Kraft Foods

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FSIS Docket Clerk
Docket No. 95-051P, rm. 102
Cotton Annex Bldg.
Food Safety and Inspection Service
U.S. Department of Agriculture
300 12th St. SW
Washington, DC 20250-3700

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: Docket No. 95-051P (FSIS) and 1995N-0294 (FDA); Food Standards; General Principles and Food Standards Modernization; Proposed Rule; 70 Fed. Reg. 29214 (May 20, 2005)

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) is a U.S. based $32 billion global company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells. Today, Kraft brands are found in more than 99% of all U.S. households and over 155 countries around the world. About 25% of the products we make are regulated by food standards. Thus, we comment from the perspective of a consumer driven company with substantial interest in finding practical ways to bring existing food standards, most of which are over 50 years old, into the 21st century.

I. Summary

The Food and Drug Administration (FDA) and Food Safety and Inspection Service of the U.S. Department of Agriculture (FSIS) have proposed to start the standards modernization process by adopting new rules on petitions. In theory, the new rules should produce better petitions and thus make possible faster government action. We respectfully question whether the theory will work in practice.

We are unaware of any evidence that suggests the current backlog of petitions is due to drafting deficiencies. The preamble to the proposal does not cite any example of a

deficient petition, nor do the agencies claim that resources to process the petitions quickly would have been available, had the petitions included more information.

We are deeply concerned, therefore, that the proposal fails to address the key issue: the extensive resources needed for timely standard-by-standard notice and comment or formal rulemaking. In recognizing the need to focus on the resource issue, we do not mean to be critical of the agencies; we understand that food safety and health and wellness issues routinely and appropriately receive higher priority than food standards. Instead, we simply suggest that resources are limited and should be used in a way that offers the best chance of successfully modernizing food standards. Rather than working on rules for writing petitions, Kraft urges the agencies to develop an approach that updates, simultaneously rather than one-by-one, the large number of outdated standards that stand in the way of innovation to the detriment of consumers.

II. The Existing U.S. Food Standards Can and Must be Brought Up-to-Date.

In preparing these comments, we first questioned whether standards of identity remain useful in light of developments such as nutrition labeling, full ingredient labeling, rules for ensuring ingredient safety, the evolution of First Amendment case law, and the steady increase in nonstandardized products, which now make up 75% or more of the market. We think a persuasive case can be made that current labeling and other regulatory requirements adequately address the concerns that food standards originally were intended to remedy. Certainly, most consumers do not know whether a product is or is not subject to a standard;[1] and it seems highly questionable to suggest that consumers who buy French dressing are better protected than consumers who buy any other kind of pourable salad dressing, just because the government dictates the recipe.

Although we are convinced that the time is right to eliminate selectively some standards, other standards remain popular with many industry and consumer groups. The political will to eliminate standards entirely seems unlikely to develop in the foreseeable future.[2] If food standards will not be eliminated, it must be possible to update them so they do not prevent manufacturers from adopting more efficient technologies, improved ingredients, and recipes that reflect current nutrition science.

[1] S.C. Cates, et al., Consumer Attitudes Toward and Preferences for Food Standards of Identity, J. Food Prod. Mktg Vol.10(1), 67, 72 (2004) (noting that the "vast majority" of participants in focus group research were unaware of federal standards).

[2] Moreover, as FDA has pointed out, the elimination of federal food standards might prompt individual states to attempt to establish inconsistent standards of their own, when national uniformity for food labeling is imperative. 60 Fed. Reg. 67492, 67501 (Dec. 29, 1995).

We note with concern what appears to be gridlock in the standards process, where even projects that are designated by the agencies as priority items take years to publish, and numerous proposals, petitions, and stayed regulations have not been addressed in a timely fashion. This, in our view, is where the current proposal falls short: if there are inadequate agency resources to review and assess multiple standards in a case-by-case petition process, then even the best of petitions will not result in any meaningful progress.

Based on our experience, we suggest that the reality of resource constraints presents an opportunity for creative thinking and leadership. The first step inevitably begins with a return to the language of the statutes that provide the authority to create federal food standards. Under the Federal Food, Drug, and Cosmetic Act, standards may be established "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers."[3] Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), standards may be established by the Secretary "whenever he determines such action is necessary for protection of the public."[4] The breadth and timeless nature of these provisions are striking. Kraft is committed to the principles of "honesty and fair dealing" and suggests that these terms offer the flexibility needed to reform food standards in an efficient manner.

More specifically, we respectfully suggest that, instead of focusing on guidelines for petitions, the agencies consider developing a single regulation and general standard that maintains the essential characteristics of standardized foods, but also allows for advances in technology and nutrition science that can benefit consumers. By issuing a single regulation authorizing appropriate flexibility in the production of standardized foods generally, the agencies could accomplish most of the modernization contemplated by the proposal, without the huge resource investment required to change standards in separate rulemaking proceedings. This type of "horizontal approach" would allow for timely implementation of new technologies, production methods, and similar measures that the general principles expressly recognize as promoting honesty and fair dealing in the interest of consumers.

We recognize that use of a general regulation to achieve broad food standards modernization may seem both familiar and novel. The idea is familiar because both agencies have historically advanced their thinking about what standards should accomplish, from setting strict recipes, to allowing for flexibility in ingredients, to allowing for increased marketing of nonstandardized foods through more modern requirements for "imitation foods" and common or usual names, to allowing for generic or general regulations like 21 C.F.R. § 130.10. In fact, the possibility of a general regulation was briefly discussed in the 1995 and 1996 advance notices of proposed rulemaking (ANPRs) on modernizing standards, although the current proposal says

[3] FFDCA § 401, 21 U.S.C. § 341.

