



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

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

CITIZEN PETITION

The undersigned International Ice Cream Association submits this petition under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. §§ 341 and 371(e), to request the Commissioner of the Food and Drug Administration (FDA) to amend various sections and delete other sections of Part 135 of FDA regulations, the standards of identity for Frozen Desserts. This petition conforms with the requirements for citizen petitions set forth in FDA regulations.¹

The International Ice Cream Association (IICA) is the national trade association representing manufacturers and distributors of frozen desserts that is a constituent organization of the International Dairy Foods Association (IDFA). IICA's 81 members manufacture nearly eighty-five percent of all frozen dessert products consumed in the United States.

A. ACTION REQUESTED

IICA is proposing amendments to the frozen dessert standards of identity to improve efficiency by bringing the regulations up to today's technological standards. Specifically, IICA proposes to replace the minimum percent nonfat milk solids standards for ice cream with a minimum milk-derived protein standard; remove the maximum 25% restriction on whey solids in ice cream to allow for any combination of safe and suitable dairy-derived ingredients, provided the minimum milk-derived protein content is satisfied; reduce the minimum weight per gallon for reduced-fat ice cream; remove the minimum percentage requirements for various flavoring ingredients; create categories of ingredients to be declared on labels under a common name; provide for declaration of the source-animal for milk in ice cream,

¹ See 21 C.F.R. § 10.30.

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and delete the standard for goat's milk ice cream; delete the mellorine standard; replace the minimum percent nonfat milk-derived solids standards for sherbet with a minimum milk-derived protein content; change the minimum percent fruit content for sherbet to make it uniform for all fruits; provide for declaration of the source-animal for milk in sherbet; and provide for the use of optional fruit-characterizing ingredients in water ices. A version of the current frozen dessert standards marked to indicate the changes proposed by IICA is included in Appendix A. A complete version of the standard as amended, without mark-ups, is included in Appendix B.

B. STATEMENT OF GROUNDS

IICA proposes several changes to the frozen dessert standard of identity. All of these changes serve the purpose of increasing efficiency by reducing unnecessary regulatory burdens and will allow manufacturers to take advantage of new manufacturing and ingredient technologies. By providing greater flexibility, these changes will provide a nutritionally equivalent product and allow manufacturers to reduce costs and pass these savings on to consumers. Because these changes require that the finished product be nutritionally equivalent to a product manufactured pursuant to the current standard, no economic harm or deception to the consumer will result. Further, by removing unnecessary regulatory burdens, these changes will reduce the expenditure of resources required of the Agency, while still maintaining full assurance of consumer health and safety.

1. The IICA Proposal Would Further FDA's Efforts to Streamline its Regulations

A prime focus of FDA's efforts to streamline its regulations has been reform of the agency's food standard regulations. FDA has stated that these regulations "appear to be exactly the kind of regulations that need reform" because of their level of detail and their "potential to limit technological advances."² As a result of its review of food standard regulations, FDA has revoked standards of identity for foods including lowfat milk, sour half-and-half, cottage cheese products,³ canned fruit nectars,⁴ and corn grits products,⁵ and has proposed to revoke standards of identity for lowfat and nonfat yogurt.⁶ FDA also has revoked quality standards for foods with no identity standards, such as oysters, on the basis that the action would benefit consumers and industry "by eliminating regulations that are unnecessary and that, therefore, have the potential to be confusing and, as a result, burdensome."⁷

² 60 Fed.Reg. 67492 (December 29, 1995).

³ 61 Fed.Reg. 58991 (November 20, 1996).

⁴ 60 Fed.Reg. 565513 (November 9, 1995).

⁵ 61 Fed. Reg. 27771 (June 3, 1996).

⁶ 61 Fed.Reg. 58991.

⁷ 61 Fed.Reg. 27771.

In undertaking its extensive regulatory review, FDA has recognized that, while food standards have helped protect consumers from economic fraud and promote honesty and fair dealing in the marketplace, they also may impede the adoption of beneficial advances in food science and technology, which limits consumer choice in the marketplace. For example, in response to comments opposing FDA's proposal to revoke standards of identity for certain low-fat dairy products and providing for their composition and labeling in accordance with a general standard, FDA stated that its proposal would "provide maximum flexibility for manufacturers in using new ingredients and technologies and increased product choices for consumers."⁸ On this basis, FDA concluded that the proposal "most closely fulfills the goals of the President's reinventing government initiative of simplifying regulations and easing the burden on the regulated industry."⁹ Thus, in striving to achieve the objectives of the Reinventing Government Initiative, FDA has looked critically at its food standards to determine how to foster the twin goals of protecting consumers and fostering innovation and choice in the marketplace.¹⁰

By granting this petition, the agency would further the objectives of the Reinventing Government Initiative and would foster FDA's stated goal of protecting consumers while promoting enhanced flexibility and efficiency of the manufacturing process. This greater efficiency would benefit consumers by providing more affordable frozen desserts of consistent high quality.

2. Changes to Definitions

IICA proposes to amend the current definition section for frozen desserts, 21 C.F.R. § 135.3, to include a definition of "ultra-pasteurized." This change is consistent with the definition of ultra-pasteurized contained in the standard for milk and cream products.¹¹ Ultra-pasteurization is a well-recognized process in the dairy industry, and this amendment is included to clarify that ultra-pasteurization is an acceptable process for frozen dessert products.

IICA also proposes to include a new definition "milk-derived protein" used to satisfy the minimum milk-derived protein content proposed elsewhere in this petition. The definition of "milk-derived protein" includes the two forms of protein found in milk; whey proteins and casein, including all types of milk protein derivatives, components, hydrolysates, polymers and fractions such as, casein, caseinate, hydrolyzed milk protein, milk protein concentrate and filtered milk which are permitted to satisfy the minimum milk-derived protein content.

3. Safe and Suitable Milk-Derived Ingredients

⁸ 61 Fed.Reg. at 58998.

⁹ Id.

¹⁰ 60 Fed.Reg. 67492, 67498.

¹¹ 21 C.F.R. § 131.3.

IICA proposes to amend the ice cream standard to provide for the use of safe and suitable milk-derived ingredients. Milk-derived ingredients encompass a broad range on ingredients derived from milk or any component or fraction of milk such as milk fat, milk proteins (defined in 135.3 (e) Milk-derived proteins), milk sugars and minerals. This change is intended to streamline the existing regulation, which contains an extensive listing of the individual ingredients allowed in ice cream. The standard IICA is proposing will promote increased efficiency because manufacturers will now be able to use newly-developed milk-derived ingredients without the need to file a petition to amend the standard with each change. This will allow manufactures to take advantage of the latest processing techniques and use the most efficient means available that will continue to yield a product of equivalent nutritional quality. It will also promote efficiency because FDA will no longer need to expend resources reviewing petitions that have no effect on public health or safety, as only safe and suitable ingredients may be used.

4. Safe and Suitable Non-Dairy Ingredients

The inclusion of safe and suitable non-dairy ingredients will be limited to those that have a useful purpose and do not adversely impact the nutritional quality of the frozen dessert. IICA's petition allows frozen dessert manufacturers to take advantage of new, highly functional ingredients from a variety of sources that provide excellent flavor and texture to satisfy the increasing demands of America's consumers. Allowing the manufacturer the flexibility to include these functional non-dairy derived ingredients in ice cream will provide greater efficiencies of manufacture and will not adversely impact the nutritional quality of the product.

