



18 August 2005

Division of Dockets Management
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FSIS Docket Clerk
Docket No. 95-051P
rm. 102, Cotton Annex Bldg.
300 12th St. SW.
Washington, DC 20250-3700

Re: Docket No. 1995N-0294

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The Grocery Manufacturers Association (GMA)¹ appreciates the opportunity to comment on the set of general principles for food standards proposed by the Food Safety and Inspection Service (FSIS), USDA, and the Food and Drug Administration (FDA), HHS [Proposed Rule, Food Standards; General Principles and Food Standards Modernization, 70 FR 29214, May 20, 2005].

GMA and its members fully support both components of Regulatory Option Two. This support is described more fully below. However, we are concerned that the proposed approach will simply preserve the *status quo* with respect to food standards. Therefore we are proposing additional complementary actions based on previous FDA and FSIS action regarding standardized foods that will, in our opinion, achieve substantial modernization without requiring the extensive resources of a standard-by-standard petition process. Our proposal is also described more fully below.

1. The GMA Proposal for Additional, Complementary Actions

The FDA and FSIS are proposing to establish a set of principles that the agencies will use when assessing food standards, and a system by which FDA and FSIS intend to revise, eliminate, or establish standards in response to petitions submitted by external parties or on the initiative of FDA or FSIS.

GMA and its members are concerned that the proposed approach will simply preserve the *status quo* with respect to food standards. We are also concerned that the new process may even perpetuate out-dated standards or expand standardization unnecessarily. The FDA/FSIS “principles/process” proposal took a decade to prepare and does not deal with the fundamental issue: Whether the government could or should spend the resources necessary to go through

¹ The Grocery Manufacturers Association (GMA) represents the world’s leading branded food, beverage and consumer products companies. Since 1908, GMA has been an advocate for its members on public policy issues and has championed initiatives to increase industry-wide productivity and growth. GMA member companies employ more than 2.5 million workers in all 50 states and account for more than \$680 billion in annual sales. The association is led by a board of member company chief executives. For more information, visit the GMA Web site at www.gmabrands.com.

notice and comment rulemaking addressing individual standards as the proposal appears to suggest.

We wish to make it clear that we are not proposing to do away with food standards completely. GMA and its members support truly useful food standards—standards that promote honesty and fair dealing in the interest of consumers and to protect the public; that allow for technological advances in food production; that are appropriately consistent with international food standards to the extent feasible; and, especially, that are clear, simple, and easy to use for both manufacturers and the agencies that enforce compliance with the standards.

Instead, we recognize that the FDA (and later, FSIS) dealt with substitute standardized foods following the Nutrition Labeling and Education Act (NLEA), specifically the use of a standardized name by foods altered to make a nutrient content claim, resulting in an amended 21 CFR §130.10.² GMA and its members strongly believe that, going forward, FDA and FSIS could and should build on this precedent that cut across all food standards horizontally to add responsible flexibility.

In the Final Rule amending 21 CFR § 130.10, FDA commented that the agency:

believes that establishing a general definition and standard of identity for modified versions of standardized foods that qualify for use of a nutrient content claim is a more efficient way to provide consumers with these foods than having to issue temporary marketing permits to each manufacturer desiring to market test a new modified food and, ultimately, establishing individual new food standards for each new modified version.³

More recently, FSIS applied similar flexibility:

FSIS agrees that certain technologies used to prepare standardized foods may yield a product with the same physical, nutritional, and sensory characteristics as the food made in accordance with the traditional standards. To reflect this fact, instead of specifying that substitute standardized products must contain all ingredients specifically required by a standard of identity or composition, and that the meat or poultry portion of substitute products come from the same anatomical location, be of the same kind and amount, and undergo the same basic processing procedures as the standardized product as was proposed, FSIS [will] require only that substitute standardized products comply with all other applicable standards of identity or composition.⁴

GMA and its members believe that the approaches of FDA and FSIS equally apply to other aspects of food standards. In particular, we believe that responsible flexibility could be added horizontally across all food standards in a manner consistent with the general principles by, for

² 58 FR 2431. Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term. Final Rule. January 6, 1993.

³ At 58 FR 2432.

⁴ At 70 FR 33811. Food Standards: Requirements for Substitute Standardized Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term. Final rule. June 10, 2005.

example, allowing for the use of safe and suitable alternative optional ingredients, the use of mandatory/characterizing ingredients at different levels as needed to fulfill a legitimate objective (e.g., improving the nutritional profile of the product), the use of alternative manufacturing processes, the addition of safe and suitable nutrients not listed in a food standard as needed to achieve a legitimate purpose, and appropriate variations in standardized macronutrient content (e.g., decreases from minimum fat standards or substitution of non-nutritive sweeteners as appropriate for nutritive carbohydrate sweeteners).

