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FSIS Docket Clerk
U.S. Department of Agriculture
Cotton Annex Building, Room 102
Food Safety and Inspection Service
300 12th Street, S.W.
Washington, D.C. 20250-3700

Re: Docket No. 05-013N; Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry; Comment

Dear Sir or Madam:

Nestlé USA, Inc. commends the Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS) (collectively, "the Agencies") for the leadership and cooperation that produced the *Federal Register* notice "Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry"[1] and the planned changes to the regulatory jurisdiction of certain foods containing meat and poultry. There is inherent value in rationalizing jurisdiction between the two agencies to the greatest extent possible to allow for predictable and logical regulation to the benefit of industry and consumers alike. Perhaps most importantly, an efficient and rational inspection system allows both agencies to target resources in ways that will best serve their regulatory responsibilities in the area of food safety.

Nestlé produces a large number of product lines, many of which fall under the dual jurisdiction of the Agencies. While the Agencies have made great strides in harmonizing labeling, ingredient safety, and related requirements, significant differences remain. The present initiative provides an important opportunity for the Agencies to bring to an end duplication and inconsistency in regulations in the several food categories identified in the Notice. Nestlé also encourages the Agencies to address certain related, broader issues identified below.

There is a great need for clear principles that provide predictability and certainty once the planned changes are in place. Presently, the mere process of determining the scope of products that fall under each agency's rules can itself necessitate a lengthy dialogue with one or both Agencies, thereby diverting resources away from critical agency functions. This is particularly true for new, innovative products that may not have been contemplated when many of the current policies were established. For example, Nestlé met on several occasions with FSIS

[1] 70 Fed. Reg. 67490 (Nov. 7, 2005).

staff about a new product only to learn well into the process that the agency determined that the product falls outside of its jurisdiction. Accordingly, the present system serves as a barrier to industry innovation and the ability to respond to consumers ever-growing demand for convenient, healthful, and innovative foods.

I. GUIDING PRINCIPLES: THE NEED FOR CONSISTENCY

Nestlé fully agrees and is encouraged by recognition by the Agencies that a clearer approach to determining jurisdiction is both necessary and possible. The Agencies should make jurisdiction determinations based on the basic principle set forth in the Notice — "the contribution of the meat or poultry ingredients to the identity of the food."[2] The Agencies have prudently acknowledged that, in some cases, "the meat or poultry ingredients are distinctive and significantly contribute to a food's basic nature by characterizing the food," while in other cases, "the meat or poultry ingredients are used in such a way that they do not contribute to the product's basic nature because they are not easily distinguished and are used to simply add flavor."[3]

It is important that the updated policies contemplated by the Notice be fashioned in a manner that avoids placing similar food categories under the jurisdiction of different Agencies. This circumstance creates confusion, wastes resources, and serves no obvious public health goal. Hence, in fashioning the policies that will implement the Notice, Nestlé deems it vital that the Agencies take a careful look at all related product lines and move all such products to the jurisdiction of a single agency. In this regard, Nestlé offers several instances where clarity and consistency in defining the scope of like products for purposes of jurisdiction are important.

A. Relevance of Product Name

To establish and maintain the planned change in how jurisdictional limits will be defined, the Agencies should not give undue consideration to the product name or other attributes of a product label that highlight the meat or poultry component of the product. As a "flavor designator" within a larger product line, the product name (or other means of prominently featuring the meat or poultry component) is an effective way to enable consumers to readily distinguish like products offered under a common brand name. Inhibiting the ability of food processors to highlight the meat or poultry component out of concern that the product will be deemed as misrepresented as subject to FSIS jurisdiction would significantly undermine the benefits of the planned jurisdictional changes. This concern is illustrated below with respect to pizza products.

B. Inspection and Reinspection

The Agencies should focus on whether the meat or poultry product is being inspected for the first time by FSIS or re-inspected when the meat or poultry is a component in a

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[2] *Id.* at 67491.

[3] *Id.*

further processed food. Efficient use of enforcement resources to ensure a safe food supply is an important consideration that should underscore the Agencies' policy with respect to basic principles, and it should be applied in examining amenability/jurisdictional issues for individual products.

