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

December 27, 2005

The Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857
Submitted electronically to: www.fda.gov/dockets/ecomments

Re: Docket No. 2003P-0132 Frozen Desserts; Petition to Revoke Standards for Goat's Milk Ice Cream and Mellorine and to Amend Standards for Ice Cream and Frozen Custard. (Advanced Notice of Proposed Rulemaking)

Dear Sir/Madam:

The International Dairy Foods Association (IDFA) and one of its constituent organizations, the International Ice Cream Association (IICA) appreciate the opportunity to provide comments to the Advanced Notice of Proposed Rulemaking to revise the standards of identity for specific frozen desserts. The IICA is the national trade association representing manufacturers and distributors of frozen desserts. IICA's 81 members manufacture about 85 percent of all frozen dessert products consumed in the United States.

IDFA strongly supports the Agency's actions to move forward with updating the existing Federal standards of ice cream and frozen desserts with their publishing of an Advanced Notice of Proposed Rulemaking in the *Federal Register* on September 27, 2005 (Docket No. 2003P-0132) Frozen Desserts; Petition to Revoke Standards for Goat's Milk Ice Cream and Mellorine and to Amend Standards for Ice Cream and Frozen Custard. The existing standards for ice cream and frozen desserts are outdated and need revision to reflect and accommodate new technology for food ingredients and processing methods, as well as, current consumer preferences. IDFA has worked with our members in the ice cream and frozen desserts industry to formulate consensus and provide additional support and information on the numerous proposed amendments to these standards. Listed below, are general comments and more detailed information that FDA was seeking on specific aspects of the IICA's petition:

General comments:

The current ice cream standards present unnecessary formulation requirements that add significantly to the costs of producing standardized frozen desserts. Ice cream processors need to have ingredient options that keep their product prices reasonable and affordable. The vast array of safe and suitable ingredients have different market prices throughout the year and are often substitutable. Formulators need to have the ability to make reasonable adjustments to their formulas within certain ranges in order to maximize quality while keeping the price attractive to consumers.

These proposed changes in the ice cream standards will be transparent to the consumer. Ice cream makers will continue to make the products that their customers demand. The only real effect will be in the product development laboratory and in the processing room. The range of available technology will be expanded, the rate of new product rollouts will continue, but the price of new, indulgent, innovative ice cream flavors will not exceed the consumer's ability to pay.

Overall, the proposed changes offer flexibility to ice cream makers to create attractively priced high quality products that meet consumer demand. More so for ice cream, than many other foods, there is absolutely no danger of the consumer being offered a product that is of inferior quality or benefit, simply because ice cream is a category that is extremely sensitive to consumer preference, perceptions of quality, and price. Ice cream is not a necessity and consumers buying the product are using their limited discretionary dollars. In return they demand, and get, the best quality at the lowest price.

Specific comments:

The use of filtered milk in the making of frozen desserts:
IDFA strongly supports amending the ice cream standard to provide for the use of safe and suitable milk-derived ingredients. Milk-derived ingredients encompass a broad range of 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 would also specifically permit the use of all types of filtered milk in frozen desserts. IICA believes that the use of filtered milk in ice cream and frozen desserts is appropriate and will maintain the basic nature of the food as related to consumer expectations.

In general, the term "filtration" describes one of several membrane filtration techniques used by the food industry. In filtration, a pressurized fluid stream is passed over a semipermeable membrane which separates the liquid into two effluent streams. The "permeate" is the water phase stream that has passed through the membrane, while the "retentate" is the solids stream that has not passed through the membrane. The size of the pores in the membrane and the number of membranes the fluid is passed over determine the concentration (e.g., 2x to 6x) of the retentate and the proportion of the water phase that has been removed as permeate.

The composition of the retentate and permeate will vary depending on the type of filtration process. Membrane separation processes are classified according to the size of the

components separated and pressure used during processing. The general classification system is reverse osmosis (RO), nanofiltartion (NF), ultrafiltration (UF) and microfiltration (MF).[1] Reverse osmosis is generally used to remove water concentrating milk similar to evaporation. Nanofiltration membranes remove very small molecules with a single charge, such as sodium chloride. Ultrafiltration membranes typically allow smaller molecular weight compounds (lactose, minerals, vitamins, and smaller proteins) into the permeate, while retaining larger compounds such as fat and protein. Microfiltation membranes range from those that can separate specific proteins to membranes that permit the permeate to contain all proteins, lactose and minerals with fat and large protein remaining in the retentate. Appendix A provides detailed information on these different filtration processes.