FDA regulations governing nutritional modifications of standardized foods including frozen desserts (i.e., "generic standard of identity") provide for the use of "safe and suitable" ingredients under conditions in which the nutritional quality of the finished product is maintained. 21 C.F.R. 130.10(d). The IICA proposal is consistent with current FDA policy in this regard. In contrast to the generic standard of identity, however, the IICA proposal is more limited and confines the use of safe and suitable ingredients to those that can be integrated into the product formulation without diminishing the nutritional quality of the finished food – without fortification. The generic standard of identity authorizes deviations in product formulation which can reduce the nutritional quality of the finished food and thus provides for nutrient additions to offset these losses. 21 C.F.R. 130.10(b). For example, under this provision, fat soluble vitamins can be added to restore those losses attributable to the elimination/reduction of dairy fats in the product formulation. The IICA proposal includes no similar provision for food fortification because ingredient modifications are permitted only to the extent that nutritional quality is maintained without reliance on fortification.

5. Alternative Make Provisions

IICA proposes to amend 21 C.F.R. § 135.11(a) to include a new subheading (2) that provides for “alternate make” procedures in the manufacture of ice cream. This is completely consistent with other dairy product standards of identity¹² and will provide the manufacturer greater flexibility to integrate improvements in food technology into the manufacture of ice cream under the standard. The well established alternate make procedure provisions of the existing FDA cheese standards have enabled cheesemakers to make continued improvements in manufacturing processes which maintain the quality of the finished cheese product and at the same time promote efficiency and the food value that can be offered to consumers. Because of the flexibility of the alternate make procedure provisions, cheesemakers have been able to make improvements in manufacturing processes and embrace innovations without becoming enmeshed in burdensome regulatory proceedings with each innovation to amend the standards of identity first. The IICA proposal would integrate this same concept into the ice cream/frozen dessert standards to enable manufacturers of these products to benefit from advances in food technology that have genuine scientific merit without being deterred from innovation by regulatory barriers that offer no genuine consumer protection or other public benefit. Under the IICA proposal, the manufacturing processes authorized under the alternate make procedures, consistent with the policy that applies under the cheese standards, would be confined to those processes that produce a finished food product that is equivalent to the product yielded by the respective traditional make procedure with respect to physical, chemical (including nutritional), and organoleptic properties.

The IICA proposal would support the Agency’s regulatory priorities by helping to avoid the need for FDA to expend resources to amend standards of identity where the particular amendment addresses changes in manufacturing processes which have no material impact on the nature or quality or safety of the finished food product, and otherwise presents no public health or consumer protection concern.

6. Replacing Minimum Nonfat Milk Solids Content with Minimum Milk-Derived Protein Level

IICA proposes that the minimum nonfat milk solids requirements contained in the current ice cream standard be replaced with a minimum milk-derived protein percentage. IICA proposes to retain the minimum 10 percent milkfat requirement for ice cream and insert a new minimum of 2.95 percent milk-derived protein. The revised standard would include a scale similar to the current scale that as the milkfat content increases, the minimum milk-derived protein content shall decrease proportionately, as demonstrated by the chart in revised section 135.110(a)(3). This provision ensures that frozen desserts of differing fat levels will maintain their nutritional value proportionately to the current values of nonfat milk solids.

IICA’s proposal to replace the minimum nonfat milk solids content requirement with a minimum milk-derived protein content is based on an idea first proposed by FDA in 1974. FDA concluded at that time that a minimum milk protein requirement was a better standard than

¹² See 21 C.F.R. Part 133.

the then applicable nonfat milk solids requirement.¹³ FDA proposed a minimum milk protein content of 2.7 percent, relying on the then current standards for ice cream products to determine the protein level of a product complying with the milk solids content requirements. FDA adopted this standard in 1977.¹⁴ Subsequently, in response to objections and requests for hearings, FDA stayed the effectiveness of this rule to gather additional information.¹⁵ During those hearings, evidence was provided that demonstrated the possibility that the proposed 2.7 percent minimum milk protein content could result in a measurable decrease in calcium of greater than 2 percent of the U.S. RDA per serving and decrease in potassium and an increase in sodium.¹⁶ Based on this information, FDA determined that the 2.7 percent milk protein level could potentially result in a product that was not nutritionally equivalent to the standardized product and revoked the provisions in the ice cream standard relating to minimum milk protein requirements.¹⁷ IICA has devised a system to ensure that nutritional equivalence to the current standard is maintained when a minimum protein level is used as a compositional bench-mark for frozen dairy desserts.

To address the concern that calcium, potassium and sodium levels in ice cream could decrease more than 2 percent of the daily values when changing to a minimum a protein measurement we assert that the nutrient composition of ice cream under today's current standards vary considerably. A market basket survey of vanilla ice cream found the percent daily values of calcium as stated in the nutrition facts panel, to range from 6 to 15 percent, and sodium ranged from 35 to 70 mg per serving. A comparison of potassium was not made since this nutrient is not declared in the nutrition facts panel. The fluctuation in nutrient levels of ice cream result from formula variations allowed under the present standards such as increased milk fat, less air incorporation and selection of dairy ingredients and or flavorings. Table 1 contains detailed information on the nutritional break down of store brand, premium and super premium ice cream.

Additionally, it is important to note that nutrients such as calcium, sodium, potassium contained in dairy ingredients, which are currently allowed in ice cream, naturally fluctuate within a well defined range based on the breed of cow, geographical region, or seasonal variation. Table 2 provides a nutrient comparison of dairy ingredients permitted under the current ice cream standard; whole milk and nonfat dried milk, dried sweet whey and demineralized (whey- lactose removed). The percent daily values of calcium, sodium and potassium vary significantly for each of these dairy ingredients. For example the amount of

¹³ 39 Federal Register 27144 (July 25, 1974).

¹⁴ 42 Federal Register 19127 (April 12, 1977).

¹⁵ 42 Federal Register 35152 (July 8, 1977).

¹⁶ Memorandum, from Acting Director, Division of Nutrition to Acting Director, Division of Foods, Re: Assessment of Nutritional Changes Caused by a Proposed Change in Ice Cream Standards, January 6, 1978.

¹⁷ 43 Federal Register 4596, 4597 (February 3, 1978).

calcium in 100 grams of nonfat dried milk may range from 1200 to 1340 mg or more than 10 percent of the daily value. Therefore the proposed change to a minimum percent milk protein will not potentially result in a product that is different in respect to calcium, potassium and sodium than product produced under the current standards.

Using the techniques employed by FDA in its 1974 proposal to evaluate the minimum milk-derived protein requirement that will result in a nutritionally equivalent ice cream product, IICA evaluated the average protein content of ingredients allowed under the current standard. Because the protein content of these ingredients may vary based on a variety of factors, such as breed of cattle, season, geographical location, and type of feed,¹⁸ IICA employed both minimum and average protein values for each ingredient. IICA agrees with FDA that it is not appropriate to use maximum protein levels to determine nutritional equivalency.¹⁹ Based on a typical ice cream formulation under the current standard, the range of protein content that would result in a nutritionally equivalent product was 2.85 (minimum) to 3.03 (mean) percent. IICA chose 2.95 percent minimum protein content as a reasonable position between these two values. Also, IICA's proposal maintains the protein efficiency ratio (PER) of 108 percent of casein, which is the PER of whole milk protein. This ensures that the milk-derived protein is of sufficient quantity and that the protein and nutritional value of ice cream made under the proposed standard is equivalent to ice cream made under the current standard.²⁰

IICA's proposed revision to the ice cream standard carries the replacement of minimum nonfat milk solids levels with minimum milk-derived protein levels throughout the standard. Thus, where the current standard provides for a decreasing amount of nonfat milk solids content based on increased milkfat content, IICA's proposal provides for a corresponding decrease in minimum milk-derived protein percentage. Also, when one or more bulky flavors are used, the minimum milkfat content drops to 7.5 percent, and the milk-derived protein content in IICA's proposed standard correspondingly goes to not less than 1.8 percent.²¹ These changes provide consistency in the standard, that milk-derived protein content shall be the standard against which compliance is measured.

