

# National Milk Producers Federation

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Upstate Farms Cooperative Inc.  
Zia Milk Producers

December 27, 2005

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

RE: Docket No. 2003P-0132

Dear Sir/Madam:

The following comments are being submitted on behalf of the National Milk Producers Federation (NMPF) to FDA's Advanced Notice of Proposed Rulemaking; Frozen Desserts; Petition to Revoke Standards for Goat's Milk Ice Cream and Mellorine and to Amend Standards for Ice Cream and Frozen Custard, Sherbet, and Water Ices (Docket No. 2003P-0132). 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 this advanced notice to proposed rulemaking (ANPR) to amend ice cream standards is of great interest to NMPF.

## General Comments

With regard to Federal Standards of Identity for dairy foods, NMPF believes it is vital that the interests of the affected industry be balanced in accord with the interests of the consuming public. This view is similarly expressed in Title 21 of the Code of Federal Regulations, Section 130.5 Procedure for establishing a food standard, Part (b): "Any proposal for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers".

NMPF also 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. It is NMPF's view that the potential changes suggested in the ANPR by FDA will neither advance nor even retain the current quality, and might not preserve the labeled nutritional value of these products.

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 a certain chemical definition. Indeed, while some would argue that a standard of identity should render no judgment in regard to quality ("let the marketplace decide"), NMPF firmly believes that by their very nature, standards of identity prescribe a minimum level of product quality sufficient to merit the use of the standardized designation. 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 has a deep and abiding concern that the potential changes suggested in the ANPR will lead to the introduction of inferior ice cream and related products and will result in unfulfilled consumer expectations and declining sales. Although the International Ice Cream Association (IICA) petition purports that the changes are needed to "allow more flexibility in processing and the use of new ingredients, including all types of safe and suitable dairy ingredients rather than restricting dairy ingredients to a prescribed list", many of the current provisions which protect product quality would be, at best, overlooked and, at worst, eliminated.

NMPF fully understands the desire on the part of manufacturers to achieve greater flexibility in production technologies. Many changes to dairy product standards over the years have provided the industry with the necessary technical tools to produce products which meet the wants and needs of consumers. Earlier changes to the ice cream standard in the 1990's permitted the addition of "safe and suitable sweeteners" to meet the needs of health conscious consumers looking for products with fewer calories. In addition, a change to permit the removal of lactose from skim milk by any "safe and suitable procedure" was approved in recognition of the need to prevent sandiness, especially in lower fat ice creams.

These earlier changes were sought by the industry in order to meet consumers' demands for products with specific attributes and to improve product quality. As such, the changes were not opposed by NMPF. Unfortunately, the changes now under consideration appear to have been proposed primarily to meet industry desire for lower cost ingredients.

Following a thorough review of the information presented in the ANPR, NMPF finds there has been no technological justification (other than vague references to “efficiency” and “alternate make procedures”) provided by the advocates for the proposed standards changes. Unless or until there is a more transparent revelation as to the types of products or product attributes that the consumer is not currently able to obtain as a result of the so-called “limitations” to the standards, NMPF sees no reason for the standards of identity to be changed.

In fact, the need for many of the proposed changes can be questioned precisely on the basis that the current standards have already provided for various advances in technology in both the ingredient and processing areas. Evidence for this assertion is readily available by observing the hundreds of new product introductions by the ice cream industry over the past few years.

Changing standards to merely allow for cheaper ingredients and consequently changing the basic nature of the product is an unacceptable justification for such changes. The current standards are particularly well-balanced in that while providing for sufficient processing “flexibility” they also include important limitations as to how much substitution of milk, cream, and nonfat dry milk can occur, in an effort to ensure the integrity, quality, and basic nature of these products.

### **Specific Comments**

FDA requested comments on eleven topics for amending ice cream standards. NMPF has reviewed the entire ANPR and will provide comment on each topic for which comments were requested.

(1) *The use of filtered milk in the making of frozen desserts;*

In general, filtered milk describes a broad range of products derived from a variety of processing technologies (including ultra- and micro-filtration). In the recent *Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk* (*Federal Register* vol. 70, no. 201), FDA clearly acknowledges that some forms of filtration result in “*concentrates [that] are specific individual components of milk resulting in a retentate that is no longer milk. For example, microfiltration can be used to separate whey proteins along with lactose, minerals, and water soluble vitamins from milk resulting in the concentration of casein fractions*”. Moreover, as FDA previously noted, when providing flexibility for use of advances in food technology, food standards should ensure that the basic nature of the food remains essentially the same (60 FR 67492 at 67499, December 29, 1995).