[4] FMIA § 7(c), 21 U.S.C. § 607(c); PPIA § 8(b), 21 U.S.C. § 457(b).

very little about why the agencies decided not to pursue this approach.[5] The idea may seem novel, however, because it requires acceptance that standards can be something more than static definitions that do not allow for innovation or change without case-by-case assessments and debate. Yet we venture to suggest no stakeholder is well-served by the paralysis that has made the current system dysfunctional.

In other words, based on the statutes the agencies are required to administer, we are convinced that the entire U.S. standards system can and must be brought up to date. We respectfully recommend consideration of a horizontal and not a standard-by-standard approach, to reflect (1) the numerous developments that influence the meaning of "honesty and fair dealing" today; (2) the fundamental concepts widely viewed to promote honesty and fair dealing, including those identified in the general principles, that the present system seems unable to advance consistently; (3) the numerous improvements that can be readily and efficiently achieved with a horizontal approach; and (4) the advantage of a horizontal approach from an international perspective.

A. "Honesty and Fair Dealing" Must Be Interpreted In Light of Modern Consumers, the Totality of Government Requirements, and the Real-time, Constantly Changing World in Which We Live.

As a matter of law and sound policy, "honesty and fair dealing" must be interpreted in light of present and reasonably foreseeable future circumstances, including the modern consumer, the totality of agency requirements, and the advances in communication technology that have made real-time change the touchstone of commercial practices today. For example, when companies are trying to conceive and introduce products in three to six months, a temporary marketing permit (TMP) process that takes a year and allows for no change during that time just does not work. A brief review of the history of standards shows how much the circumstances surrounding their use have changed since 1938 and why a flexible approach is not only justified but essential.

Food standards were initially created to prevent fraud and make purchasing decisions easier for consumers.[6] At the time the first standards were issued, consumers used the product name to judge what was in the package, for that was the main piece of information

[5] 60 Fed. Reg. at 67503 (noting the possibility of expanding the concept of 21 C.F.R. § 130.10 to areas beyond nutrient content claims); 61 Fed. Reg. 47453, 47458 (Sept. 9, 1996) (identifying development of a general standard for all meat and poultry products as an option). In the current proposal, the agencies state only that comments on the idea of a general regulation were mixed. 70 Fed. Reg. at 29218.

[6] *See, e.g.*, H. Thomas Austern, The F-O-R-M-U-L-A-T-I-O-N of Mandatory Food Standards 2 Food, Drug, Cosm. L.Q. 532, 541-42 (1947); Richard A. Merrill and Earl M. Collier, Jr., "Like Mother Used to Make": An Analysis of FDA Food Standards of Identity, 74 Colum. L. Rev. 561, 576 (1974).

available.[7] In the late 1930's, and for many years afterward,[8] there were no nutrition labeling rules, limited ingredient labeling requirements, and no regulations to govern common or usual names for non-standard foods. Standards, or more descriptively, government-regulated recipes, helped otherwise uninformed consumers make purchasing decisions by limiting choice and variability in the composition of similarly marketed products. In reality, as a general rule, technology permitted few accepted ways to make a product, so flexibility in manufacturing or formulation was not a widespread concern.

For many years, standards also played an important role in ensuring food safety and wholesomeness. Significantly, for the first 20 years that FDA food standards were in effect, there were no food additive rules, prompting FDA to use standards of identity to ensure that common foods contained only ingredients the agency specifically identified as safe and suitable. There were no formal rules to guide use of good manufacturing practices until 1969. Thus, early standards promoted "honesty and fair dealing" by regulating not only identity, but safety and wholesomeness as well.

The role of standards has changed significantly as consumers, industry, and government have changed. Modern consumers have access to increased information to guide product choices, including full ingredient labeling, nutrition labeling, and information from other sources, such as the media, the internet, and toll-free numbers. As FDA explained in 1995:

> The 1990 amendments require that virtually all foods bear nutrition labeling. This information, plus the full ingredient list that is now required, ensures that consumers will have vastly more information about the make-up of a particular food product than was available in 1938. This information should make it immediately apparent if a marketer is attempting to sell a debased or watered down food.[9]

There is also a noteworthy emphasis on diversity and individuality now that did not exist in 1938. In fact, today's increasingly sophisticated consumers do not necessarily seek traditional products: they want variety, healthfulness, convenience, value, novelty, ethnically inspired foods, and sometimes, several or all of the above. Modern conveniences, such as the freezer and the microwave, and consumer habits, like buying meals in cafeterias and restaurants instead of making them at home, have also influenced how consumers view and consume food.

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[7] *See, e.g.*, Austern, *supra* note 6, at 559 (describing use of a panel of "[e]ight women . . . around a table in the Department of Agriculture Building" to judge whether a canned pea product would be satisfactory if identified "simply as 'peas'").

[8] See *infra* footnotes 13-15 and accompanying text.

[9] 60 Fed. Reg. at 67497.

Consumer expectations still define the basic nature of a food, such as the status of cheddar cheese as a dairy product with an expected texture and flavor. There are, however, no generally held consumer expectations today concerning the precise technical elements by which most food is produced; rather, technology-savvy consumers expect the use of modern processes and improved ingredients as soon as they become available. Consumers, therefore, are not reasonably anticipated to have formed expectations as to production methods, aging time, or specific ingredients used for technical improvements, including manufacturing efficiencies.