An example illustrates how such flexibility could assist consumers in meeting dietary recommendations. The Dietary Guidelines for Americans 2005 and MyPyramid.gov both encourage consumers to add whole grains to their diet. The Dietary Guidelines for Americans recognizes that the “Since . . . recommended [amount of whole grains] may be difficult for young children to achieve, they should gradually increase the amount of whole grains in their diets.”⁵ Similarly, MyPyramid.gov includes the slogan “Steps to a Healthier You”, which is explained as “Gradual improvement is encouraged by the slogan. It suggests that individuals can benefit from taking small steps to improve their diet and lifestyle each day.”⁶ A number of our members have found that consumers are interested in whole grain products, but that for some products there is a limit to the amount of whole grain or whole flour ingredients beyond which the product’s taste and/or performance is not acceptable. Spaghetti or other macaroni products made with less than 100% whole wheat flour could be more palatable, a way to introduce whole grains to children and a way for adults to take small steps towards a better diet. However, spaghetti made with 50% whole wheat flour does not comply with either the FDA standard for macaroni products or the standard for whole wheat macaroni products⁷. Therefore, a spaghetti made with 50% whole grain flour would need to be labeled with a non-standardized common or usual name that may not be as familiar or clear to consumers (e.g., using terms such as “spaghetti style” or “spaghetti substitute” rather than more direct names such as “Whole wheat spaghetti, 50% whole grain wheat”).

Certainly not all situations that may involve mandatory/major/characterizing ingredients are as obviously in need of flexibility as this example. We are confident, however, that there are numerous other cases that would benefit from such action, and that would benefit consumers and industry alike.

We also recognize that appropriate boundaries need to be established for this kind of flexibility in food standards, as was done when FDA and FSIS permitted variations for the purpose of meeting nutrient content claim criteria. Consistent with the general principles and regulatory precedent (e.g., regulation of alternate make procedures in cheese standards), a horizontal regulation of the type suggested could include objective criteria for ensuring that the changes do not meaningfully alter the basic nature or essential characteristics of the food. To the extent that a variation is intended to characterize the food in a meaningful way but still remain faithful to the standard (e.g., by simply adding a characterizing ingredient such as whole grain wheat to a macaroni product), the principles detailed in 21 C.F.R. § 102.5, which are broadly useful for both FDA and FSIS-regulated products, could be referenced. Nutrition information and full ingredient labeling, which were not required at the time most standards were issued, will further assist consumer understanding of the product.

⁵ Dietary Guidelines for Americans 2005. U.S. Department of Health and Human Services, U.S. Department of Agriculture. p. 25. Available at www.healthierus.gov/dietaryguidelines

⁶ Anatomy of My Pyramid, available at http://www.mypyramid.gov/downloads/MyPyramid_Anatomy.pdf

⁷ 21 CFR § 131.100 and 138, respectively.

We appreciate that the details of this complementary additional approach would benefit from a more in-depth discussion than is practical to offer here. To that end, GMA and its members intend to prepare a detailed petition on how we believe horizontal flexibility can be applied. We look forward to working with the FDA and FSIS, with the rest of the food sector, and with consumers on this important project.

2. The FDA/FSIS Proposal

As mentioned above, GMA and its members fully support both components of Regulatory Option Two. These are the establishment of a set of principles that FDA and FSIS will use when assessing food standards, and a statement of the system by which FDA and FSIS intend to revise, eliminate, or establish standards in response to petitions submitted by external parties or on the initiative of FDA or FSIS.

The result of this option is, we believe, desired by all, namely, principles for better, more complete petitions by interested parties, resulting in more efficient and effective action by FDA or FSIS. This objective is consistent with previous FDA actions establishing principles and a process for, for example, food additive petitions⁸ and affirmation of generally recognized as safe (GRAS) status.⁹

GMA and its members also support the objectives of truly useful food standards themselves: to promote honesty and fair dealing in the interest of consumers and to protect the public; to allow for technological advances in food production; to be consistent with international food standards to the extent feasible; and, especially, to be clear, simple and easy to use for both manufacturers and the agencies that enforce compliance with the standards.

We offer the following four general comments, and additional detailed comments on a number of the individual proposed principles.

