



International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association

August 18, 2005

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

Re: Docket No. 1995N-0294—Food Standards; General Principles and Food Standards Modernization

The International Dairy Foods Association (IDFA) offers these comments regarding the Food and Drug Administration (FDA) proposal to amend 21 C.F.R. § 130.5 to establish a general set of principles for establishing, revising, and eliminating food standards, a topic of great importance to both industry and consumers. IDFA is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA comprises three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). Its 500-plus members range from large multinational corporations to single-plant operations, and represent more than 85% of the total volume of milk, cultured products, cheese, ice cream, and frozen desserts produced and marketed in the United States.

A large segment of the current food standards of identity are dairy standards, and IDFA endorses the idea of useful food standards—those that promote honesty and fair dealing in the consumer interest by providing for the development of nutritionally enhanced products, technological advances in food production, consistency with international food standards to the extent feasible, and clear guidance for manufacturers and enforcement agencies. IDFA applauds any effort to develop an improved mechanism to update current standards in a timely way. To this end, we support FDA's proposal to establish a set of principles to guide the modernization process.

Although the need to update individual food standards is clear, the resources to do so are seemingly unavailable. Over the years and with good reason, the agency's priorities for allocating its limited resources have shifted from largely economic concerns to public health and safety concerns. Accordingly, FDA has developed a considerable back log of pending food standard petitions, and it has taken a decade for the agency even to publish this food standards modernization proposal. The proposal, however, does not address the agency's resource dilemma. It simply is not feasible to think that the agency could make meaningful and timely changes on a standard-by-standard basis if notice-and-comment rulemaking is required for each standard, which now number over 280. Simply put, although the proposed principles for evaluating food standards are laudable, and long sought by the food industry, we fear that they may leave us with the same gridlock that we experience today.

Looking to past agency successes, we believe that by taking a "horizontal," instead of a "vertical," approach, FDA can go further to truly "modernize" food standards. Indeed, by issuing a single regulation that adds flexibility to all food standards at once, the agencies could accomplish most of the modernization contemplated by the proposal, without the enormous resource investment required to change standards in separate notice-and-comment rulemaking proceedings. As explained more fully below, FDA could use the framework of its precedent in 21 C.F.R. § 130.10, which took a horizontal approach to improving flexibility in all food standards by allowing for variations for the purpose of meeting nutrient content claim criteria. IDFA encourages the agency to consider this type of approach so that it can make a real difference and do more than simply preserve the status quo.

The Horizontal Approach

The general principles proposed by FDA identify fundamental features of a modernized food standards system, but they do little—if anything—to advance the modernization process, which seemingly has stalled in recent years. While important, the principles appear to add a layer of requirements and will continue to be resource-intensive. The general lack of agency resources, the numerous standards petitions currently pending, the difficulty and length of time required to obtain temporary marketing permits, and the ten years required to develop the proposed general principles all suggest that a standard-by-standard petition process simply will not achieve true modernization.^{1/}

^{1/} Even with a revised, more flexible approach to food standards, temporary marketing permits still may be necessary in some circumstances because no standard or general regulation can anticipate all future technical, scientific, nutritional, and consumer developments.

To achieve efficient and timely modernization, IDFA recommends that the agency model its modernization efforts on past successes in the standards area. In our view, helpful precedent is provided by 21 C.F.R. § 130.10, which permits variations from standards for the purpose of meeting nutrient content claim criteria. We believe that the approach taken in 21 C.F.R. § 130.10 could be used to permit any standardized food to make appropriate variations that are in the interest of consumers, provided that such variations are in accordance with specific criteria.

The idea of a horizontal regulation is not only based in FDA precedent, it also is consistent with the principles outlined in FDA's proposal. For example, a general regulation could achieve the flexibility embodied by the general principles by 1) permitting safe and suitable ingredients that fall within the same categories as ingredients expressly identified in a standard, or 2) allowing the use of any alternate manufacturing procedures, including technological advances, that result in a product with the same basic nature and essential characteristics as food produced under a given standard, provided functional differences are disclosed as permitted in § 130.10. Flexibility of this type promotes fair dealing in the interest of consumers because, as the proposal notes, increased diversity of the food supply and enhanced trade can benefit both consumers and industry.

We appreciate that FDA may be concerned that allowing such variations may change the basic character or essential characteristics of a standardized food. Just as the agency accomplished with § 130.10, however, FDA could set qualifying objective criteria or measures for flexibility in the standards. For example, a variation in manufacturing process could be permitted so long as it results in no significant change to the physical, nutritional, or organoleptic qualities of the standardized product. FDA has long applied such objective measures in the area of cheese standards having alternate make provisions.

The General Principles

IDFA expects that a horizontal regulation of the type described above may address the majority of modernization issues. As resources and time permit, however, we fully support the establishment of a series of general principles to guide any necessary further development, amendment, or elimination of food standards of identity. We note, in particular, that the principle that the "food standard should contain clear and easily understood requirements to facilitate compliance by food manufacturers" and the principle that standards "should permit maximum flexibility in the technology used" are of utmost importance to our members. Further, although the proposed principles will generally streamline the process and content of food standards, making it easier to develop and amend such standards while maintaining their underlying purpose, IDFA believes that

some clarifications to the principles are needed to avoid unnecessary confusion.

