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December 27, 2005

The Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

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, Sherbet, and Water Ices (Advance Notice of Proposed Rulemaking)

Dear Sir/Madam:

These comments are submitted by Fonterra (USA), Inc., Lemoyne, Pennsylvania, a wholly-owned subsidiary of Fonterra Co-operative Group Limited ("Fonterra"), Auckland, New Zealand. Fonterra is a New Zealand based multinational dairy company that manufactures and exports dairy ingredients and consumer products to over 140 countries worldwide. Fonterra has a longstanding relationship with the U.S. market, as a supplier of quality dairy ingredients, and through the manufacture and export of dairy products produced in the United States from U.S. milk. In partnership with Dairy Farmers of America ("DFA"), Fonterra manufactures dairy products in ten sites across the United States, and its Portales, New Mexico facility was the first

U.S. plant to manufacture milk protein concentrate ("MPC"), the dry form of ultrafiltered ("UF") milk. Fonterra USA is headquartered outside Harrisburg, Pennsylvania.

In a Federal Register notice dated September 27, 2005, the Food and Drug Administration ("FDA") of the United States Department of Health and Human Services ("HHS") issued an advance notice of proposed rulemaking ("ANPRM") seeking comments regarding certain requested amendments to the FDA's Standards of Identity for ice cream and frozen custard, sherbet and water ices, as detailed in a petition filed by the International Ice Cream Association ("IICA"). *See Frozen Desserts: Petition to Revoke Standards for Goat's Milk Ice Cream and Mellorine and to Amend Standards for Ice Cream and Frozen Custard, Sherbet, and Water Ices; Petition to Amend Standards for Parmesan and Reggiano Cheese*, 70 Fed. Reg. 56,409 (Sept. 27, 2005) (Advance Notice of Proposed Rulemaking). These comments detail Fonterra's position regarding certain of the proposed amendments to the ice cream and frozen custard standards set forth in 21 C.F.R. Part 135, namely those that would revise the current standards to take into account the development of new dairy processing technologies, and the resulting products.¹

¹ The ANPRM also seeks comments regarding proposed amendments to the standard of identity for Parmesan and Reggiano cheese, as presented in an August 28, 2000 petition by Kraft Foods. Fonterra does not address the amendments proposed by Kraft Foods.

Overview

Developments in dairy processing technology have resulted in a notable expansion of ingredient options for the manufacture of ice cream. Manufacturers now have the ability to more precisely regulate and modify milk fractions and components, such as milk fat, milk proteins, milk sugars and minerals.

Filtration and other processes enable separation of either whole milk or skim milk into permeate (which consists of water and water soluble constituents including lactose, non-protein nitrogen, and ash), and retentate (which contains the casein and whey proteins in addition to remaining water phase constituents, and, if it is whole milk that is filtered, butterfat). Retentate is used in combination with milk, nonfat dry milk, or cream and other dairy ingredients, including milk permeate, to provide a concentrated form of milk solids that is high in protein and low in lactose. By varying the concentrations of filtered milk components, as well as other dairy ingredients, manufacturers can refine and improve the production process for ice cream, for example by utilizing better mix processing and freezing, which in turn creates better texture and consequently a more desirable ice cream.

This ability of processors to substitute different dairy products and to modify content levels of milk and dairy-derived ingredients is not adequately addressed by the existing ice cream standards. The proposed amendments would allow the use of currently accepted technologies and ingredients, while allowing sufficient flexibility for the development of new technologies

and ingredients in the future. At the same time, the proposal would ensure that the essential nature and nutritional composition of the ice cream is maintained.

In keeping with these evolving ingredient and processing technologies, the proposed use of general category designations for groups of nutritionally and functionally equivalent ingredients would adequately apprise consumers of product content, while simultaneously allowing manufacturers to take advantage of the types of innovations and technological capabilities described above. Accordingly, Fonterra supports the proposed changes to the ice cream and related standards and believes that their implementation would be advantageous to both consumers and manufacturers.

Current Standards - Definitions

Currently, the regulations setting forth the standards for ice cream and frozen custard (21 C.F.R. § 135.110) state in pertinent part:

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, 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 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...

(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 may be concentrated, and from which part or all 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., 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...

(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.

Current Standards - Labeling

The current labeling standard (21 C.F.R. § 135.110(g)) provides that:

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 the sources of 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....

The Proposed Amendments

As noted above, Fonterra supports the proposed amendments as they would allow manufacturers to pursue product innovation while ensuring product quality and nutritional composition. Fonterra offers the following specific comments in support of: (1) the specific

inclusion of filtered milk as an ingredient in ice cream and frozen desserts; (2) the general inclusion of any safe and suitable dairy derived ingredient in ice cream and frozen desserts; (3) inclusion in the ice cream and related standards of an "alternate make" provision; and (4) the labeling of ingredients based on categories that are functionally and nutritionally equivalent.²

1. Filtered milk is an appropriate ingredient in the making of ice cream and other frozen desserts.

Fonterra supports expanding the definition of "milk" to specifically include filtered milk in both liquid and dry form.³ While certain filtered milk is allowed pursuant to the current standards (*i.e.*, skim milk from which all or part of the lactose has been removed by filtration, a safe and suitable procedure), the revision of the definition of "milk" to specifically include filtered milk in all forms would simply allow the standard to catch up with existing technology.

