



August 18, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Comments to the Proposed Rule on Food Standards: (Docket No. 1995N-0294).

Dear Sir or Madam:

The National Yogurt Association (“NYA”) is pleased to submit these comments to the Food and Drug Administration (“FDA” or the “Agency”) in response to the Proposed Rule on “Food Standards; General Principles and Food Standards Modernization,” (“Proposed Rule”) published in the *Federal Register* of May 20, 2005.¹

NYA is the national nonprofit trade association representing producers of live and active culture (“LAC”) yogurt products as well as suppliers to the yogurt industry. NYA’s member companies are among the largest yogurt manufacturers in the United States. NYA sponsors scientific research regarding the health benefits associated with the consumption of yogurt with LAC and serves as an information resource for the American public about these attributes.

NYA applauds FDA’s proposed general principles as an important first step in modernizing outdated food standards. The usefulness of the general principles and the effective modernization of food standards, however, will depend upon the creation of a process that works through differences in industry opinion and advances citizen petitions to a decision point.



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¹ 70 Fed. Reg. 29214 (May 20, 2005).

I. Background on the Food Standards Proposed Rule

In recent years, FDA and the U.S. Department of Agriculture's ("USDA's") Food Safety and Inspection Service ("FSIS") have identified problems with existing food standards of identity, which are used to ensure that products sold under a particular name have the characteristics expected by consumers.² Notably, there is a concern that some food standards may be outdated, inflexible, and impede technological innovation in the food industry.³

In an effort to modernize the food standards of identity, the agencies propose to establish a set of "general principles" for evaluating whether to revise, eliminate, or create new standards.⁴ Consumer, industry, commodity, and other external groups are to use these proposed general principles to draft recommended revisions and submit them as petitions to FDA or FSIS.⁵ If the agencies determine that a petition is consistent with the general principles, and provides adequate data and support for the suggested change, they plan to more quickly propose and finalize the new or revised standard.⁶

The agencies hope the general principles will result in updated standards that: (1) better promote honesty and fair dealing in the interest of consumers and protect the public; (2) allow for technological advances in food production; (3) are consistent with international food standards to the extent feasible; and (4) are clear, simple, and easy to use.⁷

² 70 Fed. Reg. at 29217. FSIS is responsible for food standards of identity related to meat, poultry, and processed egg products, while FDA regulates standards for all other foods.

³ *Id.*

⁴ *Id.* at 29219.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.* at 29214.

II. NYA Supports FDA's Proposed General Principles

A. Background on NYA's Citizen Petition

NYA believes in the importance of clear, consistent, modernized, and flexible food standards that will benefit both industry and consumers. In fact, on February 18, 2000, NYA petitioned FDA to modernize the over twenty-year-old standards of identity for yogurt.⁸

FDA published a final rule establishing three yogurt standards of identity in 1981.⁹ Due to objections FDA received on certain provisions of the final rule, FDA amended some provisions and stayed other provisions pending a hearing.¹⁰ As a result, the standards of identity for yogurt have been a combination of stayed, outdated, and amended provisions with multiple gaps for which no regulatory guidance exists.

In its citizen petition, NYA requested that FDA revoke these confusing and unhelpful standards of identity for yogurt and replace them with NYA's proposed standard, which would: (1) require a minimum level of LACs at the time of manufacture and anticipated consumption; (2) remove heat-treated products from the category of yogurt; (3) resolve labeling issues by ensuring that product claims such as "lowfat" and "nonfat" are consistent with provisions of the Nutrition Labeling and Education Act of 1990 ("NLEA"); and (4) provide flexibility in the ingredients that may be included in yogurt. The petition also addressed issues related to acidity, homogenization/pasteurization, nomenclature, and conforming changes to the cultured milk standard.¹¹

⁸ NYA Citizen Petition on the Standard of Identity for Yogurt, (February 18, 2000), found at <http://www.aboutyogurt.com/pressRoom/petition2.pdf>.

⁹ 46 Fed. Reg. 9924 (January 30, 1981).

¹⁰ 47 Fed. Reg. 41519 (September 21, 1982). FDA stayed provisions relating to the use of reconstituted dairy ingredients, milk-derived ingredients, and preservatives. FDA also stayed provisions on the timing of measuring milkfat percentage, and the minimum acceptable titratable acidity of yogurt.

¹¹ NYA Citizen Petition, found at <http://www.aboutyogurt.com/pressRoom/petition2.pdf>.

B. NYA’s Citizen Petition Reflects Many of FDA’s Proposed General Principles

FDA’s proposed general principles are a great first step in its efforts to effectively modernize food standards. As highlighted below, many of these principles were reflected in NYA’s citizen petition to amend the yogurt standards of identity.