Years of experience with consumer research have taught us that consumer expectations, especially those that concern nutrition, are a moving target that evolves with the surrounding environment. For example, scientific evidence and media stories about the nutritional benefits of a new ingredient, such as a whole grain flour with attributes of refined flour, might reasonably create expectations among some consumers that these flours will be used to create new versions of traditional grain products, like bread or macaroni. If standards are to be truly modern, they must be designed in a way that allows beneficial technologies, useful ingredients, and other improvements that are consistent with the basic nature of the food. [10]

As consumers have grown more sophisticated, so has industry. In the 1920's, grocery stores contained, on average, only 700 items; by 1980 this had increased to 14,000, but today, the variety offered has increased to more than 30,000 items.[11] Many of these items are made possible by improved technology that creates an array of products and ingredients not previously available. It is noteworthy that the vast majority of products marketed today (over 75%) are not standardized products, but are well accepted by consumers and the government alike. Intense competition ensures that food products that fail to meet consumer expectations will not survive in the marketplace.

Finally, the law has evolved in several important respects. In contrast to 1938, FDA and USDA now have detailed regulatory requirements that ensure food safety and wholesomeness, so standards no longer carry this burden. Beginning in the 1960's, FDA has also consistently sought to broaden its standards-related policies to incorporate more flexibility. For example, in 1965, FDA departed from a strict recipe approach and began to allow "safe and suitable ingredients" in standards, such as the safe and suitable "batter and breading ingredients" permitted in breaded shrimp products.[12] In 1973, FDA recognized the value of new technologies

[10] The agencies state that the basic nature of a food is directly related to consumer expectations, while "essential characteristics" are technical attributes that make a food what it is (e.g., composition, like fat content). 70 Fed. Reg. at 29221. Based on our experience, a range of processes, ingredients, and other characteristics can be used to produce a food of the same basic nature, meeting consumer expectations.

[11] Food Marketing Institute News Release, America Celebrates the 75th Anniversary of the Supermarket (Aug. 1, 2005).

[12] 30 Fed. Reg. 2860 (Mar. 5, 1965).

and decided to narrow the scope of "imitation" products and address common or usual names for nonstandardized foods.[13] Later, Congress required nutrition labeling and full ingredient declarations on almost all foods.[14] Perhaps the most significant changes occurred in 1993 and earlier this year, when FDA and FSIS respectively adopted general definitions and standards of identity for foods that vary from a standard for the purpose of complying with a nutrient content claim. The agencies have confirmed this natural progression: as FDA stated, "its policies have always evolved, even in the absence of significant legislative amendments to the act."[15]

There have also been several important changes in other aspects of the law. In 1994, Congress approved and President Clinton enacted into law the Uruguay Round Agreements Act. This law included two new international trade agreements that are relevant to the U.S. food standards system: the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") and the Agreement on Technical Barriers to Trade ("TBT Agreement"). These agreements are intended to facilitate trade by encouraging the adoption of international standards, guidelines, and recommendations, such as food standards issued by the Codex Alimentarius Commission. As a world leader, the U.S. has an obligation to assure that our rules are consistent with the multi-lateral agreements to which this country is a party. For example, measures adopted by the United States (or any other WTO Member) intended to protect human, animal, or plant life or health may violate the SPS agreement if they are not scientifically based and interfere with trade; TBT measures may be of concern if another less-trade restrictive measure is reasonably available to fulfill a legitimate government objective. These important agreements underscore the need for U.S. standards to stay current, especially to support an ongoing U.S. leadership role in Codex.

Another noteworthy development took place in 2002, when FDA clarified that it will use a "reasonable consumer" standard to assess whether food labeling is misleading, consistent with the approach taken by the Federal Trade Commission (FTC).[16] Accordingly, the agency confirmed it will not evaluate labeling information from the perspective of the "ignorant, the unthinking, and the credulous" consumer—an important clarification that directly affects what is reasonably considered to promote "honesty and fair dealing." Informative labeling may not be sufficient for the "ignorant, the unthinking, and the credulous" consumer, but it is for the reasonable consumer seeking information about the product.

[13] 38 Fed. Reg. 6964 (Mar. 14, 1973) (issuing final rule to govern the common or usual name of nonstandardized food); 38 Fed. Reg. 20702 (Aug. 2, 1973) (issuing final rule to provide that a food substituting for another food is not required to be labeled as an "imitation" unless nutritionally inferior to that food).

[14] Nutrition Labeling and Education Act of 1990, Pub. L. 101-535.

[15] 56 Fed. Reg. 60512, 60517 (Nov. 27, 1991).

[16] 67 Fed. Reg. 78002, 78003-04 (Dec. 20, 2002).

All of these factors—the modern consumer, the modern world, and current national and international requirements—suggest to us a compelling need for FDA and FSIS to evaluate carefully what is meant by "honesty and fair dealing in the interest of consumers," and equally important, what strategies will best ensure that food standards are updated and keep up with the times and the global marketplace.[17]

B. Honesty and Fair Dealing in the Interest of Consumers Require Flexibility that the Current System is Consistently Unable to Provide.