2.1. General Comments

Our first general comment is to compliment both FDA and FSIS for jointly proposing the set of principles and the process for submissions to add, revise or eliminate food standards. GMA and its members very much appreciate the agencies' efforts to work together and encourage them to strive as much as possible for consistency/commonality/equivalence in the development, interpretation and enforcement of food standards in the future. For example, a consistent interpretation of "safe and suitable" would be very useful.

The second general comment concerns which of the proposed principles are mandatory and which are not, and in what manner these must be addressed. The agencies are clear that the first four principles¹⁰ are fundamental to a truly useful food standard, and any standard - existing or proposed - that does not adequately meet any one of these four principles would need to be corrected. A petition to eliminate a food standard must include a comprehensive statement that explains how the subject standard does not meet the first four proposed principles, and a petition

⁸ 21 CFR §171

⁹ 21 CFR § 170.35

¹⁰ Proposed 7 CFR § 410 (a) (1)–(4) / 21 CFR § 130.5 (b) (1)–(4).

that does not do so will be denied.¹¹ The agencies have indicated that this is the same requirement they would impose on themselves if they were to propose to revoke a standard.¹² In our opinion, addressing the subsequent proposed principles (7 CFR § 410 (a) (5)-(15) / 21 CFR § 130.5 (b) (5)-(13)), will generally provide supporting and substantiating information to demonstrate that the fundamental four principles have been met. For example, proposed 7 CFR § 410 (a) (6) / 21 CFR § 130.5 (b) (6) allows for maximum flexibility in technology and manufacturing processes as long as the resulting product meets the standard with respect to basic nature, essential characteristics, nutritional quality and safety--that is, that the resulting product meets proposed 7 CFR § 410 (a) (1)-(4) / 21 CFR § 130.5 (b) (1)-(4). We suggest that petitioners should be able to demonstrate adherence to the necessary principles using any manner or organizational approach that makes sense.

Similarly, we would ask the agencies for clarification regarding proposed 7 CFR § 410 (a) / 21 CFR § 130.5 (b). This principle states that a petition for a new standard “must be consistent with all of the following general principles that apply to the new standard” and that a petition to revise a standard “must be consistent with all of the following general principles that apply to the proposed revision to the existing standard.” Thus, for example, it appears clear to us that petitions to revise the terms for naming a food would need to address only “the general principles that apply to the proposed revision”, namely 7 CFR § 410 (a) (12) / 21 CFR § 130.5 (b) (12). Confirmation of this by the agencies would be helpful to industry and other potential petitioners, as well as for the agencies in terms of managing their resources.

The third general comment concerns the timing of the process. FDA and FSIS accurately characterize establishing the general principles as their “first step in instituting a process to modernize their standards of identity (and any accompanying standards of quality and fill of container) and standards of composition.” GMA and its members believe that the agencies need to take the second step, too. That is, the eventual rule must also establish a time-frame for the various stages of the process, including acknowledgement of receipt of a petition, publication for public notice and comment, finalization of a new or revised standard or elimination of an existing standard.

In the notice of proposed rulemaking, the agencies thoroughly discussed, for the different regulatory options, the costs to the agencies themselves of reviewing, revising, accepting and/or rejecting petitions. The agencies also estimated the time costs, in total and per principle, for industry and other interested parties to prepare and submit petitions. We will not comment on the accuracy of the estimates here. However, if a petitioner takes the time to enter the process by preparing a petition according to the general principles, it is entirely reasonable for the petitioner to expect that FDA or FSIS, as appropriate, will have committed in advance to act on the petition in a defined and reasonably finite period of time. Both agencies are aware of already submitted petitions, most of which probably meet the first four proposed principles, that have not been acted upon in a reasonable period of time, in some case not even after five years. If the second step of establishing the time-frame for the process is not taken by the agencies, the intended “modernization” will be in name only.

Our fourth general comment concerns the transition from the current situation to the eventual principles and process. As mentioned above, there are a number of pending petitions for new or revised food standards. GMA and its members request FDA and FSIS to not wait for the final rule

¹¹ Proposed 7 CFR § 410 (c) / 21 CFR § 130.5 (d).

¹² At 70 FR 29225.

on the principles and process before acting on these petitions. We strongly encourage the agencies instead to review the pending petitions in light of the proposed principles. Where the principles are met, we urge the agencies to act on the standards; where the principles are not met, we ask that the agencies inform the petitioners of the gaps so that complete petitions may be prepared. Similarly, since the rulemaking process can take a number of years, we would encourage the agencies to indicate clearly that until the final rule is established, any interested party should organize and prepare a petition in line with the proposed principles.