Historically there has been widespread safe use of filtration technology and the resulting filtered milk for use in various dairy products including ice cream and frozen desserts. The retentate is used in ice cream and frozen desserts in combination with milk, nonfat dry milk, or cream and other dairy ingredients to provide a concentrated form of nonfat milk solids that is also high in protein and low in lactose. The present ice cream standards already provide for the use of some forms of filtered milk in that mechanical filtration technology is a recognized safe and suitable processing method to concentrate and remove lactose from milk.[2] Therefore, filtered milks have been allowed and used in the production of ice cream and frozen desserts.

IICA believes that all forms of filtered milk should be allowed in ice cream and frozen desserts. Typically ultrafiltered milk would be used in varying amounts dependent on the concentration of the filtered milk components, in addition to other dairy ingredients for the purpose of increasing functional properties of the ice cream mix. Ultrafiltered milk can increase the whipability and stability of ice cream mix during freezing. Functional properties of ultrafiltered milk in ice cream mix formulation include excellent solubility and dispersion, natural emulsification, better gelation, increased water binding and viscosity, and better aeration. These functional attributes result in ease of mix processing and freezing, producing a creamy textured ice cream, with less ice crystals, more stability during storage and resistance to heat shock.

Published research on the use of filtered milk and milk protein concentrate in ice cream have demonstrated that higher levels of milk protein and replacement of milk solids with milk proteins result in a high quality, creamy textured and good tasting product. Researchers studied substitution of 20% and 50% milk protein with two milk protein concentrates.[3] Their findings were that milk protein concentration formulas have a higher mix viscosity, larger amount of fat destabilization, narrower ice melting curve, and greater

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[1] Smith K., Wisconsin Center for Dairy Research, Dairy Proteins - Relative milk component sizes in comparison with membrane pore size ranges, available on line at http://144.92.196.21/pdf/resources/whey/dairyproteins.pdf

[2] 21 C.F.R. § 135.110(a)(2)(b)

[3] Alvarez, V.B., Woulters, C.L. Et al., 2005, Physical properties of ice cram containing milk protein concentrates, J. Dairy Sci. 88:862-871

shape retention compared to the control. The use of milk protein concentrates did not change the physical properties of ice cream on a constant protein basis when substituting up to 50% of the protein supplied by nonfat dry milk. Other scientists have confirmed that the addition of whey protein concentrate and milk protein concentrates can enhance the nutritional value of the product and also eliminate the use of stabilizer.[4] Their research showed that ice cream made with increased protein levels of 5.07%, 6.24%, and 7.41% with the addition of whey protein concentrate and milk protein concentrate resulted in reduction of ice crystal size thus giving an improved mouth feel.

IICA also fully supports the use of 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. This should include that ability for safe and suitable dairy ingredients such as milk, filtered milk in dried and liquid form, and dried milk are labeled as "milk." 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 use of any safe and suitable ingredient to accomplish a specific function in the manufacture of frozen desserts:
IICA acknowledges FDA's comments that the existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose. Under the provisions of 21 CFR 130.10, standardized foods that make a nutrient content claim may be modified to contain nutrients not specifically permitted by the relevant standard of identity. However, IICA believes that this provision does not fully accommodate technological advances in food additives and consumer's demand for functional ingredients that are beyond the allowed nutrient content claims.

As indicated in our petition, 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 or alter the basic nature or essential characteristics of the food.

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[4] Patel, M. R.[1], Baer1R. J[1]., and Acharya M. R. [2]. 2004, Abstract presented at International Food Technologist Annual Meeting Abstract(1) Dairy Science Dept., South Dakota State Univ., DM 301, Brookings, SD, (2) Wells' Dairy, Inc., Research Scientist, Technical Center, 1st Street SW, Le Mars, IA

As consumers strive to eat healthy foods, ice cream manufacturers want to best meet this demand. One example would be the formulation of a more healthy ice cream, by reducing the fat to produce a nonfat product and being allowed to add a safe and suitable ingredient such as Omega-3 fatty acids to produce a heart healthy ice cream.

