November 4, 2005

MEMORANDUM FOR AMI INSPECTION AND SCIENTIFIC AFFAIRS COMMITTEE MEMBERS

FROM: LYNN MORRISSETTE & MARK DOPP

SUBJECT: POSSIBLE CHANGES TO REGULATORY JURISDICTION OF CERTAIN PRODUCTS CONTAINING MEAT AND POULTRY

The Food Safety and Inspection Service (FSIS or the agency) and the Food and Drug Administration (FDA) (collectively the agencies) have issued a notice announcing a public meeting to be held December 15 to discuss which of the two agencies should have jurisdiction over certain types of food products that contain meat and poultry as ingredients. The agencies are soliciting comments on their decision-making approach.

The agencies share regulatory responsibility for the food supply. In the past, FSIS has determined its jurisdiction based on various factors including: the amount of meat or poultry in the product; whether the product is labeled as a meat or poultry product; and whether consumers perceive the product as a meat or poultry product. FSIS acknowledges that some of its past decisions were based on issues of consumer perception that are inconsistent with other decisions that had been made regarding FSIS jurisdiction over other products and at best the basis for certain decisions regarding jurisdiction is unclear. As a result, the agencies are struggling to determining regulatory jurisdiction for some new foods that contain meat and poultry ingredients (e.g. wrap-type sandwiches).

FSIS and FDA formed a working group to explore jurisdictional issues and to develop “an approach for making sound, clear, and transparent decisions about product categorization and agency jurisdiction.” The working group determined that the agencies could provide a clearer approach to deciding jurisdiction based on the contribution of the meat or poultry ingredients to the food’s identity. In other words, does the addition of the meat or poultry contribute to the food’s basic nature by characterizing the food?

Applying this approach to jurisdictional decisions may result in a change of jurisdiction for some foods. In the notice the agencies indicated that they anticipate changes of jurisdiction
from FDA to FSIS for foods such as: bagel dogs, closed-face meat and poultry-containing sandwiches, and natural casings, because these products are characterized or identified by terms that refer to meat and poultry ingredients and reflect the contribution of the components to the food. Using the same approach, FSIS and FDA anticipate vesting jurisdiction within FDA for foods such as: bread/rolls/buns, cheese products, flavors, pizzas, and salad dressings, which contain meat or poultry that add flavor to foods but do not alter the character of the product. The notice explores each of these food categories and the concepts underlying such changes in greater detail.

The agencies recognize that establishments affected by jurisdictional changes will encounter additional administrative, inspection, and labeling requirements. Specifically, establishments producing FDA regulated products that could become subject to FSIS inspection will have to receive a grant of inspection, develop and implement a HACCP system, implement SSOPs, implement pathogen controls and conduct testing where appropriate, develop and implement recordkeeping, and receive label approvals from FSIS.

The agencies will hold a joint meeting December 15, 2005, from 10 AM to 4 PM at the Donald E. Stephens Convention Center located in Rosemont, IL to solicit input on the new approach to determining regulatory jurisdiction of products containing meat and poultry ingredients. In that regard, the agencies are looking for answers to the following questions.

- Is the approach suggested by the agencies a reasonable one and if not, why?
- Are there other food products or product categories that have been the subject of historical regulatory jurisdictional decisions by FSIS, which were based on a consumer perception factor, that should be considered by the agencies?
- How many firms or establishments would be affected for each product and product category? What is the volume of production for each product or product category?
- Would modifications in equipment, facility design, labeling, recordkeeping, or processing and reporting responsibilities be needed in order for current operations to continue making the products that are the subject of the suggested changes, and if so what are they?
- What would the administrative, operational, marketing, and labeling costs be associated with changes in product jurisdiction?
- What would be a reasonable process and time frame within which to implement any changes in jurisdiction?
- What would be consumers’ views on the subject products under the suggested approach? More particularly, what effect would changing regulatory jurisdiction have on consumers’ perceptions of the subject products? For example, what would consumers’ reaction be to the fact that dried chicken soup mix is regulated by FDA?
- What effects would there be, if any, on the way the subject products are marketed?
To register for the meeting, please refer to the instructions in the notice available at: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/05-013N.pdf.

AMI will submit written comments in response to this notice and will attend the December 15 meeting. If you have comments on the notice or answers to the questions posed by the agency that you would like AMI to include in its comments please send them to Lynn Morrissette at: Lmorrissette@meatami.com or call (202) 587-4237.

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