June 20, 2014

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
1400 Independence Avenue, SW
Room 8–163B, Mailstop 3782
Washington, DC 20250-3700

Re: Docket No. FSIS-2013-0029; Notice of Availability and Opportunity for Comments: Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling; 79 *Fed. Reg*. 22083 (April 21, 2014)

To Whom It May Concern:

Formed in 1906, the American Meat Institute (AMI) is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. AMI members manufacture more than 90 percent of these products. Also, approximately 80 percent of AMI member companies are classified as small or very small according to Small Business Administration standards. AMI members continue to adopt food safety practices to produce meat products, which are safe, affordable, and available. The safety of the products AMI members produce is their top priority.

In 2012 more recalls were related to improper labeling of allergens than recalls due to pathogens. AMI appreciates the opportunity to comment on the *Federal Register* Notice, FSIS-2013-0029 (the Notice) and Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling (compliance guideline, guide or guideline) in order to provide feedback and reduce allergen related recalls.

Focus the Guideline on Allergen Control

Throughout the guide it is clear that the Big 8 allergens are the focus of the guide through identification, prevention, control and declaration. However, on page five one paragraph discusses ingredients of concern that may cause an adverse reaction in susceptible individuals. AMI agrees that product should not be misbranded but some ingredients of concern are discussed and are in the guide without referencing the source of the list. In that regard, a list of ingredients of public health concern should be created in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) or similarly informed entity.

Solutions to Recalls Are Needed

The agency has categorized the cause of allergen related recalls. On page six of the guide the agency lists seven categories that are causes of allergen related recalls: new ingredient, new supplier, misprinted label, product in wrong package, product reformulation and ingredient reformulation. To make this guide more valuable and reduce allergen related recalls AMI suggests that the solution or corrective actions that address the cause of the recall be included in the guide. This information could be gathered from food safety assessments (FSA) that were completed as a follow-up to the recall or through the collaboration with trade associations such as the American Meat Institute. This solution-based information could be presented as scenarios without reference to specific products or locations.

Process Review Should be based on Prudent Control Strategies

The guide states that "**a review should be conducted on a continuous basis for each lot with increased attention when an establishment has changed supplier or the supplier has modified the ingredient formulas.**" Although this method could create control it is prescriptive and would create unjustified increases in manufacturing cost. Establishments should be allowed to develop allergen control procedures that address internal controls as well as supplier controls. This section of the guide (page nine) also states that the establishments review letters of guarantee (LOG). A review of letters of guarantee should not be confused with certificates of analysis (COA). The COA typically addresses a specific lot of product. In contrast, the LOG has no relation to a specific lot but is a more general statement of meeting regulatory requirements.

Role of Testing For Allergens Should Be Clarified

Page 10 of the guide states that an allergen testing program would supplement documenting the cleaning procedures and a visual cleaning assessment. Using allergen testing programs should be approached cautiously. Specific control procedures such as those that require allergen containing product to be run at the end of the production day should not be subjected to allergen testing procedure. However, allergen testing could be a viable means to address manufacturing practices that are not routine. These non-routine situations could relate to operational breakdowns, schedule changes, new product introductions or validation of suppler clean out programs. Testing ingredients should only be done in cooperation and knowledge of the supplier. This would help assure that the product related to the test was properly held.

Pages 16 and 18 refer to test results as well as procedures for verification of sanitation effectives. The guide states that [there should be] no allergens present on the production line and equipment or in the product. If the agency is suggesting that testing is the only way to meet the guideline then this guide has become an *ad hoc* regulatory requirement and proper rulemaking should be followed. If not, then examples of cleaning controls, and procedure of sanitation verification should be addressed in the guideline.

Properly Labeled and Packaged Products Constitute Appropriate Separation

Page 12 provides that "the storage of allergenic and non-allergenic final product needs to be easily identifiable as well as not cross-contaminated when placed in freezers, refrigeration units or dry warehouses." The guide goes onto say that "FSIS **recommends** (emphasis added) this process be included within an establishment's HACCP system." AMI contends that if products are properly labeled and packaged this constitutes product separation. To recommend unrealistic definitions of separation would thrust upon the industry unwarranted expense and have zero impact on correcting the cause of allergen recalls.

The Guide Purpose and Implementation; "Recommendation" or "Regulatory Requirements"?

The Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling states that the information in the guide are recommendations not requirements. FSIS, however, on page 12 states the recommendations are to be included in a HACCP system. This inconsistency strongly suggests that this compliance guide establishes regulatory requirements. In addition, on page two the agency states, "Although FSIS is requesting comments on this document, this guidance represents FSIS's current thinking. FSIS encourages establishments to use it." This is another example of compliance guides being issued without consideration for comments submitted and a command and control approach to compliance guideline material.

AMI appreciates the opportunity to submit these comments. If you have any questions about these comments or would like to discuss any aspect of them please contact me at 202 587 4254 or sgoltry@meatami.com.

Sincerely,

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Vice President
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