The use of any safe and suitable milk-derived ingredients in the manufacture of frozen desserts:

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. This provision ensures that frozen desserts of differing fat levels will maintain their nutritional value proportionately to the current values of nonfat milk solids. This change to a milk-derived minimum is solely for the purpose of providing greater flexibility for the use of different milk-derived ingredients that are needed for cost efficiency and functionality. IICA respectfully disagrees with FDA's comments that this proposed change is based on the fact that nonfat milk solids cannot be differentiated from other solids in the foods. Today's analytical tests can differentiate between different types of milk solids such as casein and whey, from other total solids.

IICA strongly believes the change to a minimum milk-derived protein content is appropriate and necessary to provide a measurement that provides for nutritional equivalence with the present standards, but provides flexibility for use of new ingredients that are both functionally and nutritionally superior for the formulation of ice cream and frozen desserts. IICA's proposal ensures 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.

IICA’s proposal to replace the minimum nonfat milk solids content requirement in the ice cream standards with minimum milk-derived protein content is based on an idea that was first proposed by FDA in 1974. Additionally, international Codex standards for milk products use milk protein (%m/m) for setting minimum compositional criteria since any form of milk or milk product is permitted as a milk ingredient. Although there is no Codex standard for ice cream, there is a international standard for yogurt and fermented milks which would be similar in that it is a dairy product that combines various dairy ingredients and flavoring. The Codex standard for fermented milks, 243-2003, uses a minimum of 2.7% milk protein, which replaced the previous 1977 version that required a minimum 8.2% nonfat milk solids.

The use of various forms of milk-derived ingredients is consistent with the basic nature and essential characteristics of ice cream, in that the current standards presently allow for the use of many different milk ingredients, such as whey products, optional caseinates, and hydrolyzed proteins. However modernization of the standards is needed to provide more flexibility to use these valuable milk-derived ingredients without unnecessary and arbitrary restrictions on the level of use.

Development of 2.95% minimum milk protein to replace the current 10% minimum nonfat milk solids:

The proposed 2.95% minimum milk protein is aligned with the present 10% minimum nonfat milk solids in the compositional requirements under current standards. Additionally, these new standards are a floor, not a ceiling. Companies may still choose to have a higher milk protein level. The protein values used for each milk ingredient were supplied by the American Dairy Products Institute (ADPI) and software supplied by dairy scientists at Pennsylvania State University. See Tables 1-3.

The calculation for percent protein under current regulations using **minimum** protein values is shown below. The mix prepared in this model has 10% fat and 10% milk solids nonfat (MSNF) with 75% of the MSNF from buttermilk solids, and approximately 25% from whey solids. All of the butterfat is from butteroil.

Minimum Protein Content of Ice Cream Under Current Regulations

Ingredient	% MSNF in Mix	% Fat in Mix	%Protein in Mix
MSNF (from Buttermilk Solids	7.51	.59	2.53
MSNF (from Whey Powder)	2.46	.04	.29
Butteroil	.03	9.37	.03
Total	10.00	10.00	**2.85**

Assumes minimum protein values for buttermilk solids is 30.0% and sweet whey powder is 11.0%

The calculation for the percent protein under current regulations using **average** protein values is shown on the following table. As with the calculation for minimum protein values, the model is a 10% fat and 10% MSNF mix with 75% of the MSNF from buttermilk solids, and approximately 25% from whey solids. Composition of ingredients is the same as the minimum calculation shown above except for protein. The values for protein are average values according to ADPI.

Average Protein Content of Ice Cream Under Current Regulations

Ingredient	% MSNF in Mix	% Fat in Mix	%Protein in Mix
MSNF (from Buttermilk Solids)	7.51	.59	2.66
MSNF (from Whey Powder)	2.46	.04	.34
Butteroil	.03	9.37	.03
Total	10.00	10.00	**3.03**

Assumes average protein value for buttermilk solids is 31.5 and sweet whey powder is 12.75%

The IICA petition proposes a minimum protein value of 2.95% be adopted for ice cream standards. This figure is an average of the minimum (2.85%) and mean (3.03%) protein values found in ice cream under current regulations.