USDA has examined the relative value of re-inspection of further processed foods that contain a meat component that has already been subject to inspection by FSIS. A 1983 study determined that there is no food safety basis for duplicative inspection. The Report's conclusions include the following.

> The study found that inspection of many processed products involves the reinspection of previously inspected products. The analysis indicated that the health and safety risks associated with such products were similar to those under FDA jurisdiction....The study did not identify any special concerns for these types of processed products related to their use of a meat or poultry food product.

There is no health or safety justification for duplicative FSIS continuous inspection when the meat component of the further processed product is fully cooked and has already undergone FSIS inspection. [4]

The study's findings remain relevant today. Realigning the jurisdictions of the Agencies does nothing to undermine the current effectiveness of the present FSIS continuous inspection system. As noted in the Jurisdiction Q&A, "products that are determined not to be under FSIS regulatory jurisdiction must still be prepared with USDA inspected and passed meat or poultry, or with meat or poultry from an inspection system equivalent to the USDA inspection system." [5]

II. JURISDICTIONAL ADJUSTMENTS TO RATIONALIZE CURRENT INSPECTION SYSTEMS

Nestlé is supportive of the initiative and, in particular, favors the tentative decisions reached with respect to pizzas and flavors. At the same time and as described in greater detail below, several adjustments are necessary to ensure consistency with the stated logic of the Notice and to best serve the efficient allocation of regulatory resources. It is imperative that the Agencies redefine the product categories in a fashion that keeps similar products at a single agency in order to meet the underlying objectives of the present initiative.

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[4] The study reasonably concluded the opposite with respect to meat or poultry components that are not fully cooked. The study determined: "For this very important health reason, this type of assembly operation, one which includes uncooked or partially cooked meat/poultry required to be cooked before eating is not appropriate to be considered for exemption." *Id.* at 17.

[5] Q&A at 3.

This comment also provides the Agencies with input on three additional issues related to the initiative underway. First, the Agencies should anticipate and alleviate, to the extent possible, certain implementation issues that may follow any jurisdictional shifts. Second, the Agencies should consider which of the planned changes can be implemented by way of a second Notice in the *Federal Register*, such that notice-and-comment rulemaking is unnecessary. Such action would enable the Agencies to more readily reach the planned benefits of this initiative. Third, the present initiative provides a valuable opportunity for the Agencies to consider how differences that remain between the agencies can be better reconciled, particularly with respect to the necessity of prior label approval and the degree of reliance on food standards (particularly informal food standards that were not created pursuant to notice and comment rulemaking).

A. Comment On Specific Product Categories

1. Pizzas with Meat or Poultry

Nestlé fully supports the determination by the agencies that all pizzas and like products should fall under the jurisdiction of a single agency, FDA. In making this long-needed adjustment in jurisdiction it is important that the Agencies clarify the scope of products that will be covered as there are many products that FSIS has historically regulated as pizzas that properly should be regulated by FDA, including hand-held items, whose primary components include tomato sauce, bread/crust, cheese, and other toppings added for flavor. Nestlé markets many such products under its Hot Pockets® and Lean Pockets® brands, along with many other companies. The marketplace reflects the variety of different pizza-like products.

In 2003, FSIS properly rescinded its antiquated pizza standard, recognizing that the concept of a "pizza" had moved well beyond the requirement that such products are composed of sauce and cheese and contain two percent or more of meat or poultry. It has long been a curious sight in food processing plants to observe two pizza lines running side-by-side producing nearly identical product, yet the line that adds several slices of pepperoni to the product falls under a distinct set of federal regulatory requirements. Certainly the distinction drawn by federal regulators would be lost on consumers. Material to consumer purchases is the quality and safety of the food product. There is no question that the products coming off the "FDA-line" are identical to the products with meat toppings coming off the adjacent line.