IICA's proposed changes to the standard will allow manufacturers greater flexibility in the formulation of their products, while maintaining the nutritional quality and product consistency consumers have come to expect. Regional variations, supply, and price of milkfat and nonfat milk solids can impose hardships upon the manufacturer. Using the product's protein content as the compositional criteria allows for use of new ingredients without sacrificing nutritional quality. IICA's proposed standards will allow manufacturers to utilize equivalent ingredients interchangeably thereby enhancing the ability to better manage cost to reflect market conditions.

¹⁸ 42 Federal Register at 19129.

¹⁹ Id.

²⁰ Id.

²¹ 21 C.F.R. § 135.110(a)(2).

7. Delete 25 Percent Maximum Restriction on Whey Solids

IICA proposes removing the restriction on whey and modified whey products which are currently limited to not more than 25 percent of the total nonfat milk solids content of the finished food used in ice cream and frozen custard, provided that the minimum milk-derived protein content is already satisfied. There are many reasons for this change but the primary benefits are: a) nutritional value and b) enhanced functionality and c) product innovation to meet consumer needs. In addition to the traditional ingredients sweet whey powder, improved processing technology using membrane filtration allows for concentration and or selections of constituents to produce new versions of whey protein such as whey protein concentrate and whey protein isolate that offer superior nutritional quality and improved functionality in ice cream formulations.

Nutritional Value – Whey proteins have a higher nutritional value than other milk proteins. The protein efficiency ratio (PER) of whey protein is 3.6 while the PER of milk is 3.1 and casein is only 2.9. In addition, whey proteins have higher protein digestibility value than milk and are a good source of the important amino acids leucine, isoleucine, and valine. By removing the 25% cap on whey solids, more whey proteins can be used to satisfy the 2.95 minimum protein requirement. This change will provide a more nutritious product to the consumer. Additionally by allowing the unrestricted use of whey proteins ice cream manufacturers have the ability to use whey protein concentrates and whey protein isolates that are manufactured with filtration technology to remove lactose thus product a high quality protein without higher sugar content.

Enhanced Functionality – Although historically prized for their nutritional superiority to other proteins, including soy and casein, whey proteins have been under utilized in ice cream and frozen desserts due to off taste and poor functionality. In many cases, this has been the result of excessive thermal processing that denatured the protein structure and reduced their functionality in frozen dairy desserts. However, times have changed, and the technology has evolved tremendously in this area. Today, whey proteins are highly valued for their contribution to product functionality and taste. For example, whey proteins available today have excellent gellation properties that improve water-binding capacity, increase meltdown resistance, and enhance the thermal shock resistance of ice cream. The use of reduced lactose whey products are also critical for functionality of ice cream freezing as high levels of lactose normally found in sweet whey powder can cause ice crystals formation during freezing and storage of ice cream.

Product Innovation - In addition to the contribution whey proteins make to product nutrition and functionality, whey proteins are economical. Their use in ice cream helps keep the formula cost low, thus providing savings to the consumer. Consumers demand new and innovative food products and food manufactures must respond to this demand. Dairy Field magazine from reports from ProductsCan.com there were 197 new ice cream, novelties and frozen yogurt product introductions representing 562 stock keeping units in 2002. Revision of the ice cream standards to allow for unrestricted use of whey facilitates new products development reflecting new technology and allows use of alternative ingredients based on availability and increased value, thereby better serving consumers.

8. Inclusion of Milk Source Animal Name and Deletion of Goat's Milk Ice Cream Standard

The inclusion of the name of the milk-producing animal in the name of the ice-cream, when the milk is from an animal other than a cow promotes efficiency in the regulatory regime. Rather than having separate duplicative regulations, declaring the animal source of the milk will be a more efficient means of conveying this information to consumers. Declaration of the source animal when the milk used is cow's milk had been unnecessary, as ice cream has traditionally been made with cow's milk, and consumers expect the milk in ice cream to be cow's milk. The original proposed standard of identity for cow's milk stated "[t]he term 'milk' as used in this section means cow's milk."²² This language remains in the current standard.²³ The source animal is only relevant for labeling purposes if it is an animal other than a cow. Consumers will be adequately informed of any alternative milk source by compliance with the provisions of IICA's proposal. Whenever the source of the milk is an animal other than cows, this shall be reflected in the name of the product, such as "___milk ice cream." Because the other requirements for the ice cream remain the same, having separate standards of identity is unnecessarily duplicative, and it limits the possibilities for source animals to those that have gone through the burdensome and expensive process of amending the standards of identity. Deleting the standards for goat's milk ice cream and creating flexibility for naming the milk source animal within the general ice cream standard will fulfill the Agency's mission to streamline the regulatory scheme and reduce unnecessary or duplicative regulations.

10. Minimum Weight for Reduced Fat Ice Cream

Another requested change is to amend the ice cream standard to provide for a minimum weight of 4.0 lbs per gallon for reduced fat ice cream. IICA first proposed this level in the context of FDA's rulemaking to establish requirements for naming foods using a nutrient content claim and a standardized term, which led to the creation of 21 C.F.R. § 130.10.²⁴ Although FDA did not amend the ice cream standard at that time, in its preamble discussion establishing the regulation, FDA stated that it "does not believe that fat reduced ice cream products should contain less than 4.0 pounds per gallon, . . . , because the desired effects can be achieved within this allowance, and the modified foods should resemble the traditional standardized foods as closely as possible."²⁵

IICA is now proposing that the standard of identity for ice cream be specifically modified to reflect this level. As FDA stated, the fat reduction in ice cream can be achieved within this limitation, and including this level in the ice cream standard will ensure that

²² Proposed 21 C.F.R. § 20.1(b), __ Federal Register 5112, 5120 (August 8, 1950).

²³ 21 C.F.R. § 135.110(b).

²⁴ 58 Federal Register 2431 (January 6, 1993).

²⁵ Id., at 2434.

consumers receive a minimum weight per gallon product. This will provide uniformity throughout the industry, and greater assurance to consumers purchasing fat reduced ice cream products.

11. Removing Minimum Fruit Content Percentages

Under current standards, ice cream is subject to rigid requirements prescribing the minimum amount of flavorant that regarding how much flavorant must be used and defining flavor “predominance,” as a matter of law, with reference to standardized quantitative thresholds which do not always reflect the actual predominance of flavors as a matter of fact. These requirements dictate the declaration of flavors as part of the product name, and pose an obstacle to the manufacturer’s ability to declare actual flavorant usage accurately in product labeling. This problem has become amplified by innovations in flavor development which affect the amounts of flavors that are used and the relative predominance of flavors used in various combinations. The IICA proposal would enable manufacturers to declare flavors in a manner that is reflective of the actual facts concerning the predominance of flavors in particular food products. IICA’s proposal will retain the current provisions specifying artificial flavoring nomenclature when a combination of vanilla beans or vanilla extract is used with vanillin. IICA proposes eliminating the current required minimum flavorant levels for citrus, berry, other fruits and nuts, and leaves it to the discretion of the manufacturer to determine whether the natural or artificial ingredients provide the characterizing flavor of the product, and label the product accordingly. If the natural flavor ingredient is predominant, then the product may be labeled “_____ ice cream,” or “_____ flavored.” If, on the other hand, the artificial flavor predominates, then the product would be labeled as “artificially flavored _____” or “artificial _____.”

Removal of the minimum fruit percentage will allow manufacturers to utilize a wider variety of natural flavors and flavoring ingredients, and will provide greater efficiency for both the manufacturer and the consumer.