IICA does not believe that the proposed minimum milk-derived protein content requirement should be implemented in addition to the current requirement for minimum nonfat milk solid. This requirement would only stifle the ability to formulate novel and more healthful products.

In the initial petition IICA has demonstrated how replacing a minimum nonfat milk solid requirement with a minimum milk-derived protein requirement would affect the compositional and nutritional profile of the product.

It is important to understand that the above calculations represent the protein level in a calculated ice cream mix formulation. This proposed protein minimum should not be confused with protein values the IDFA submitted to FDA for nutrient determination on the level of protein in milk solids (0.39 grams of protein per gram of msnf) for nutritional labeling purposes (Table 4). It would be wrong to assume that the IDFA's nutrient data base for the level of protein in milk solids for nutritional labeling should be used to determine the minimum level of protein in ice cream. The IDFA database was developed based on the level of protein solely in milk solids, not from a variety of ingredients allowed to formulate ice cream. Ice cream manufacturers clearly understand that nutritional labeling for protein and other nutrients will vary depending on the type and amount of dairy ingredients used. When submitting the IDFA nutrient database to FDA, detailed information was provided to demonstrate the approach used to determine the nutrient values for the dairy components.

The use of "alternate make'' procedures in the manufacture of ice cream and frozen custard and sherbet:

IICA fully supports the use of “alternate make” procedures in the manufacture of ice cream. This is completely consistent with other dairy product standards of identity 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. The use of the "alternate make" procedure provisions in the ice cream and frozen dessert standards will allow improvements in manufacturing processes and embrace innovations without becoming enmeshed in burdensome regulatory proceedings with each innovation to amend the standards of identity first. 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) properties. However, it is not appropriate to require that products made using an "alternative make" have identical

organoleptic properties as this measurement is often subjective or the new process is selected specifically to produce a different rather than identical taste or texture.

One example of a novel process being explored for the manufacturing and freezing of ice cream is the use of high-pressure liquid carbon dioxide atomization in a cryogenic chamber. John Brisson, Associate Professor of Mechanical Engineering at the Massachusetts Institute of Technology recently presented a paper on this novel ice cream technology. His abstract stated "This project proposes a cheaper more energy efficient process that could substantially change the way ice cream is made and improve the end product. This new approach would be less expensive and could have unique and desirable properties." However, this process would not meet the current requirements that "ice cream is a food produced by freezing while stirring" since the novel process involves atomization of the ice cream mix at cryogenic temperatures of -40 º F, rather than the required freezing and stirring.

A minimum weight requirement of 4 pounds per gallon for reduced fat ice cream:
IICA believes to avoid confusion in the market place and provide a level playing field for all processors, it is important to codify the change to 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.[5] 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."[6]

Due to the obesity crisis, manufacturers are striving to develop new more healthful ice cream products with lower fat content, and fewer calories. 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 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.

A minimum milk-derived protein requirement based on the amount of fat:
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

[5] 58 Federal Register 2431 (January 6, 1993).

[6] Id., at 2434.

than 1.8 percent.[7] These changes provide consistency in the standard, that milk-derived protein content shall be the standard against which compliance is measured.

The removal of the requirement of the maximum 25-percent restriction on whey solids in ice cream and frozen custard:
One of the most important aspects of IICA's proposal is to remove the maximum 25-percent restriction on whey solids in ice cream and frozen custard to allow for any combination of safe and suitable dairy-derived ingredients, provided the proposed minimum milk-derived protein content is satisfied. IICA strongly asserts that it is appropriate to remove the arbitrary restriction of 25-percent whey solids.

Historically whey proteins have been under utilized in terms of their functionality. In many cases, this has been the result of excessive thermal processing that reduced their functionality in frozen dairy desserts. However, today the technology has evolved tremendously in this area resulting in whey proteins that are highly valued for their nutritional value, functionality, and taste.

Whey proteins are easily digestible high-quality proteins with significant amounts of the important amino acids leucine, isoleucine, and valine. They are superior in nutritional value to soy protein and casein in providing 14% higher nutritional value.

New versions of whey proteins such as Whey Protein Concentrate (WPC), Whey Protein Isolate (WPI), and the more traditional whey ingredients such as sweet whey powder, offer high performance to ice cream formulators:

- Whey proteins possess excellent gelation properties which increases their ability to hold water in foods. This is especially important in ice cream and other frozen dairy desserts.