The Notice correctly finds that the "base onto which toppings are placed represents the majority of the product, and meat or poultry ingredients may be among any number of toppings used for flavoring purposes."[6] The Agencies further note that the nature of the toppings influences the flavor of the finished pizza product but does not "change the character of the food." Nestlé further concurs with the Agencies' observation that "meat and poultry ingredients that are added to breads, cheese products, flavors, pizzas, and salad dressings

[6] 70 Fed. Reg 67490, 67493 (Nov. 7, 2005).

are used to accentuate flavor but do not contribute to the fundamental identification of the products."[7]

Having recognized the need and value of rationalizing inspection jurisdiction it is important that the Agencies extend the underlying rationale to all pizza and like products where the meat component is but one of several optional ingredients that are added to the finished product as a flavor or different variety of the same, like product. Hand-held items placed on or wrapped within a soft crust are essentially the same, both with respect to the nature and the amounts of the ingredients associated with a pizza. As FSIS recognized in removing the pizza standard, consumer expectations of this product category include a wide and varied range of products that continues to evolve. As noted in the preamble: In some cases, "the meat or poultry ingredients are used in such a way that they do not contribute to the product's basic nature because they are not easily distinguished and are used to simply add flavor."[8]

A source of concern and potential confusion is a statement in the preamble to the Notice that could be construed as suggesting that the prominence of a meat or poultry term in the product name could dictate the Agencies' decision on the jurisdictional question. In reference to foods that are predominantly characterized by the meat or poultry content, the preamble notes that "these products are identified by terms that refer to the meat and poultry ingredients, reflecting the contribution of the meat and poultry components."[9]

Nestlé is concerned that framing the policy in this fashion will cause confusion and undercut the purposes of the planned changes. That is, merely referencing a meat or poultry term as part of the product name should not have a bearing on the planned policy. If that were the case, a "Pepperoni Pizza" would remain under FSIS jurisdiction because the meat component is prominently featured in the product name. Clarity in this regard is particularly important given FSIS' view that it can take action against an FDA-regulated product containing no meat or poultry if a flavor term (i.e., "chicken" or "beef") is prominently featured either as a front panel claim or a product name. Nestlé recommends that the Agencies revisit the noted preamble language and consider framing the broader issue in a manner that avoids the potential confusion that could arise.

Beyond the commonality of different types and configurations of pizza and like products, FSIS itself historically has viewed so-called "hand-held" items as pizza products. Indeed, prior to elimination of this standard, all of the Nestlé hand-held products were required to meet the pizza standard. This policy reflected a determination by FSIS that consumers held similar expectations for these products as were held for traditional pizza products, where the toppings sit atop, rather than within, the dough/crust. Consistent with the principles articulated in the Notice, other products that combine dough, cheese, and various ingredients added to

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[7] FSIS & FDA Jurisdiction Q&A's at 3.

[8] 70 Fed. Reg. at 67491.

[9] *Id.* at 67492.

characterize the particular flavor of a product should similarly be moved under FDA jurisdiction. Ensuring regulatory consistency supports clarification by the Agencies that these so-called hand-held pizza products and similarly formulated items will be regulated with the rest of the pizza category by FDA.

Similar to pizza and portable, hand-held items, the Agencies should also give some consideration to other products that are essentially FDA-regulated foods, but for the addition of some quantity of meat or poultry as a flavor. For example, lasagna products with and without meat are essentially the same basic product (flat noodle, cheese, tomato sauce) whereby the meat is used to flavor the product. The consideration of these additional categories of common products is further supported when the meat or poultry component has already undergone FSIS inspection and is fully cooked when added to the further processed product.

2. Flavors and Seasonings

Nestlé also fully supports the determination by the Agencies to consolidate jurisdiction for flavors and flavor bases under the FDA. As stated in the Notice, meat and poultry are used in these products only for a flavoring effect, and pursuant to the guiding principle in the Notice, these types of products, therefore, fall more rationally into the realm of FDA jurisdiction.

Consistent with the rationale applied to flavors and bases, all similar products should also fall under FDA jurisdiction. This would include seasoning blends and gravy mixes. Like flavors and flavor bases, these products, when they contain meat or poultry, only contain the meat or poultry for flavoring. Further, they only contain meat or poultry that has been previously inspected by FSIS. This previous inspection provides adequate protection to consumers.