NMPF believes that this same logic should apply to standards of identity for ice cream manufacturing. NMPF may support the use of fluid ultrafiltered milk

in the manufacture of ice cream if the fluid ultrafiltered milk is appropriately defined. NMPF proposes that if ultrafiltered milk is allowed for the manufacture of ice cream that the standard of identity include a definition for ultrafiltered milk that is the same as proposed in the recent *Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk* (*Federal Register* vol. 70, no. 201): “(1) Provide for the ultrafiltration of milk and nonfat milk and (2) define UF milk and nonfat milk as raw or pasteurized milk or nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein-to-whey protein ratio of the milk and resulting in a liquid product”.

NMPF does not support the use of dry ultrafiltered milk or other ingredients derived from filtration of milk in the manufacture of ice cream. Allowing for the use of technologies or ingredients that could potentially result in the widespread use of specific components of milk, such as caseins, rather than milk, as the starting ingredient would be inconsistent with the basic nature of ice cream. NMPF acknowledges that whey (up to 25%) can be utilized in the manufacture of ice cream. Neither the use of clearly defined fluid ultrafiltered milk (with a casein to whey ratio identical to that of milk) nor a continued prohibition on use of other filtered ingredients would prohibit the use of whey in the manufacture of ice cream.

(2) *The use of any safe and suitable milk-derived ingredients in the manufacture of frozen desserts;*

FDA recently reaffirmed (*Federal Register* vol. 70, no. 201) that ingredients other than those specifically provided for by individual standards cannot be used in the making of standardized cheeses and related cheese products. NMPF believes that this logic applies to ice cream standards as well. Ingredients provided for in the standard of identity allow for the manufactured product to consistently meet consumers’ expectations in terms of sensory fulfillment and nutritional value.

NMPF can certainly understand how the concept of “safe and suitable” dairy ingredients would be appealing to the manufacturing sector. While NMPF believes that virtually all dairy-derived ingredients can be considered safe, they cannot all be considered “suitable” for use in the manufacture of ice cream and related products. This issue was addressed by the FDA in 1994 (*Federal Register* Vol. 59, no. 177) at which time the agency recognized that some ingredients that may be derived from dairy sources are not suitable as replacements for the milk solids in ice cream, or that these ingredients are only suitable when used in limited amounts because they are no longer equivalent in composition to milk and cream. NMPF concurs with the assessment by FDA and believes that this assessment holds true today, just as it did in 1994.

In determining the “suitability” of an ingredient, both the functionality and the quality of the ingredient as they affect the product’s performance and palatability must be examined. NMPF believes most ice cream manufacturers would not be anticipated to use off-grade butter or other milk products such as ghee or old whey solids. However due to the virtual non-enforcement of standards by FDA in reference to the concept of “suitable” ingredients, such ingredient choices would remain legal possibilities for the manufacturer who is attempting to keep dairy ingredient costs to a minimum. The introduction of such inferior ingredients in the manufacture of ice cream would lead to inferior products in the marketplace and undoubtedly result in consumer dissatisfaction for ice cream products in general. It could also eventually lead to consumers being misled with regard to their expectations regarding ice cream.

Paragraph (b) of the current standard (*Optional Dairy Ingredients*) contains several references to quality parameters for individual dairy ingredients. For example in reference to modified skim milk, it is specified that the reconstituted product “is substantially free of lactic acid, and it has a pH in the range of 8.0 to 8.3”. NMPF interprets this and other provisions as clear indications of FDA’s belief that certain dairy ingredients are not suitable from a quality perspective for use in ice cream.

In addition, FDA’s more recent allowance for alternate ingredients in standardized foods (as outlined in 21 CFR 130.10) has been to allow for ingredients that are necessary to achieve a specific functional effect. It is not clear from the information provided by the petitioner how any of the ingredients being sought by the IICA petition will provide for a functional effect above and beyond that already provided by the ingredients currently permitted in frozen desserts.