- The gelation properties of whey proteins increase the thermal shock resistance of ice cream.

- The gelation properties of whey proteins increase ice cream’s meltdown resistance.

- Whey proteins are good emulsifiers, providing smoother, creamier consistency and offering better utilization of stabilizers.

In summary, the development of whey proteins is an excellent example of how technical progress can be incorporated in the ice cream industry. IICA’s proposed changes to the standards will allow expanded use of such ingredients that will promote quality, innovation and better meet consumer demands and expectations.

America's dairy farmers have been funding research on whey applications in ice cream and other foods. An applications monograph "Whey Products in Ice Cream and Frozen

[7] 21 C.F.R. § 135.110(a)(2).

Desserts" by Dr. Steven Young, Ph.D. published by the U.S. Dairy Export Council (USDEC) provides an excellent overview. USDEC is a non-profit organization that represents the interests of U.S. milk producers, dairy cooperatives, proprietary processors, export traders and industry suppliers. USDEC funding comes primarily from the dairy farmer check-off program.

Information in the USDEC monograph supports the contention in the petition that whey protein currently used in the market is of higher nutritional value, higher quality and protein digestibility than protein currently used in ice cream and custard. Dr. Young states that "Whey and whey products have been used successfully in ice cream and other frozen desserts for years. Sweet whey, modified whey, and whey protein concentrates (34-80% protein) are among the most commonly used whey products. Delactosed and demineralized whey can also be used. Cost efficiency and quality improvements are key drivers in using whey products. The nutritional value of whey is also an important reason why an increasing number of manufacturers worldwide, include whey products in their formulations."

Although technically possible, IICA discounts concerns that whey protein will be used as a main ingredient in the manufacture of ice cream and frozen custard. It is important to realize that under IICA's proposal minimum milk-derived protein and minimum milk fat levels must be met. Ice cream processors will strive to formulate their products with the best tasting, functional and cost efficient ingredients. Developing a product using large amounts of the less expensive sweet whey would not be practical since this ingredient is low in protein and high in lactose. The total amount of lactose in an ice cream formula is typically less than 7.5% of the total mix to minimize lactose crystallization that results in a "sandy" ice cream. Alternatively, the sole use of whey protein concentrates, which are high in protein, are not practical due to the high cost. Therefore, it is believed the ice cream manufacturers will strive to use a variety of milk and whey ingredients that are best suited for functionality, quality and cost. Dr. Young states that the typical recommended use rates for sweet whey are dependent upon all key considerations affecting the frozen dessert composition and the individual functionality of the specific whey ingredient used. However, in general the following initial recommendations can be considered: Sweet Whey 2.0 -3.0%, Whey Protein Concentrate (WPC) 34% protein 1.5-3.0%, WPC 60-80% protein 0.5-2%, Whey Protein Isolate (WPI) 90% protein 0.5 - 1.0%.

Dairy farmer organizations have cited that off-flavors and other defects may occur in the ice cream mix due to the excessive use of whey. However, the dairy farmer funded monograph targeted to increase foreign sales of U.S. whey ingredients cites that: ""Whey flavor" or other flavor defects called "cardboard", "oxidized" or "cheesy" flavors-can be sourced from whey ingredients, particularly sweet whey. This defect may occur in low quality or poorly processed ingredients. U.S. whey ingredients typically have a wonderful pleasant dairy flavor which is highly compatible with frozen dessert mixes."

To address FDA's questions on technical advance in the whey processing Polly Olsen from Davisco Foods, one of the leading U.S. whey processors, provided insight on this matter in her letter to the editor to Cheese Reporter, June 6, 2003 and Cheese Market News, June 30, 2003. She stated; "The whey processing industry has gone through tremendous changes in

the past 25 years and is providing nutritious and functional whey proteins in the form of isolates and concentrates. These newer protein ingredients would allow innovative frozen product developers to utilize the unique functionalities of whey proteins. Whey proteins are highly digestible proteins that provide nutritionally important amino acids. Nutritionists and dietitians have long recognized the nutritional significance of whey proteins. Consumers widely accept whey proteins in the label as healthful ingredients. Many product developers of high-protein foods seek whey protein isolates and concentrates to add nutritional impact to their products. The ice cream industry can certainly benefit from such high-quality, dairy-derived protein ingredients."

