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Lynn Morrissette



August 18, 2005

Docket No. 95-051P
FSIS Docket Clerk
Cotton Annex Bldg., Room 102
300 12th St., SW
Washington, DC 20250-370

Re: Docket No. 95-051P – Food Standards; General Principles and Food Standards Modernization

Dear Sir/Madam:

The American Meat Institute (AMI or the Institute) submits the following comments regarding the above-referenced proposed rule. AMI represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb, and veal products and 70 percent of the turkey products in the United States. The Institute provides legislative, regulatory, public relations, technical, scientific, and educational services to the meat and poultry packing and processing industry.

AMI applauds the Food Safety and Inspection Service (FSIS or the agency) and the Food and Drug Administration (FDA) for recognizing the need for a systematic approach to modernize food standards. Further, we commend the agencies decision to work collaboratively toward this goal.

Because AMI represents manufacturers of FSIS regulated products, our comments will be aimed at the proposed FSIS general principles but should be applied to FDA's proposed general principles where the two are similar.

AMI agrees that food standards should be based on the finished product and should be used to protect consumers without unduly inhibiting technological advances in food production and marketing. We further agree that reliance upon external groups (*e.g.* consumer, industry, commodity, or other groups) to draft recommended revisions to existing food standards allows for participation in the review process by all interested parties. As the proposal suggests, industry likely has the most interest in, and knowledge of, food standards. Unfortunately, choosing this option also places the largest burden upon industry to change federally mandated food standards. Industry would be responsible for: reviewing existing standards; determining costs associated with existing standards or changes to the standards; gathering supporting documentation for needed changes; realizing consumer expectations associated with standards; and packaging the information into a format that meets the agency's needs. The process will likely be time consuming and resource intensive. As a result, it is unlikely that some small, and most very small manufacturers, would have the resources necessary to petition the agency for changes.

AMI supports the concept of general principles for petitioning the agency to change standards of identity. However, the general principles proposed are vague and need further clarification. In that regard, amending the proposed general principles or issuing supporting documents that explain the agency's expectations of how industry would meet the general principles would help.

For example, it is unclear how the *basic nature* of a product differs from the *essential characteristics* of a product. According to the proposal, the *essential characteristics* of the food are the "attributes of a food that make the food what it is even though they may not be readily apparent to the consumer." In contrast, the *basic nature* of the food is said to be "directly related to consumer expectations and beliefs about the food." The proposal provides an example describing the *basic nature* of a hotdog as "comminuted, semisolid sausage prepared from one or more kinds of raw skeletal muscle meat and/or cook poultry meat." It is difficult to believe that consumers actually understand that hotdogs are comminuted (they don't appear this

way in their finished form), semisolid, and prepared from one or more kinds of skeletal muscle tissue. This terminology is highly technical in nature and can be difficult to understand. The agency should further clarify the specifics of what elements comprise the *essential characteristics* and what elements comprise the *basic nature* of a food product. Additionally, FSIS should make clear how much data in support of claims regarding consumer expectations will be necessary.

We agree that food standards should provide flexibility in use of food technologies and ingredients. Removing language that requires using specific food technologies or ingredients is preferable. However, when elimination is not possible, a food standard that includes a specific manufacturing technology or process should allow for use of alternative methods so long as the resulting product has similar (but not identical) physical, nutritional, and sensory characteristics as the food made with the process specified in the existing standard. Similarly, AMI agrees that standards should specify ingredient use only in the broadest terms based on their function (*e.g.* sweeteners, stabilizers and thickeners) to maximize flexibility. Names of ingredients and functional use categories should be consistent across standards when possible.

The agency has proposed to begin compliance checks on finished products in-distribution. Traditionally, the agency has monitored product formulation to ensure compliance with the standard of identity. The agency asserts that conducting checks on finished products in-distribution will save agency resources. AMI disagrees with this assertion. Checking finished products in distribution would require that FSIS sample and perform chemical analyses on the products to determine their composition. Has the agency considered the expense associated with sampling and testing? Further, moving compliance checks to product that is in-distribution has the potential to increase the number of recalls. AMI recommends that finished product compliance checks be conducted at the establishment following pre-shipment review similar to the way FSIS conducts pathogen tests on finished product. To minimize the potential for recalls, establishments should be given sufficient notification to allow them the opportunity to hold the sampled lot prior to compliance sampling.

The agency is proposing to require that the standard of identity for foods include a declaration of whether the product is considered ready-to-eat

(RTE), or not RTE. Additionally, the agency is proposing that this information should be required to appear on the label of standardized foods. Unclear from the proposal is how this requirement would be applied to standards of identity for products where the standard allows for either raw or cooked forms of the product to be sold? For example, the standard of identity for meatballs applies to both raw and cooked forms of pork, beef, veal, or lamb and ingredients in ball form. It is not possible to include a declaration in the standard of identity that considers meatballs to be RTE or not RTE. It is more valuable to consumers to provide them with information regarding cooking requirements and safe handling of the product rather than simply labeling the product as RTE or not RTE, without defining what the terms mean and how it affects product preparation.

Lastly, AMI recommends that the agency continue to move forward with efforts to harmonize U.S. food standards with international food standards when possible. As global trade continues to grow, the need for consistent standards of identity becomes critical.

We appreciate the opportunity to provide you with our thoughts and recommendations on the agencies' proposed general principles and food standards modernization. We look forward to working with you on this effort as it progresses.

Sincerely,



Lynn Morrissette
Director Regulatory Affairs

cc: J. P Boyle
M. Dopp
J. Hodges
S. Seward