



**International Dairy Foods Association**  
Milk Industry Foundation  
National Cheese Institute  
International Ice Cream Association

2243 '03 APR 30 P1:51

April 23, 2003

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

**RE: Docket number: 03P-132/CP 1** -- International Ice Cream Association's Citizen Petition to amend various sections of Part 135 of FDA regulations, the standards of identity for Frozen Desserts

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) and its constituent organization the International Ice Cream Association (IICA) wish to respond to allegations and misinformation presented in a letter sent by the National Milk Producers Federation (NMPF) on April 11, 2003 opposing changes to the ice cream and frozen desserts standards of identity petitioned by IICA earlier this month.

The IICA is the national trade association representing manufacturers and distributors of frozen desserts that is a constituent organization of IDFA. IICA's 81 members manufacture nearly 85% of all frozen dessert products consumed in the United States.

#### **General Comments**

IICA dismisses out of hand – and FDA should also – the central premise of NMPF's complaint, namely that the proposed changes “will lead to the introduction of inferior products, and as a result, unfulfilled consumer expectations and declining sales.” This is an empty claim given that manufacturers must offer the products that consumers want in order to achieve maximum sales.

In addition, certain portions of NMPF's letter suggest that they misread some of the information in the IICA petition, as will be shown.

03P-0132

C 2

## **The Quality Issue**

Unlike many other food products, frozen desserts are manufactured expressly for the consumer to enjoy a quality eating experience; it is absurd to suggest that a manufacturer might use government standards as a way to compromise that experience, and therefore harm a company's ice cream sales and brand identity.

Ice cream is extremely sensitive to consumer preference, perceptions of quality and price. Consumers buy these products using limited, discretionary dollars. Manufacturers already have it within their power to make a broad range of products – from the economy ice creams to highly indulgent products – and stay within government standards of identity. Consumers recognize and appreciate this range of products that allows them to choose based on the price-value benefit of the product. This will not change under the new standards.

In point of fact, manufacturers have found in recent years that market growth is due almost entirely to sales of superpremium and premium ice creams, especially innovative and indulgent products. While these premium category segments accounted for almost 70% of ice cream dollar sales in 2001, the economy category provided only 3% of volume, and only 2% of dollar sales. IICA's proposed changes offer flexibility to ice cream makers to create high-quality, innovative products and to offer them at attractive prices. The current standards are hopelessly out of date in allowing for the innovation that is critical to the industry.

## **Dairy Farmers Agree that Whey is a Superior Dairy Ingredient**

NMPF's criticism of the request to remove the limitation of whey solids in ice cream manufacture is puzzling given U.S. dairy farmers' interests in promoting high-quality whey proteins to dairy and other food manufacturers – both domestically and abroad.

Regarded as recently as 15-20 years ago as an unwanted by-product of cheesemaking, whey is now a highly valued and nutritional dairy protein which is used as an ingredient in thousands of foods such as energy bars, cereals, snack foods, bakery items, crackers and cookies, beverages and sports drinks.

Many of NMPF's members manufacture these new types of high-quality whey protein ingredients such as whey protein concentrate, whey protein isolate and sweet whey solids. In fact, dairy farmers have invested millions of dollars to promote whey ingredient usage in a vast variety of food products, touting whey's superior nutritional and functional properties to both domestic and foreign markets.

Information on dry whey, whey protein concentrate and whey protein isolate ingredient marketing to food formulators can be found at the Dairy Management

Inc. (DMI) website [www.doitwithdairy.com](http://www.doitwithdairy.com) and its publication *Whey Ingredients - Dairy Ingredient Application Guide*. In one area of the site, the following benefits are listed for dry sweet whey use in ice cream: “Permits the development of subtle flavors... contributes to uniform air incorporation and foam formation... stabilizes the emulsion, etc.” DMI uses dairy producer promotion check-off funds to conduct integrated programs on marketing, communications, promotion, education and research on behalf of America's dairy farmers.

Despite NMPF’s allegation about ingredient quality – and notwithstanding the strict quality standards used by ice cream manufacturers in choosing their ingredients – the fact is that new technologies allow concentration of proteins with the removal of lactose, resulting in whey proteins without off flavors. Additionally, due to the high protein levels in whey protein concentrate and whey protein isolate, only a small amount of these ingredients will be needed in an ice cream – not the excessive amounts that NMPF suggests in its letter.