The establishment of categories of ingredients to be declared on labels under common names for ice cream and frozen custard:

The concept of establishing categories of ingredients to be declared on labels under a common name has been a practice allowed in US food labeling[8] and Codex standards[9] defined as ingredient labeling using "class names." This currently allowed practice is used by manufacturers to adjust their formulas based on ingredient availability without the need to print new labels. IICA asserts that the milk-derived ingredients that are proposed to be included in the within the common name categories are nutritionally and functionally equivalent when used in frozen desserts, and therefore, consumers would not be deceived by the proposed categories because the final product would be nutritionally equivalent regardless of which individual ingredient was used within the class. Additionally, the current standards of identity for ice cream and frozen desserts, must declare sources of milkfat and milk solids either in descending order of predominance or by very general collective terms "milkfat and nonfat milk" when one or any combination of two or more dairy ingredients are listed. IICA believes that the present label declaration is appropriate and adequately informs the consumers about the specific ingredients that are used to make the food, therefore the additional expansion of the categories of ingredients should also not pose any confusion to consumers.

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 “butterfat.” Buttermilk, sweet cream buttermilk, condensed or dried buttermilk could be declared as “buttermilk.” 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.”

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[8] CFR 21 §101.4

[9] General Standard for the Labelling of Prepackaged Foods (CODEX STAN1-Rev 2001)

IICA asserts that the proposed change to ingredient designations apply the same principle of food designation of ingredients in the nomenclature section of the ice cream standards as that already exist in general food labeling regulations. IICA merely proposes expanding 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 therefore, all the suggested collected names should be permitted as listed in the IICA petition.

The use of milk from source animals other than cows in the making of ice cream and frozen custard and sherbet and removal of the standard for goat's milk ice cream:
As stated in the IICA petition, the sole reason for proposing that the name of the milk-producing animal be included in the name of the ice cream, when the milk is from an animal other than a cow, is to promote efficiency in the regulatory process. IICA assumes that eliminating the standard for goat's milk ice cream and declaring the animal source of the milk will be a more efficient means of conveying this information to consumers.

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 "goat's milk ice cream." Because the other requirements for the ice cream remain the same, having separate standards of identity is unnecessarily duplicative, and limits the possibilities for source animals.

IICA's amendment would clearly provide consumers with information about the animal sources of milk or milk ingredients, as the information on the species would be stated in the name of the product, such as "goat's milk ice cream" on the package's principal display panel. Contrary to assertions, these changes would not allow for the undefined use of milk and milk products from animal other than cows.

The removal of the requirements for the amounts of fruits, fruit juices, and nut meats needed to determine if an artificial flavor simulating a characterizing flavor is the predominant flavor when naming an ice cream or frozen dessert product:
IICA proposes removing the amounts of fruits, fruit juices, and nut meats in the ice cream and frozen custard standard used to determine whether an artificial flavor simulating a characterizing flavor is the predominant flavor when naming the product. IICA states that under its proposed amendments, the manufacturer would determine whether the natural or artificial flavor ingredients provides the characterizing flavor of the product and would label the product accordingly. In its petition, IICA also proposes changing the requirements in sherbet for the amounts of fruit or fruit juice from a minimum of 6-percent for berry sherbets and a minimum of 10-percent for sherbets from other fruits to a minimum of 2-percent. FDA implemented the current requirement for determining whether the fruit ingredient or artificial flavor is the characterizing flavor of the food in 1964 when a final rule on frozen desserts was published.

IICA believes the current requirements for flavor labeling of ice cream based on prescribing the minimum amount of flavorant that regarding how much flavorant must be used and defining flavor "predominance," are too rigid. 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. The IICA proposal eliminates the required minimum flavorant levels for citrus, berry, other fruits and nuts, leaving 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. The 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.

IICA contends that standard amounts of fruits, fruit juices, and nut meats are not needed to determine if an artificial flavor simulates a characterizing flavor when naming the product. It is appropriate for the manufacture to determine whether the fruit ingredient or artificial flavor predominates in characterizing the flavor of the product and label the product accordingly. The manufacturer develops the formulation and flavoring levels and is an appropriate judge of which flavor is predominate and characterizing. Allowing this change for flavor labeling of ice cream and frozen desserts would ensure products are labeled in a way that would not be misleading to consumers.