In the proposal, the agencies state that "all of the general principles set forth in this proposal have been designed to achieve honesty and fair dealing in the interest of consumers."[18] Based on the general principles, therefore, honesty and fair dealing are promoted by food standards that, among other things—

- Describe the basic nature of the food to ensure that consumers are not misled by the product name and that expectations for product characteristics and uniformity are met (principle 2);[19]
- Reflect the essential characteristics of the food (principle 3);
- Are clear and consistent with other agency requirements and international standards (principles 5, 7, and 11);
- Permit maximum flexibility in the technology used to prepare the standardized food, so long as the technology doesn't affect the food's basic nature, essential characteristics, nutritional quality, or safety (principle 6);
- Describe ingredients as broadly and feasibly as possible (principle 6);
- Are simple, including only the elements necessary to define the basic nature and essential characteristics of the food (principle 8); and

[17] We recognize that the statutory standards for FDA and FSIS differ slightly in wording, but respectfully suggest that standards at both agencies have historically served to promote honesty and fair dealing in the interest of consumers.

[18] 70 Fed. Reg. 29214, 29221 (May 20, 2005).

[19] The second general principle states specifically that a food standard should ensure that "consumers' expectations of product characteristics and uniformity are met." We agree that consumer expectations are relevant insofar as they define the basic nature of the food, but caution that the diversity of today's consumers makes it difficult, if not impossible, to identify a single set of "consumer expectations" that define all aspects of standardized foods, including the technical elements such as aging time, required production methods, or specific ingredients used for technical improvements in product quality or nutrition attributes.

- Allow for variations in physical attributes (principle 9).

Kraft agrees with the agencies that these factors, which reflect common themes of clarity and flexibility, promote honesty and fair dealing in the interest of consumers. We also agree that current standards require updating to reflect these sound principles. The key issue, therefore, seems to be what strategy can realistically accomplish these important goals.

We see no evidence that the proposed standard-by-standard petition process will achieve the necessary reform now or in the foreseeable future. As presently drafted, the general principles are highly subjective, opening the door to many different interpretations.[20] As a result, we suspect that companies may expend more resources than the agencies anticipate in trying to determine just what information should be included in a petition and in providing supporting information and documentation. In fact, due to the lack of specificity, the proposed principles do not provide any assurance that the volume of information—and concomitant expenditure of review time—will be any different under the proposed rule than under the current regulatory structure. The current framework has proven too burdensome, especially on the agencies, to be effective.

We also question whether clarification of the principles will effectively address the challenge facing the agencies. For example, there are currently at least 10 standards petitions[21] pending before FDA. Many of these petitions have been pending for five or more years, even though several have been specifically highlighted as priorities. One of the petitions is a five year old Kraft submission that requests a straightforward change—a decrease in the amount of aging time for parmesan cheese, from 10 to 6 months, due to the availability of

[20] Kraft's estimation of the burden to prepare a petition has been submitted previously to FSIS (*see* letter from S. Marcouiller to R. Murphy-Jenkins, dated July 22, 2005). We attach this letter and incorporate it by reference.

[21] *See, e.g.*, Docket No. 1994P-0286 (U.S. Tuna Foundation petition to amend portions of the canned tuna standard (July 28, 1994); Docket No. 1995P-0078 (Calorie Control Council petition to permit the removal of fat from standardized foods) (withdrawn and resubmitted to Docket No. 96P-0143); Docket No. 1997P-0043 (American Bakers Assoc. petition to amend definitions and standards of identity for bakery products (Feb. 4, 1997); Docket No. 1997P-0142 (International Jelly & Preserve Assoc. petition to repeal standards of identity for artificially sweetened jam) (Apr. 7, 1997); Docket No. 1998P-0047 (Association for Dressing & Sauces petition to amend identity standards for mayonnaise, French dressing, and salad dressing) (Jan. 16, 1998); Docket No. 2000P-0685 (National Yogurt Association petition to revise yogurt standards) (Feb. 18, 2000); Docket No. 2000P-1491 (Kraft Foods, Inc. petition to amend definition and standard of identity for parmesan cheese (Aug. 30, 2000); Docket No. 2000P-1687 (Sartori Foods Corporation petition to amend definition and standard of identity for parmesan cheese) (Dec. 20, 2000); Docket No. 2003P-0171 (Del Monte Corp. petition to amend the standard of identity for canned tomatoes) (Apr. 23, 2003); Docket No. 2005P-0295 (Alaska Birch Syrupmakers Association petition to amend standard for Pure Birch Syrup and Birch Breakfast Style Syrup) (July 26, 2005). In addition, this past November, FDA withdrew four standard of identity proposals the agency indicated it had been unable to consider in a timely manner. 69 Fed. Reg. 68831, 68832, 68835-36 (Nov. 26, 2004) (withdrawing proposals to create standards of identity for "certain other cheeses" and frozen yogurt, and to amend U.S. standards of identity and quality for pineapple juice and canned pineapple).

advanced enzyme technologies that allow faster ripening. FDA previously approved a similar change, for similar reasons, and the product that is the subject of the petition is presently marketed without concern under a temporary marketing permit. Despite these circumstances, FDA has decided to publish not a proposal but an ANPR to first seek comment on the petition. The ANPR, which is designated as an "A list" priority, has not yet published.

Another submission that is currently pending seeks amendment of the yogurt standard. Submitted by the National Yogurt Association (NYA) in 2000, the petition noted that portions of the yogurt standard were stayed in 1982, creating what NYA felt were gaps in the standard. FDA stayed the provisions in 1982, intending to hold a hearing at a later date, but a hearing has never been scheduled. Three years after the 2000 petition, FDA published an ANPR seeking comment on NYA's proposal, but has taken no further public action to date.

