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FSIS Docket #97-013P
USDA, Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street, S.W.
Washington, DC 20250

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97-013P
Teresa Frey

Re: Docket #97-013P, Performance Standards for the Production of Processed Meat and Poultry Products, Proposed Rule, *Federal Register* Tuesday, February 27, 2001

National Meat Association [NMA] respectfully submits the following comments on *Docket #97-013P, Performance Standards for the Production of Processed Meat and Poultry Products, Proposed Rule.* NMA represents over 300 firms who have a USDA grant of inspection. These firms manufacture a significant portion of the ready-to-eat [RTE] meat and poultry products produced in the United States. Specifically, they specialize in manufacturing high quality gourmet and traditional RTE products.

These firms are keenly sensitive and supportive of USDA's effort to ensure the safest meat and poultry products for American consumers. NMA is pleased to work cooperatively with regulatory and legislative bodies to this end. It is in the public interest that we maintain the highest standards for production of meat and poultry products that can be reasonably attained and supported by science.

To this end, NMA member firms have voluntarily implemented, at great expense, programs and procedures to reduce the incidence of foodborne illness that may result from the consumption of RTE products. These programs and procedures include the development and implementation of Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs); and Environmental Sampling and Testing Programs beyond those currently required federal regulations. In 1999, NMA developed, in cooperation with several industry and academic organizations, GMP, SOP and environmental sampling guidelines as a resource for RTE processors, and these have been widely used throughout the industry. These guidelines are available free of charge and may be downloaded from the NMA web site at www.nmaonline.org.

Actions taken to reduce pathogens and prevent foodborne illness need to be based on sound science with evidence that they will produce outcomes that have effects on food safety and

improve consumer protection. This is particularly important when these actions are codified in government regulations as they will affect the economic condition of the industry.

NMA is of the opinion that FSIS has failed to demonstrate, in either this proposed regulation or in related public meetings, that this regulation will improve food safety or protect consumers. In fact, NMA asserts that this regulation is a detriment to food safety because it is unsupported by science.

Lethality and Stabilization Performance Standards for RTE Products

NMA agrees that any detectable level of viable *Salmonella* microorganisms adulterates a RTE meat or poultry product. NMA also agrees that it is reasonable for consumers to expect RTE products to meet this standard. In addition, a recent private industry survey revealed that the majority of inspected establishments currently employ a CCP that meets this proposed requirement for lethality. However, we question the agency's basis for codifying that plants validate their RTE processes to either a 6.5-log reduction in *Salmonella* for RTE meat products or a 7.0-log reduction in *Salmonella* for RTE poultry products.

In the preamble, FSIS states that it derived "worst case" microorganism levels using data from the *USDA/FSIS 1994 Nationwide Microbiological Baseline Data Collection Program Surveys.* This data is seven years old and based on samples taken prior to the implementation of HACCP. FSIS claims that pathogen levels on meat and poultry products are declining since the implementation of HACCP. Agriculture Secretary Veneman announce earlier this year the release of an FSIS report that showed the decrease in *Salmonella* prevalence levels in 1998-2000 than in the baseline studies. Therefore, a regulatory requirement based on outdated data may cause a huge impact on the industry and no consumer protection benefit. This is an unjustified government mandated burden that is unacceptable.

Large establishments have the technical and economic resources *(private industry surveys report the cost of validating a CCP for lethality ranges from $10,000 to over $300,000, depending on the complexity and variety of products)* to establish their own "worst case" levels and validate alternative lethality methods, thus allowing them greater flexibility in their processes. Small establishments, particularly those who produce a variety of products, will most likely employ the "*FSIS Schedule-A Lethality Guidelines*" or any subsequent FSIS guidelines to meet the 6.5-log/7.0-log *Salmonell*a reduction standards. By setting the 6.5-log/7.0-log pathogen reduction as a regulatory standard, FSIS is locking these smaller establishments into what could become more costly production methods then those employed at large processors, thus putting them at an economic disadvantage. NMA therefore suggests that the agency review this hypothetical "worst case" level and re-propose based on more current data.

