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Food Safety Inspection Service Docket Clerk
U.S. Department of Agriculture
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, D.C. 20250

Subject: Docket Number 05-013N - Regulatory Jurisdiction of Certain Food Products
Containing Meat and Poultry

To Whom It May Concern:

On behalf of the American Spice Trade Association (ASTA), I am pleased to submit the following comments concerning "Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry," 70 Fed. Reg. 67490 (November 7, 2005). ASTA represents the interests of approximately 300 members including companies that grow, dehydrate and process spices and seasoning blends. ASTA members create a wide variety of products, such as seasoning blends, dried soup mixes and gravy mixes, flavors, and flavor bases that currently fall under the jurisdiction of both the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS).

ASTA Supports the Joint Effort to Clarify Jurisdiction

ASTA supports the attempt to provide clarity and consistency with respect to which of the two agencies, FDA or FSIS, has jurisdiction over certain types of food products that contain meat and poultry as ingredients. There are several factors that support consolidating jurisdiction over seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases under a single federal agency - the U.S. Food and Drug Administration (FDA).

Reasons for Clarifying that Certain Products Fall Exclusively Under FDA Jurisdiction

There are several reasons to consolidate regulatory oversight over seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases made with previously inspected meat and poultry products under the FDA. Several relevant statutes make it clear that flavors are not to be considered meat or poultry products and jurisdiction for regulations

affecting flavors or additives lies with the FDA. The products manufactured and processed by ASTA members, such as seasoning blends, dried soup mixes and gravy mixes, are similar in nature to flavors, meaning they are ingredients and not meat products. Under the provisions of the Federal Meat Inspection Act, “meat food product” means:

any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such products are not represented as meat food products...¹

A provision in the Poultry Products Inspection Act defines “poultry product” in a similar way, exempting products which contain poultry ingredients only in a relatively small proportion or those historically not considered by consumers as products of the poultry food industry.² Seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases made with small amounts of meat or poultry products are consistent with these definitions of products excepted from the definitions of meat and poultry product.

USDA jurisdiction over seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases made with small amounts of meat and poultry is inconsistent with the basic nature of these products. We agree with the comments in the *Federal Register* notice related to dried poultry soup mixes, but we feel that the reasoning should be applied to all of the following products: seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases, when made with less than 50% dried meat or dried poultry. These products contain meat and poultry products that have been previously inspected and therefore they should be under FDA jurisdiction.

Additional guidance on this subject comes from Congress in the Federal Food, Drug & Cosmetic Act with authority given to the Department of Health and Human Services and then delegated to the FDA for establishing regulations affecting flavors, colors and spices when they are sold as ingredients in foods.³ From these provisions we clearly see that Congress did not intend for products such as seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases to be covered by the meat and poultry statutes. Therefore, consolidating jurisdiction over these products under the FDA is consistent with the provisions of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act.

¹ 21 U.S.C. 601(j)

² 21 U.S.C. 453(f)

³ 21 U.S.C. 301 et. seq.

Predictability of requirements for the regulated industries is another reason for consolidating jurisdiction for most of these products under the FDA. As stated in the *Federal Register* notice soliciting comments, “Confusion persists about the reasoning used with respect to various decisions about which agency has jurisdiction over certain food products containing meat and poultry.”⁴ This confusion results in an uneven and wasteful oversight that sometimes challenges the regulated industries to guess which agency covers a particular product. It should also be noted that continuous inspection as required under USDA regulations results in more costs than necessary for the protection of the consumer.

Because of the wide variety of products that seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases are used in, FDA currently has jurisdiction over a larger number and greater variety of products containing these ingredients than does USDA. This is another justification for consolidation under the FDA.

Finally, seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases are made with small amounts of previously inspected and passed dried or powdered meat and poultry. This previous inspection provides adequate protection to consumers.

Dried Poultry Soup Mixes

We agree with the suggestion in the *Federal Register* notice that “dried poultry soup mixes” should fall under FDA jurisdiction. As stated in the notice, the components used to prepare these products are not in a form that is recognized as “meat” or “poultry” and are used at low levels for seasoning or flavoring effects. Therefore jurisdiction over these products should be moved from FSIS to FDA.

Response to Members of the Task Force

During the joint FDA/FSIS public meeting held in Chicago on December 15, 2005, members of the joint agency panel requested that ASTA provide a suggested definition of “seasoning blend” since there is not one found in the CFR. We propose that “seasoning blend” means: a mixture of dry food ingredients, used to impart flavor that contains flavoring constituents, including natural and artificial flavors, spices, carriers, starches, sugars and color additives, whose significant function in food is flavoring rather than nutritional.”

Answers to Questions in Federal Register Notice

ASTA provides the following answers to the specific questions posed in the November 7, 2005 *Federal Register* notice:

Q: Is the approach that is suggested by the agencies a reasonable one? If not, why not?

A: Yes, providing consistency and predictability with respect to which of the two agencies should have jurisdiction over certain types of meat and poultry products is a reasonable effort that ASTA supports.

⁴ 70 Fed. Reg. 67491 (November 7, 2005)

Q: 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?

A: We estimate that dozens of U.S. based companies are currently under FSIS inspection only because they use previously inspected meat or poultry products in limited quantities in the manufacture of seasoning blends, dried soup mixes and gravy mixes, flavors and flavor bases. We also believe that many companies have decided not to manufacture these products because of the costs and uncertainty associated with these jurisdictional issues.

Q: What would be a reasonable process and time frame within which to implement any changes in jurisdiction?

A: ASTA requests that any proposed changes follow the notice and comment rulemaking provisions of the Administrative Procedures Act and that there be a reasonable amount of time from the publication of a final rule until changes become effective.

Q: What would be consumers' views of 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 the FDA?

A: We believe that the average consumer does not understand the difference between FSIS and FDA jurisdiction or inspection oversight.

Conclusion

ASTA is grateful for the opportunity to comment on this important issue. This effort should not be viewed as an effort to de-regulate certain products made with meat or poultry ingredients, but rather it would simplify the regulatory process by placing jurisdiction under a single federal agency and would enhance consumer safety. The FSIS, the FDA, and most importantly, the consumer, would benefit greatly from the clarification and consistency that could be achieved. ASTA looks forward to additional announcements from the agencies on this issue and we are available to provide additional information.

Sincerely,



Cheryl Deem
Executive Director