12. Ingredient Listings

IICA proposes to amend the ice cream standard of identity to provide for seven general ingredient names, under which several alternative varieties of each ingredient may be included. These changes allow a manufacturer to substitute similar ingredients without requiring costly labeling changes in the ingredient statement. For example, cream, whey cream could be labeled “cream.” Butter oil, anhydrous milkfat, dried cream, and plastic cream may be declared as “butter fat.” Buttermilk, sweet cream buttermilk, condensed or dried buttermilk could be declared as “butter milk.” Whey, concentrated whey, reconstituted whey, and dried whey could be labeled as “whey.” Safe and suitable dairy ingredients such as milk, filtered milk in dried and liquid form, and dried milk are labeled as “milk.” The milk-derived proteins such as whey protein concentrate, whey protein fractions and whey protein isolate, casein, caseinates, and can be labeled as “milk protein.”

These changes would allow manufacturers to adjust their formula based on ingredient availability within each class of ingredients without the need to print new labels. This increased efficiency could then be passed on to consumers, as manufacturers would have the flexibility to use plentiful ingredients within each defined name, rather than being tied to a particular ingredient.

The ingredient names are generally in accordance with the names defined in 21 C.F.R. § 101.4(b). When FDA established the ingredient class names, it only included those ingredients that are nutritionally and functionally equivalent in a class.²⁶ IICA included those ingredients that are nutritionally and functionally equivalent when used in ice cream within each proposed ingredient name. For example, use of whey cream in ice cream mix results in a product that is nutritionally identical to a similar product made with cream. This is because in ice cream, the milkfat is complemented by other dairy ingredients used for the solids-not-fat portion to produce an equivalent compositional profile. Thus, for purposes of ice cream labeling, these ingredient classes are appropriate. Because the nutritional profile of finished ice cream is based on a protein equivalent, no consumer will be deceived by the proposed categories, as the product they are receiving will be essentially the same regardless of the individual ingredient within the class that is used.

The proposed change to ingredient nomenclature codifies the current labeling provision 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 additional ingredient components and subcomponents that serve an appropriate function in a similar role functionally and nutritionally under the conditions of use previously established in the standard.

13. Changes to Sherbet Standard

IICA is proposing that many of the changes made to the ice cream standard also be made to the sherbet standard: allowing safe and suitable milk-derived ingredients; allowing milk from animals other than cows, whose source will be reflected in the product name; replace the minimum percent nonfat milk-derived solids standards for sherbet with a minimum milk-derived protein content; and change the minimum percent fruit content for sherbet to make it uniform for all fruits. Just as with the ice cream standard, these changes will promote greater efficiency in the manufacture of sherbet, allowing manufacturers to make a functionally and nutritionally equivalent product available to the consumer at a lower cost.

IICA is also proposing that the varying minimum levels of fruit content in the current standard be changed to a standard 2 percent minimum content. This will allow manufacturers greater flexibility in developing the new and exotic flavors popular with today's consumers. Flavors such as kiwi, mango, guava, elderberry exhibit intense flavors that when used in combination with other bland flavorings will overpower other flavors if the 10 percent minimum flavor requirement for other fruit flavors were maintained.

²⁶ 41 Federal Register 1156, 1158 (January 6, 1976).

14. Delete Mellorine Standard

IICA is proposing to delete the standard for mellorine in 21 C.F.R. § 135.130. Industry has found that this is a product that is not in great demand, and is not associated with significant consumer familiarity. Even with the deletion of this standard, frozen dairy desserts formulated by replacing milkfat with vegetable fat may still be manufactured, but would be labeled with a common or usual name that is more descriptive to consumers such as “frozen dessert” or “frozen dairy dessert,” if the milk solids predominate. These names allow manufacturers greater flexibility to address consumer demand, and more accurately describe the product to the consumer.

15. Water Ices

IICA is proposing to amend the standard for water ices, 21 C.F.R. § 135.160, to provide for the use of optional fruit-characterizing ingredients in water ices. Also, additional changes to the language simplifying the regulation by reference to the sherbet standard of identity will also be made, though water ice will not require the 2 percent minimum fruit content of sherbet.

C. ENVIRONMENTAL IMPACT

Preparation of an environmental assessment is not required for a petition to repeal or promulgate a food standard.²⁷ IICA is not aware of any extraordinary circumstances, as defined in 21 C.F.R. § 25.21, that exist that would require an environmental assessment for this petition.

D. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to petitioners which are unfavorable to the petition.

For the foregoing reasons, we request that FDA grant this petition.

Respectfully submitted,



By: Cary Frye
Vice President, Regulatory Affairs
International Ice Cream Association

²⁷ 21 C.F.R. § 25.32(a).

● IICA Proposed Changes ●
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

APPENDIX A

(Changes are denoted in bold for additions and struck for deletions)

§135—FROZEN DESSERTS

Subpart A-General Provisions

§135.3 Definitions.

For the purposes of this part:

- (a) A a pasteurized mix is one in which every particle of the mix has been heated in properly operated equipment to one of the temperatures specified in the table in this section and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

| Temperature | Time |
|--------------|------------------|
| 155°F | 30 min. |
| 175°F | 25 sec. |
| 180°F | 15 sec. |
| 191°F | 1 sec. |
| 204°F | 0.05 sec. |
| 212°F | 0.01 sec. |

- (b) **Ultra-pasteurized** when used to describe a dairy product means that such product shall have been thermally processed at or above 280° F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

● IICA Proposed Changes ●
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

(c) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, filtered milk, reconstituted milk, and dry whole milk. Water in sufficient quantity to reconstitute concentrated and dry forms may be added.

(d) *Nonfat milk* means skim milk, concentrated skim milk, filtered skim milk, reconstituted skim milk and nonfat dry milk. Water in a sufficient quantity to reconstitute concentrated forms may be added.

(e) *Milk-derived protein*: means casein and/or whey protein(s) and its constituents, fractions, hydrolysates or polymers derived from milk.

(f) *Milk-derived ingredients* means any ingredient derived from milk or any component or fraction of milk such as milk fat, milk proteins defined in 135.3 (e), milk sugars and minerals.

[42 FR 19132, Apr. 12, 1977]

Subpart B-Requirements for Specific Standardized Frozen Desserts

§135.110 Ice cream and frozen custard.

(a) *Description*. (1) Ice cream is a food produced by freezing, while stirring, a pasteurized ~~acrated~~ mix consisting of ~~one or more of the optional dairy ingredients specified in paragraph (b) of this section,~~ safe and suitable milk-derived ingredients alone or in combination; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. The use of milk and milk products from cows as well as other milk source animals (e.g., goat, sheep) is permitted. Water may be added, or water may be removed from the mix. ~~and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, one or more of the optional hydrolyzed milk proteins as provided~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~for in paragraph (d) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions.~~ **Safe and suitable non-dairy derived ingredients that serve a useful function may be added.** Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients.

(2) Ice cream is a food prepared by the procedures set forth in paragraph (a) of this section, or by any other procedure which produces a finished product which has essentially the same physical, chemical and organoleptic characteristics.

(3) (2) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon, except where the ice cream is a fat reduced ice cream as defined by applicable sections of §130.10, reduced fat ice cream shall weigh not less than 4.0 pounds per gallon. Ice cream contains not less than 10 percent milkfat, **nor less than 2.95 percent milk-derived protein**, except that when it contains milkfat at ~~1 percent~~ increments above the 10 percent minimum, it may contain the following milkfat ~~to nonfat milk solids~~ **milk-derived protein** levels ~~to nonfat milk solids levels~~: **specified in the table in this section.** The protein to meet the minimum milk-derived protein requirement shall be provided by milk-derived ingredients, and shall have a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein) as determined by the method prescribed the most recent edition of AOAC Approved Methods for protein levels.

**IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)**

| Percent milkfat | Minimum percent nonfat milk solids |
|-----------------|------------------------------------|
| 10 | 10 |
| 11 | 9 |
| 12 | 8 |
| 13 | 7 |
| 14 | 6 |

| Percent milkfat | Minimum % nonfat milk solids | Minimum % milk-derived protein |
|-----------------|------------------------------|--------------------------------|
| 10 | 10 | 2.95 |
| 11 | 9 | 2.66 |
| 12 | 8 | 2.36 |
| 13 | 7 | 2.07 |
| 14 | 6 | 1.77 |

Except that when one or more bulky flavors are used, the weights of milkfat ~~and total milk solids~~ **are** is not less than 10 percent ~~and 20 percent, respectively,~~ of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat ~~or total milk solids~~ less than **8 7.5 percent** ~~and 16 percent, respectively,~~ of the weight of the finished food, **nor is the milk-derived protein content less than 1.8 percent of the weight of the finished food.** Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard, **french ice cream or french custard ice cream** shall contain **at a minimum** 1.4 percent egg yolk solids by weight of the finished food: *Provided, however,* That when bulky flavors are added the egg yolk solids content of frozen custard, **french ice cream or french custard ice cream** may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

food less than 1.12 percent. A product containing egg yolk solids ~~in excess of~~ **of at least** 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph ~~(c) (e)(1)~~ of this section.

(4) (3) When calculating the minimum amount of milkfat and **milk-derived protein** ~~nonfat milk solids~~ required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

~~(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream; dried cream; plastic cream (sometimes known as concentrated milkfat); butter; butter oil; milk; concentrated milk; evaporated milk; sweetened condensed milk; superheated condensed milk; dried milk; skim milk; concentrated skim milk; evaporated skim milk; condensed skim milk; superheated condensed skim milk; sweetened condensed skim milk; sweetened condensed part skim milk; nonfat dry milk; sweet cream buttermilk; condensed sweet cream buttermilk; dried sweet cream buttermilk; skim milk that has been concentrated and from which part of the lactose has been removed by a safe and suitable procedure; skim milk in concentrated or dried form that has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate, and whey and those modified whey products (e.g.,~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent, is substantially free of lactic acid as determined by titration with 0.1N NaOH, and it has a pH value in the range of 8.0 to 8.3.~~

~~(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section that may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.~~

~~(d) *Optional hydrolyzed milk proteins.* One or more of the optional hydrolyzed milk proteins referred to in paragraph (a) of this section may be added as stabilizers at a level not to exceed 3 percent by weight of ice cream mix containing not less than 20 percent total milk solids, provided that any whey and modified whey products used to contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~finished food. Further, when hydrolyzed milk proteins are used in the food, the declaration of these ingredients on the food label shall comply with the requirements of §101.22 of this chapter.~~

~~(b)(e) *Methods of analysis.* (1) The fat content shall be determined by using the Mojonier method prescribed in the most current edition of the "Official Methods of Analysis of the Association of Official Analytical Chemists AOAC INTERNATIONAL" 13th Ed. (1980), sections 16.287 and 16.059, as the reference method. under "Fat, Reese-Gottlieb Method Official Final Action," which is incorporated by reference. Copies may be obtained from AOAC INTERNATIONAL, First Union National Bank Lockbox, PO Box 75198, Baltimore, MD 21275-5198 USA. the Association of Official Analytical Chemists International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC 20002.~~

(2) The protein content shall be determined by one of the following methods; "Nitrogen Official Final Action," Kjeldahl Method, Section 16.285, or Dye Binding Method, Section 16.286 found in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL" as the reference method.

(3) PER shall be determined by the method: "Biological Evaluation of Protein Quality - Official Final Action, sections 43.212-43.216" found in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL" as the reference method.

**IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)**

~~(c)(f)~~ *Nomenclature.* (1) **When the food is made exclusively from cows milk, the** ~~The~~ name of the food is "ice cream "; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is "frozen custard " or "french ice cream" or "french custard ice cream." **When the food is made exclusively from the milk of a single milk source animal other than cows (e.g., goats), the name of the food is “ _____milk ice cream”, or as appropriate, “frozen_____milk custard”, “french_____milk ice cream”, “french custard_____milk ice cream” (the blank being filled in with the name of the milk source animal, e.g., "goat's milk ice cream").** **When the food is partially made with milk or milk products from milk source animals other than cows, the name of the food is accompanied by the phrase "made with _____milk" (the blank being filled in with the name(s) of all milk source animals).**

(2) (i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla," in letters not less than one-half the height of the letters used in the words "ice cream."

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream," followed by the word "flavored," in letters not less than one-half the height of the letters in the name of the

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

characterizing flavor, e.g., "Vanilla flavored," or "Peach flavored," or "Vanilla flavored" and "Strawberry flavored."

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream," preceded by "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "artificial Vanilla," or "artificially flavored Strawberry" or "artificially flavored Vanilla and "artificially flavored Strawberry."

(3)(i) If the food is subject to the requirements of paragraph ~~(c)~~(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial ____ flavor added," the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: *Provided, however*, That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: *And provided further*, That if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., "Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added."

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor."

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in §169.3(c) of this chapter.

(ii) In determining the characterizing flavor of products other than those in paragraph 5(i), it shall be incumbent on the manufacturer to conclude whether the natural

**IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)**

or artificial flavor intensity predominates. The manufacturer shall determine which flavor is present in the greatest intensity and label the product accordingly. For example, strawberry ice cream consists of a combination of natural strawberries and artificial strawberry flavor. If the natural strawberry component were stronger in flavor intensity it would be deemed to predominate and the ice cream would be labeled “strawberry flavored”. If, on the other hand, the artificial strawberry flavor component was stronger in flavor intensity, the artificial flavor component would be deemed predominate and the ice cream would be labeled “artificially flavored strawberry” or “artificial strawberry”. ~~In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.~~

~~(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream, the weight of the nut meats is less than 2 percent.~~

(iii) ~~(iv)~~ In the case of two or more fruits or fruit juices, or nut meats or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is not sufficient to characterize the flavor, the products would be labeled as “a blend of artificial and natural fruit and/or nut

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

flavoring." ~~less than one-half the applicable percentage specified in paragraph (f)(5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be "artificially flavored banana almond ice cream."~~ However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "banana almond flavored ice cream."

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this **standard paragraph** shall govern each flavor of ice cream comprising the combination.

~~(7) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "ice cream" but in any case no smaller than one-sixteenth of an inch. If the food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.~~

~~(d) (g)~~ *Label declaration.* Each of the ~~optional~~ ingredients **used in the food** shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Milk, concentrated milk, evaporated milk, dried milk, filtered milk in dried and liquid forms, may be declared as "milk".

**IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)**

(2) Nonfat milk, skim milk, condensed skim milk, evaporated skim milk, nonfat dried milk, filtered nonfat milk in dried and liquid form, may be declared as "nonfat milk".

(3) Buttermilk, sweet cream buttermilk, condensed sweet cream buttermilk and dried sweet cream buttermilk may be declared as "buttermilk".

(4) Cream, whey cream, dried cream, plastic cream (sometimes known as concentrated milkfat), and may be declared as "cream".

(5) Butter, butter oil, and anhydrous milk fat may be declared as "butter fat".

(6) Milk-derived protein such as casein, whey protein and its constituents, fractions, hydrolysisates or polymers derived from milk, except filtered milk, may be declared as "milk proteins".

(7) Whey, concentrated whey, reconstituted whey and dried whey may be declared as "whey".