The use of a 2-percent minimum level of fruit content in sherbet:
IICA also proposed amending the current standard of identity for sherbet to provide for a 2-percent minimum fruit content for all sherbet. IICA strongly believes that the current sherbet standard, requiring varying and higher minimum amounts of fruit content depending on the flavoring used is unnecessary and stifling innovation of flavored sherbet. For example under the current standards if a sherbet was developed that is made with a tropical flavor such as mango puree, the product would be required to contain 10% mango fruit to be labeled as mango, even if 5% mango puree was sufficient to produce the appropriate delicate tropical flavor. As a result of this current limitation it is not desirable to consumer taste preference to produce many of the exotic and novel sherbet flavors. Additionally it is not necessary to set varying minimum levels for different fruits as currently done in the sherbet standard.

Additional considerations for sherbet
It has come to IICA's attention that a provision exists in the Sherbet standard that was not addressed in our original petition. The present standard of identity for sherbet (21 CFR § 135.160 (f)(2)(iii) requires that the label designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with artificial coloring", or "_____,

an artificial color added", the name of the blank being filled in with the name of the artificial coloring used. IICA believes this added requirement for declaring artificial color on the label be removed from the sherbet standard. Removing this labeling provision from the standards would require that sherbet using artificial color be labeled in a consistent manner as other foods, appearing solely in the ingredient declaration. This change would not in any way misleading, but would align the sherbet standards with other foods and provide consistency with the labeling information provided to consumers.

Summary:
We strongly urge FDA to move forward with the proposed rulemaking to modernize the standards of identity for ice cream and specific frozen desserts. IDFA feels that it is very important to provide the frozen dessert industry updated standards of identity that provide for the use of novel processing and ingredient technology to meet consumer demands for new innovative, healthful and exciting products.

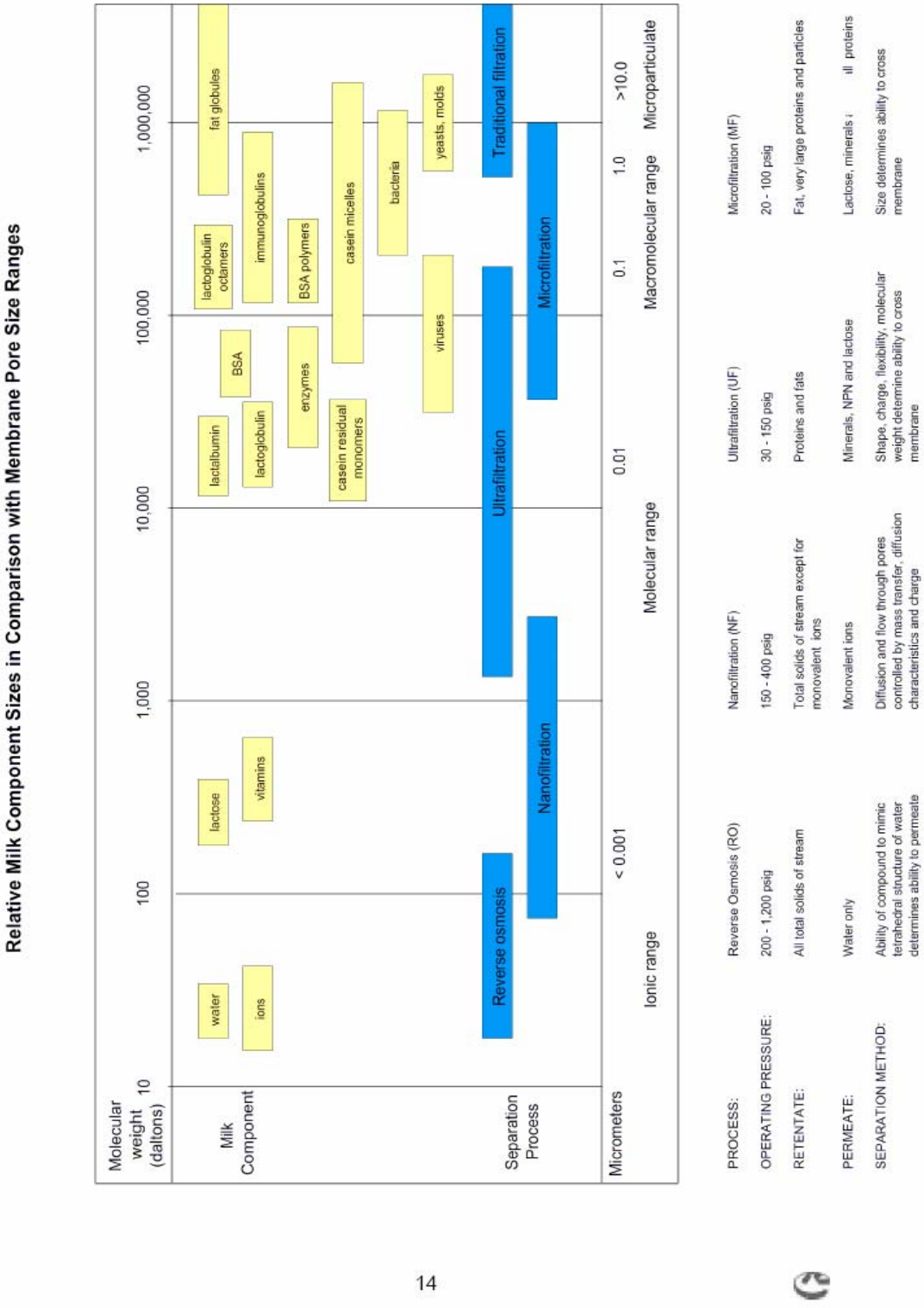
Our staff looks forward to providing the Agency with more detailed and comprehensive information as may be required to act, and to answer any questions you may have.