During and after the transition, the agencies need to consider temporary marketing permits (TMPs); we request that both FDA and FSIS continue to allow for TMPs. In their earlier request for comments on existing food standards¹³, FDA indicated that modernization could reduce the number or eliminate the need for TMPs. However, there is no discussion or mention of TMPs in the current proposal. While we recognize that the focus of the current proposal is to establish principles and define a process for food standards, and while we agree with the objective of flexibility to avoid the need for testing “substitute” standardized foods, GMA and its members believe that no system can anticipate all advances in food science, nutrition, technology, and consumer needs. Therefore we request that the agencies will allow the use of TMPs in the future, particularly during the transition period.

2.2. Comments on Selected Proposed Principles

- *Proposed 7 CFR § 410 (a) (3) / 21 CFR § 130.5 (b) (3)*
We assume that the intent of the text “. . . foods may be defined or distinguished by . . . the manner in which they are produced” is to refer to methods such as barbecued, concentrated, reconstituted, etc., which have an effect on the characteristics of the food. We believe it would be helpful for both FDA and FSIS to confirm that, consistent with FDA’s 1992 Statement of Policy: Food Derived From New Plant Varieties¹⁴, this principle does not require, or would not support a petition seeking to require, defining or distinguishing a standardized food or an ingredient used in a standardized food if it was produced or derived from plants or animals resulting from biotechnology, where the food’s characteristics were essentially the same as the traditional standardized food. This Policy also requires that if such foods or ingredients are significantly different from their traditional counterparts then they would need to be labeled¹⁵, and such differences would apply to standardized foods as well.
- *Proposed 7 CFR § 410 (a) (4) / 21 CFR § 130.5 (b) (4)*
The term “vehicle” suggests the food will carry some additional benefit, i.e., that within a standard a food may have its micronutrients restored, enriched or fortified. This principle also needs to allow standards to be sufficiently flexible to spur industry innovations in the development of healthier food products. This includes changes in macronutrients that will potentially reduce the calorie levels in a significant number of foods. For example, the new ingredient enzyme modified egg yolk is much more stable and is a better emulsifier than traditional egg yolk. This new ingredient would enable a food manufacturer to use less egg

¹³ 60 FR 67492, December 29, 1995.

¹⁴ “The method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.” At 57 FR 22984. Available at <http://www.cfsan.fda.gov/~dms/biolabgu.html>

¹⁵ See “Guidance for Industry. Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.” Available at <http://www.cfsan.fda.gov/~dms/biolabgu.html>

yolk and less vegetable oil in the formulation of “mayonnaise.” The product would contain less cholesterol and fewer calories than traditional mayonnaise yet meet consumer expectations of quality and functionality for mayonnaise.

- *Proposed 7 CFR § 410 (a) (5) / 21 CFR § 130.5 (b) (5)*
This principle would not only facilitate compliance by manufacturers, but also would promote consistent interpretation by field staff in both agencies. Further, it could help in the development of clear C.F.R. standards, to the extent that codification is necessary, as FSIS evaluates which meat and poultry “policy” standards to switch from the FSIS “Food Standards and Labeling Policy Book” to the Code of Federal Regulations. Concerning the FSIS “policy” food standards, we request that the agency, as part of any process to codify or eliminate such standards, provide the opportunity for public notice and comment so as to minimize disruption to the affected industry and impact on consumers.
- *Proposed 7 CFR § 410 (a) (6) / 21 CFR § 130.5 (b) (6)*
This general principle provides the desired opportunities for flexibility and innovation. GMA and its members believe this principle is part of the core of modernization and definitely should be included.
- *Proposed 7 CFR § 410 (a) (7) / 21 CFR § 130.5 (b) (7)*
For various reasons, different national or regional compositional and/or production standards have been problematic for the US food and beverage industry. As a result, we have long supported harmonization of food regulations between countries, as evidenced in part by our participation in Codex activities, either by providing expertise as members of the US delegations or as industry observers to the various Codex Committees and Task Forces.

However, we do not wish to have US food standards slavishly subordinated to Codex standards. In the notice it is stated at 70 FR 29220 “In the event we do not receive a petition requesting that we revise, revoke, or establish a food standard, we, on our own initiative, may, when appropriate, propose to revise, revoke, or establish a standard.” GMA and its members request that FSIS or FDA clarify that this does not mean they plan to make wholesale adjustments to existing US standards to meet Codex standards if they differ. We do not believe that it would be the best use of the resources of the agencies to impose revisions on long standing and widely recognized US food standards simply to be consistent. We assume that the agencies interpret consistent to mean “equivalent” not “identical”, and that US food standards that are not worded exactly the same as international standards but that achieve an equivalent product would be left intact.