~~(e). Sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in §101.4(d)(1), (d)(2), (d)(3), and (d)(4) of this chapter are used or alternatively as permitted in §101.4 of this chapter.~~ Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by §101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

[43 FR 4598, Feb. 3, 1978, as amended at 45 FR 63838, Sept. 26, 1980; 46 FR 44433, Sept. 4, 1981; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 59 FR 47079, Sept. 14, 1994; 63 FR 14035, Mar. 24, 1998; 63 FR 14818, Mar. 27, 1998]

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~§135.115 Goat's milk ice cream.~~

~~(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in §135.110 for ice cream, and complies with all the provisions of §135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates and hydrolyzed milk protein may not be used; and paragraphs (f)(1) and (g) of §135.110 shall not apply.~~

~~(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form.~~

~~(c) *Nomenclature.* (1) The name of the food is "goat's milk ice cream" or, alternatively, "ice cream made with goat's milk," except that when the egg yolk solids content of the food is in excess of that specified for ice cream in paragraph (a) of §135.110, the name of the food is "goat's milk frozen custard" or, alternatively, "frozen custard made with goat's milk," or "goat's milk french ice cream," or, alternatively, "french ice cream made with goat's milk," or "goat's milk french custard ice cream," or, alternatively, "french custard ice cream made with goat's milk."~~

~~(2) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one half the size of the type used in the term "goat's milk ice cream" but in any case no smaller than one sixteenth of an inch. If the food purports to be or is~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.~~

~~(d) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.~~

~~[47 FR 41526, Sept. 21, 1982, as amended at 58 FR 2896, Jan. 6, 1993; 59 FR 47080, Sept. 14, 1994]~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

§135.130 Mellorine.

~~(a) *Description.* (1) Mellorine is a food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including, but not limited to, milk derived nonfat solids and animal or vegetable fat, or both, only part of which may be milkfat. Mellorine is sweetened with nutritive carbohydrate sweetener and is characterized by the addition of flavoring ingredients.~~

~~(2) Mellorine contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Mellorine contains not less than 6 percent fat and 2.7 percent protein having a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein) by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. In no case shall the fat content of the finished food be less than 4.8 percent or the protein content be less than 2.2 percent. The protein to meet the minimum protein requirements shall be provided by milk solids, not fat and/or other milk derived ingredients.~~

~~(3) When calculating the minimum amount of milkfat and protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~(b) *Fortification.* Vitamin A is present in a quantity, which will ensure that 40 international units (IU) are available for each gram of fat in mellorine, within limits of good manufacturing practice.~~

~~(c) *Methods of analysis.* Fat and protein content, and the PER shall be determined by following the methods contained in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW Suite 700, Washington, DC 20002.~~

~~(1) Fat content shall be determined by the method: "Fat, Roesse-Gottlieb Method Official Final Action," section 16.287.~~

~~(2) Protein content shall be determined by one of the following methods: "Nitrogen Official Final Action," Kjeldahl Method, section 16.285, or Dye-Binding Method, section 16.286.~~

~~(3) PER shall be determined by the method: "Biological Evaluation of Protein Quality Official Final Action," sections 43.212-43.216.~~

~~(d) *Nomenclature.* The name of the food is "mellorine." The name of the food on the label shall be accompanied by a declaration indicating the presence of characterizing flavoring in the same manner as is specified in §135.110(e).~~

~~(e) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that sources of~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~milkfat or milk solids not fat may be declared, in descending order of predominance, either by the use of the terms "milkfat, and nonfat milk" when one or any combination of two or more of the ingredients listed in §101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used, or alternatively as permitted in §101.4 of this chapter.~~

~~[42 FR 19137, Apr. 12, 1977, as amended at 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

§ 135.140 Sherbet.

(a) *Description.* (1) Sherbet is a food produced by freezing, while stirring, a pasteurized **aerated** mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, **safe and suitable milk-derived ingredients alone or in combination; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. The use of milk and milk products from cows as well as other milk source animals (e.g., goat, sheep) is permitted. Water may be added, or water may be removed from the mix. and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Caseinate is prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.** **Safe and suitable non-dairy derived ingredients may be added that serve a useful function.** Sherbet is sweetened with **safe and suitable nutritive carbohydrate** sweeteners and is characterized by the addition of one or more of the ~~characterizing~~ **optional fruit-characterizing** ingredients specified in paragraph (d) (b) of this section or one or more of the **optional** nonfruit-characterizing ingredients specified in paragraph (e) (c) of this section.

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

(2) Sherbet is a food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure, which produces a finished product, which has essentially the same physical, chemical and organoleptic characteristics.

(3) (2) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent nor more than 2 percent, the ~~nonfat~~ milk-derived solids **protein content is not less than **± 0.295** percent, and the total milk or milk-derived solids content is not less than **2 and not greater than 1.18 percent in the case of 1 percent milk fat, and not greater than 0.89 percent in the case of 2 percent milkfat.** ~~percent, nor more than 5 percent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than 0.35 percent.~~**

~~(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milkfat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, and whey and those modified-whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

~~concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent calculated as lactic acid. The term "milk" as used in this section means cow's milk.~~

~~(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section which may be added to sherbet mix are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali, such caseinates are not considered to be milk solids.~~

~~(b) (d) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the~~

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent. ~~in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits.~~ For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

~~(c)~~ **(e)** *Optional nonfruit characterizing ingredients.* ~~The Optional optimal~~ nonfruit characterizing ingredients **may be used.** ~~Referred to in paragraph (a) of this section include but are not limited to the following:~~

~~(1) Ground spice or infusion of coffee or tea.~~

~~(2) Chocolate or cocoa, including syrup.~~

~~(3) Confectionery.~~

~~(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.~~

~~(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).~~

~~(d)~~ **(f)** *Nomenclature.* (1) The name of each sherbet is as follows:

(i) When the food is made exclusively from cows milk, the ~~The~~ name of each fruit sherbet is " ___ sherbet," the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

**IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)**

(ii) **When the food is made exclusively from cows milk, the** The name of each nonfruit sherbet is "___ sherbet," the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, "peppermint", except that if the characterizing flavor used is vanilla, the name of the food is "___ sherbet," the blank being filled in as specified by §135.110(e)(2) and (5)(i).

(iii) When the food is made exclusively from the milk of a single milk source animal other than cows (e.g., goats), the name of the food is specified as in (d)(1)(i) and (ii) above, except that the phrase "_____milk" shall immediately precede the word "sherbet" (the blank being filled in with the name of the milk source animal, e.g., "goat's milk ice cream"). When the food is partially made with milk or milk products from milk source animals other than cows, the name of the food is accompanied by the phrase "made with _____milk" (the blank being filled in with the name(s) of all milk source animals).

(2) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(i) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be "artificially flavored."

(ii) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be "artificial and natural flavoring added."

(iii) The label shall designate artificial coloring by the statement "artificially colored," "artificial coloring added," "with added artificial coloring," or "____, an artificial color added," the blank being filled in with the name of the artificial coloring used.

IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)

(e) ~~(g)~~ *Characterizing flavor(s)*. Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraph (f)(2) (i) and (ii) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word Asherbet® may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(f) ~~(h)~~ *Display of statements required by paragraph (f)(2)*. Except as specified in paragraph (e)~~(g)~~ of this section, the statements required by paragraph (d)~~(f)~~(2) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(f) ~~(i)~~ *Label declaration*. Each of the ingredients used ~~in the food~~ shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 4599, Feb. 3, 1978, as amended at 46 FR 44434, Sept. 4, 1981; 58 FR 2896, Jan. 6, 1993]

**IICA Proposed Changes
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (11/18/02)**

§135.160 Water ices.

(a) *Description.* Water ices are the foods each of which is prepared from **safe and suitable ingredients** ~~the same ingredients and in the same manner prescribed in §135.140 for sherbets, except that the mix need not be pasteurized,~~ and complies with all the provisions of §135.140 (a) (1) and (2) except that **stirring while freezing or aerating is not required**, and the mix need not be pasteurized, and no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

(b) *Optional fruit-characterizing ingredients.* **The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.**

(c) *Optional nonfruit characterizing ingredients.* **Optional nonfruit characterizing ingredients may be used.**

(d) *Nomenclature.* The name of the food is "___ ice," the blank being filled in, in the same manner as specified in §135.140 ~~(d)(2)~~ (I), (ii) and (iii) **(e), (f), and (g)**, as appropriate.

