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

Re: Docket No. 2000P-0586, Cheeses and Related Cheese Products:
Proposal to Permit the Use of Ultrafiltered Milk

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 for domestic sale 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"). Within the

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next few months United Dairymen of Arizona ("UDA") and Fonterra will begin production of MPC outside of Phoenix, Arizona. Fonterra USA is headquartered outside Harrisburg, Pennsylvania.

In a Federal Register notice dated October 19, 2005, the Food and Drug Administration ("FDA" or "Agency") of the United States Department of Health and Human Services ("HHS") published a proposed rule to amend FDA's regulations to provide for the use of fluid ultrafiltered milk ("UF") in the manufacture of standardized cheese and related cheese products (21 C.F.R. § 133). The proposed amendments arise from a petition filed by the American Dairy Products Institute ("ADPI") and another submitted jointly by the National Cheese Institute ("NCI"), the Grocery Manufacturers of America, Inc. ("GMA"), and the National Food Processors Association ("NFPA"). *See Cheese and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk*, 70 Fed. Reg. 60,751 (Oct. 19, 2005) (Proposed Rule). These comments detail Fonterra's position regarding the proposed amendments to the definitions of "milk" and "nonfat milk" set forth in 21 C.F.R. § 133(a) and (b) respectively, namely those that would revise the current definitions to allow for the use of liquid ultrafiltered milk and liquid ultrafiltered nonfat milk in the manufacture of standard of identity cheese.

In brief, Fonterra supports FDA's conclusion that the basic nature and essential characteristics of cheese are maintained when fluid ultrafiltered milk is used in the cheesemaking process. However, Fonterra believes that there is no justifiable basis for distinguishing between the use of liquid UF milk and dry UF milk in cheesemaking - the basic nature and essential

characteristics of cheese are maintained whether the ultrafiltered milk used is liquid or dry. Moreover, Fonterra believes that based on sound food science and technology, FDA should harmonize with the international standards adopted by the Codex Alimentarius Commission ("Codex") that allow the use of any milk and/or products obtained from milk in cheesemaking, so long as the cheese produced is equivalent to that produced using traditional methods. Further, the Agency's proposed requirement for ingredient labeling of UF milk and UF nonfat milk, separate and distinct from labeling for milk, would create an onerous burden on cheesemakers, with no offsetting benefit to consumers or anyone else. Finally, the cost benefit analysis prepared in conjunction with the proposed rulemaking fails to consider a number of factors which are particularly relevant to the cost savings in the use of liquid UF milk, and, more notably, in the use of dry UF milk. The economic analysis also fails to consider the extraordinarily disproportionate impact that creating a distinction between liquid and dry UF milk would have on small cheesemakers.

Overview

Fundamental to an understanding of the use and function of UF milk and other milk-derived ingredients in cheesemaking is an appreciation of the fact that cheesemaking is, at its core, a separation technology. In traditional cheesemaking processes, this separation is accomplished by the draining of whey from the curd following coagulation/precipitation of casein, but membrane processing has revolutionized cheesemaking and has led to a whole range of new processes to effect this separation. These developments have also resulted in a notable

expansion of ingredient options for the manufacture of cheese. 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.

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 was widely recognized.

Capitalizing on the success with ultrafiltered whey proteins, the technology was applied to the separation of milk proteins as an alternative to traditional casein and caseinate manufacturing technology. Not only did this eliminate many of the effluent issues created by the use of acids and alkalis 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 cheese 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).¹ Specifically, the ITC found that:

Technical factors

The presence of high levels of lactose in many dairy products is problematic for manufacturers. In interviews with Commission staff, industry and academic experts stressed the importance of controlling the amount of lactose present during the manufacturing of both natural and processed cheese.² Excess lactose reacts with water to form crystals, results in poor cooking and melting properties, and over time, may alter the color, flavor, and consistency of the product.³ Industry experts noted that MPC produced using the ultrafiltration process is a superior ingredient to SMP in cheese manufacturing. MPC has similar solubility, color, and flavor characteristics as SMP, but has less lactose. The use of MPC allows for protein standardization without the addition of large amounts of lactose. In conjunction with this advantage, the use of MPC could increase both yield and throughput in the production of natural cheese.⁴

¹ In its preamble discussion of the proposed rule not a single reference is made to this study, the most comprehensive ever undertaken on this subject. FDA's analysis would have benefited significantly from a review of this study and the record developed by the ITC in its investigation. We would urge the FDA to review these materials as it considers a final rule.