(3) *The use of milk from source animals other than cows in the making of ice cream and frozen custard and sherbet;*

NMPF does not support the use of milk from other source animals if the intention is to merely substitute cheaper ingredients in the manufacture of ice cream. Because of the long standing standard of identity to which consumers have developed an expectation to the taste and functionality of ice cream, simply allowing the use of milk from other source animal’s without its identification in the product name would be a disservice to the consumer. Simply including the source milk in the ingredient list (i.e. “goat milk”, “sheep milk”, etc.) is not acceptable. To promote honesty and fair dealing in the interest of consumers, NMPF would support the use of milk from other source animals for the manufacture of ice cream as long as such products are labeled accordingly in the product name (such as “Goat’s Milk Ice Cream”, “Sheep’s Milk Ice Cream”, etc.). By labeling the products in such a manner, the

consumer will have the opportunity to select ice cream manufactured from the milk of their choice.

*(4) The use of “alternate make” procedures in the manufacture of ice cream and frozen custard and sherbet;*

The IICA petition does not appear to reference any specific “alternate make” procedures for the manufacture of ice cream products. The “alternate make” process has allowed for innovation in technology in the manufacture of cheese, and NMPF understands how an “alternate make” process for the manufacture of ice cream products could allow for innovation in the marketplace. We strongly believe that “alternate make” allows for the use of alternate manufacturing procedures, but not alternate ingredients.

Recently, FDA affirmed as much for the manufacture of standard cheeses in *Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk* (Federal Register vol. 70, no. 201). FDA stated “rather than restricting the manufacturing procedure to the one specifically described in the standard, this provision allows manufacturers to use alternate manufacturing procedures, but not alternate ingredients, provided the alternate manufacturing procedure does not adversely affect the physical and chemical properties of the cheese. However, the alternate make procedure provision does not permit the use of dairy or other ingredients that are not specifically provided for in the cheese standard.”

NMPF would only support the allowance of “alternate make” processes in the manufacture of ice cream provided that the alternate manufacturing procedure does not adversely affect the physical and chemical properties of the ice cream; and the alternate make procedure provision does not permit the use of dairy or other ingredients that are not specifically provided for in the ice cream standard.

*(5) A minimum weight requirement of 4 pounds per gallon for reduced fat ice cream;*

At this time, NMPF has no additional comments or problems with codifying the current requirement that lower fat ice creams have a minimum weight of 4 pounds per gallon.

*(6) A minimum milk-derived protein requirement based on the amount of fat;*

NMPF has concerns with establishing such a provision. The first concern focuses on what the proposed level of minimum milk protein would be. The IICA petition suggests 2.95% would be appropriate. NMPF is concerned about the validity of this figure as it relates to the labeling of the final product.

The frozen dessert industry has a well-established practice of generating most nutrition labeling by using a dairy ingredient nutrient database. NMPF is aware of only one dairy ingredient database that has been recognized by FDA for use by the industry that was developed by IICA and submitted to FDA in the early 1990's. The IICA nutrient database references the protein content of milk solids nonfat (MSNF) as 0.39g of protein per gram of MSNF.

Using this protein value, an ice cream mix containing 10% MSNF would be assumed to contain 3.9% milk protein according to the following calculation:

<u>Component</u>	<u>%Wt/Wt in Mix</u>		<u>%Protein in Ingredient</u>		<u>%Protein in Mix</u>
MSNF	10	x	39	=	3.9

NMPF realizes that the figure proposed by IICA correctly reflects the fact that ice cream mixes may contain up to 25% whey solids and that any determination of standards equivalence should, realistically, reflect this possibility. However, even if the mix formula were to incorporate a level of approximately 25% whey solids (containing the minimum percent protein), as used in the IICA example, the minimum milk protein figure would be closer to 3.6% than 2.95%:

<u>Component</u>	<u>%Wt/Wt in Mix</u>		<u>%Protein in Ingredient</u>		<u>%Protein in Mix</u>
MSNF	8.442	x	39	=	3.29
Whey powder	2.632	x	11	=	.29
Anhydrous mf	9.419	x	.28	=	<u>.03</u>
Total					3.61

NMPF is deeply concerned by the fact that the numbers in the various examples clearly do not agree with a methodology widely used to calculate nutrition labeling information. NMPF clearly cannot support the IICA petition for a minimum protein requirement of 2.95%. With current allowed ingredients, NMPF could not support a minimum protein requirement of less than 3.6% for the manufacture of ice cream.