Although the above examples focus on FDA resources, we are similarly concerned that FSIS lacks adequate resources to engage in standard-by-standard rulemaking in an efficient manner. To date, FSIS has generally managed the resource issue by developing informal or "policy" standards used to guide the label approval process. These standards are problematic because they are procedurally questionable and are largely not, as FSIS concedes, consistent with the general principles.[22] For these reasons, we support the FSIS decision to eliminate the informal standards; however, once FSIS resorts to rulemaking to regulate meat and poultry standards, as it must as a matter of law, it is unlikely that any necessary new standards or updates to existing standards could be achieved in a timely way.[23]

The general lack of agency resources, the numerous standards petitions currently pending (some of which are already outdated), the difficulty and length of time required to obtain temporary marketing permits, and even the ten years required to develop the general principles themselves all demonstrate that a piecemeal petition process simply will not achieve true modernization – no less honesty and fair dealing – in the interest of consumers.

C. A Horizontal Approach Is Needed for True Reform.

Looking to the agencies' past successes, a horizontal approach by which all standards broadly could be updated, rather than a vertical approach dictating standard-by-standard amendment, offers a realistic way to modernize multiple standards at the same time. For example, as early as the 1970's, FDA embraced a horizontal approach by issuing generally applicable regulations to clarify the scope of imitation foods and provide guidelines for developing common or usual names for nonstandardized foods. FSIS adopted a horizontal

[22] 70 Fed. Reg. at 29226.

[23] *See* 68 Fed. Reg. 44859 (July 31, 2003) (eliminating federal standards for "pizza with meat" and "pizza with sausage" more than four years after February 4, 1999 industry petition); 70 Fed. Reg. 33803 (June 10, 2005) (issuing final rule addressing substitute meat and poultry products nearly ten years following December 29, 1995 proposal).

approach to authorize use of safe and suitable binders and antimicrobial products where existing standards permit these types of ingredients.[24] In enacting 21 C.F.R. § 130.10 and the FSIS equivalents (9 C.F.R. §§ 319.10 and 381.172), the agencies were able, in one regulation, to improve the flexibility of the standard-setting process by allowing for variations for the purpose of meeting nutrient content claim criteria. We recommend building upon such successes by enacting a regulation to allow variations for other appropriate purposes that promote honesty and fair dealing in the interest of consumers.

Such a regulation could achieve the flexibility embraced by the general principles by allowing, in standardized foods generally, differences such as those in the list below—

- The use of any alternate make procedures resulting in a product with a basic nature and essential characteristics that are substantially similar to food produced under a given standard.

- The use of safe and suitable ingredients that fall within the same functional categories as ingredients expressly identified in a standard (e.g., where one specific antimycotic agent is allowed, other antimycotic agents also could be used).

- The use, by functional category, of safe and suitable ingredients that are appropriate in a wide variety of foods, such as safe and suitable dairy ingredients, antimicrobial agents, antioxidants, and processing aids as defined in 21 C.F.R. § 170.3(o). If an ingredient or processing aid can perform a legitimate function in a nonstandardized food, as it must under the applicable rules governing food ingredients, such ingredients should be allowed in standardized foods as well.

- The use of safe and suitable ingredients that provide nutritional benefits, so long as any characterizing ingredients are labeled in accordance with applicable common or usual name requirements (e.g., 21 C.F.R. § 102.5) and any differences in performance characteristics are identified as described in 21 C.F.R. § 130.10 and the FSIS equivalents. An alteration of this type would provide for greater flexibility in the use of ingredients such as whole grains and non-nutritive sweeteners. In the case of whole grains, compositional requirements that whole wheat macaroni products contain 100% whole grain wheat flour as the sole wheat ingredient create an unfortunate “all or nothing” situation that impedes stepwise increases in whole grain intake, to the detriment of consumer acceptance and public health. For example, for familiar products like macaroni and cheese, our

[24] 9 C.F.R. §§ 319.1(b); 381.155(b).

research indicates that stepwise increases in whole grain content are necessary to avoid alienating loyal consumers, particularly children.

- Appropriate deviations for the purpose of complying with a nutrient content claim, as the current regulations allow.

- Variations from minimum fat and oil content requirements that do not result in fat reductions large enough to support a nutrient content claim, provided that appropriate information panel labeling is used if such reductions result in perceptible organoleptic differences (e.g., "Regular _____ 11 g fat, this product, 9 g").

- Variations from other characteristics identified in food standards (e.g., minimum moisture content, minimum aging periods), if such variations are necessary to achieve reductions in fat or oil content or to take advantage of new technologies that promote honesty and fair dealing in the interest of consumers. An example of a beneficial new technology is an improved enzyme technology that allows a cheese to age in less time than called for in a standard, but that results in a product with substantially similar physical and organoleptic characteristics as products produced under the applicable standard.

In suggesting a horizontal approach, we recognize that FDA has historically addressed many of these issues, such as alternative ingredients, on a standard-by-standard basis. The experience of 21 C.F.R. § 130.10 and the FSIS equivalents (9 C.F.R. §§ 319.10 and 381.172), however, shows that it is possible to address these issues in a horizontal manner. Moreover, the general principles and other relevant precedent create a presumption that changes of the type described above promote honesty and fair dealing in the interest of consumers and should be broadly permitted so long as the basic nature and essential characteristics of a food are maintained.