Moreover, flavors, and like products, should not fall under the jurisdiction of USDA because they do not fall within the statutory definition of meat or poultry product. The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) exempt from the definition of meat and poultry food products those products that "historically have not been considered by consumers as products of the meat/poultry food industry."[10] Indeed, meat and poultry flavors are not considered by consumers to be products of the meat or poultry industry. The meat and poultry flavors have intense flavors, limiting their use, and do not share the physical or organoleptic properties of traditional meat or poultry products. Moreover, these ingredients are not sold directly to consumers but are intended for use by food manufacturers as ingredients that will be used in finished foods. Accordingly, there is no element of "consumer expectations" that would dictate which agency should regulate this category of products.

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[10] 21 U.S.C § 601(j) (meat); 21 U.S.C. § 453(f) (poultry).

FSIS has established a regulation to clarify the poultry products that are exempt from inspection.[11] . FSIS specifically recognizes in Section 381.15(c) that bouillon cubes, poultry broths, gravies, sauces, and flavorings are not amenable when:

> (1) They contain poultry meat and/or "Mechanically Separated (Kind of Poultry) as defined in § 381.173 or poultry fat only in condimental quantities;
>
> (2) They comply with the provisions of paragraph (a)(3), (4), and (5) [*i.e.*, the poultry ingredients must be prepared under inspection, the immediate container bears a label with the name of the product, and the product is not represented as a poultry product]; and
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> (3) In the case of poultry broth, it will not be used in the processing of any poultry product in any official establishment.

FSIS, however, has never defined "condimental quantities," and the resulting ambiguity has led to much inconsistency among companies and, more importantly, among the agency's amenability decisions.

All meat and poultry flavors should fall within the FDA definition for "natural flavor," regardless of the level of meat or poultry in the product. While the PPIA and FMIA are silent on the regulation of flavors, the Federal Food, Drug, and Cosmetic Act (FFDCA) contains a statutory provision that specifically addresses the labeling requirements for flavors.[12] This statutory provision evidences a congressional intent for FDA, rather than USDA, to have jurisdiction over flavors. Moreover, FDA has established a definition for "natural flavor" that includes extractives, protein hydrolysates, or any product of roasting, heating or enzymolysis, containing the flavor constituent derived from meat and poultry "whose significant function in food is flavoring rather than nutritional."[13]

The statutory reference to flavors in the FFDCA and the FDA definition for "natural flavors" encompassing meat and poultry flavors provides a compelling argument that flavors should be regulated by FDA and not USDA. Accordingly, there is not only a strong legal basis for the changes identified but, current law compels the Agencies to make these changes to properly align the reach of their respective jurisdictions with the statutory authority under which they operate.

The current system also creates substantial practical difficulties for food processors that greatly complicate and increase operational costs without any corresponding benefit to consumers. Different labeling requirements are imposed on the same flavors,

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[11] 9 CFR § 381.15.

[12] FFDCA § 403(i)(2)

[13] 21 CFR § 101.22(a)(3).

depending on whether the flavors are used in a FSIS-regulated product or a FDA-regulated product. For example, differences in the common or usual name of certain ingredients.

To avoid this practice that has long confused consumers and industry, the Agencies should clarify that any ingredient that falls under the FDA regulation governing flavors and the like should be regulated by FDA irrespective of the incidental or small amount of meat or poultry in the flavor. The adoption of such a policy would provide consistency and be in keeping with the general principle. Flavors and seasonings are not considered by consumers to be food, but rather ingredients that make the consumption of foods more enjoyable.

B. Implementation Issues

Implementation of the proposed jurisdictional changes will require further Agency guidance in several areas. Specifically, the Agencies should consider the following:

1. Label Change Grace Period

The jurisdictional changes will require some label changes, such as removal of the USDA inspection legend and revisions to some ingredient statements (as flavors are declared differently). These label changes, in some cases, will be costly. To minimize the impact on firms, a compliance grace period should be provided to allow for the use of reasonable amounts of existing label stock.

