec . Therefore, it is entirely appropriate and desirable that detailed regulatory requirements, such a s those currently codified in the Code of Federal Regulations, are prescribed to control this sign ficant public health threat. We applaud the agency's desire to provide the industry more regulato y flexibility, but the production of commercially sterile, shelf stable food products present unique challenges that require specific procedures and controls to prevent a potential catastr phic outcome. FSIS cannot justify replacing the existing regulations simply on the belief t iat the current rules are inconsistent with FSIS's other regulatory initiatives. The existing can ning regulations have been validated over time as effective in safeguarding public health. Replac ing these proven regulatory standards with an untested regulatory approach based on performance standards cannot be justified.

Protection of public health 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 and places the industry in an untenable and precarious position. Less industry guidance and more agency discretion is a prescription for creating, not solving problems.

Additionally, 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.

Finally, 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 separately regulated by FSIS and

FDA. FDA regulations codified in 21 CFR Part 113 govern the prodı ction of thermally processed low-acid foods packaged in hermetically sealed containers ɔther than meat and poultry products. These regulations are very similar to the existing regulatioı s codified in 9 CFR Part 318 and Part 381 that govern meat and poultry products. The propose d rule would significantly alter the rules for producing meat and poultry products, thereby creati ıg two vastly different regulatory regimes for foods that have virtually identical food safety l azards. FSIS has provided no rationale to justify this regulatory disparity.

In summary, the proposed rule to change the way thermally processec , commercially sterile products are regulated is unnecessary, burdensome and not justified b ısed 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 ıections of the proposed rule that pertain to thermally processed, commercially sterile products. Thank you for the opportunity to comment on this important proposal.