We also recognize that a horizontal regulation will need objective qualifying criteria to ensure that the basic nature and essential characteristics of the standardized food are maintained, much like the criteria included in 21 C.F.R. § 130.10 and 9 C.F.R. §§ 319.10 and 381.172. These regulations, which have worked so well, provide a useful reference for flexibility within defined limits. Of course, as is current policy, development of nonstandardized foods that meaningfully differ from standardized products and are described by appropriate common or usual names would continue to be acceptable.

To the extent that there is concern about the adoption of flexible qualifying criteria, the agencies may wish to consider incorporating into a horizontal regulation a notification process through which the government could be informed of industry interpretations and provided an opportunity to object. We would not expect such a process to place a

meaningful burden on the agencies, especially because a reduction in TMPs would reasonably be expected to result from a more flexible rule.

D. A Horizontal Approach Satisfies International Trade Obligations and Would Demonstrate U.S. Leadership.

One of the more important developments in recent years has been a dramatic increase in global trade. As a result, food standards modernization is even more necessary now than when the agencies undertook this initiative ten years ago. A horizontal approach would promote honesty and fair dealing in the interest of consumers by facilitating legitimate international trade, creating a level playing field for domestic producers and importers, and strengthening the U.S. position in Codex.[25]

As a Member of the World Trade Organization (WTO), the United States has entered into several trade agreements that are relevant to food standards. The most pertinent is the TBT agreement, which requires the United States and other countries to ensure that technical regulations, including most food standards, are no more trade-restrictive than necessary to fulfill a legitimate objective, such as the prevention of deceptive practices.[26] The TBT agreement also requires that technical regulations be expressed in terms of product requirements such as performance and not "design or descriptive characteristics." Of particular relevance to standards, technical regulations are not to be maintained if the circumstances leading to their adoption no longer exist or if the objectives can be addressed in a less trade restrictive manner. Because the U.S. system of food standards is outdated in several respects, and because the necessary revisions do not seem realistic under the present circumstances, one might conclude that the system could be seriously undermined by challenges under the TBT agreement.

We recognize that TBT challenges are rare, but the risk of challenge should not be the primary factor driving modernization anyway. Rather, we respectfully suggest that the United States, as a global leader, should aim to bring U.S. standards into TBT compliance as a matter of principle. This important exercise of leadership would have three desirable results. First, it would facilitate legitimate international trade by eliminating prescriptive requirements that exist only for outdated or arbitrary reasons. Second, a modern system would create a level playing field for domestic producers who make standards compliance a priority. Currently, imported products are subject to little or no enforcement on standard of identity issues.

[25] The general principles recognize expressly that fair trade is in the consumer interest: "With the rising trend in globalization and increased accessibility of U.S. goods to other nations' markets, efforts to harmonize U.S. food standards with international food standards will facilitate international trade and foster competition. These efforts may also result in lowered costs and the increased diversity of the food supply, which in turn would benefit consumers." 70 Fed. Reg. at 29223.

[26] Some standard of identity requirements, such as pasteurization requirements for dairy products, would be classified as health and safety measures that are subject to the SPS agreement.

Consequently, the domestic industry, which places a high priority on compliance with TMPs and related U.S. labeling rules, is at a significant competitive disadvantage. Finally, and perhaps most important, a modern U.S. system is necessary for influential U.S. work in Codex. U.S. standards may be used as a reference point for Codex standards;[27] in order for the United States to maintain credibility and be in the best possible position to ensure that international standards are harmonized in a direction that benefits U.S. consumers, the U.S. system must be functional and serve as a model for others to emulate.

III. Additional Steps: Obsolete Food Standards and General Principles Clarification

In our view, the suggested horizontal approach is reasonably anticipated to address most of the modernization issues the agencies face today. We recommend, therefore, that consideration of this approach be made a priority. In addition to a horizontal regulation, there are several other steps that in our opinion would help to bring the U.S. food standards system up to date.

First, we recommend that the agencies eliminate standards that are obsolete, inappropriate, or unnecessarily restrictive. Examples include "salad dressing" and "mellorine," both of which have different meanings today than when these standards were first enacted. We understand most consumers to consider a "salad dressing" to be a pourable dressing used to top a salad of leafy greens; consumers are probably entirely unfamiliar with the term "mellorine." Standards such as these are inconsistent with consumer practice and understanding and, therefore, do not promote honesty and fair dealing in the interest of consumers.[28]

Standards should also be eliminated for foods, such as mayonnaise, that are commonly the subject of cookbook recipes and restaurant experimentation. If consumers and restaurants may experiment with a food, and are in a good position to judge its contents readily, then the food industry should not be held to a strict recipe standard. Accordingly, consistent with the recent FSIS decision to revoke the pizza standard, which was based on similar considerations,[29] we suggest that FDA revoke the standard for mayonnaise and similar recipe standards, like the standard for frozen cherry pie. Other examples of standards that no longer

[27] 60 Fed. Reg. at 67499 (noting that U.S. delegates often rely upon criteria established in U.S. food standards in deciding compositional requirements for Codex standards).