Similarly, NMA agrees with the agency that the proper monitoring of stabilization of meat and poultry products is necessary to ensure food safety and consumer protection. However, FSIS has used the same outdated *USDA/FSIS 1994 Nationwide Microbiological Baseline Data Collection Program Surveys* to establish the "worst case" microbiological levels for the

stabilization standard. If finalized as written, this section of the regulation would require that the processing of RTE products prevent the multiplication of microorganisms such as *Clostridium botulinum* and allow no more than 1-log multiplication of *Clostridium perfringens* within the product. FSIS is aware that the infective dose for *C. perfringens* is a cell population of 10^5 CFUs or more. FSIS has set the standard for *C. perfringens* multiplication at 1-log or less based on obsolete surveys. NMA encourages FSIS to re-propose a stabilization standard that is based on current data and that allows for the measuring of actual level of *C. perfringens* to establish the wholesomeness of RTE products.

Validation of Fermented Meat or Poultry Products Containing Beef

This proposed regulation would require that firms producing fermented meat or poultry products containing beef validate their process to achieve a performance standard probability of no surviving *E. coli* O157:H7 given an incoming raw material "worst case" level. Plants may also employ processes validated to achieve a 5-log reduction of *E. coli* O157:H7 throughout a finished RTE product containing beef. NMA understands the potential of serious illness associated with this organism, yet advises the agency to provide firms that produce fermented products with the with sufficient regulatory flexibility by which to meet these standards. The NCBA, Blue Ribbon Task Force, *Dry Fermented Sausage and E. coli O157:H7* Research Report may provide some assistance to the agency in this task.

Many of these products currently employ traditional processing methods and consistantly produce wholesome products. However, they may lack scientific validation, due to their relatively limited share in the market. By providing flexibility for these product in meeting this performance standard, the agency avoids the risk of driving these traditional, fermented beef products from the market place.

Validation Throughout Product Shelf-Life

NMA is concerned that FSIS is proposing to require that, "*Establishments would be required to maintain these levels of pathogen reduction and pathogen growth in their products, under normal handling conditions, and until their products reach the consumer* (page 12592)." NMA feels that this italicized statement contained in the proposed regulation is sufficiently vague as to invite contention and needs clarification.

Testing for *Listeria* (species)

NMA has supported environmental testing of product contact surfaces for *Listeria species* as a tool for plants to evaluate the effectiveness of their sanitation programs and recommends to its members that they consider implementing such a program as appropriate for their operation. NMA's Environmental Sampling and Testing Recommendations (ESTRs) for RTE product production is a guideline for developing such programs. A recent industry survey conducted by several trade associations indicates that many firms conduct extensive environmental testing on a voluntary basis.

NMA cannot, however, support a regulation that would require plants to either test product contact surfaces for *Listeria* (species) at prescribed frequencies based on plant size or identify *Listeria monocytogenes* as a hazard reasonably likely to occur and control it in their HACCP

plan. These actions are not supported by science and most likely will become a detriment to human health and food safety. The basis for this statement is in the following paragraphs.

Food processing experts agree that the most effective means to prevent post lethality contamination of RTE products is to focus on sanitation. Control of *L. monocytogenes* belongs in a plant's sanitation program, not in its HACCP program. Plants that attempt to control *L. monocytogenes* in their HACCP plan may divert establishment resources and personnel from focusing on sanitation activities, which may actually increase the risk of *L. monocytogenes* contaminating a RTE product.

The agency has failed to provide any scientific evidence that would show how the proposed, prescriptive environmental testing frequencies based on plant size as set forth in this proposed regulation will reduce the incidence of *L. monocytogenes* in RTE products. In fact, FSIS states in the preamble to the rule, "FSIS has not been able to correlate risk of product contamination with production volume or establishment size." In addition, NMA contends that any mandatory testing program that ultimately punishes plants that find *Listeria* (species) on product contact surfaces will discourage plants from aggressively testing and locating potential *Listeria* reservoirs. Current voluntary testing programs are aggressive and designed with the intent of locating potential *Listeria* reservoirs. If finalized as written, this regulation may discourage plants from implementing aggressive programs as they will lead to punitive regulatory actions and mislead new processors into implementing an ineffective program.

