

National Milk Producers Federation

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Agri-Mark, Inc.
Arkansas Dairy Cooperative Association
Associated Milk Producers, Inc.
California Dairies, Inc.
Cass-Clay Creamery, Inc.
Continental Dairy Products, Inc.
Cooperative Milk Producers Assn.
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Dairylea Cooperative Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
First District Association
Foremost Farms USA
Just Jersey Cooperative, Inc.
Land O'Lakes, Inc.
Lone Star Milk Producers, Inc.
Manitowoc Milk Producers Coop.
MD & VA Milk Producers Cooperative Association, Inc.
Michigan Milk Producers Assn.
Mid-West Dairymen's Company
Niagara Milk Cooperative, Inc.
Northwest Dairy Association
Prairie Farms Dairy, Inc.
St. Albans Cooperative Creamery, Inc.
Scioto County Co-op Milk Producers' Assn.
Select Milk Producers, Inc.
Southeast Milk, Inc.
Swiss Valley Farms, Co.
Tillamook County Creamery Assn.
United Dairymen of Arizona
Upstate Farms Cooperative Inc.
Zia Milk Producers

August 18, 2005

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

RE: Docket No. 1995N-0294

Dear Sir/Madam:

The following comments are being submitted on behalf of the National Milk Producers Federation (NMPF) to FDA's proposed rule to amend 21 CFR Part 130: Food Standards; General Principles and Food Standards Modernization (Docket No. 1995N-0294). NMPF, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 33 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 50,000 dairy producers on Capitol Hill and with government agencies. NMPF member cooperatives also manufacture a number of dairy products regulated by FDA, including milk, cheese, ice cream, and butter, so the proposed revisions to 21 CFR Part 130.5 are of great interest to NMPF.

General Comments

In regard to revising the Federal Standards of Identity for foods, NMPF believes that while the interests of the consuming public remain of fundamental importance, the interests of the affected industry must be balanced in accord with the overall regulatory framework. NMPF believes that food standards provide an economic level playing field as well as promoting fair dealing and honesty in the interest of consumers. NMPF fully understands the desire on the part of FDA to achieve greater flexibility in establishing, revising, or eliminating food standards. In fact, many changes to dairy product standards over the years have provided the dairy industry with the necessary flexibility and technical tools to produce products which meet the wants and needs of consumers. However, NMPF cautions that care must be taken to not dilute the value of the reference product when additional flexibility is introduced into an individual standard of identity. Without such diligence, it can be rather easy to "lose" the essential characteristics of a reference food when changes are made to a standard in the interest of flexibility.

Jerry Kozak, President/Chief Executive Officer

Charles Beckendorf, Chairman

Standards of identity serve as the “gold standard” for consumer confidence in food products. NMPF believes that a standard of identity best serves consumer interests when a product manufactured according to the provisions of that standard consistently meets consumers’ expectations in terms of sensory fulfillment and nutritional value. In other words, a standard of identity should preserve the integrity of that product by delivering the attributes the consumer associates with the name of the food each and every time the product is purchased. Consequently, standards provisions related to product quality are particularly critical since they have such a significant impact on sensory fulfillment.

In addition, it is NMPF’s view that a standard of identity should not be viewed merely as a compositional endpoint to be achieved through whatever combination of ingredients will meet the product’s chemical definition. Indeed, while some would argue that a standard of identity should render no judgment in regard to quality (“let the marketplace decide”), we would argue that by their very nature, standards of identity prescribe a minimum level of product quality sufficient to merit the use of the standardized designation. For example in the case of ice cream, the United States has been the world’s leader in per capita production for many years largely as a result of an on-going commitment to product quality and adherence by the industry to a standard of identity which reinforces that commitment.

NMPF also believes that product composition and essential characteristics are equally important to product quality and must also be protected by a standard of identity. As flexibility in technology and ingredients is considered, the essential characteristics and composition must not be compromised. NMPF is concerned that any proposed changes to existing standards, the stated purpose of which are to allow for more flexibility, could lead to the introduction of inferior products, and as a result, unfulfilled consumer expectations and declining sales. In other words, those desiring to substitute or introduce inferior ingredients into standardized products should not be permitted to disguise those desires under the banner of “greater flexibility”.

While the revisions are intended to address “flexibility in food technology” and “flexibility in ingredients used to formulate standardized products”, some aspects of the proposed changes would not protect product quality or ensure that consumers’ “expectations about the basic nature of those foods” are maintained. The dairy industry has many years and many dollars invested in the standardized names used in dairy product standards of identity. Regulatory schemes are devised around standardized product names and promotion programs are centered on promoting the good name of a product. FDA should not allow an effort to address possible shortcomings in promulgating standards of identity to disrupt the years of effort that the dairy industry has invested in promoting the value of dairy product standards in the marketplace.

The following are specific concerns NMPF has with the proposed changes to 21 CFR 130.5.

