CHEESES AND RELATED CHEESE PRODUCTS: PROPOSAL TO PERMIT THE USE OF ULTRAFILTERED MILK	Docket No. 2000P-0586
Food and Drug Administration of the United States Department of Health and Human Services	

AFFIDAVIT OF NANA FARKYE, PH.D.

I, Nana Farkye, do hereby depose under oath as follows:

1. I am over the age of 18, have personal knowledge of the facts cited herein, and am competent to testify.

2. I am a dairy food scientist. Since 1990, I have been a professor in the Dairy Science Department at California Polytechnic State University. Much of my research is focused on Dairy Chemistry and the Chemistry and Technology of Cheese Manufacture and Ripening. In addition to the more than 100 book chapters, review articles, refereed journal publications, abstracts and presentations that I have authored over the last twenty years, I have also been a cheesemaker and dairy plant operator, and hold a number of U.S. and foreign patents related to cheesemaking. A copy of my curriculum vitae is attached hereto as Exhibit A.

3. I have conducted research and authored numerous publications concerning the manufacture and ripening of Cheddar, Mozzarella, lower-fat cheeses, Hispanic and Specialty cheese, the influence of storage on properties of milk powder, the use of milk powder in cheese and yogurt manufacture, and the properties of cheese powders. Among the publications I have authored are recent articles detailing my research specifically

relating to the use of liquid and dry milk protein concentrate in various cheeses, reduced-fat Cheddar cheese, pizza cheese and Mozzarella cheese.

4. I have reviewed the proposed rule entitled *Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk*, 70 Fed. Reg. 60,751 *et seq.* (Oct. 19, 2005). Of particular relevance to the proposed rule are the following publications that I have authored:

> Shakeel-Ur Rehman, Farkye, N.Y., and Drake, M.A. 2003. Reduced-fat Cheddar cheese from a mixture of cream and liquid milk protein concentrate. Int. J. Dairy Technol. 56(2):94-98. (Attached as Exhibit B).
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> Shakeel-Ur-Rehman, Farkye, N.Y., Considine, T., Schaffner, A.A., and Drake, M.A. 2003. Effects of standardization of whole milk with dry milk protein concentrate on the yield and ripening of reduced-fat Cheddar cheese. J. Dairy Sci. 86:1608-1615. (Attached as Exhibit C)
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> Shakeel-Ur-Rehman, Faryke, N.Y. and Yim, B. 2003. Use of dry milk protein concentrate in pizza cheese manufactured by culture or direct acidification. J. Dairy Sci. 86:3841-3848. (Attached as Exhibit D).
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> Shakeel-Ur-Rehman and Farkye, N.Y. 2006. Effect of setting pH on the properties of Mozzarella cheese made by direct acidification of whole milk standardized with dry milk protein concentrate. Australian J. Dairy Technol. In press. (Attached as Exhibit E).

5. Based on my research and experience, I offer the following comments regarding the proposed rule, and in particular, the proposed rule's authorization to use liquid ultrafiltered ("UF") milk in cheese production, but not dry UF milk or liquid or dried filtrates from other membrane filtration processes, such as microfiltration ("MF").

The Composition of Milk

6. One hundred pounds of raw bovine milk contains about 12.6 pounds of milk solids and 87.4 pounds of water. The milk solids consist of about 4.0 pounds of fat and 8.6 pounds of solids-not-fat that is made up of 3.2 pounds milk proteins, 4.7 pounds lactose and 0.7 pounds minerals. The milk proteins consist of 2.5 pounds casein and 0.6

pounds whey proteins – giving a casein to whey protein ratio of 1 part casein to 0.25 parts whey proteins. Caseins represent approximately 80% of the total protein in milk and whey proteins represent approximately 20%.

7. Removal of fat from milk by mechanical separation results in skim milk and cream. Skim milk powder ("SMP") (or nonfat dry milk) is produced from skim milk by vacuum evaporation of water from the skim milk to about 45-55% dry matter followed by drying of the concentrate by spray or drum (roller) drying methods. The ratio of casein to whey protein in skim milk powder is similar to that of skim milk.