NMPF concedes that, from a strict regulatory perspective, there is no direct connection between the standard of identity for ice cream and the nutrition labeling of ice cream. However, NMPF believes there is a direct link between the two as they relate to the integrity of the product and how it is marketed to the consumer. This would seem especially true since the protein values used in the supporting calculations do not reflect the values previously submitted to FDA for use by the ice cream industry in determining protein values for nutrition labeling (see IDFA Nutrition Information Database, November 1993). This inconsistency reflects the fact that either the industry is currently overstating protein levels in its nutrition labeling or the example calculations reflect an unrealistic product formulation. In fact, the example used by the

petitioners in which buttermilk solids, whey, and butteroil are used to manufacture ice cream highlight the exact reasons for NMPF's objections to allowing for any milk derived ingredient rather than establishing a base set of necessary ingredients. A product manufactured according to those parameters would certainly not meet the basic nature of ice cream as expected by consumers.

NMPF is also concerned that a total protein value is being proposed as the fundamental basis for the identity of ice cream. Since ice cream contains a minimal level of protein and, in fact, is not even a "good source" of protein as defined by FDA nutrition labeling regulations, establishing a minimum protein content as a principal "identifier" for ice cream is not appropriate. The current provisions specifying minimum nonfat solids and fat levels are much more appropriate and ensure that the basic nature of ice cream is maintained, provided the ingredients list is not altered to allow for inappropriate sources of dairy ingredients.

By proposing to establish both a minimum milk protein level and the use of any milk-derived ingredient to meet this minimum, the enforcement of a limitation on casein, caseinates and "dried forms of filtered milk" becomes impractical. Regulatory agencies are simply not equipped to evaluate the level and use of these ingredients in the finished product. For example, lifting the limitation on whey solids would make it possible to blend dry forms of casein and certain whey proteins to the extent that the casein limitation is meaningless. Such ingredients would be indistinguishable from the casein and whey proteins found inherently in the optional dairy ingredients listed in the current standard. Until very recently, it has not even been possible to readily determine excessive levels of cheese whey in ice cream mixes. The use of "safe and suitable" dairy ingredients would make it virtually impossible to detect the level of use of any dairy ingredient upon which a limitation has been placed.

*(7) The removal of the requirement of the maximum 25-percent restriction on whey solids in ice cream and frozen custard;*

The limitation on whey solids in the ice cream standard was originally included in the recognition of quality problems that arise when significant amounts of whey are utilized in ice cream mixes. While it may be argued that the quality and availability of whey-based ingredients has improved over the years, it is still recognized that off-flavors and other defects can and do occur in ice cream mix with the excessive use of whey.

"Salty" and "graham cracker-like" are off-flavor problems associated with excessive use of whey proteins in ice cream mix. Additionally, poor quality whey solids are known to exhibit oxidized, cheesy, rancid, or unclean flavors. While many manufacturers may assure that they are using quality whey solids (to avoid the aforementioned flavor defects), such assertions cannot be

guaranteed on an industry-wide basis. A standard which would allow greater than 25 percent (and up to 100 percent) of the protein content in ice cream to be from whey solids will more likely result in products with flavor defects than the current limit. Certainly this is not consistent with promoting honesty and fair dealing in the interest of consumers.

In addition, while whey is surely a valuable source of protein and can be sourced as a high-quality ingredient, to establish the ability to use 100% whey as the sole nonfat solids source in ice cream would not be meeting consumer expectations or the basic nature of the product. The product that consumers know as ice cream has always been comprised primarily of milk and cream, with other ingredients being used for functional effects. Removing this whey limitation is too drastic a measure and will change both the basic nature of the product and the consumer satisfaction when consuming ice cream.

*(8) The removal of the requirements for the amounts of fruits, fruit juices, and nut meats needed to determine if an artificial flavor simulating a characterizing flavor is the predominant flavor when naming an ice cream or frozen dessert product, and providing that the manufacturer may determine whether the natural or artificial flavor ingredients provide the characterizing flavor of the product for purposes of labeling;*

The current system for flavor labeling and requirements for amount of fruit for frozen desserts seems to serve the consumer well in that it provides appropriate information on the label. If changes are needed to accommodate new fruit flavors being desired, these could be added, rather than wholesale changes to the entire flavor labeling requirements.