Elimination or Revision of a Food Standard

NMPF is concerned that the provision for eliminating a food standard (“...*not consistent with any one of the general principles in paragraphs (b)(1) through (b)(4) of this section.*”) is too broad. Previously established food standards which “promote honesty and fair dealing in the interest of consumers” have become accepted by consumers to ensure product quality and identity. NMPF believes interpretation of any one of the first four principles could lead to the unwarranted elimination of a food standard thereby failing to provide the protection to the consumer that food standards are intended to provide.

NMPF does not believe that FDA should undertake a full revision of a standard when a petition to change a standard is submitted. There are instances when a minor change is needed and not a full change to the standard. FDA should only address those parts of the standard that are referenced in the petition. Addressing the entire standard may actually discourage petitions that are needed for the very reasons FDA identified in the proposal.

Flexibility in a Food Standard

While NMPF understands the desire for flexibility in food standards to allow for processing technologies (as proposed in 21 CFR 130.5(b)(6)) or variations in physical attributes (as proposed in 21 CFR 130.5(b)(9)), NMPF has great concern about the use of such provisions as a mechanism to merely allow the use cheaper ingredients in the manufacture of products. In particular, NMPF believes such provisions will have a negative impact on the use of milk in standardized dairy foods and will, thus, negatively impact dairy producers across the U.S. Of equal or greater importance is the fact that the potential for confusing labeling inconsistencies and for inferior quality products will not promote honesty and fair dealing in the interest of consumers. It is imperative that FDA ensure the integrity of the reference product is maintained if flexibility in standards is permitted. This is very difficult to enforce after a standard has been changed, so the guarantee that the basic nature and essential characteristics of a reference food will not be altered or diluted must occur when the petition is submitted. FDA should not use flexibility in standards as an excuse to lessen enforcement activities related to compliance with standards of identity.

In addition, the requirement to simplify food standards (as proposed in 21 CFR 130.5(b)(8) is appropriate, provided the basic nature and essential characteristics of the food is still protected. Allowing for functional classes of ingredients is appropriate for some ingredients. However, the ingredients that make-up the basic nature of the food (e.g., the dairy ingredients) must be carefully considered as changes to existing standards are considered. As stated earlier, it is very easy to lose the identity of a product by allowing for non-traditional ingredients. This use of non-traditional ingredients will not provide honesty and fair dealing in the interest of consumers.

FDA's proposal to allow for variations in physical attributes (as proposed in 21 CFR 130.5(b)(9)) must also be undertaken with great care. There are instances where different standards currently exist for similar products because of differences in physical attributes. One example is milk and nonfat dry milk. These products are obviously physically different (liquid versus dry) and should not be combined into one standard. The quality, nutritional value, and functional characteristics associated with a liquid product are much different than a dry product. Additionally, consumers expect that milk in packaged form is a liquid product and not a re-hydrated nonfat dry milk.

Accepted Terms for a Food Standard

NMPF strongly supports the use of specified name(s) within a food standard for product and ingredient identification (as proposed in 21 CFR 130.5(b)(12) and (13)). The use of specified name(s) for product and ingredient identification provides confidence to the consumer for the integrity of the purchased food products. Use of specified name(s) for product and ingredient identification also provides a level playing field for food processors ensuring that cheaper (and potentially inferior) ingredients are not substituted. Accordingly, this confidence is only maintained by vigorous enforcement of food standard identities.

Harmonization with International Standards

NMPF agrees that every effort to coordinate the domestic standards with international standards should occur. However, NMPF believes that this is adequately addressed in 21 CFR 130.6. No additional reference to Codex standards is needed in the new guidelines, so this section (as proposed in 21 CFR 130.5(b)(7)) should be removed. NMPF is concerned that too much focus on international standards will not assist in developing standards that are relevant for U.S. consumers. While the U.S. is involved in Codex and the development of Codex standards (to the extent that such standards have taken on increased significance within the scope of the World Trade Organization), the U.S. position is not always fully accepted

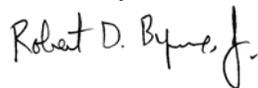
in a Codex standard, due to the consensus nature of Codex. In fact, all provisions of a Codex standard may not even be relevant to the domestic product. In addition, some Codex standards are in direct conflict with domestic regulations. For example, while the U.S. generally allows for more flexibility in food additives than Codex standards permit, Codex, on occasion, has allowances for certain additives that the U.S. does not. One specific example is the allowance for nitrates in cheese, which is prohibited for safety reasons in the U.S. Standards of identity developed in the U.S. for U.S. consumers should not be overly concerned with international Codex standards.

Conclusion

NMPF strongly affirms that food standards guard the integrity of that product by delivering the attributes the consumer associates with the name of the food each and every time the product is purchased. For the most part, the guidelines as proposed (except as noted previously) will continue to promote honesty and fair dealing in the interest of the consumer in balance with the needs of industry. However, NMPF does not believe that these guidelines should lead to general review and revision of existing standards. Rather, they should be a guide going forward as petitions for new standards, changes to existing standards, or elimination of standards are considered.

Thank you for the opportunity to provide these comments. If you have any questions or would like to discuss these comments further, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Byrne, Jr." The signature is written in a cursive style with a small "Jr." at the end.

Robert D. Byrne, Ph.D.
Vice President, Regulatory Affairs