For example, the second principle listed in proposed § 130.5(b) states, “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.” Indeed, food standards should describe the basic nature of a food and promote uniformity, but a focus on “consumers’ expectations” could be distracting and unhelpful. Consumer expectations vary greatly and can be quite subjective depending on personal preferences. Moreover, the increased information available to today’s consumers must be taken into account when judging the nature of information that must be conveyed by the product name alone. At the time the first standards were issued, consumers used the product name alone to judge what was in the package because that was the primary information available. Today, however, consumers rely not just on a name, but on Nutrition Facts panels and ingredient statements to assess a product. Although federal standards certainly should describe the basic nature of food and are needed to promote uniformity by precluding inconsistent state laws, this general principle should not be clouded by a strict adherence to a nebulous consumer expectation.

The diversity of today’s consumers also is a reason why consumer testing data is not necessary to establish what the content of a food standard should be. In establishing any component of a standard, whether it is composition or identity of a standardized food, the driving factors are honesty and fair dealing in the consumer interest, both of which may be readily assessed without quantitative or qualitative data.

Clarification also is needed to the seventh principle listed in proposed § 130.5(b). This principle states, “[t]he food standard should be harmonized with international food standards to the extent feasible,” but it goes on to say, “[i]f the food standard is different from the requirements in a Codex standard for the same food, the petition should specify the reasons for these differences.” As a Member of the World Trade Organization, the United States should maintain an efficient standards-setting process that is no more trade-restrictive than necessary and that facilitates, where appropriate, harmonization with international standards, guidelines, and recommendations. However, all differences between U.S. and international standards are not *per se* objectionable. Standards need be compatible, not identical.

Finally, IDFA is concerned that the principles create the impression that each and every one must be addressed in a standards

petition, which could defeat the very purpose of the proposed rule. To truly simplify and streamline the process, IDFA recommends that FDA designate the first four listed principles as the only “mandatory” principles that need to be addressed directly, with the remainder being “optional” and to be addressed as needed. This would make the petition process much less burdensome while still accomplishing the underlying objective.

Of course, if petitioners focus on FDA’s new general principles and put the requisite amount of effort into developing high quality petitions to amend the food standards, there should be a reasonable expectation of a timely review and response at the agency. The proposal, however, specifies no such time frame. Many food standard petitions submitted by IDFA and its members have languished for years, and as noted above, there has been some concern about the pace of the agency’s responses to petitions once received. ^{2/} To that end, FDA should consider adding to its final rule timeframes for agency review and action on petitions. A good model for such a timeframe may be the 180-day period the agency sets for responses to GRAS affirmations.

Formal Rulemaking

Because dairy products are the only major category of food standards of identity that still are subject to formal rulemaking, IDFA would like to take this opportunity to address the formal rulemaking process. We recognize that the Federal Food, Drug, and Cosmetic Act mandates that the agency consider formal rulemaking for dairy standards upon request, ^{3/} but recommend that the agency consistently abide by their existing criteria for formal hearings as set forth in 21 C.F.R. § 12.24 so that the process is not abused or unduly slowed, particularly for reasons of pure economic interest. Formal hearing criteria must be tied to an important issue such as consumer deception or safety, and to adequately raise such an issue, the requestor of a formal hearing should have science-based data to support its assertions, not just baseless allegations. To preserve limited agency resources, FDA should consider clarifying that requests for hearings will be denied if assertions are not well-substantiated or are otherwise frivolous.

^{2/} For example, IDFA still awaits action on its February 2000 petition jointly filed by the National Cheese Institute and the Grocery Manufacturers Association regarding the use of ultrafiltered milk in cheese (Docket # 2000P-0586). IDFA also awaits action its April 2003 petition to amend the frozen dessert standards (Docket # 2003P-0132) and the February 2000 petition it supported to revise yogurt standards (Docket # 2000P-0685).

^{3/} 21 U.S.C. § 371(e); FDCA § 701(e).

Transition Policy

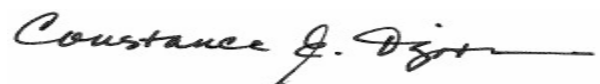
Lastly, IDFA encourages FDA to be open to consideration of petitions and reform in advance of publication of its final rule. As mentioned above, there are a number of pending petitions at FDA for new or revised food standards, including several filed by our association. Accordingly, FDA should implement a “transition” policy such that 1) FDA continues to process pending petitions that have been given priority status, and 2) FDA welcomes new petitions that follow the general principles outlined in the proposed rule. Because publication of a final rule could take several years, it would be unreasonable to impose a “moratorium” on food standards work. While FDA prepares its final rule, a potentially lengthy process, we encourage the agency to be receptive to and to act upon pending petitions, as well as new petitions prepared in accordance with the proposed general principles.

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In summary, IDFA applauds FDA’s efforts to introduce flexibility into the food standards while preserving the underlying purposes of such standards. To truly modernize the food standards and to effectively address the agency’s resource constraints, however, we strongly encourage the agency to consider a regulation of general applicability. While FDA considers its final rule, we hope that FDA will apply its general principles, reasonably interpreted, to the number of pending and new petitions before it.

Thank you for the opportunity to participate in this important process.

Sincerely,

A handwritten signature in cursive script that reads "Constance E. Tipton". The signature is written in black ink and is positioned above the printed name and title.

Constance E. Tipton
President and CEO