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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 Flavor and Extract Manufacturers Association of the U.S. (FEMA), 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). FEMA is the national association of flavor manufacturers and represents the vast majority of flavor companies in the United States. FEMA members create flavors for use in a wide variety of food and beverage products including those currently under the jurisdiction of both the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS).

FEMA Supports the Joint Effort to Clarify Jurisdiction

FEMA 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 flavors under a single federal agency - the U.S. Food and Drug Administration (FDA). Although any regulatory changes should address the wide variety of categories of meat and poultry products used to make flavors, FEMA encourages the agencies to adopt the following general principle when addressing this issue:

All flavors, flavor bases and seasoning blends shall be manufactured under the exclusive jurisdiction of FDA. Any meat or poultry product previously inspected by USDA may be used as an ingredient in flavors, flavor bases and seasoning blends without any additional inspection by USDA.

The adoption of this general principle is consistent with the relevant statutes and it is in the best interest of the consumer, the agencies and the flavor industry.

Reasons for Clarifying that Certain Products Fall Exclusively Under FDA Jurisdiction

There are several reasons to consolidate regulatory oversight for flavors made with 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. 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 Flavors, flavor bases and seasoning blends made with meat or poultry products are consistent with these definitions of products excepted from the definitions of meat and poultry product as they typically are not considered by consumers to be meat or poultry products and do not contain significant amounts of recognizable meat or poultry ingredients.

Consumers do not consider flavors as food but rather as ingredients that make the consumption of food a more enjoyable experience. These ingredients are used in products that are regulated by the FDA or the USDA and their presence is self limiting due to their potent aroma and flavoring properties. This fact has been recognized by Congress and additional guidance on this subject is outlined under the Federal Food, Drug & Cosmetic Act with authority given to the Department of Health and Human Services and then delegated to FDA for establishing regulations affecting flavors, colors and spices when they are sold for ingredients in foods.³ From these provisions we clearly see that Congress did not intend for products such as flavors to be covered by the meat and poultry statutes.

¹ 21 U.S.C. 601(j)

² 21 U.S.C. 453(f)

³ 21 U.S.C. 301 et. seq.

Moreover, FDA promulgated regulations in 1979, establishing definitions for spices and flavors and their proper labeling requirements.⁴ USDA adopted FDA's definitions for spices and natural flavors by incorporating them into their own regulations. These definitions of natural flavor include specific references to flavors containing ingredients derived from meat and poultry, for the function of their flavor properties, not nutrient purposes: "The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional."⁵

FDA has jurisdiction over a larger number and greater variety of products than USDA and also has more experience and expertise in dealing with flavors, flavor bases, spices and seasonings. FDA has a long history of assessing the safety and use of these ingredients and is best suited to exclusively regulate those containing meat or poultry products as well. USDA jurisdiction over flavors made with small amounts of meat and poultry is inconsistent with the basic nature of these products. In flavors, flavor bases and seasoning blends, the meat and poultry ingredients do not contribute to the product's nutritional value but rather they are simply used to impart flavor. Additionally, flavors, flavor bases and seasoning blends are not typically consumed as such, but are added to other products for flavoring purposes. 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, the Federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations.

Predictability of requirements for the regulated industry 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."⁶ This confusion results in an uneven and wasteful oversight that sometimes challenges the regulated industries to guess which agency covers a particular product.

This is particularly true for flavors because USDA does not have clear cut regulations or guidance detailing what amounts of specific forms of meat or poultry ingredients present in a product cause it to be amenable. FEMA members often are unclear as to when a particular flavor, flavor base or seasoning blend might be subject to USDA jurisdiction. The agency, itself, is often inconsistent in determining amenability for flavors, flavor bases and seasoning blends and offers conflicting determinations over nearly identical formulations.

⁴ 21 CFR 101.22

⁵ 9 CFR 317.2(f) and 381.118c

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

To eliminate this confusion, ALL flavors, flavor bases and seasoning blends should be regulated exclusively under the jurisdiction of FDA.

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. Again, it is FDA which has the greater experience in regulating flavors, flavor bases and seasoning blends. FDA alone can provide consumers adequate protection.

As mentioned above, FEMA urges the agencies to adopt an overall approach that allows the use of any previously USDA inspected meat or poultry product as an ingredient in flavors, flavor bases or seasoning blends. Should the agencies disagree with this position, then FEMA urges that, at a minimum, they clarify with specificity which types or forms of previously inspected meat and poultry products may be used in flavors, flavor bases, and seasoning blends without additional USDA inspection.

During the joint FDA/FSIS public meeting held in Chicago on December 15, 2005, members of the joint agency panel requested that FEMA 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 and color additives, whose significant function in food is flavoring rather than nutritional.”

Answers to Questions in Federal Register Notice

FEMA 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 FEMA supports.

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 flavor manufacturers are currently under continuous FSIS inspection only because they use previously inspected meat or poultry products in certain quantities in the manufacture of flavors, flavor bases, or seasoning blends.

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

A: If the Agencies concur with FEMA's recommendations and establish corresponding regulations or statements of policy, implementation could be effective concurrent with the Agencies' determination. Otherwise, FEMA requests that any proposed changes be implemented as soon as possible in compliance with the Administrative Procedures Act.

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. This is particularly true of flavors which are not directly consumed by the public. As long as the consumer feels that all food items in their shopping cart are safe, they are unlikely to care significantly about which agency oversees the inspection during manufacture, storage or transportation.

Conclusion

FEMA is grateful for the opportunity to comment on this important issue. This effort would simplify the regulatory process by placing jurisdiction under a single federal agency and would enhance consumer safety. We strongly urge the agencies to adopt and implement FEMA's position that:

All flavors, flavor bases and seasoning blends shall be manufactured under the exclusive jurisdiction of FDA. Any meat or poultry product previously inspected by USDA may be used as an ingredient in flavors, flavor bases and seasoning blends without any additional inspection by USDA.

FSIS, FDA, Industry, and most importantly, the consumer, will benefit greatly from the clarification and consistency that will be achieved. FEMA looks forward to additional announcements from the agencies on this issue and we are available to provide additional information.

Sincerely,



Glenn Roberts
Executive Director