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HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
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FSIS Docket Clerk
Docket No. 95-051P, Room 102
Cotton Annex Building
Food Safety and Inspection Service
U.S. Department of Agriculture
300 12th St., S.W.
Washington, D.C. 20250-3700

**Re: Comment; Food Standards; General Principles and
Food Standards Modernization; Proposed Rule (Docket No.
1995N-0294 and Docket No. 95-051P)**

Dear Sir or Madam:

Nestlé USA, Inc. (“Nestlé”) welcomes the joint efforts of the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) for the coordinated, thoughtful effort in addressing the modernization of food standards. The statutory mandates, which require FDA and FSIS to ensure fair dealing and to protect consumers, remain important. Against the backdrop of a marketplace and consumer very different from the time when food standards were promulgated, a more flexible, efficient framework is sorely needed.

Building on the “General Principles” of the proposed rule, two objectives central to standards modernization should be advanced by the present rulemaking. First, FDA and FSIS should place a high priority on ensuring a regulatory structure that supports timely reform, with particular focus on modernization that can be accomplished, where possible, without the need for petitions and notice-and-comment rulemaking. Second, FDA and FSIS should take

action to put into place a flexible framework that keeps pace with the dynamic marketplace without requiring piecemeal or incremental changes to individual standards.

The proposed rule provides a valuable set of principles that should inform and guide standards reform. Publication of a final rule, however, is simply not enough. Nestlé, in large measure, supports the proposed rule but rejects the implicit notion that actual reform would take place only in an incremental fashion via the contemplated standard-by-standard petition process. While FDA and FSIS have developed and rely on standards in somewhat different ways, there are avenues available to each agency by which meaningful and more timely reform is possible.

Nestlé includes Nestlé Brands Company, Nestlé Prepared Foods Company, Buitoni North America and Nestlé Purina PetCare Company, and it is part of Nestlé S.A. in Vevey, Switzerland—the world’s largest food company. Through its family of familiar and trusted brand names, Nestlé operates under the labeling rules of FDA and FSIS and offers consumers a wide array of food products across virtually every food product category. Nestlé has worked closely with several of its trade organizations and provides many of its comments by reference to the association comments. At the outset, Nestlé offers the following key recommendations.

- Modify certain features of the General Principles themselves.
- Develop a new regulation that would permit modification of virtually all existing standards, allowing for innovation and flexibility while abiding by guidelines drawn from the General Principles.
- Eliminate unnecessary FSIS “informal standards” in a timely manner.

The substance and justifications for these recommendations are set forth below.

I. NEED FOR REFORM

A. Administrative Record Demonstrates Need

The broad consensus for standards modernization is well established and long standing. Some incremental changes, most notably FDA's modified standards regulation (21 C.F.R. § 130.10), have proven beneficial. Nevertheless, much of the need for reform, articulated in comments responding to the 1995 Advanced Notices of Proposed Rulemaking, remains true today. Shortcomings and disadvantages with the current food standards continue to include impediments to technological innovation, conflicts with contemporary notions of valued constituents and formulation of healthful foods, and failures to reasonably advance consumer protection.

B. Role of Food Standards in a Changing World

1. Historical Perspective

The statutory mandates governing food standards – “promote honesty and fair dealing”^{1/} and “protection of the public”^{2/} – remain in force and relevant. The need for, and role of, food standards has changed significantly since these statutory mandates were enacted by Congress. Similarly, the marketplace, the consumer, and the face of the food label all have changed significantly since the decades of the 1950's – 1970's, when most standards were adopted through rulemaking.

In very general terms, Nestlé considers food standards to fall into two categories, the first related to commodities (e.g. chocolate, evaporated milk, and canned tomato products) and the second to recipe-type products (e.g. chili with beans, ice cream, and corned beef hash). For basic commodity-type products, some existing standards that focus largely on certain mandatory components or characterizing ingredients may well be meaningful and relevant to today's consumer, but many other recipe-type standards go beyond merely specifying characterizing ingredients by prescribing specific methods of manufacture, specified optional ingredients, and minimum quantitative amounts of specified ingredients.

The need for food standards arose from FDA's inability (prior to 1938) to take enforcement action against fraudulent products that purported to be a traditional food yet were formulated with ingredients widely viewed at the time as

^{1/} Federal Food, Drug, and Cosmetic Act § 401 (21 U.S.C. § 341).

^{2/} Poultry Products Inspection Act § 8 (21 U.S.C. § 457); Federal Meat Inspection Act § 7 (21 U.S.C. § 607).

inferior (and often less costly). ^{3/} Such standards also were premised on consumer expectation, which corresponded to how foods typically were prepared in the home. Development of standards as a primary consumer protection tool made good sense at a time when the food standards were able to keep pace with the growth in the food category.

