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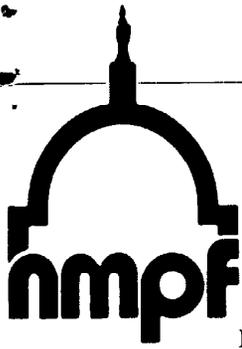
TITLE: Part 135 FDA regulations standard of identity frozen dessert
ACTION OFFICE: HFS-024

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CP1	04/02/03	04/02/03	C	International Dairy Foods Association Signature: Cary Frye				1	ACK 04/02/03
ACK1	04/02/03	04/02/03	E	HFA-305 Signature: Lyle D. Jaffe				1	
C1	04/11/03	04/11/03	D	National Milk Producers Federation Signature: Jerome J. Kozak				1	

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National Milk Producers Federation

National Milk Producers Federation • 2101 Wilson Blvd., Arlington, VA 22201 • 703-243-6111 FAX 703-841-9328

Agr-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.
Country Classic Dairies, Inc.
Dairy Farmers of America, Inc.
DairyLea Cooperative Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
First District Association
Foremost Farms USA
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
Milwaukee Cooperative Milk Producers
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

April 11, 2003

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

Dear Sir or Madam:

The purpose of this letter is to communicate the views of the National Milk Producers Federation (NMPF) on a Citizen Petition, dated April 2, 2003 and submitted to FDA on behalf of the International Ice Cream Association (hereafter, "IICA petition"). The IICA petition seeks an amendment to the Standards of Identity for frozen desserts in 21 CFR 135. The intent of the petition is to allow for a variety of dairy ingredients and to eliminate the current restriction on the level of whey proteins that may be used to manufacture ice cream. NMPF unconditionally objects to many of the provisions in the petition. For this very compelling reason, we are obliged to take the preliminary action of submitting this letter at this time as an objection to the IICA petition.

The National Milk Producers Federation, 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 32 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 60,000 dairy producers on Capitol Hill and with government agencies. The changes proposed in the IICA petition have no technological justification to them, may result in a lower quality product for consumers, and will have a significantly negative impact on all U.S. milk producers. Therefore, NMPF unequivocally urges the Agency to reject the petitioner's request.

General Comments

Following a thorough review of the IICA petition to change the Federal Standards of Identity for Ice Cream and Frozen Desserts, NMPF has concluded that the proposed changes cannot be supported. While there are several specific technical factors which have contributed to this conclusion, the overriding factor influencing NMPF's decision is that any benefits to be

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achieved as a result of these changes appear only to serve the interests of the manufacturing sector.

In 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" (emphasis added).

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 changes proposed by IICA will not advance the quality, and might not preserve the 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 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. 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 is concerned that the changes proposed by IICA will lead to the introduction of inferior products, and as a result, unfulfilled consumer expectations and declining sales. Although IICA describes the changes as 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 appear to have been, at best, overlooked and, at worst, eliminated. In describing the changes desired, IICA does not provide any technological justification as to why flexibility in processing is necessary; they merely assert that it is so. Without such a justification, NMPF does not agree with IICA as to this necessity. In fact, the only justification provided seems to be one of desiring cheaper ingredients for manufacturing purposes. The

advances in technology in both the ingredient and processing areas are available for use under the current standards of identity for ice cream and frozen desserts. The current standards provide important limitations as to how much substitution of milk, cream, and nonfat dry milk can occur. This limitation is to ensure the integrity and quality of these products.

In terms of nutritional equivalency, the data put forth by IICA are intended to demonstrate how the proposed changes will guarantee nutritional equivalency with products manufactured according to the existing standard. Unfortunately, the protein values used in the supporting calculations do not reflect the values previously submitted to the 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.

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 demands for lower cost ingredients.

The following lists the specific reasons NMPF is not in support of the proposed changes to the dairy provisions of 21 CFR 135.110 *Ice cream and frozen custard*:

- **IICA Proposal: "Delete the 25% maximum of whey solids, which would allow for any combination of 'safe and suitable' dairy derived ingredients as long as the minimum 2.95% milk protein was met."**

NMPF Comments on Whey Solids: The limitation on whey solids in the ice cream standard was originally included in recognition of quality problems associated with significant amounts of whey in ice cream mixes. While it can be argued that the quality and availability of whey-based ingredients has

improved somewhat over the years, it is still recognized that off-flavors and other defects may occur in ice cream mix due to the excessive use of whey.

Descriptions associated with flavor problems stemming from the increased use of whey proteins include “salty” and “graham cracker–like”. In addition, old or poor quality whey solids are known to exhibit flavors that are oxidized, cheesy, rancid, or unclean. While many manufacturers might assert that they would use only the freshest whey solids (thus avoiding the aforementioned flavor problems) or specific whey proteins, such assurances cannot be guaranteed on an industry-wide basis. A standard that would allow whey solids to account for 100% of the protein content is surely more likely to result in products with flavor defects than one that limits the amount of whey.

NMPF Comments on “safe and suitable” dairy derived ingredients: NMPF certainly understands how the concept of “safe and suitable” dairy ingredients would be appealing to the manufacturing sector. However, NMPF believes that while virtually all dairy-derived ingredients can be considered “safe”, they cannot all be considered “suitable” for use in ice cream. In fact, this issue was addressed by the Food and Drug Administration as recently as 1994 (*Federal Register* Vol. 59, no. 177, September 14, 1994). At that 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 are suitable only when used in limited amounts because they are no longer equivalent in composition to milk and cream. NMPF concurs with this assessment by FDA.