² Fonterra does not offer specific comments on the remainder of the issues addressed by the ANPRM, in particular: the use of milk from source animals other than cows in the making of ice cream and frozen custard and sherbet; the removal of the requirements for the amounts of fruits, fruit juices and nutmeats needed to determine if an artificial flavor simulating a characterizing flavor is the predominate flavor when naming an ice cream or frozen dessert product, and providing that the manufacturer may determine whether the natural or artificial flavor ingredients provide the characterizing flavor of the product for the purposes of labeling; the removal of restrictions on ingredients in goat's milk ice cream; and the use of a 2-percent minimum level of fruit content in sherbet. *See* 70 Fed. Reg. at 56,411.

³ Pursuant to the proposed amendments, "[m]ilk 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." 70 Fed. Reg. at 56,413. (emphasis added). "Milk-derived ingredients" is defined by the proposed amendment to mean "any ingredient derived from milk or any component or fraction of milk, such as milkfat, milk proteins defined in 135.3(e), milk sugars and minerals. *Id.* "Milk-derived protein means casein and/or whey protein(s) and its constituents, fractions, hydrolysates or polymers derived from milk." *Id.*

Historically, milk was manufactured into cheese and cream based products. The skim milk and whey from the cheese were considered by-products and used as feed. As more value was attributed to the non-fat solids component of milk, the industry started to manufacture skim milk powder ("SMP") and whey powder by simply removing water by evaporation and drying.

Commercially, protein can be isolated from milk by precipitation, which is the technology used to produce casein. This involves the addition of one or more acids, enzymes, and/or heat to precipitate the protein, which is then recovered by physical separation processes such as screening or decanting. In this form, the protein is insoluble in water, so acid casein is often further processed to caseinate, which is a soluble and very functional form of casein.

Use of membranes as a separation technology in the dairy industry first occurred in the late 1960s. By the mid 1970s, ultrafiltration had been established for the production of whey protein concentrates ("WPC") with protein levels between 34 and 75 percent. By the early 1980s, the value of membrane processing for both separation and concentration were widely recognized.

Capitalizing on the success with ultrafiltered whey proteins, the technology was applied to the separation of milk proteins as an alternative to the traditional casein and caseinate technology. Not only did this eliminate many of the effluent issues created by the use of acids and alkalines in casein/caseinate production, but as the technology developed it was found that milk could be ultrafiltered cold, which left the protein in a more functional state than the more

aggressive earlier manufacturing technologies. The development of membrane filtration technology for the isolation of milk proteins has led to the development of a wide range of protein ingredients whose suitability for use in ice cream was highlighted in the recent International Trade Commission ("ITC") report *Conditions of Competition for Milk Protein in the U.S. Market*, Investigation No. 332-453, USITC Pub. 3692 (May 2004).

Specifically, the ITC found that:

Ice cream and other frozen deserts, and yogurt and other cultured products, require both casein and whey protein. Ice cream requires the casein proteins for its emulsifying properties, and the whey protein for its water-binding properties. Yogurt requires the casein protein for gel formation and the whey protein for its water-binding properties. However, for both ice cream and yogurt, a complete milk protein (such as SMP or MPC) is better than using a casein protein and a whey protein separately (such as casein or caseinate and WPC). Since casein is not readily soluble, it is not widely used in the production of ice cream and yogurt. The presence of alkali in caseinates makes them a less desirable ingredient than a complete milk protein. Higher-protein WPC in ice cream production would result in too much gel formation. As a result of these technical problems, a MPC, in particular a MPC produced using the ultrafiltration method, is considered a superior ingredient to other forms of milk proteins in ice cream and yogurt production. Academic experts consulted by Commission staff indicated that such a MPC would be a superior ingredient to SMP in the production of ice cream and yogurt.⁴ Since high lactose levels lower the freezing point of ice cream, complicating the production process and storage of the finished product, the low lactose levels available in MPC are attractive for the production of ice cream and yogurt.

Interviews with these experts indicated that the main reason MPC is not used in ice cream and yogurt production are regulatory restrictions that limit the use of MPC in these products. In the case of yogurt, the current FDA standards of

⁴ Mr. Thomas Palchack, Dr. John Flores, and Dr. Bob Roberts, Pennsylvania State University, interview by USITC staff, July 22, 2003.

identity allow for the use of MPC in the production process.⁵ However, regulations require that any dairy ingredient used in the production of yogurt be a Grade A product as determined by the U.S. Department of Agriculture (USDA), and currently MPC does not have Grade A status.^{6 7}

See USITC Pub. 3642 at 7-13-14.

Fonterra has directed considerable resources to exploring the impact of using UF milk and milk protein concentrates in ice cream and frozen desserts and has reached similar conclusions, namely that these ingredients, in either liquid or dry form, are appropriate and valuable additions to ice cream and frozen desserts. Use of UF milk and MPCs does not affect the basic nutritional character of the final product and can enhance desirable characteristics, such as texture and mixability. Ice cream made with these products easily comports with consumer expectations, and does not diminish satisfaction with the product.