Environmental testing is costly. NMA estimates that for a small processor environmental testing could cost around $10,000 a year. A small firm would more effectively control *Listeria* by focusing financial resources on sanitation activities and plant improvement projects.

In addition, FSIS has ignored differences in certain RTE foods in regards to the *Listeria* testing and to stabilization. Specifically, the inclusion of dried meat snacks in the environmental testing and stabilization proposed requirements is not supported by any of the available scientific or epidemiological data. Shelf Stable Dried Products such as meat snack sticks and jerky have a water activity of 0.85 or less and will not support the post processing growth of pathogens such as *L. monocytogenes or C. perfringens.* FSIS writes in the discussion on hazards presented by the dried products category that "based on the epidemiological data and research studies on jerky, it does not appear that *E. coli* O157:H7 or *Listeria* represent serious hazards in commercially produced jerky." The 1999 FDA Food Code defines a food that is "potentially hazardous." Shelf stable dried and fermented products produced under a validated HACCP plan that include control of water activity and other barriers when the water activity is less than 0.85 would be specifically exempted from this categorization. Based on this evidence, NMA recommends that the categories of shelf stable dried and fermented products be eliminated from the proposed requirements for environmental testing and stabilization.

Thermally Processed Commercial Products

The National Meat Association strongly disagrees with the Agency's proposed changes to the current regulations pertaining to Canning and Canned Products contained in 9CFR 318.300 - 318.311 and 381.300 - 381.311 for the following reasons. FSIS has again failed to demonstrate how these proposed regulations will improve food safety and consumer protection. The current regulations are "HACCP" based and have demonstrated over many years to have effectively ensured the safety of shelf stable canned meat and poultry products. In fact, these regulations have virtually eliminated the potential severe public health hazard (i.e., *C. botulinum*) associated with improperly canned product. This fact alone warrants leaving the current regulations in place. In addition, current regulations are consistent with those of the Food and Drug Administration (FDA). Removing large portions of the current requirements would create a great deal of confusion in plants that produce both FDA and USDA product and weaken controls currently in place at plants producing only canned meat and poultry products.

Summary

Actions taken to reduce pathogens and prevent foodborne illness need to be based on sound science with evidence that these actions will affect food safety and improve consumer health. FSIS has failed to demonstrate, in either this regulation or subsequent public meetings, that this regulation will improve food safety or consumer health. NMA asserts that this regulation is a detriment to food safety as it is unsupported by sound science.

NMA agrees that any detectable level of viable *Salmonella* microorganisms adulterates a RTE meat or poultry product but questions the agency's basis for the lethality standard on data that is seven years old. Similarly, NMA agrees with the agency that the proper monitoring of stabilization of meat and poultry products is necessary to ensure food safety and protect human health but disagrees with setting the standard for *C. perfringens* multiplication at 1-log or less and not allowing for the actual measurement of *C. perfringens* to determine the wholesomeness of product.

NMA understands the potential of serious illness associated with this *E. coli* O157:H7, yet advises the agency to provide firms that produce fermented products with the with sufficient regulatory flexibility by which to meet this standards. By providing flexibility for these product in meeting this performance standard, the agency avoids the risk of driving these traditional, fermented beef products from the market place.

NMA is concerned that FSIS is proposing to require that, "*Establishments would be required to maintain these levels of pathogen reduction and pathogen growth in their products, under normal handling conditions, and until their products reach the consumer* (page 12592)." NMA feels that this italicized statement contained in the proposed regulation is sufficiently vague as to invite contention and needs clarification.

NMA will not support a regulation that would require plants to either test product contact surfaces for *Listeria* (species) at prescribed frequencies based on plant size or identify *L.*

monocytogenes as a hazard reasonably likely to occur and control it in their HACCP plan because these actions are not supported by science and most likely will become a detriment to human health and food safety. NMA also contends that FSIS has ignored differences in certain RTE foods in regards to the *Listeria* testing and to stabilization. Specifically, the inclusion of dried meat snacks in the environmental testing and stabilization proposed requirements.

NMA appreciates the opportunity to comment on this proposed rule.

Sincerely,

Teresa Frey
Director of Technical Services