Respectfully submitted,

Cary Frye
Vice President,
Regulatory Affairs

cc: Constance Tipton, President & CEO IDFA

Appendix A: Smith K., Wisconsin Center for Dairy Research, Dairy Proteins, Relative milk component sizes in comparison with membrane pore size.



Appendix B:

Table 1: IICA Values to Calculate 2.95% Minimum Milk Protein Reference

Ingredient	Mean Protein (g)	Minimum Protein (g)
Dry Buttermilk	31.5	30
Sweet Dry Whey	12.75	11

Values expressed per 100 gram of product as is

Table 2: Nutrient Values for Dairy Products

Ingredient	Protein* (g)	Lactose (g)	Total Fat (g)	Moisture (g)
Nonfat Dry Milk	36 (34-37)	51 (49.5 - 52)	0.8 (0.6-1.5)	3.4 (3.0- 4.0)
Dry Buttermilk	32 (30-34)	48 (46.5-49)	5.0 (4.5 - 7.5)	3.5 (3.0-4.0)
Ultrafiltered nonfat milk 42%	42	46	0.8	3.5
Ultrafiltered nonfat milk 56%	56	31	1.2	3.8
Ultrafiltered nonfat milk 80%	82.8	4.1	1.8	3.9
Sweet Dry Whey	12 (11-14.5)	63-75	0.5-1.5	3.5-5.0
Whey Protein 34%	35 (34-36)	48-53	3.0 - 4.5	4.0
Whey Protein 50%	50 (50-52)	25-30	4.0 -6.0	4.0
Whey Protein 80%	79 (80-82)	4-8	4.0-8.0	4.0
Whey Protein Isolate	(90-92%	0.5-1.0	0.5 -1.0	4.5

Values expressed per 100 gram of product as is
*Protein is calculated as Nitrogen X 6.38%

Source: American Dairy Product Institute, USDEC 1977, and Phillip S. Tong Ph.D., California Polytechnic State University, presented to IDFA 2004 Cream Technology Conference

Table 3: USDA National Nutrient Database for Standard Reference Release 18

Ingredient	Protein (g)	Total Fat (g)	Moisture (g)
Nonfat Dry Milk	36.16	0.77	3.16
Dry Buttermilk	34.3	5.78	2.97
Sweet Dry Whey	12.93	1.07	3.19

Values expressed per 100 gram of product as is

Table 4: IDFA Nutrient Database for Nutritional Labeling - Accepted Values

Component	Protein (g)	Total Fat (g)
Per gram of milk fat	-	1.0
Per gram of nonfat milk solids (SNF)	0.39	-

Source: IICA Labeling Manual, 2004 edition