For a time, FDA and FSIS struggled to adopt new standards to keep pace with the ever-growing number of food products offered by food processors in the face of demand for high quality, convenient, affordable foods. By the 1980's, FDA and FSIS all but abandoned the adoption of food standard regulations as impracticable. Significantly, FSIS attempted to keep pace with the marketplace through the development of so-called "informal standards," memorialized in several Policy Memoranda and in the *Food Standards and Labeling Policy Book* ("Policy Book"). These efforts tapered in the mid-1990's although a vast number of such standards remain and are applied routinely by FSIS. These informal standards were adopted without the benefit of notice-and-comment rulemaking, thereby allowing FSIS to address these policies without the need for public comment. ^{4/}

2. Pressing Need for Reform

The pace and sophistication of innovation brings ever-changing challenges to the food industry, and the industry, in turn, provides solutions to American consumers. Today's consumer can find nearly any food available for sale in packaged form through a diverse number of "retail settings," from supermarkets and convenience stores to on-line grocers and numerous specialty formats. Last year alone, 851 new packaged food and beverage products were introduced. ^{5/} This rapid pace of innovation and consumer-driven diversity of packaged foods stand in stark contrast to the world as it existed and was envisioned when food standards were adopted. As a result, many standards are meaningless to consumers while

^{3/} See, e.g., Richard A. Merrill and Earl M. Collier, "Like Mother Used to Make: An Analysis of FDA Food Standards of Identity," 74 Columbia Law Review 561 (1974).

^{4/} As discussed below, FSIS can and should move quickly to bring standards reform to these informal standards because notice-and-comment rulemaking is not required.

^{5/} Information Resources, Inc. (2005).

others are far more inflexible than is required from the perspective of consumer protection.

The chief “cost” of existing food standards is the impediment to innovation. Put simply, product names are vital to the successful marketing of foods, yet many food standards prohibit or inhibit use of recognizable product names. Without the ability to name a food in a way that is meaningful to consumers, manufacturers lack the incentive to bring to market beneficial foods, such as those with improved nutritional profiles, greater functionality, or enhanced quality.

FDA’s Obesity Working Group Report recommends research to identify regulatory barriers to the marketing of healthful foods. ^{6/} FDA and FSIS need not undertake any research to validate what is widely recognized – successful marketing of healthful products is stymied by many food standards. For example, standards that dictate meat minimums effectively mandate higher fat levels than are desirable to health-conscious consumers committed to fashioning their diet consistent with the Dietary Guidelines. Unlike dairy ingredients where the milkfat can be readily removed, technological limits preclude removing fat from the meat block in most instances. Swift action is important to ensure that food standards advance rather than impede offering healthful and innovative foods to consumers.

Consumer experience should guide a regulatory assessment as to whether a particular standard serves to protect consumers or merely impede innovation. Rescission of the “pizza” standard by FSIS is instructive. For many years FSIS prohibited the marketing of a frozen pizza if it contained no tomato sauce. This produced unexpected results, including some firms that added a very small amount of tomato sauce simply to establish compliance with the pizza standard. Nestlé was able to market a “white pizza” only after it successfully petitioned FSIS to adopt an informal “white pizza” standard. Until the pizza standard was revoked, consumers could not find the quality, convenience, and value of many products commonly understood and acceptable to consumers that were widely available from restaurants. It was the restriction on use of the term “pizza”

^{6/} “Calories Count: Report of the Working Group on Obesity,” Center for Food Safety and Applied Nutrition, Food and Drug Administration (March 12, 2004).

as part of a product name that impeded the many innovations and choices now available to consumers. Numerous other standards pose similar impediments. ^{7/}

Noticeably absent from the proposed rule is a mechanism akin to Section 130.10 that would allow timely reform without numerous petitions and lengthy rulemakings, as explained further below. The imperative for a unifying approach to standards modernization is reinforced by the substantial length of time between the ANPR and the proposed rule. Nestlé does not object to publication of a final rule (with some modifications). The final rule itself, however, will accomplish very little, and FDA and FSIS should not miss the present opportunity to advance standards reform.

3. Optimizing Food Standards: Consumer Protection With Regulatory Flexibility

Application of FDA's and FSIS' respective statutory mandates should be guided by the realities of the marketplace and the consumer. From Nestlé's perspective, standards of identity have no intrinsic value absent a clear nexus to an identifiable consumer protection objective, but standards can be of great value when framed and applied in a fashion that reflects the realities of the marketplace and the "modern consumer." Unfortunately, many legally-binding food standards are neither relevant nor beneficial. The challenge is to eliminate and streamline antiquated standards and to establish a flexible, adaptable regulatory framework that will allow standards to be modified in the face of an ever-changing market without the need for repeated government rulemaking.