2. Manufacturers should be permitted to use any safe and suitable milk-derived ingredients in the production of frozen desserts.

The proposed amendments would also update the definition of "ice cream" to permit the

⁵ Food Standards & Labeling, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration staff, interview with USITC staff, Dec. 8, 2003.

⁶ Industry and academic experts consulted by Commission staff indicated that a MPC produced using the ultrafiltration process would be a superior product to MPC produced via blending or co-precipitation for the production of ice cream and yogurt. The ultrafiltration process leaves the proteins in their native state, while the production process of blended or co-precipitated MPC requires chemical and/or heat treatments that can alter the proteins' chemistry thereby altering their functionality.

⁷ We would note that Grade A MPC is now available from domestic U.S. production.

use of "any safe and suitable milk-derived ingredient." 70 Fed. Reg. 56,412.⁸ By adopting this amended language, FDA would again further the goal of promoting innovation that could result in a superior product at a lower cost without altering its fundamental characteristics.

While the current standards allow for the use of a wide range of milk-derived ingredients such as casein, whey,⁹ and hydrolyzed milk proteins, both the listing of specific products and the limitations on their use are counterproductive. The flexibility offered by the proposed amendments would make clear, for example, that milk permeates could be used as an ingredient in formulating ice cream.

Any concern that allowing the use of the full range of safe and suitable dairy derived ingredients could result in the economic degradation of ice cream is addressed by the amendment's proposed adoption, within a sliding scale, of minimum content requirements for the two most valuable components of ice cream – fat and protein. This is a more straightforward and easily measurable standard for ice cream and frozen dessert fat and protein content than exists at present.

⁸ The proposed language would define ice cream as "produced by freezing, while stirring, a pasteurized aerated mix *consisting of safe and suitable milk derived ingredients, alone or in combination...*" 70 Fed. Reg. at 56,413. (emphasis added).

⁹ In keeping with Fonterra's support for a manufacturer's ability to use any safe and suitable ingredient, Fonterra also supports the proposed amendment removing the maximum 25 percent restriction on whey solids in ice cream and frozen custard.

3. Permitting the use of "alternate make" procedures in the manufacture of ice cream, frozen yogurt and sherbet would encourage the expansion of innovative uses of dairy products.

Fonterra also supports the proposed amendment to the current standards that would permit the manufacture of ice cream by any procedure which produces a finished product which has essentially the same physical and chemical characteristics as the product produced by the standard make procedure. Everyone would benefit from this proposed amendment. Consumers would enjoy the benefits and cost savings of the innovations encouraged by this proposal, but at the same time be safeguarded by the requirement that the resultant product have the same essential characteristics of ice cream manufactured under the current standard. Manufacturers would have the flexibility they need to pursue innovations that enhance their products and update or streamline manufacturing processes.

Current FDA standards for production of cheese include an "alternate make" provision that has enabled cheese manufacturers to make improvements in their production process, while simultaneously maintaining the quality and characteristics of their cheese products. Such a provision would operate similarly with respect to ice cream and frozen dessert production.

Fonterra agrees with the comment offered by the International Dairy Foods Association which recommends omitting a requirement in the proposed language that the product resulting from the alternate make process share organoleptic properties with product made through more

"traditional" processes.¹⁰ Such a standard would be subjective and is not necessary as long as there is physical and chemical (including nutritional) comparability. Indeed, it may be that the purpose of an innovation would be to improve an organoleptic property, such as the texture of an ice cream or frozen dessert, in which case there would be an intentional difference between the traditional and alternate make products. The assurance that a consumer needs, and that the amendment would require, is that the chemical and nutritional content is essentially the same. Ultimately, products that consumers do not find to be organoleptically appealing will not be successful.

4. The establishment of categories of ingredients to be declared on labels under common names for ice cream and frozen custard would meet consumer needs and create more efficient labeling procedures for producers.

Fonterra supports the proposal to establish categories of ingredients for labeling purposes. This practice would allow manufacturers to adjust their use of ingredients within a functionally and nutritionally equivalent category, without costly label modifications that would increase the cost of the product to consumers.

Use of the category names described in the proposed amendments would not mislead or confuse consumers. The selection of one ingredient in a category over another would not result in consumer misunderstanding regarding the content and nutritional characteristics of the product, since the ingredients included in each category are functionally and nutritionally

¹⁰ The proposed language states: "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." 70 Fed. Reg. at 56,414.

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equivalent when used in frozen desserts. Use of categories could even enhance consumer understanding, since the common category names would likely have greater recognition among consumers than the particular ingredients included in the category.

We appreciate the opportunity to present these views on behalf of Fonterra, and encourage the FDA to proceed with rulemaking based on the IICA's proposed amendments.

Sincerely,

A handwritten signature in black ink that reads "Edward J. Farrell". The signature is written in a cursive style with a vertical line separating the first and last names.

Edward J. Farrell

EJF:vsf