8. Milk Protein Concentrates ("MPC") are broadly defined as concentrated milk proteins without specifications for the method of production, which may be by chemical or physical separation technologies. Physical separation by membrane filtration technologies (e.g., ultrafiltration or microfiltration) of skim milk or whole milk gives a liquid retentate that can be subsequently dried to give MPC. MPC may also be produced by blending caseins, caseinates, and whey proteins in different proportions that are chemically separated from milk (by acidification and/or enzymatic treatment of milk) followed by concentration and subsequent drying. However, for purposes of this affidavit, when I use "MPC" I refer only to products produced by membrane filtration and drying.

9. The concentrations of caseins and whey proteins in MPC produced by ultrafiltration are proportional to the concentration in original milk. However, MPC has relatively lower concentrations of lactose and higher concentrations of calcium than normal milk. Microfiltration ("MF") results in MPCs with casein to whey ratios that may differ from that occurring in the original milk. Other membrane processes include

nanofiltration ("NF") which is used to remove water and small ions, and reverse osmosis ("RO") which is used to remove water from milk. The milk components retained by the various membrane processes are given in Table 1.

Table 1. Milk components retained by various membrane processes

Process	**Molecular weights of retained components**	**Retained components**
Reverse Osmosis (RO)	<100	Everything except water
Nanofiltration (NF)	<100-1,000	Everything except water and some ions
Ultrafiltration (UF)	<1,000-100,000	Proteins, lipids, microorganisms
Microfiltration (MF)	<100,000-500,000	Proteins, lipids, microorganisms, high molecular weight components

10. I have conducted research that characterized two commercial dry milk protein concentrates – MPC65 (Main Street Ingredients, La Crosse, WI) and ALAPRO 4700 (Fonterra, PA; formerly New Zealand Dairy Board, Santa Rosa, CA) and reported protein contents of 65 and 70%, respectively. Srinivasan and Farkye (unpublished results, 1999). The percent calcium in MPC65 and ALAPRO 4700 were 1.9 and 2.2%, respectively (Table 2). The casein contents of the respective MPC were approximately 82 and 79% of the total nitrogen ("TN"). This is similar to whole milk, skim milk and SMP in which casein represents approximately 80% of the total protein in milk. The casein in MPC obtained by membrane filtration is native or micellar casein that has its normal structure in milk and contains calcium levels similar to that in milk. This property makes MPC manufactured by membrane filtration technologies uniquely different from MPC produced by blending caseinates and whey proteins.

Table 2. Chemical composition of commercial dried milk protein concentrate and skim milk powder.

Component (%)	MPC 65	ALAPRO 4700	SMP[a]
Protein (TN × 6.38)	65.0	70.0	36.16
Casein	53.44	55.63	28.93[b]
Non-casein nitrogen	0.033	0.028	
Fat	1.3	1.4	0.77
Sodium	0.22	0.3	0.45
Calcium	1.91	2.2	1.25

[a]USDA www.nal.usda.gov/fnic/foodcomp/search/
[b]By calculation (80% of total protein)

11. Electrophoresis of proteins in both MPC65 and ALAPRO 4700 revealed a ratio of casein to whey protein of 80:20 – which is similar to that in milk. The ratios of $\alpha_{(s1 + s2)}$: β: κ-casein were 4.4:2.8:0.8 and 3.7:3.3:0.8, respectively for MPC 65 and ALAPRO 4700 (Table 3). The respective ratios of the individual caseins in the MPC were similar to their ratios in milk.

Table 3. Proportions of individual caseins and whey proteins in milk protein concentrate.