Relying on the planned petition process is unlikely to yield meaningful benefits of the kind contemplated by the proposed rule and warranted by the administrative record. Incremental changes in specific standards (or grouping of like standards) will be a lengthy process, and this process is a disincentive to companies that want to launch new products quickly. The final rule likely will ensure well-prepared petitions, but limited resources and the multi-year process of many rulemakings will severely undermine standards reform. Fortunately, there are several avenues available to FDA and FSIS. These include: (1) modification and streamlining of certain features of the proposed rule; (2) development of a uniform

^{7/} Similarly, FDA still relies upon its Temporary Marketing Permit process to allow for prudent flexibility involving cheese and other standardized foods. The need and value of TMPs suggests that Section 130.10-type regulation that covers a broader range of allowable modifications to standardized foods is necessary.

regulation that would allow for modified versions of most standardized foods within appropriate parameters; and (3) elimination of “informal standards” by FSIS in the immediate future.

II. RECOMMENDATIONS

A. General Principles – Modifications and Clarification

The joint efforts of FDA and FSIS in fashioning the Guiding Principles is commendable and a necessary precursor to standards modernization. Generally, the proposed principles seemingly further the effort toward true modernization of the food standards—encouraging clear and easily understood requirements and permitting maximum flexibility in the technology used, while promoting honesty and fair dealing in the interest of consumers. Before publishing a final rule, however, certain modifications are suggested. Nestlé views each of the following suggestions as advancing the goal of ensuring flexible standards that advance consumer protection.

In general, FDA and FSIS should recognize explicitly that the General Principles are just that—guiding principles—not mandatory requirements. The principles proposed in the final rule certainly will be useful in guiding the preparation and evaluation of petitions. As drafted, however, the proposed rule could create an (incorrect) impression that strict adherence to each of the principles is necessary for a petition to be deemed sufficient. Requiring companies to fully address each principle in their petitions could be unduly burdensome on both petitioners and the agencies. To truly streamline and “modernize” the petition process, the agencies should designate only the first four listed principles as mandatory, with the remainder being optional.

Additionally, a couple of the proposed General Principles should be clarified. For example, the second proposed principle, which states that a “food standard should describe the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers’ expectations of product characteristics and uniformity,” could be misinterpreted. Indeed, food standards should accurately describe the basic nature of the food, but a stringent focus on “consumers’ expectations” and “uniformity” could be confusing and unnecessarily stall the petition process.

Just as consumers are diverse, so are expectations. Differing consumer experiences inform differing expectations. The challenge for food marketers is to name and formulate products that meet these expectations. Absent a product name

that is false or misleading, it is critical that the marketer be left with sufficient flexibility to best determine how to estimate and satisfy consumer expectation. Successful products require repeat purchases. Product names that fail to meet consumer expectations will fail in the marketplace. Accordingly, the marketplace provides a far more significant incentive to ensure food standards are applied in an appropriate fashion.

Undue government regulation that, in each instance or product category, attempts to dictate requirements based on perceived consumer expectation will undermine any standards modernization effort. Accordingly, the final rule should clarify that consumer data need not accompany petitions. It was not required during the original rulemaking, and it should not be required here. Of course, petitioners should be encouraged to provide such information if it is readily available, as well as a broader range of information, including cookbook references and deli and restaurant practices.

Clarification also is needed to the seventh proposed principle, which encourages harmonization of U.S. food standards with international standards. Such harmonization is important, but the proposal gives the impression that U.S. standards may not differ at all from international standards. As drafted, the proposed principle states, "The food standard should be harmonized with international food standards to the extent feasible," but it goes on to say, "If the food standard is different from the requirements in a Codex standard for the same food, the petition should specify the reasons for these differences." The final rule should clarify that U.S. standards may differ from Codex standards, as long as they do not contradict these standards.

B. Flexible, Uniform Regulation That Would Diminish the Need for Incremental Rulemakings

The single greatest shortcoming of the proposed rule is that it is unlikely to actually change the status quo. The General Principles framework is invaluable, yet Nestlé urges FDA and FSIS to consider how it might accomplish flexible and efficient standards modernization through an approach comparable to the framework reflected in Section 130.10. The lack of agency responsiveness to pending petitions and the ten years that have passed since the 1995 ANPRs indicate that simply developing a set of principles to guide food standard petitions will do little to reduce the backlog of pending petitions or to address future petitions more efficiently. Accordingly, the agencies should look to their past successes, namely FDA's § 130.10 and FSIS' equivalents (9 C.F.R. §§ 319.10 and 381.172) in formulating an appropriate strategy.

A regulation of general applicability (a so-called “horizontal” approach), as opposed to individual notice-and-comment rulemaking for each standard or group of standards, could be used to permit any standardized food to make appropriate variations. Such a regulation could achieve the flexibility and efficiency sought by the proposal. For example, such a regulation could allow in standardized foods generally (1) the use of alternate make procedures, including technological advances, resulting in products with the same basic nature and essential characteristics of a standardized food, or (2) the use of safe and suitable ingredients that fall within the same categories as ingredients identified in a standard. This type of cross-cutting regulation provides flexibility while promoting honesty and fair dealing in the interest of consumers—the essence of true modernization.