Proposed General Principle	NYA Petition
The food standard should promote honesty and fair dealing in the interest of consumers.	The petition provides for product uniformity by resolving certain nutrition labeling issues, and requiring that yogurt contain a minimum level of LACs.
The 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.	The petition reinforces consumers’ expectation that yogurt contains LACs, and creates uniform criteria for culture count and nutrition labeling.
The food standard should reflect the essential characteristics of the food.	Most experts agree that LACs are the characterizing ingredient in yogurt, and the petition reflects this essential characteristic.
The food standard should ensure that the food does not appear to be better or of greater value than it is.	The petition resolves stayed and other issues prevalent in the current standard.
The food standard should contain clear and easily understood requirements to facilitate compliance by food manufacturers.	The petition resolves and clarifies all unresolved and ambiguous issues in the current standard.
The food standard should permit maximum flexibility in the technology used to prepare standardized foods.	The petition permits the use of “safe and suitable” ingredients and allows for future advances in technology.

Proposed General Principle (continued)	NYA Petition (continued)
The food standard should be harmonized with international food standards to the extent feasible.	The petition accounts for (and in general aligns with) the recently revised Codex Alimentarius standard for fermented milk. ¹²
The food standard provisions should be simple, easy to use, and consistent among all food standards. Food standards should include only those elements that are necessary to define the basic nature and essential characteristics of a particular food, and any unnecessary detail should be eliminated.	The petition simplifies the yogurt standards of identity by eliminating unnecessary detail and resolving ambiguous process and labeling issues. For example, the petition broadly permits “safe and suitable” sweeteners without specifying a list.
The food standard should allow for variations in the physical attributes of the food. Where necessary to provide for specific variations in the physical attributes of a food within the food standard, the variations should be consolidated into a single food standard.	The petition consolidates the three yogurt standards into one comprehensive and clear standard.
The food standard should take into account other relevant regulations.	The petition resolves NLEA discrepancies, and aligns with other relevant regulations.

¹² NYA’s citizen petition proposes that yogurt contain at least 10⁷ cfu/g active cultures of *Lactobacillus delbrueckii* subspecies *bulgaricus* and *Streptococcus thermophilus* at the time of manufacture, and at least 10⁶ cfu/g at the anticipated time of consumption. Codex requires yogurt to contain at least 10⁷ cfu/g active cultures of *Streptococcus thermophilus* and *Lactobacillus delbrueckii* subspecies *bulgaricus* that are viable, active, and abundant in the product to the date of minimum durability. CODEX STAN 243-2003, Codex Standard for Fermented Milk, found at http://www.codexalimentarius.net/web/standard_list.do.

Although NYA supports the general principles as a whole, we caution there may be instances in which international harmonization is infeasible despite the industry's best efforts. We respectfully request that FDA acknowledge this difficulty. Moreover, the general principles will have no practical effect unless FDA creates a mechanism to sort out differences in opinion within the industry and advance matters to a decision point.

III. FDA Can Enhance the Usefulness of the General Principles by Creating a Process That Moves Petitions to a Decision Point

A. Process Issues are the Real Impediments to Food Standards Modernization

Given the absence of strict deadlines for decision, the current process for modernizing food standards is long and laborious. For example, FDA did not publish an Advance Notice of Proposed Rulemaking ("ANPR") announcing NYA's February 18, 2000 petition to amend the yogurt standards of identity until July 3, 2003.¹³ On January 27, 2004, the ANPR comment period closed, following an extension. On December 1, 2004, FDA published a Center for Food Safety and Applied Nutrition ("CFSAN") priorities for 2005, which identify as a "B" priority the "[d]evelopment of a proposed rule to amend the standard of identity for yogurt."¹⁴ For over five years, FDA has failed to take *material* action on NYA's petition even though it is consistent with many of the proposed general principles. The existing standards of identity for yogurt remain unchanged. This suggests that process issues are the real impediments to the modernization of food standards.

Moreover, it is inevitable that industry will have different views on the appropriate standard of identity for a food product. The establishment of concrete deadlines and a process to sort out these differences in industry opinion will help the modernization effort.

¹³ 68 Fed. Reg. 39873 (July 3, 2003).

¹⁴ CFSAN, "CFSAN 2005 Program Priorities" (December 1, 2004), found at <http://www.cfsan.fda.gov/~dms/cfsand04.html>.