2. Exports

Many foreign governments currently require that exports of products that contain meat or poultry be inspected by FSIS, regardless of FSIS's amenability determination. When the jurisdiction of some products is moved from FSIS to FDA, inspectors will be withdrawn and export certificates will no longer be readily available.

3. School Food Service

Similarly, USDA's Food and Nutrition Service (FNS) requires USDA inspection for products to be used in the Child Nutrition programs. FSIS should work with FNS to avoid imposing FSIS inspection requirements on foods that are otherwise solely within FDA's jurisdiction.

4. Standards and Labeling Policy Book

FSIS should identify and remove entries for products that fall under the categories of products moving to FDA. Moreover, other comparable standards for products that are largely or exclusively regulated by FDA similarly should be removed.

C. Rulemaking

As a preliminary matter, Nestlé believes that the Agencies should consider whether rulemaking is necessary to make the proposed jurisdictional changes. FSIS routinely makes amenability decisions on a case-by-case basis without going through the arduous process of notice-and-comment rulemaking. Accordingly, the Agencies may be able to make these jurisdictional decisions without undertaking a lengthy rulemaking process.

If the Agencies believe rulemaking to be necessary or desirable in this circumstance, we would encourage the Agencies to consider adopting certain of the proposed changes on an interim basis pending submission and consideration of public comment. The area of flavors is an area where no significant changes would result such that rulemaking is presumably necessary or useful in advance of jurisdictional changes.

D. Broader Issues

This initiative to adjust the regulatory jurisdiction of the Agencies invites consideration of some broader policy issues. The Agencies could seize this opportunity to address these issues where practicable. Final decisions on the proposed jurisdictional shifts, of course, should not be delayed pending resolution of these issues. We simply believe that this evaluation of the Agencies' respective jurisdictional boundaries provides an excellent opportunity to also evaluate other related issues. In this fashion, the Agencies can further optimize their respective inspection and regulatory systems such that food safety is not compromised, while the benefits of greater harmonization between the Agencies can be realized.

1. Prior Approval System

A significant difference between FDA and FSIS is the notion of prior label approval. Consumers surely do not make distinctions among product labels on the basis of which agency has jurisdiction or whether the label received prior approval. FDA and FSIS maintain the same basic labeling requirements. The process by which companies bring a product to market are significantly different. As Nestlé has commented in prior rulemakings, prior label approval is unnecessary, imposes substantial administrative costs on both industry and FSIS, stifles innovation, and yields no discernable consumer benefit relative to FDA-regulated products that are not pre-approved.

2. Greater Harmonization in Food Standards

On August 18, 2005, Nestlé submitted comments to the Agencies in response to the Food Standards Modernization proposed rule.[14] As noted in that submission, Nestlé believes that the Agencies should act to simplify standards wherever possible and to truly modernize the food standards to permit reasonable flexibility. The need for reform is particularly great for FSIS because it has developed an entire manual of so-called "informal standards" that are, in many cases, antiquated or otherwise unnecessary. Accordingly, Nestlé urges FSIS to revoke the entire

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[14] 70 Fed. Reg. 33803 (June 10, 2005).

Standards and Labeling Policy Book and codify those standards deemed useful through notice-and-comment rulemaking.

3. Dictating meat/poultry minimum content

There is also great value to FSIS reconsidering what level of meat or poultry is sufficient to characterize a product as being considered subject to its jurisdiction. The Notice notes that 50 percent meat or poultry content can be a reasonable/useful measure for evaluating amenability for products. FSIS should revisit the value of the meat minimum requirements.

* * *

Nestlé supports the Notice and urges expeditious adoption of the planned changes so that the benefits identified are realized in a timely fashion. In adjusting the Agencies' jurisdiction, it is vital that like products are regulated by a single agency. Particularly with respect to pizza and similar hand-held, portable products, uniform regulation by FDA is appropriate and fully consistent with the principles articulated in the Notice.

Nestlé appreciates the opportunity to present its views on this important issue. We look forward to working with the Agencies in seeing the promise of the Notice fully realized.

Sincerely,

Michael R. Ionni
Director of Quality Management