C. Immediate Transition Away from “Informal” Standards

Nestlé is encouraged by the statement in the preamble to the proposal with respect to informal standards: “FSIS intends to eliminate all informal or ‘policy’ standards in the Policy Book, which address the meat or poultry content of certain products or define methods of processing.” Nestlé fully supports FSIS’ tentative conclusion but takes issue with the accompanying statement suggesting that it would eliminate all entries if no petition were received. As discussed more fully above, the petition process will take a great deal of time. With no definite end-point for when such petitions must be filed, the prospect of the Policy Book lingering for many years to come is great. More immediate action is possible and necessary.

The Policy Book represents a vast compendium of approximately 800 standards and policies, which are treated as having the force and effect of law but have never benefited from notice-and-comment rulemaking. Leaving aside the implications of this practice under the Administrative Procedures Act, sound public policy dictates that informal standards be codified into the Code of Federal Regulations when warranted. There is no legal bar, of course, to FSIS acting promptly, rather than deferring elimination of the Policy Book only at the end of the process, as suggested by the proposed rule’s preamble.

The Policy Book is replete with entries that are antiquated, unduly inflexible, meaningless to consumers, and, therefore, serving no clear consumer protection function. The problems with food standards recognized by FDA and FSIS are as true for Policy Book-based standards as for those that were promulgated through rulemaking.

Many categories of informal standards found in the Policy Book are of no current consumer protection value, including:

- Standards that address products that contain no meat or poultry ingredients (e.g., cheeses, dry milk products);
- Obscure and obsolete standards that convey no meaning to the typical consumer (e.g., caddies, fries, frizzes, New England boiled dinner, tzimmes);
- Standards that largely reiterate other provisions or regulations and that render the Policy Book entries redundant (e.g., country, farm, spaghetti);
- Ingredient-specific policies that are unnecessary (e.g., antioxidants, enzymes – proteolytic, vinegar);
- Meat and/or poultry minimum requirements (e.g., meat dressing v. meat and dressing with gravy, beef and gravy v. gravy and beef, spaghetti sauce with meat v. spaghetti with meatballs v. spaghetti with meatballs and sauce); and
- Other odd, unusual, or misplaced standards that do not appear to advance consumer protection (e.g., dog/pet food, sandwich – closed v. sandwich – open, pizza dogs, snacks).

Addressing the Policy Book provides FSIS with a rare, immediate opportunity to meaningfully advance standards reform. Beyond the reform of standards, eliminating the Policy Book also will improve the efficiency of the prior label approval process. That is, FSIS will be bogged down by far fewer standards that presently burden the current sketch-approval process.

There are several options available to FSIS, including elimination of the Policy Book. Alternatively, FSIS should consider publishing a Notice in the *Federal Register* advising that it will revoke the Policy Book effective in 60 days. An “exception” would be permitted—whereby existing informal standards would be retained for an interim period—for those standards that interested parties submit to FSIS as reasonably necessary to ensure consumer protection. Accordingly, subsequent to the close of the comment period, FSIS promptly would publish a second notice identifying the specific informal standards to be retained on an interim basis, pending receipt of a petition and necessary rulemaking.

Swift elimination of the Policy Book, in whatever fashion, will address many of the current impediments to product innovation posed by meat minimum levels and other features of informal standards that impede product innovation.

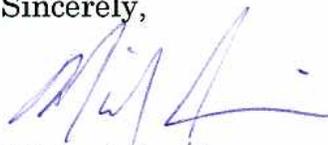
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In sum, Nestlé agrees and fully supports recognition by FDA and FSIS of the fact that, as stated in the proposal, a system is needed “to facilitate the timely revision, implementation, and elimination of standards regulations.” The General Principles will provide an important foundation to guide such efforts.

FDA and FSIS should endorse, as part of the final rule, the value of a uniform approach and express an intention to develop an across-the-board standard that will enable the marketing of modified standardized foods. In the interim, current standards should be applied in a flexible fashion, whereby regulatory action is considered only where the purported violation of a standard bears a clear nexus to consumer protection. Moreover, more immediate steps toward reform should be considered, such as the elimination of the Policy Book and greater flexibility in granting temporary marketing permits.

Nestlé greatly appreciates the opportunity to share its views on this important subject. Too many innovative products never make it off of the drawing board and onto store shelves because of antiquated food standards. Standard modernization directly benefits consumers. It is only a question of how quickly these regulatory impediments are removed.

Sincerely,



Michael Ionni
Director of Quality Management
Nestlé Prepared Foods Company