NMA

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Teresa Frey

FSIS Docket Room
Docket #00-014R2
Room 102 Cotton Annex Building
300 12th Street, S.W.
Food Safety and Inspection Service
Washington, DC 20250-3700

RE: Announcement of and Request for Comments Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection

Dear Ms. Moore:

The National Meat Association (NMA) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) Notice on the Industry Petition to amend certain sections of the Agency's HACCP regulations. As a signatory to the petition, NMA strongly urges FSIS to grant the requested relief and amend the existing HACCP regulations as soon as is practical.

NMA represents the interests of meat packers and processors in the United States manufacturing under a USDA Grant of Inspection. These establishments have invested significant amounts of time and money to develop and implement HACCP plans as required by the HACCP regulations. NMA strongly supports HACCP, as it is the best system available to control and eliminate food safety hazards. Importantly, HACCP is a dynamic system, designed to adapt and adjust as its purpose and needs change. It is imperative that both industry and government work together to reach a common understanding on maintaining a HACCP systems approach within an inspection environment. We must achieve some level of consensus in order to preserve consumer health and safety and these firms' investments. It is in this spirit that the industry petition was submitted.

In addressing the Agency's six specific questions, NMA encourages the Agency to consider the suggested changes to the HACCP regulation and its interpretation of its current regulatory language.

Question 1: Is there Information to Support the Requested Action?

The FSIS HACCP regulations, as currently written, are a hazard identification system, requiring establishments to identify all potential food safety hazards. However, the regulations do not provide a meaningful criterion for distinguishing among the potential hazards to ensure that a HACCP plan focuses on true food safety concerns. Therefore, all potential hazards are treated the same, regardless of the severity of the consequences of exposure to the hazard or the likelihood of its occurrence. Both of these need to be considered in order to assess risk. Without them, the HACCP system mandated by current regulations can hardly be described as a "risk-based" system.

The National Advisory Committee on Microbiological Food Criteria (NACMFC) 1997 *Hazard Analysis and Critical Control Point Principles and Application Guidelines* provides a meaningful criterion for distinguishing among potential hazards to ensure that a HACCP plan focuses on true food safety concerns. The Guidelines state, *"When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled."*

Question 2: Would Amending the Regulations Provide the Level of Public Health Protection Required by the Inspection Acts?

The addition of a hazard risk assessment criterion to the HACCP regulation would provide a basis for uniformed inspection, target enforcement actions towards significant hazards and reduce enforcement disputes. Currently, insignificant hazards receive the same attention, resources and enforcement actions as significant hazards.

Attention to insignificant or unlikely hazards impedes the current system and hinders both the industry and the Agency's food safety efforts by diluting resources. By adopting a meaningful hazard risk assessment criterion similar to the existing NACMFC criterion, both the industry and the Agency can focus their resources on protecting consumers from true food safety concerns. Public health protection would improve by targeting actions on actual food safety hazards rather than perceived ones.

Absence of a hazard risk assessment criterion also results in the creation of arbitrary Critical Control Points (CCPs) often mandated by the Agency. CCPs developed to control insignificant or perceived hazards undermine the significance of the CCPs developed to control actual hazards and divert the focus and the resources of all parties from controlling actual hazards. Each CCP requires that the dedication of establishment and Agency resources for monitoring, documenting and verifying activities as mandated by the HACCP regulation. The potential for a significant food safety hazard to be overlooked or under-controlled increases with the addition of every CCP developed to control either insignificant or perceived hazards. In addition, in would be difficult for either the Agency or the industry to respond to an unforeseen hazard in an environment where resources are already overtaxed. In summary, the addition of unnecessary CCPs will fatally weigh the HACCP system down.

A hazard risk assessment criterion would also provide a basis for a gradation of enforcement actions. Currently, each deviation carries equal weight and is subject to the same level of enforcement action. For example, an establishment that receives product at 41 ° F rather than 40 ° F receives the same regulatory response as an establishment that fails to reach the required cooking temperature of a ready-to-eat product. The latter has a potential for significant public health consequences and should be classified by the Agency as such. It should be noted that FSIS is very familiar with estimating the magnitude of risk posed by a hazard. It's recall procedures assign a risk classification for every recall. In a former regulatory scheme -- PBIS -- the Agency had a "Deficiency Classification Guide" to classify deficiencies as "critical," "major," and "minor."