[28] Both FDA and FSIS have previously withdrawn food standards that are no longer in the consumer interest. For instance, in 1996, FDA withdrew four standards for grits and nine for various types of oysters, finding these standards to be obsolete, unnecessary, or no longer in the public interest. 61 Fed. Reg. 27771, 27779 (June 3, 1996). In 2003, FSIS similarly withdrew standards for "pizza with meat" and "pizza with sausage." 68 Fed. Reg. 44859 (July 31, 2003). FSIS specifically found that federal pizza standards may inhibit manufacturers from marketing the styles of pizza today's consumers demand. *Id.*

[29] 68 Fed. Reg. at 44859.

serve a valid purpose are the recipe standards for canned fruit cocktail and artificially sweetened fruit cocktail,[30] which consumers are able to assess readily based on discernable ingredients.

Standards adopted by policy rather than as required by the Administrative Procedure Act, such as those set out in the FSIS Food Standards and Labeling Policy book, are also inappropriate. We support FSIS's intention to eliminate these standards and suggest that the agency do so as soon as possible.

Second, to provide a clear process for addressing emerging issues, proposing new or revised standards for individual products, proposing to eliminate standards, or addressing other issues, we recommend that the agencies clarify the general principles, but though guidelines, not regulations. We think several clarifications would be of particular value.

Specifically, concerning general principle 2, which states that a standardized food should "meet consumers' expectations of product characteristics and uniformity," we respectfully suggest that references to "consumers' expectations" and "uniformity" may be misleading. Diverse consumers have diverse expectations, so there will generally be no single consumer "expectation" for most characteristics, especially those of a technical nature. We are also concerned about the suggestion that the agencies "do not intend to accept statements about consumer belief or expectations for the purposes of defining the basic nature of a food without data or evidence supporting such statements." In some circumstances, the agencies may be in a position to judge what promotes honesty and fair dealing on the basis of precedent and expertise. In others, it may be necessary to look to a broader range of information, such as cookbooks, restaurant practices, and consumer experience gained through TMPs. We would not agree, nor do we understand the agencies to suggest, that qualitative or quantitative consumer testing data is essential or even appropriate in every instance. In this regard, it is meaningful that the pertinent statutes refer to "consumer protection" and "honesty and fair dealing in the interest of consumers"—standards the agencies may judge flexibly based on experience and evidence.

Accordingly, to avoid confusion about the nature of information required to establish, revise, or eliminate a food standard, we suggest that principle 2 be revised to state simply that "The food standard should describe the basic nature of the food, so consumers are not misled by the name of the food." In our view, this addresses the key issue—consumer understanding of the product identity. Reference to "consumers' expectations of product characteristics and uniformity" is unnecessary.

It also strikes us that some confusion may be created by the overlapping nature of the general principles. For example, it is a fundamental statutory requirement that food standards should protect the public and "promote honesty and fair dealing in the interest of consumers." Further, the agencies correctly point out that all of the principles are specifically designed to

[30] 21 C.F.R. §§ 145.135, 145.136.

accomplish these necessary and fundamental objectives. The presentation of these and similar ideals as distinct principles in separately numbered paragraphs, however, raises a question as to whether the agencies intend petitioners to address each of these concepts independently, through a separate factual or other showing. Such an approach would seem to be unnecessarily repetitive and burdensome.

We believe that the general principles are best addressed by a thoughtful and holistic discussion of what a particular petition seeks to accomplish. Accordingly, we suggest that the agencies consider clarifying that, of the general principles, only the first four are mandatory items that must be explicitly addressed in every submission, with the remaining principles addressed as necessary. In addition, we suggest that the agencies clarify that the principles may be addressed in any appropriate order or manner. Finally, it seems to us that the agencies need not issue a final regulation to clarify and implement these general principles; in fact, a guidance document format would be preferable and would provide desirable flexibility.

IV. Conclusion

Kraft is committed to the development of food standards that truly promote honesty and fair dealing in the interest of consumers. The current system does not appear to accomplish these objectives. We know from past agency successes with horizontal regulations, however, that a functional system can be designed to achieve modernization without the enormous resources required by case-by-case rulemaking. We recommend that the agencies revisit the idea of a horizontal approach as described in these comments and stand ready to work with the government in this important policy area.

We appreciate this opportunity to comment on the general principles for food standards modernization. Please do not hesitate to contact us if we can be of assistance or if there are questions about these comments.

Respectfully submitted,

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July 24, 2005

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Re: Docket No. 1995N-0294; RIN 0910-AC54
Food Standards; General Principles and Food Standards Modernization; Estimate of Time to Prepare a Petition to Modernize a Food Standard; 70 *Fed. Reg*. 29214 (May 20, 2005)

Dear Ms. Murphy-Jenkins:

Thank you for notifying Kraft of the opportunity to comment on the time involved in preparing a petition under the proposed rule titled, "Food Standards; General Principles and Food Standards Modernization." 70 *Fed. Reg*. 29214 (May 20, 2005). We understand that the Office and Management and Budget asked the Food Safety and Inspection Service (FSIS) to gather industry perspectives on the paperwork burden associated with the proposal and are pleased to share the information available to us.

We comment from the perspective of a $32 billion global company, the largest food manufacturer in the United States, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells, which are found today in more than 99% of all U.S. households and over 150 countries around the world. Kraft makes many meat and poultry products that are regulated by FSIS standards of identity. We also make many dairy and other foods that are subject to standards adopted by the Food and Drug Administration (FDA). Thus, Kraft has a substantial interest in the development of an effective process for bringing these standards up-to-date.

We recognize that the task of estimating the time it would take to prepare a generic petition to establish, revise, or eliminate a standard for any food is challenging. The time investment actually required will no doubt vary, depending upon factors such as the regulatory

history associated with the food product category, the complexity of the proposed standard, the difficulty of obtaining consensus with consumers and within the industry, the precedent set by the agencies on previously submitted similar petitions, and international trade considerations.