In determining the “suitability” of an ingredient, it is critical to examine both the functionality of the ingredient and the quality of the ingredient as it affects the product’s performance. NMPF concedes that most ice cream manufacturers would not be expected to use off-grade butter or other milkfat products, such as ghee, or old whey solids. However, due to the virtual non-enforcement of standards by the 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 products into the marketplace would, undoubtedly, result in an erosion of the overall quality of the product category in the eyes of consumers.

Paragraph (b) of the current standard (*Optional dairy ingredients*) contains several references to quality parameters for individual dairy ingredients. For example, in regard to buttermilk solids, it is noted that the reconstituted product should have “a titratable acidity of not more than 0.17 percent, calculated as lactic acid.” 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 these provisions as clear indications

of FDA's belief that certain dairy ingredients are not suitable from a quality perspective for use in ice cream and frozen custard.

NMPF Comments on "2.95 % minimum milk protein: NMPF has two concerns with establishing such a provision. The first concern focuses on the proposed level of minimum milk protein – 2.95%. As mentioned previously, NMPF is concerned about the validity of this figure as it relates to the labeling of the final product.

It is a well-established practice in the frozen dessert industry that most nutrition labeling is generated using a dairy ingredient database. NMPF is aware of only one dairy ingredient database that has been recognized by FDA for use by the industry. It 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	=	.03
Total					3.61

NMPF is troubled 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 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.

- **IICA Proposal: Allowance for the use of casein, caseinates, and “dried forms of filtered milk” after the minimum 2.95% milk protein level has been met with other dairy ingredients.**

NMPF Comments: NMPF appreciates the concern expressed by IICA regarding the use of imported casein, caseinates, and “dried forms of filtered milk”. However, by proposing to establish a minimum 2.95% 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. 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.

- **IICA Proposal: Permit new ingredient labeling provisions “that will allow more flexibility in substituting similar ingredients without making labeling changes in the ingredient statement.”**

NMPF Comments: NMPF opposes the proposed changes on the basis that several of the changes are in direct conflict with 21 CFR 101.4 *Food; designation of ingredients*. In addition, NMPF is concerned that several of the proposed changes appear 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 “dairy dessert”. Such a designation is patently misleading to those who would assume the product to be manufactured entirely from dairy ingredients.

Other Labeling Inaccuracies

NMPF is also concerned that the present serving size for ice cream that appears on labels of packaged products is not accurate. The *Reference amounts customarily consumed per eating occasion* are defined in 21 CFR 101.12 and indicate that the reference amount for ice cream is ½ cup. NMPF believes that this is as equally deceptive as some of the other changes proposed by IICA. The proposed rule published by FDA prior to establishing these reference amounts had a value of 1 cup, whereas the final rule contained an apparent typographical error with a value of ½ cup. NMPF believes that the data which FDA reviewed clearly supported the reference amount of 1 cup. The ability to deceive consumers with claims such as “light” and “reduced fat” are directly linked to this reference amount. Therefore, in the interest of providing accurate information to consumers, NMPF urges FDA to review the record to ascertain the appropriate reference amount for ice cream and frozen desserts.

Economic Impact of the Petitioner’s Request

Allowing for dried forms of any milk ingredient in ice cream and frozen desserts will have a significant adverse impact on dairy producers throughout the United States. In fact, our preliminary analysis indicates that the impact will be classified as a significant regulatory action, as defined in Executive Order No. 12866 (Regulatory Planning and Review), in that the annual effect of the change on the dairy farm sector of the economy will be greater than \$100 million.

Dry forms of many milk ingredients cannot be effectively sourced within the U.S. due to the fact that manufacturers of these products in other countries are heavily subsidized by their governments or benefit from single-desk seller (monopolistic) export programs. Permitting dry forms of these ingredients to be used will allow the unrestricted importation of these ingredients into the United States. Due to the lack of import controls (i.e., tariffs and quotas) on these ingredients, these heavily subsidized products will directly displace domestic dairy ingredients if they are permitted for use in manufacturing ice cream under the Federal Standards of Identity. These displaced dairy ingredients will, in turn, enter other domestic market channels, further depressing dairy prices paid to producers. In other words, the proposed change in the IICA petition would, in effect, endorse the distortion of current trade practices and would undermine U.S. efforts to achieve fair trade in the ongoing international trade negotiations.

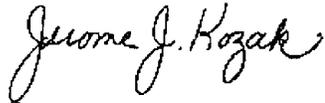
Conclusion

The National Milk Producers Federation has carefully reviewed the IICA Petition to change the Federal Standards of Identity for ice cream and frozen desserts. As a result of this review, NMPF has concluded that the proposed changes would undermine the current high quality image and integrity of the

ice cream manufactured in the United States. As such, the 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. 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. This Petition is an attempt to have FDA endorse the use of cheap ingredients in ice cream to help out the bottom line for many ice cream manufacturers.

Thank you for the opportunity to provide these comments. We would be pleased to answer any questions or provide additional information, upon request.

Sincerely,

A handwritten signature in black ink that reads "Jerome J. Kozak". The signature is written in a cursive, flowing style.

Jerry Kozak, President/CEO
National Milk Producers Federation

cc: Joseph A. Levitt, Director of CFSAN, FDA