Proportions of proteins	MPC65	SEM[1]	ALAPRO 4700	SEM[1]
	(% Total N)			
α_s-casein (α_{s1}-+α_{s2}-)	43.8	0.45	36.6	0.18
β-casein	28.0	0.34	33.1	0.20
κ-casein	8.2	0.13	7.9	0.23
Bovine Serum Albumin	< 1.0	--	< 1.0	--
β-lactoglobulin	16.2	0.18	18.4	0.10
α-lactalbumin	3.8	0.16	3.1	0.11

[1]SEM = standard error of mean

12. When MPC is used in cheesemaking, it will most likely be used in lieu of SMP or condensed skim milk ("condensed skim") for fortification of milk. Unpublished research by Srinivasan and Farkye (1999) showed that dry MPC (MPC65) has a whey protein nitrogen index (WPNI) of ~15 mg/g – indicating a low-heat treatment during manufacture and making it comparable to the standard of > 6 mg/g for low-heat SMP.

WPNI expresses the amount of undenatured whey proteins and is a measure of the sum of heat treatments given to milk prior to evaporation and spray drying. High-heat SMP has a WPNI index of less than 1.5, indicating high heat treatment. The WPNI levels observed are in the same range as those of UF nonfat milk currently being sold for cheesemaking.

Cheesemaking

13. In the conversion of milk into Cheddar cheese, milk constituents are separated into 2 groups – those that are retained in the cheese and those that are lost in the whey (Table 4). The solids components of milk most important to cheese are casein and fat. Whey proteins do not play a role in cheesemaking as most of the whey proteins are lost during traditional cheesemaking.

Table 4. Separation of milk constituents during Cheddar cheese manufacture

Constituent	Milk (lb)	Cheese (lb)	Whey (lb)
Water	87.4	3.70	83.70
Lactose	4.7	0.40	4.30
Fat	4.0	3.70	0.30
Casein	2.5	2.40	0.10
Whey Proteins	0.7	0.05	0.65
Minerals	0.7	0.35	0.35
Total	100.0	10.60	89.40

14. Standardized cheeses must meet legal requirements for fat and moisture, therefore the composition of the milk for cheesemaking must be standardized. The components most often adjusted are the casein and fat contents. Standardization is achieved by: (1) the addition or removal of fat as cream; or (2) the addition of casein (in the form of skim milk, condensed skim, or SMP).

15. Standardization by cream removal requires major capital investment in the acquisition and installation of a cream separator which may be a costly investment expense for small to medium-size cheese plants. Cream can be blended with UF nonfat milk for cheesemaking (Shakeel-ur Rehman et al., 2003) (*see* Exhibit B). However, this is not a normal practice. Most plants prefer standardization by increasing casein content. Traditional methods for increasing the casein content of cheese milk are to add known amounts of skim milk, SMP or condensed skim. The drawback of adding SMP and condensed skim is that they contain high levels of lactose which are lost in the whey and pose disposal problems. Similarly, condensed skim contains high lactose content and presents the same drawback as using SMP. Hence standardization with MPC is an attractive alternative to using SMP or condensed skim because of the relatively high protein and low lactose content of MPC and UF nonfat milk. In such a process, MPC would perform in exactly the same manner as UF nonfat milk.

16. The use of UF milk may be desirable for large scale manufacturing plants that can afford the investment of installing membrane filtration systems on site. Those that do not have in-house filtration systems can purchase UF milk from external sources who sell by the truck load (i.e., 50,000 lb quantities). For small and medium scale manufacturers, however, the purchase of such quantities poses both economic and logistic problems. Economically, purchasing a truck load of UF milk is like purchasing three truck loads of milk. Logistically, the plant may not have enough storage for this volume of product, which has a shelf life similar to that of raw milk. Therefore, the most practical approach is to use MPC.