FDA and FSIS should make it clear that changes will be considered only in those cases where a US standard contradicts an international standard.

- *Proposed 7 CFR § 410 (a) (9) and (10) / 21 CFR § 130.5 (b) (9) and (10)*
These principles are useful but are, in the absence of a need to consolidate standards in order to comply with the first four principles, essentially housekeeping matters. GMA and its members recommend that there are and will be more important aspects of food standards to deal with first.
- *Proposed 7 CFR § 410 (a) (11) / 21 CFR § 130.5 (b) (11)*
We would ask the FDA for clarification on the proposal “any specific requirements for foods intended for further manufacturing should be incorporated within the reference food standard

rather than being provided as a separate food standard.” Certainly the agency does not intend to eliminate the differences between, for example, cheddar cheese and cheddar cheese for manufacturing.¹⁶

- *Proposed 7 CFR § 410 (a) (12) / 21 CFR § 130.5 (b) (12)*

This proposed principle requires that the proposed terms for naming the food be included in a standard and that the terms and the order in which they may be used do not mislead the consumer. We agree that any standard of identity regulation should allow for appropriate flexibility in the way product names are presented, and suggest that good judgment should, in many or all instances, be sufficient to identify truthful and not misleading options. Indeed, in terms of the information that may be necessary to establish product names in the first place, we read with some concern the agencies’ statement in the discussion of possible costs that “we do not intend to accept statements about consumer beliefs or expectations for the purposes of defining the basic nature of a food without data or evidence supporting such statements.” Although submissions certainly must provide some type of support, we suggest that a variety of sources may be used for the purpose, and that qualitative or quantitative consumer research data should not necessarily be required.

- *Proposed 7 CFR § 410 (a) (14)*

We believe it is important to specify that “The food standard should be based on the finished product.” We note that FDA does not believe that a similar provision is necessary for its general principles, based on the nature of FDA standards as generally addressing the finished product. However, whether a product is finished or not can depend on the specific consumer. There are standards for foods sold to the final consumer as well as standards for the same foods for further manufacturing. In the spirit of clarification and harmonization we suggest the addition of a parallel 21 CFR § 130.5 (b) (14), to the effect that “The food standard should be based on the finished product as sold to the consumer or as sold for further manufacturing.” If a similar provision is not added, it could create some confusion as the regulation is applied in the future.

- *Proposed 7 CFR § 410 (b) / 21 CFR § 130.5 (c)*

On first reading this principle, we were concerned about the possible drain on the resources of the agencies if there were a large number of petitions requesting revisions or elimination of standards because they do not “meet consumers’ expectations of product characteristics and uniformity” as required in proposed principle 7 CFR § 410 (b) (2) / 21 CFR § 130.5 (c) (2). Similarly, there could be a number of petitions seeking to in effect degrade other food standards. The agencies have indicated their general approaches to dealing with inappropriate petitions¹⁷. We would like to point out that more specific guidance or documented policy in this area would be helpful for industry, consumers and ultimately the agencies’ management of resources. This equally applies to denial of a petition to revise a standard.

¹⁶ 21 CFR § 133.114. Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by § 133.113, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (b)(3)(iv) of that section do not apply.

¹⁷ “First, we will be able to identify inappropriate recommendations during the petition review process because they will be inconsistent with the proposed principles. Second, we do not intend to accept statements about consumer beliefs or expectations for the purposes of defining the basic nature of a food without data or evidence supporting such statements. Third, we will publish proposed rules for any prospective changes to the standards regulations. Other interested parties will be able to comment on those changes and help us identify any inappropriate recommendations that we may have overlooked during our initial review of the petition.” At 70 FR 29227.

3. Summary

GMA and its members fully support the proposal by FDA and FSIS to establish a set of principles for food standards and to state a process by which those principles will be applied. The result of the proposal is, we believe, desired by all, namely, principles for better, more complete petitions by interested parties resulting in more efficient and effective action by FDA or FSIS concerning food standards.

However, we are concerned that the proposed approach will simply preserve the *status quo* with respect to food standards. Therefore we are proposing additional complementary actions based on previous FDA and FSIS action regarding standardized foods that, in our opinion, will recognize the current status of, and the reasonably expected future changes to, the US food supply and food manufacturing, will provide more ways to help consumers select foods and diets to meet the US Dietary Guidelines, and will continue to meet consumer expectations.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark F. Nelson", with a long horizontal flourish extending to the right.

Mark F. Nelson, Ph.D.
Vice President, Scientific and Regulatory Policy