Whey proteins are easily digestible, high-quality proteins with significant amounts of the important amino acids leucine, isoleucine, and valine. New versions of whey proteins such as Whey Protein Concentrate (WPC), Whey Protein Isolate (WPI), along with the more traditional Sweet Whey Powder, offer high performance to ice cream formulators.

Whey proteins possess excellent gelation properties, which increases their ability to hold water in foods. This is especially important to reduce ice crystal formation in ice cream and other frozen dairy desserts to produce a creamy texture. These properties also increase thermal shock resistance and decrease melting of ice cream, preventing undesirable ice crystal formation that may occur with temperature fluctuations during freezer temperature cycles or through distribution. Finally, whey proteins are good emulsifiers, providing smoother, creamier consistency and better incorporation of stabilizers.

IICA believes that increased use of whey in ice cream and other foods will benefit consumers, dairy producers and manufacturers alike.

**Nutritional Requirements Do Not Change;  
NMPF Erred in its Protein Value Analysis**

Contrary to what NMPF suggests, the IICA petition does not change the nutritional requirements for ice cream. IICA stands by its analysis that 2.95% protein is an accurate target for the new standards, and represents an equivalent minimum protein value to current ice creams and frozen desserts on the market. IICA would be happy to walk through this analysis with FDA at any time.

In fact, IICA’s technical committee concluded that 2.85% -- 0.10% less than the proposed minimum – was an acceptable protein level under the current

standards, but because such formulations were rarely used, IICA chose 2.95% as a better minimum level for the new standards.

NMPF erred in its analysis of the IICA petition, because it used milk powder in calculating the lowest possible protein value, when in fact buttermilk solids can be used under the current standards. Buttermilk solids have 3% less protein than nonfat milk solids.

#### **Comments on "Safe and Suitable" Dairy Derived Ingredients**

NMPF's concerns regarding "safe and suitable" dairy ingredients appear to revolve around a quality concern of the finished product (addressed above) and a concern about the minimum protein level (also addressed above).

IICA carefully developed the compositional requirement of 2.95% milk-derived protein so that no matter which "safe and suitable" dairy ingredients are used, appropriate protein composition will be met.

#### **Allowance For Casein, Caseinates, and Dried Forms of Filtered Milk**

On this topic, IICA believes that NMPF has misinterpreted or did not thoroughly review the petition. The petition allows for the use of any milk-derived ingredient to meet the 2.95% minimum milk-derived protein, including whey, casein, caseinates, and fractions, hydrolysates or polymers derived from milk. While the petition allows for this range of milk proteins, there is no doubt that the largest source of protein will continue to be fresh nonfat solids, just as it is now.

#### **Permitting New Ingredient Labeling Provisions**

Again, NMPF incorrectly represents the IICA petition in the area of labeling. The petition does not group butter, butter oil and anhydrous milkfat to be labeled as "cream". For ingredient labeling purposes, the IICA petition proposes that butter, butter oil, and anhydrous milkfat may be declared as "butterfat".

This and other proposed changes to ingredient nomenclature are aligned to current labeling provisions that apply to general food labeling in 21 C.F.R. § 101.4(b). IICA proposes applying the same principle of food designation of ingredients in the nomenclature section of the ice cream standards.

In addition, IICA has expanded the subcomponent ingredient lists to allow for additional ingredient components that serve an appropriate function and have similar nutritional characteristics under conditions previously established in the standard. Clearly, the allegations made by NMPF that these changes would be deceptive to consumers is false, since the changes are generally in accordance with previously established ingredient class names for food labeling.

**Other Labeling Issues**

IICA is unclear why NMPF raises the question of the serving size for ice cream. Any discussion of reference amounts is irrelevant to the current issue of the IICA petition.

**Conclusion**

IICA has worked for several years on the petition submitted to FDA earlier this month, after extensive industry input, discussion and review. We respectfully ask FDA to consider the petition as a critical tool for growth in the ice cream and frozen desserts industry, and to act quickly on the petition.

My best regards,

A handwritten signature in black ink, reading "E. Linwood Tipton". The signature is written in a cursive, flowing style with some overlapping letters.

E. Linwood Tipton,  
President & CEO  
International Dairy Foods Association

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