*(9) The establishment of categories of ingredients to be declared on labels under common names for ice cream and frozen custard;*

NMPF opposes the proposed establishment for categories of ingredients to be declared under common names because this would be in direct conflict with 21 CFR 101.4 *Food; designation of ingredients*. In addition, NMPF is concerned that such a proposal appears to be significantly deceptive to the consumer and potentially threatening to the integrity and image of the product. For example, the proposals to permit various forms of nonfat and skim milks to be labeled as “milk”, and whey cream, butter, butter oil and anhydrous milkfat as “cream” are particularly egregious.

NMPF also opposes the IICA proposal to eliminate the Standard of Identity for Mellorine. NMPF believes one of the alternative labeling proposals offered by IICA for products now complying with the standard for Mellorine (e.g., “frozen dairy dessert”) highlights precisely why this standard should be maintained. A frozen dessert that combines dairy proteins with vegetable fat should clearly not be labeled as a “frozen dairy dessert”. Such a designation is patently

misleading to those who would assume the product to be manufactured entirely from dairy ingredients.

*(10) The removal of the restrictions on ingredients in goat's milk ice cream;*

NMPF does not oppose the removal of restrictions on goat's milk ice cream as long as the manufacture of ice cream from goat's milk or milk from other source animals conforms to the standard of identity for ice cream and is labeled appropriately. NMPF's position on labeling ice cream products manufactured from other source animals is discussed in response to Topic 3 (above).

*(11) The use of a 2-percent minimum level of fruit content in sherbet.*

At this time, NMPF has no additional comments on the 2-percent minimum level of fruit content in sherbet.

#### *Additional Comments*

Based on the petition which serves as the basis for the ANPR, it is clear that the ice cream manufacturing industry, as represented by IICA, is merely seeking to provide for a standard of identity for frozen desserts that will allow them to source various ingredients depending upon price. Otherwise, we would have expected to see examples provided of products that cannot be manufactured under the current standard of identity. While this action may seem to be warranted for some ingredients, NMPF believes that the fundamental nature of the end product can only be assured if a standard set of ingredients is used as the base, while allowing for other ingredients as needed for functional or technical effect. The assertion that many of the changes requested in the petition will benefit consumers through price savings is also questionable, in our opinion.

In addition, NMPF is concerned that the proposed changes are part of a trend that has seemingly been developing within some segments of the manufacturing industry with respect to not only standards of identity, but also to labeling and marketing of ice cream products. Indeed, while there is an effort to use the halo of dairy product names (such as milk and cream) on the label, there is actually a desire to not use these ingredients in the product. This is highlighted in the IICA petition as it relates to the use of dairy ingredients other than milk or cream. The desire to use these valued ingredient names in labeling is a clear acknowledgement that these are ingredients that consumers expect to find as the base for frozen desserts. This trend toward the use of other dairy ingredients, while attempting to persuade consumers that milk and cream are actually present, is particularly disturbing to NMPF. There is also concern that the 4 ounce serving size for frozen desserts is not commensurate with amounts that consumers

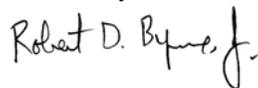
customarily consume. This fact has been scrutinized by many over the years and will also impact the nutrition labeling of frozen desserts, particularly as it relates to the use of any new sources of milk protein. Clearly, the ongoing trend and desire to use cheaper ingredients while utilizing traditional names for them in the ingredient list, coupled with labeling for nutrition based on the 4 ounce serving size for frozen desserts does not promote fair dealing in the interest of consumers.

## **Conclusion**

The National Milk Producers Federation has carefully reviewed the IICA Petition to change the Federal Standards of Identity and the FDA Advanced Notice of Proposed Rulemaking for ice cream and frozen desserts. As a result of this review, NMPF has concluded that most of the proposed changes would undermine the current high quality image and integrity of the ice cream manufactured in the United States. As such, these proposed changes have been found not to be in the best interests of consumers and are, therefore, not supported by NMPF. Ice cream manufacturers can currently use most of the ingredients sought in the IICA Petition, but the use is limited in order to protect consumers and the integrity of frozen desserts. No real hindrance on product innovation is occurring under the current standards of identity, as evidenced by the 197 new products and 562 stock keeping units referenced in the IICA Petition. NMPF urges FDA not to endorse the use of cheap ingredients in ice cream merely to help out the bottom line for many ice cream manufacturers while compromising the integrity of the product for consumers.

Thank you for the opportunity to provide these comments. If you have any questions or need additional information, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Byrne, Jr." with a stylized flourish at the end.

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