B. Examples of Potentially Effective Processes

There are a variety of ways to resolve differences in industry opinion and arrive at a decision. The Codex Alimentarius Commission (“CAC” or “Codex”), for example, relies on a consensus-based approach. FDA could also develop a unique process incorporating: (1) mandatory deadlines; and (2) an informal hearing conducted by an entity outside the agency to resolve differences in opinion.

i. Codex

The CAC is an international standard-setting body established in 1962 by the United Nations World Health Organization (“WHO”) and the United Nations Food and Agriculture Organization (“FAO”) to facilitate international trade of food. The CAC receives assistance from various subsidiary Committees, such as the Codex Committee on Milk and Milk Products, to establish food standards, codes of practice, and other guidance.¹⁵

Codex food standards are developed through a consensus-based procedure, consisting of eight stages or steps. Consensus means that member countries reach substantial agreement and attempt to resolve all objections before a standard is adopted. If consensus cannot be achieved, then it is possible for a vote to be called, but this is avoided if possible.¹⁶ In essence, the CAC process for establishing a standard is as follows:

- A proposal to develop a new food standard is submitted by a national government or a subsidiary Committee of the Commission.
- The Commission or the Executive Committee decides whether the proposal should proceed. A list of formal criteria helps to guide the Commission in its

¹⁵ Codex, “*The Codex System: FAO, WHO and the Codex Alimentarius Commission*,” found at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/w9114e/W9114e04.htm.

¹⁶ Codex, “*Codex Alimentarius Commission: 14th Procedure Manual*” at 15, found at http://www.codexalimentarius.net/web/procedural_manual.jsp.

decision-making process, and in selecting the Committee responsible for steering the standard through development.

- The Commission Secretariat arranges for the preparation of a proposed draft standard. The proposed draft standard is circulated to governments and interested international organizations for comment.
- Comments are sent to the responsible Committee, which has the power to consider the comments and amend the proposed draft standard.
- The amended proposed draft standard is sent to the Commission for adoption as a draft standard.
- If the Commission adopts the draft standard, it is sent to governments and interested international organizations for further comment.
- The responsible Committee receives the comments and has the power to make further amendments to the draft standard.
- The draft standard is submitted to the Commission (together with any further written proposals received from governments and international organizations for amendments at this stage) with a view to its adoption as a Codex standard.¹⁷

The 160-plus member countries of Codex are encouraged to accept and implement Codex-approved food standards nationally, but are not obligated to do so. This type of consensus-based process is one way industry conflicts are handled, and food standards established and revised.

NYA does not encourage FDA to adopt the Codex process in its entirety because we understand it may be time consuming and easily derailed. FDA, however, could utilize a Codex-inspired “consensus” approach to food standards modernization instead of trying

¹⁷ *Id.* at 22-24. See also “*The Codex System: FAO, WHO and the Codex Alimentarius Commission*,” found at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/w9114e/W9114e04.htm. Please note that in an accelerated procedure, the number of steps required for the development of a standard varies from a maximum of eight to a minimum of five. The Commission and its Committees also revise Codex standards and related texts as necessary. The procedure for revision follows that used for the initial preparation of the standards.

to resolve all industry conflicts and requiring virtual unanimity from industry before making changes to existing food standards. One way to establish this consensus approach is through an internal FDA committee or an external third party that would be responsible for: (1) reviewing specific issues raised in industry comments on a petition to revise a food standard; (2) getting a sense of the affected industry's general position; and (3) relaying this position to FDA so that it can move forward with the citizen petition.

ii. External Informal Hearing Process

Another way to effectively modernize food standards is through a process comprised of: (1) strict agency deadlines; and (2) an informal hearing conducted by a third party to resolve outstanding issues. This hypothetical review process could look like the following:

- FDA receives a citizen petition to amend, revise, or revoke a food standard.
- Within 30 days of receipt, FDA publishes a notice for comment on the petition to help assess whether it should be subject to full review.
- Within 30 days following close of the comment period, FDA decides whether to review the petition, taking into account the proposed general principles and comments received. If FDA decides not to review the petition, it immediately sends a letter to the petitioner with its decision.
- If FDA decides to review the petition, it immediately publishes a proposed rule.
- Within 30 days following close of the proposed rule comment period, FDA drafts a summary of issues needing resolution and sends it to a third party outside the agency who would hold an informal hearing on the issues.
- Within 30 days of receiving FDA's summary, the third party holds an informal hearing. The informal hearing could be structured like a congressional hearing whereby representatives from industry briefly testify on the issues, followed by a question and answer period.

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- Within 30 days of the informal hearing, the third party sends FDA a report of its findings and recommendations.
- Within 60 days of receiving the report, FDA reaches a final decision on whether to amend, revise or revoke the food standard and publishes a final rule.

This type of process not only allows third party experts to help resolve industry differences of opinion, but provides clear deadlines for action. An uncertain food modernization process that sometimes takes a decade, could potentially be shortened to a year or two.

IV. Conclusion

NYA supports FDA's effort to establish a set of general principles for food standards. In order to maximize the utility of the general principles, however, NYA respectfully requests that FDA establish a process to advance petitions to a decision point.

Respectfully submitted,



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President

National Yogurt Association