A. The Food Standards Proposal

As we will explain in substantive comments on the proposed rule to be submitted later, the general principles outlined in the proposal are perhaps necessarily broad, but therefore highly subject to differing interpretations. As a result, it is likely that a company would expend more resources than the agencies anticipate in trying to determine just what information should be included in a petition and in providing supporting information and documentation. In fact, due to the lack of specificity, the proposed principles do not provide any assurance that the volume of information – and concomitant expenditure of review time – would be any different under the proposed rule than under the current regulatory structure, which has proven too burdensome, especially on the agencies, to be effective. We suggest that goal of the modernization effort should be to streamline the process requiring only truly essential information.

B. FDA's Estimate of Burden

We note that FSIS and FDA reached significantly different conclusions about the amount of time needed to prepare a compliant petition, a signal that the proposed requirements may not be as clear as necessary. While FSIS estimated 40 hours of petitioner preparation time, FDA estimated an average of 136 hours, with a range of 88 to 504 hours. Although FSIS does not provide a detailed basis for the 40 hours estimate, FDA offers considerable analysis to support its estimate of the burden associated with the necessary information collection activities. We can confidently advise that the high end of the FDA range is much more consistent with our experience than the lower estimates. We arrived at this conclusion after analyzing the details of the proposal; considering both the FSIS and FDA estimates, reviewing our recent experience in submitting petitions for rulemaking and comments on proposals, and considering experience with the Codex standards-setting process.

To us, even the FDA estimate looks conservative. For example, no time is allocated to meetings with the agency for consultation prior to the drafting and submission of a petition. Although the proposed principles may be designed to substitute for this consultation, our experience is that these face-to-face meetings with agency representatives are indispensable for establishing expectations and working out potential differences prior to the expenditure of substantial time and resources in drafting the actual petition.

Although there is some discussion in the preamble to the proposed rule about the need for reaching consensus on the substance of a food standard, FDA does not allocate any time

to achieving this consensus in its estimate. It is our experience that building consensus, particularly among industry participants and trade associations that may have disparate agendas, is an extremely time and labor-intensive effort. Even preparing a report to the agencies on attempts to build consensus takes time.

As noted in the proposed rule, the establishment, revision, or elimination of a standard should be done with some consideration of international trade implications, including Codex Alimentarius activities and existing standards. The time burden necessary to coordinate a U.S. food standard with those contemplated or established by other governments and Codex would far exceed the eight hours FDA allocated for this task.

C. Recent Experience in Petitioning FDA

In estimating the hourly burden of preparing a petition in accordance with the proposal, we reviewed records of the time involved in petitioning the agencies for other matters. Most recently, for example, Kraft submitted a petition to FDA to establish nutrient content claims for carbohydrates in food. The preparation of this petition took over 500 hours of time, including the time to outline and write a proposed regulation; research relevant regulatory precedent; compile supporting scientific data; draft, review, and revise the petition; and finally attempt to gain industry consensus. The preparation of a petition regarding a revised food standard would involve a roughly equivalent process. Even a petition for straightforward revocation of a standard involves more than the average time estimated by FDA, as we know from our experience with the FSIS pizza standard revocation.

In evaluating these comments on required resources, please consider the number of people involved and variety of tasks that must be accomplished in connection with proposals to change standards.

- Marketing and marketing research personnel predict how consumers are likely to respond to the proposed change and develop support for the petition.
- Research and Development, Procurement, and Operations personnel analyze how products must or could change as well as the implications for purchasing raw materials and converting them into finished packaged food products.
- Regulatory and Graphics specialists evaluate the labeling implications and associated costs.
- Nutrition experts assess how the changes could affect consumption patterns.
- Scientific and Government Affairs personnel work with trade associations to negotiate consensus.

- Lawyers typically draft documents for final submission, after first checking to assure that the correct information has been assembled and regulatory precedent properly analyzed.

In summary, many people participate in preparing a petition, just as many people participate in the government's process of reviewing petitions and clearing new rules for final publication.

D. Codex Standards

Finally, Kraft is well aware of the extensive time and effort involved in establishing a food standard through Codex. Indeed, the proposed principles contemplate harmonization with Codex. It is generally accepted that a Codex standard takes anywhere from three to 10 years to proceed from Step 1 (*i.e.*, decision to elaborate a standard) to Step 8 (*i.e.*, critical review and approval of the standard by the Executive Committee of the Codex Alimentarius Commission) to final adoption by member countries. Although the Codex experience is not directly equivalent to the food standards modernization process proposed by FSIS and FDA, we recognize that many aspects of the processes may share common elements.

III. CONCLUSION

Despite the admittedly difficult nature of accurately estimating the time burden involved in preparing a petition to FSIS to establish, revise, or eliminate a food standard under the general principles set forth in the proposed rule, our experience indicates 500 hours would be a much more realistic typical estimate than 40 hours. The agencies could help make the process more efficient by focusing the rules on information truly necessary to set broad standards that reflect only the basic characteristics of the commodity, leaving the detailed product information to labeling. Therefore, we look forward to commenting on the substantive provisions of the proposed regulations.

Again, thank you for providing us with an opportunity to comment on the estimated burden related to the proposed rule. Please do not hesitate to contact us if we can be of further assistance or if you have questions.

Respectfully submitted,

Sheryl A. Marcouiller