17. The use of MPC in the manufacture of Cheddar and Mozzarella cheeses has been researched (Shakeel-ur Rehman et al., 2003; Shakeel-ur-Rehman and Farkye, 2006) (*see* Exhibits C-E) with successful results. Shakeel-ur-Rehman et al. (2003) (*see* Exhibits C and D) showed that the quality of reduced-fat Cheddar cheese and Mozzarella cheese made from whole milk standardized with MPC was similar to corresponding cheeses made from whole milk standardized with skim milk. The cheesemaking properties of the standardized milks were similar. The flavor and body of reduced-fat Cheddar cheese made with whole milk standardized by MPC was similar to that made from whole milk standardized with skim milk. Also, the functional properties (melt and baking properties) of Mozzarella and pizza cheese made from whole milk standardized with MPC was similar to that made using whole milk plus skim milk. Fortification of whole milk with MPC produced higher cheese yields and reduced cheesemaking costs per vat making it profitable to the cheesemaker.

18. The use of MPC benefits both consumers and manufacturers by:

a. Ease of use – The MPC product easily dissolves in milk or can be reconstituted in water before adding to milk. It provides additional savings in capital cost for small and medium size processors who do not have to have membrane processing facilities onsite.

b. Providing economic advantages – Use of MPC is economical because processors do not have to buy truck loads of liquid product from manufacturers at a time. By using the dry product, they purchase what they need. Also, storage of the liquid product increases costs because the product has to be kept refrigerated. Furthermore, if the product is not used within a

few days of receipt, it will not be suitable for use in cheesemaking and would have to be disposed of – leading to additional economic loss.

c. Improved cheese yield and cheesemaking costs – Standardization of milk with MPC results in higher cheese yields (lb cheese per lb of standardized milk) than either traditional cheesemaking processes or standardization with nonfat UF milk, leading to reduced labor cost per vat of cheese made.

d. Reduced whey volume and whey disposal – When MPC is added directly to milk for cheesemaking, the resultant volume of whey is reduced compared to using nonfat UF milk or skim milk for standardization. Also, the resultant whey produced has reduced lactose content due to the low lactose content of MPC. Because most small to medium scale cheese producers do not have facilities to concentrate and dry lactose, they will have lower whey disposal costs because of the reduced volume of whey and reduced lactose content. Because of the protein and high lactose content of whey, improper disposal creates environmental concerns with increased Biological Oxygen Demand (BOD) and Chemical Oxygen Demand (COD) in wastewater/sewer.

e. Maintaining composition and nutritional content of the cheese – Use of MPC does not result in any reduction in the quality or nutritional value of the cheese as compared to the use of liquid UF milk. Indeed, in some cheeses, the nutritional quality of the cheese is improved because of the high calcium, high protein and low lactose content in both MPC and UF milk. UF milk/MPC is healthier; it contains lower levels of sodium than normal milk (Table 2). In fresh, soft high-moisture cheeses that generally contain higher levels of

lactose than hard cheeses, the use of UF milk/MPC should appeal to lactose-intolerant consumers because of the low lactose levels in these products.

19. The use of MF milk, either in liquid or dry form, benefits both consumers and manufacturers by:

- Improving cheesemaking efficiency and reducing cheesemaking costs for manufacturers that can be passed on to consumers as reduced cheese cost.
- Providing high quality protein – the essential amino acid content of milk and cheese give them a high biological value. MF milk contains high levels of casein which contains higher levels of essential amino acids than the total protein in milk (Table 5).

Table 5. Concentration of essential amino acids in milk, casein/MF milk and reference standards (mg per g of nitrogen)

Amino acid	**Milk**	**Casein/ MF Milk**	**Reference Protein (FAO, 1973)**
Isoleucine	295	345	250
Leucine	596	607	440
Lysine	487	518	340
Methionine + cystine	208	201	220
Phenylalanine + tyrosine	633	705	380
Threonine	278	297	250
Tryptophane	88	103	60
Valine	363	430	310

I solemnly affirm under penalties of perjury that the contents of the foregoing Affidavit are true and correct.

1/12/06

Date

Nana Farkye

Subscribed to and sworn before me this 12th day of January 2006, by Nana Farkye, personally known to me or proved to me on the basis of satisfactory evidence to be the person who appeared before me.

Angela Borin

Notary Public

My commission expires:

November 20, 2009

ANGELA BORIN
Commission # 1615572
Notary Public - California
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My Comm. Expires Nov 20, 2009