Furthermore, for HACCP to be a realistic program, the Agency must acknowledge the fact that not all hazards can be prevented, eliminated or reduced to acceptable levels in all processes or products. For example, the acceptable level to prevent illness or injury due to microbiological hazards in all products is zero. However, the only technology that might possibly achieve this standard for raw meat and poultry products is irradiation. It is not yet practical to expect wide range use of this technology nor is it widely accepted by consumers.

The Agency can mandate all the CCPs it wants but the fact remains that it is unrealistic to expect raw meat and poultry products to be pathogen free. The Agency would better serve the consumer by acknowledging this fact and diverting resources that are currently spent on mandating ineffective CCPs on research that will hopefully provide the much needed technology that can be practically applied to eliminate these pathogens.

Question 3: Should FSIS Consider Regulatory Modifications to Acknowledge Prerequisite Programs?

The NACMFC HACCP Guidelines requires that the HACCP system be build upon a solid foundation of prerequisite programs. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe foods.

Incorporation of prerequisite program activities into a HACCP plan as CCPs is a misconstrued and inappropriate use of these programs. HACCP plans focus on a narrow scope of product production to ensure that food is safe to consume. Prerequisite programs span all product production activities and while they play an important role in ensuring food safety they cannot systematically ensure it. While it may be appropriate to incorporate a portion of a prerequisite program into the HACCP plan, such as oven calibration, the wholesale use of prerequisite programs in HACCP plans undermines the intent of the HACCP plan which is to control significant hazards at specific points of the process through the proper development and monitoring of CCPs.

NMA suggests that FSIS already has the regulatory authority to acknowledge prerequisite programs. FSIS has authority under the regulations to review and copy all "decision-making documents associated with the selection and development of CCPs" 9 C.F.R.§417.5(a)(2). If an establishment uses a prerequisite program to justify the absence of a CCP on the grounds that the food safety hazard is not reasonably likely to occur, the control program is a decision-making document accessible by the Agency. Should FSIS conclude that such program has not demonstrated itself capable of controlling the occurrence of the hazard, FSIS could review the supporting records to determine if the hazard analysis (and the plan itself) is inadequate. This provides FSIS with the regulatory basis to view the programs and to take action, but only when the failure of the control programs requires a reassessment of the hazard analysis.

Since control programs can be regulated by FSIS, establishments should be permitted, if not encouraged, to use such programs to assess the likelihood of the occurrence of any potential food safety hazard.

Question 4: Should FSIS Consider Implementing GMP Regulations a la FDA?

NMA does not believe separate GMP regulations are necessary. The majority of FDA GMP regulations deal with sanitation, a topic already covered by the Agency's general sanitation performance standard and SSOP regulations. 9 C.F.R. Part 416. Indeed, there is only one FDA GMP regulation not having a counterpart in FSIS regulations. This FDA regulation deals with process controls (21 C.F.R. § 110.80). On this topic, NMA believes the establishment control programs can be overseen as discussed in response to question 3 above. Accordingly, there is no need to adopt separate regulations.

Question 5: What Will Be the Effect of Making FSIS and FDA Regulations Dissimilar?

NMA respectfully submits that there already is some dissimilarity between the two agencies' HACCP regulations. This should not be surprising given that the regulations

deal with different products. Moreover, NMA anticipates that once FDA finalizes its juice proposal, there will be differences between the juice and seafood regulations. Finally, there already is different language being used by both agencies in terms of hazards.

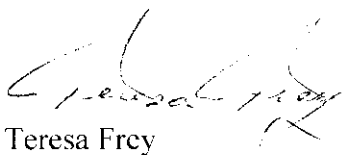
Question 6: Should the Changes be Considered in Light of the Views of Codex and Other Countries?

NMA submits that FSIS should consider the views of Codex and other countries in connection with the requested changes. NMA believes that those views will support the requested changes since the changes will improve the operation of HACCP in a regulatory environment.

NMA cannot overemphasize the need to resolve this issue. The question of whether HACCP is a hazard identification or risk management system must be answered if the Agency's food safety initiative is to proceed. Unless and until this issue is resolved: (a) training of Agency personnel cannot occur; (b) staffing needs cannot be determined; (c) effective communications with industry cannot begin; and (d) the Agency's verification activities cannot measure HACCP effectiveness. In short, until the nature of HACCP is resolved, the FSIS: Next Steps initiative will be ineffective.

NMA appreciates the opportunity to respond to the questions posed by the Agency in considering the industry HACCP petition and to reaffirm our support for the petition. Indeed, NMA respectfully submits that the petition must be adopted before any other activities are undertaken to ensure the viability of HACCP. NMA looks forward to continuing to work with the Agency on this important issue.

Respectfully submitted,



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