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# MICHAEL FOODS<sup>INC</sup>

December 12, 2005

Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
300 12<sup>th</sup> Street  
Washington, DC 20250

Re: Docket No. 05-013N "...Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry," 70 FR 67490, 67493 (November 7, 2005)

Dear Sirs:

Michael Foods, Inc. respectfully submits the following comments regarding consideration of changes to regulatory jurisdiction for certain food products containing meat and poultry.

FSIS and FDA working group presented in 70 FR 67490, 67493 (November 7, 2005) background and recommendations for transfer of regulatory jurisdiction for several categories of food products. The agencies also requested comment concerning other food products or categories of foods that should also be considered by the agencies for consolidation of regulatory jurisdiction. We are recommending that the agencies consider consolidation of regulation of egg substitutes flavored with meat or poultry under Food and Drug Administration.

Egg substitutes containing meat and poultry are new products that are expected to appear in the market in the near future. The new products will be marketed under the brand name "Better 'n Eggs.®" This brand, that has been sold for over 20 years in the United States, is exclusively associated with egg substitute products. It is relied on by customers who wish to replace whole egg in their diet with an egg substitute so as to avoid the fat and cholesterol associated with whole eggs. There are several Better 'n Eggs egg substitute products currently marketed as well as brand name egg substitutes produced by other companies. The new egg substitutes containing inspected and passed fully processed and ready-to-eat meat or poultry will be marked for the same intended use as an egg substitute – the only difference being that they would be flavored with meat or poultry. An example would be a ham and cheese flavored egg substitute.

Because the new product is an egg substitute that is prepared from inspected egg products, it is not subject to FSIS regulations governing egg products. 9 CFR 590.5. However, because it may contain more than 2% meat or poultry, we understand that it may be subject to FSIS regulations governing meat products. We note that this product is similar to a pizza made with meat in that it contains meat for flavor but is not primarily a meat product – and there fore need not be regulated by FSIS. See 70 FR 67490, 67493 (November 7, 2005) (discussing the regulation of pizza products).

As described for pizza, meat or poultry products are used in the egg substitute products as a flavoring and do not materially change the character of the food as an egg substitute product. The agencies also presented examples of other food categories, "Cheese and Cheese Products," "Bread, Rolls, and Buns," and "Salad Dressings" made with less than 50 percent meat or poultry where meat or poultry

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are included as flavoring, but do not change the primary character of those foods. In those examples, the agencies are considering changing jurisdiction of those products from FSIS to FDA.

Our recommendation, that egg substitutes flavored with meat or poultry be regulated by FDA, is consistent with proposed transfer of regulatory jurisdiction the agencies are discussing in 70 FR 67490, 67493 (November 7, 2005). We believe that such a consolidation under FDA would not be disruptive of industry and would allow efficient delivery of new egg substitute products to consumers using egg substitutes. Consolidation of regulation under FDA would also eliminate conflicting regulatory requirements regarding serving size statements and direct fortification if an egg substitute were to contain more than 2% meat or poultry as a flavoring. Examples are:

Meat and poultry regulations for products containing 2% or more meat or poultry require a serving size of 110 grams (9 CFR 317.312(b)) in contrast to 56 grams that has been consistently used and accepted by egg substitute consumers (21 CFR 101.12(b)).

FSIS policy is that meat and poultry products can not be fortified. FSIS has not allowed direct addition of nutrients to egg substitutes flavored with more than 2% meat or poultry. Under FDA regulations, an egg substitute is required to be fortified with nutrients so that it will not be nutritionally inferior to the egg products for which it substitutes. If it is not fortified, then it must be labeled as an "imitation egg" product and may not be labeled as an "egg substitute." 21 CFR 101.3(e).

Regulating meat or poultry flavored egg substitutes under FDA jurisdiction and regulations will allow consistent labeling for serving sizes and inclusion of nutritional content that egg substitutes consumers have come to expect.

We believe that FSIS and FDA have initiated much needed discussion and have laid out good arguments and solutions for removing unnecessary dual-jurisdictional regulations for several categories of foods. We recommend that the agencies consider including egg substitutes flavored with meat or poultry as a category of food that should be regulated as an egg substitute.

Respectively,

Hershell Ball, Jr., Ph.D.  
Vice President Research