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

APPENDIX B

REVISED TEXT

§135—FROZEN DESSERTS

Subpart A-General Provisions

§135.3 Definitions.

For the purposes of this part:

(a) A pasteurized mix is one in which every particle of the mix has been heated in properly operated equipment to one of the temperatures specified in the table in this section and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

| Temperature | Time |
|-------------|-----------|
| 155°F | 30 min. |
| 175°F | 25 sec. |
| 180°F | 15 sec. |
| 191°F | 1 sec. |
| 204°F | 0.05 sec. |
| 212°F | 0.01 sec. |

(b) Ultra-pasteurized when used to describe a dairy product means that such product shall have been thermally processed at or above 280F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

(c) *Milk* means the lacteal secretion, practically free from colostrom, obtained by the complete milking of one of more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, filtered milk, reconstituted milk, and dry

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

whole milk. Water in sufficient quantity to reconstitute concentrated and dry forms may be added.

(d) *Nonfat milk* means skim milk, concentrated skim milk, filtered skim milk, reconstituted skim milk and nonfat dry milk. Water in a sufficient quantity to reconstitute concentrated forms may be added.

(e) *Milk-derived protein* means casein and/or whey protein(s) and its constituents, fractions, hydrolysates or polymers derived from milk.

(f) *Milk-derived ingredients* means any ingredient derived from milk or any component or fraction of milk such as milk fat, milk proteins defined in 135.3 (e), milk sugars and minerals.
[42 FR 19132, Apr. 12, 1977]

Subpart B-Requirements for Specific Standardized Frozen Desserts

§135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is produced by freezing, while stirring, a pasteurized aerated mix consisting of safe and suitable milk-derived ingredients alone or in combination; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. The use of milk and milk products from cows as well as other milk source animals (e.g., goat, sheep) is permitted. Water may be added, or water may be removed from the mix. Safe and suitable non-dairy derived ingredients that serve a useful function may be added. Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients.

(2) Ice cream is a food prepared by the procedures set forth in paragraph (a) of this section, or by any other procedure which produces a finished product which has essentially the same physical, chemical and organoleptic characteristics.

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

(3) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon, except where the ice cream is a fat reduced ice cream as defined by applicable sections of 130.10, reduced fat ice cream shall weigh not less than 4.0 pounds per gallon. Ice cream contains not less than 10 percent milkfat, nor less than 2.95 percent milk-derived protein, except that when it contains milkfat above the 10 percent minimum, it may contain the following milkfat milk-derived protein levels specified in the table in this section. The protein to meet the minimum milk-derived protein requirement shall be provided by milk-derived ingredients, and shall have a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein) as determined by the method prescribed the most recent edition of AOAC Approved Methods for protein levels.

Except that when one or more bulky flavors are used, the weight of milkfat is not less than 10 percent of the remainder obtained by subtracting the weight of the bulky flavors from the weight

| Percent milkfat | Minimum % milk-derived protein |
|------------------------|---------------------------------------|
| 10 | 2.95 |
| 11 | 2.66 |
| 12 | 2.36 |
| 13 | 2.07 |
| 14 | 1.77 |

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

of the finished food; but in no case is the weight of milkfat less than 7.5 percent of the weight of the finished food, nor is the milk-derived protein content less than 1.8 percent of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard, french ice cream or french custard ice cream shall contain at a minimum 1.4 percent egg yolk solids by weight of the finished food: *Provided, however,* That when bulky flavors are added the egg yolk solids content of frozen custard, french ice cream or french custard ice cream may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids of at least 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (c) of this section.

(4) When calculating the minimum amount of milkfat and milk-derived protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Methods of analysis.* (1) The fat content shall be determined by using the Mojonnier method prescribed in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL" as the reference method. Copies may be obtained from AOAC

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

INTERNATIONAL, First Union National Bank Lockbox, PO Box 75198, Baltimore, MD 21275-5198 USA or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC 20002.

(2) The protein content shall be determined by one of the following methods; ANitrogen Official Final Action,” Kjeldahl Method, Section 16.285, or Dye Binding Method, Section 16.286 found in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL as the reference method.

(3) PER shall be determined by the method: " Biological Evaluation of Protein Quality - Official Final Action, sections 43.212-43.216 " found in the most current edition of the "Official Methods of Analysis of AOAC INTERNATIONAL as the reference method.

(c) *Nomenclature.* (1) When the food is made exclusively from cows milk, the name of the food is “ice cream”; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is “frozen custard” or “french ice cream” or “french custard ice cream.” When the food is made exclusively from the milk of a single milk source animal other than cows (e.g., goats), the name of the food is “_____milk ice cream”, or as appropriate, “frozen_____milk custard”, “french_____milk ice cream”, “french custard_____milk ice cream” (the blank being filled in with the name of the milk source animal, e.g., "goat's milk ice cream"). When the food is partially made with milk or milk products from milk source animals other than cows, the name of the food is accompanied by the phrase “made with _____milk” (the blank being filled in with the name(s) of all milk source animals).

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

(2) (i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., “vanilla,” in letters not less than one-half the height of the letters used in the words “ice cream.”

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words “ice cream,” followed by the word “flavored,” in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., “Vanilla flavored,” or “Peach flavored,” or “Vanilla flavored and Strawberry flavored.”

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words “ice cream,” preceded by “artificial” or “artificially flavored,” in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., “artificial Vanilla,” or “artificially flavored Strawberry” or “artificially flavored Vanilla and artificially flavored Strawberry.”

(3)(i) If the food is subject to the requirements of paragraph (c)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

the words “artificial flavor added” or “artificial ____ flavor added,” the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: *Provided, however,* That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: *And provided further,* That if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., “Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added.”

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

flavor, displayed with substantially equal prominence, e.g., “strawberry and artificial strawberry flavor.”

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in §169.3(c) of this chapter.

(ii) In determining the characterizing flavor of products other than those in paragraph 5(i), it shall be incumbent on the manufacturer to conclude whether the natural or artificial flavor intensity predominates. The manufacturer shall determine which flavor is present in the greatest intensity and label the product accordingly. For example, strawberry ice cream consists of a combination of natural strawberries and artificial strawberry flavor. If the natural strawberry component were stronger in flavor intensity it would be deemed to predominate and the ice cream would be labeled “strawberry flavored”. If, on the other hand, the artificial strawberry flavor component was stronger in flavor intensity, the artificial flavor component would be deemed predominate and the ice cream would be labeled “artificially flavored strawberry” or “artificial strawberry”.

(iii) In the case of two or more fruits or fruit juices, or nut meats or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is not sufficient to characterize the

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

flavor, the products would be labeled as “a blend of artificial and natural fruit and/or nut flavoring.”

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this standard shall govern each flavor of ice cream comprising the combination.

(7) If the food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Milk, concentrated milk, evaporated milk, dried milk, filtered milk in liquid and dried form, may be declared as “milk”.

(2) Nonfat milk, skim milk, condensed skim milk, evaporated skim milk, nonfat dried milk, filtered nonfat milk in liquid and dried form, may be declared as "nonfat milk".

(3) Buttermilk, sweet cream buttermilk, condensed sweet cream buttermilk and dried sweet cream buttermilk may be declared as “buttermilk”.

(4) Cream, whey cream, dried cream, plastic cream (sometimes known as concentrated milkfat), and may be declared as “cream”.

(5) Butter, butter oil, and anhydrous milk fat may be declared as "butter fat".

(6) Milk-derived protein such as casein, whey protein and its constituents, fractions, hydrolysates or polymers derived from milk, except filtered milk, may be declared as “milk proteins”.

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

(7) Whey, concentrated whey, reconstituted whey and dried whey may be declared as “whey”.

(e) Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by ' 101.22(c) or (k) of this chapter.

Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

[43 FR 4598, Feb. 3, 1978, as amended at 45 FR 63838, Sept. 26, 1980; 46 FR 44433, Sept. 4, 1981; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 59 FR 47079, Sept. 14, 1994; 63 FR 14035, Mar. 24, 1998; 63 FR 14818, Mar. 27, 1998]

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

§135.140 *Sherbet.*

(a) *Description.* (1) Sherbet is produced by freezing, while stirring, an aerated pasteurized mix consisting of safe and suitable milk-derived ingredients alone or in combination; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. The use of milk and milk products from cows as well as other milk source animals (e.g., goat, sheep) is permitted. Water may be added, or water may be removed from the mix. Safe and suitable non-dairy derived ingredients may be added that serve a useful function. Sherbet is sweetened with safe and suitable sweeteners and is characterized by the addition of one or more of the optional fruit-characterizing ingredients specified in paragraph (b) of this section or one or more of the optional nonfruit-characterizing ingredients specified in paragraph (c) of this section.

(2) Sherbet is a food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure, which produces a finished product, which has essentially the same physical, chemical and organoleptic characteristics.

(3) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent or more than 2 percent. The milk-derived protein content is not less than 0.295 percent and nor greater than 1.18 percent in the case of 1 percent milkfat or not greater than 0.89 percent in the case of 2 percent milkfat.

(b) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

or wholly dried. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(c) *Optional nonfruit characterizing ingredients.* Optional nonfruit characterizing ingredients may be used

(d) *Nomenclature.* (1) The name of each sherbet is as follows:

(i) When the food is made exclusively from cows milk, the name of each fruit sherbet is “___ sherbet,” the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(ii) When the food is made exclusively from cows milk, the name of each nonfruit sherbet is “___ sherbet,” the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, “peppermint”, except that if the characterizing flavor used is vanilla, the name of the food is “___ sherbet,” the blank being filled in as specified by §135.110(e)(2) and (5)(i).

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

(iii) When the food is made exclusively from the milk of a single milk source animal other than cows (e.g., goats), the name of the food is specified as in (d)(1)(i) and (ii) above, except that the phrase "_____milk" shall immediately precede the word "sherbet" (the blank being filled in with the name of the milk source animal, e.g., "goat's milk ice cream"). When the food is partially made with milk or milk products from milk source animals other than cows, the name of the food is accompanied by the phrase "made with _____milk" (the blank being filled in with the name(s) of all milk source animals).

(2) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(i) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be "artificially flavored."

(ii) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be "artificial and natural flavoring added."

(iii) The label shall designate artificial coloring by the statement "artificially colored," "artificial coloring added," "with added artificial coloring," or "____, an artificial color added," the blank being filled in with the name of the artificial coloring used.

(e) *Characterizing flavor(s)*. Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraph (f)(2) (i) and (ii) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word "sherbet" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1

● IICA Proposed Changes to ●
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)

pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(f) *Display of statements required by paragraph (f)(2).* Except as specified in paragraph (e) of this section, the statements required by paragraph (d)(2) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(f) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 4599, Feb. 3, 1978, as amended at 46 FR 44434, Sept. 4, 1981; 58 FR 2896, Jan. 6, 1993]

§135.160 Water ices.

(a) *Description.* Water ices are the foods each of which is prepared from safe and suitable and complies with all the provisions of §135.140 (a) (1) and (2) except that stirring while freezing or aerating is not required, and the mix need not be pasteurized, and no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

(b) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(c) *Optional nonfruit characterizing ingredients.* Optional nonfruit characterizing ingredients may be used.

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

(d) *Nomenclature*. The name of the food is " ___ ice," the blank being filled in, in the same manner as specified in §135.140 (d)(2) (I), (ii) and (iii) (e), (f), and (g), as appropriate.

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

**Market Basket Survey Nutritional Label Comparison of Vanilla Ice Cream - 2001
Table 1**

| | Identification | g per 1/2 cup | Calories (kcal) | Fat (g) | % Fat | Saturated Fat (g) | Sodium (mg) | Carbo (g) | Protein (g) | Protein % | Vitamin A % RDI | Vitamin C % RDI | Calcium % RDI |
|-------------------------------------|----------------|---------------|-----------------|---------|-------|-------------------|-------------|-----------|-------------|-----------|-----------------|-----------------|---------------|
| Non-Premium/ Store Brand | A1 | 71 | 150 | 7 | 9.9 | 4 | 70 | 19 | 2 | 2.8 | 0 | 0 | 8 |
| | A2* | 69 | 140 | 8 | 11.6 | 5 | 45 | 16 | 2 | 2.9 | 6 | 0 | 8 |
| | B | 64 | 130 | 6 | 9.4 | 4 | 45 | 16 | 2 | 3.1 | 4 | 0 | 6 |
| Premium | C | 65 | 160 | 9 | 13.8 | 5 | 40 | 17 | 2 | 3.0 | 8 | 0 | 6 |
| | D | 68 | 150 | 9 | 13.2 | 5 | 35 | 15 | 3 | 4.4 | 6 | 0 | 10 |
| | E | 68 | 140 | 8 | 11.8 | 4.5 | 60 | 16 | 5 | 7.3 | 4 | 0 | 15 |
| Super Premium | F | 106 | 260 | 15 | 14.2 | 9 | 55 | 25 | 5 | 4.7 | 15 | 0 | 15 |
| | G | 107 | 250 | 16 | 15.0 | 11 | 60 | 21 | 4 | 3.7 | 15 | 0 | 15 |
| | H | 106 | 270 | 18 | 17.0 | 11 | 70 | 21 | 5 | 4.7 | 15 | 0 | 15 |

*This brand differs in Copyright date

**IICA Proposed Changes to
Ice Cream and Frozen Desserts Standards of Identity
DRAFT (02/03/03)**

**Nutrient Comparison of Dairy Ingredients
Table 2**

| Dairy Ingredient | Calcium | | | Sodium | | | Potassium | | |
|---|-------------------|---------------|--------------------|-------------------|--------------|---------------------|-------------------|-----------------|---------------------|
| | Amount mg/100g | % Daily Value | Labeled % D.V.* | Amount mg/100g | %Daily Value | Labeled % D.V.** | Amount mg/100g | %Daily Value | Labeled % D.V.** |
| Non Fat Dry Milk ₁ | 1201-1340 | 120-134 | 120-130 | 447-468 | 18.6-19.5 | 19-20 | 1656-1805 | 47-51.6 | 45-50 |
| Whole Milk ₁ | 102-111 | 10.2-11.1 | 15 | 52.8-60 | 2.2-2.5 | 2-3 | 120-138 | 3.4-3.9 | 4 |
| Whey-Sweet Dried ₂ | 671-796 | 67.1-79.6 | 70-80 | 1079 | 45 | 45 | 2080 | 59.2 | 60 |
| Butter Milk Dried ₂ | 1094-1184 | 109-118 | 110-120 | 517 | 21.5 | 22 | 1592 | 45.5 | 45 |
| Whey-Lactose Removed Dried ₃ | 580 | 5.8 | 6 | 420 | 17.5 | 18 | 1100 | 31.4 | 30 |
| Whey Protein Isolate 92% Protein ₃ | 120 | 12.0 | 10 | 600 | 25.0 | 25 | 120 | 3.4 | 4 |
| Whey Protein Isolated 35% Protein ₃ | 644-788 | 6.4-7.8 | 6-8 | 608-700 | 25.3-29.1 | 25-29 | - | - | - |

Source:1-IDFA Nutrition Information Database November 1993

2- USDA Nutrient Database. NDB# 01094, 01115

3- Supplier Database

* Nutrition facts labeling for Calcium and other minerals with established RDI- Amounts less than 2% may be declared as zero.
Expressed to nearest 2% increment upto and including 10%, to the nearest 5% increments
above 10 and up to 50, and to the nearest 10% increment above 50.

** Amount is expressed to the nearest percentage.