² Dr. David Barbano, Cornell University, interview by USITC staff, July 21, 2003; Dr. Tom Flores, Pennsylvania State University, interview by USITC staff, July 22, 2003; company official, Kraft Foods, interview by USITC staff, July 23, 2003. Wisconsin Center for Dairy Research staff, presentation to USITC staff, Aug. 20, 2003. (internal citation).

³ Academic experts consulted by the Commission indicated that excess lactose levels may be of more concern in natural cheeses than in processed cheese products. The reactions that cause the lactose to alter the color, flavor, and consistency of the cheese occur over time and are not instantaneous. The production process for many natural cheeses includes an aging process. It is during this aging process that the unwanted reactions can occur. Processed cheese products that are used rapidly, either as an ingredient in other products or shipped to the retail market, may be consumed before these unwanted reactions can occur. Dr. David Barbano, Cornell University, interview by USITC staff, July 21, 2003; Dr. Mark Johnson, Wisconsin Center for Dairy Research, presentation to USITC staff, Aug. 20, 2003. (internal citation).

⁴ In cheese manufacturing, yield gains refer to the ability of the cheese manufacturer to produce more cheese from the same starting amount of milk, while throughput gains refer to the ability of the cheese manufacturer to produce more cheese by adding more ingredients and recovering the additional ingredients in the cheese, as opposed to the additional ingredients flowing out in the whey stream. (internal citation).

Natural cheese

Although the use of MPC is generally not permitted in the production of natural cheese, current FDA regulations and enforcement policy do not prohibit the use of UF milk. As a result, U.S. manufacturers of natural cheese are taking advantage of the beneficial properties of UF milk, which, like MPC, has lower levels of lactose than SMP. The use of UF milk can also increase yield and throughput in a manner similar to MPC. Some cheesemakers use UF milk purchased from third-party suppliers, while others have installed ultrafiltration equipment in their cheese plants, and the UF process is part of the entire cheese-making process.

Both industry and academic experts interviewed by Commission staff noted that MPC produced using the ultrafiltration method would function differently in the cheese-making process than MPC produced via blending or co-precipitation. In particular, experts doubted whether a blend or co-precipitate MPC would function properly in the natural cheese production process because of concern regarding the solubility and flavor; and in the case of a blend MPC produced from caseinates, because of the presence of alkalis.⁵

Processed cheese

Unlike natural cheeses, FDA regulations do not prohibit the use of MPC in processed cheese products. Processed cheese manufacturers may prefer to use MPC rather than UF milk because of important differences in the production processes between natural and processed cheese. The production process for natural cheese begins with liquid milk, so these production facilities have the infrastructure to store and process large volumes of liquid ingredients. In contrast, the production process for processed cheese begins with natural cheese (ingredient cheese or barrel cheese) as the primary ingredient. Processed cheese facilities may not have the capability to store and process large quantities of liquid ingredients. Therefore, the ability of

⁵ Dr. David Barbano, Cornell University, interview by USITC staff, July 21, 2003; Dr. Tom Flores, Pennsylvania State University, interview by USITC staff, July 22, 2003; Company official, Kraft Foods, interview by USITC staff, July 23, 2003; Wisconsin Center for Dairy Research staff, presentation to USITC staff, Aug. 20, 2003. (internal citation).

these processed cheese facilities to use UF milk is limited without significant new capital investment.⁶

See USITC Pub. 3692 at 7-10-11.

Clearly the 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 cheese standards. Amendments should be adopted to allow the use of current technologies and ingredients (e.g., dry and liquid UF milk) and emerging technologies (e.g., microfiltration), while maintaining the essential nature and nutritional composition of cheese. Sound regulatory policy dictates the provision of sufficient flexibility to allow for the use of emerging technologies and milk-derived ingredients in cheesemaking. Such revisions to the cheese and related standards would be advantageous to both consumers and manufacturers, and be consistent with the international standards adopted by other countries with whom U.S. cheesemakers compete.

The Proposed Definition of Milk and Nonfat Milk

As noted above, Fonterra supports the expansion of the definitions of "milk" and "nonfat milk" to allow manufacturers to pursue product innovation while ensuring the quality and nutritional composition of cheese. To this end, Fonterra supports permitting the use of UF milk in both liquid and dry ("MPC") forms,⁷ as well as other milk ingredients, liquid or dry, derived

⁶ Dr. David Barbano, Cornell University, interview by USITC staff, July 21, 2003; company officials, Kraft Foods, interview by USITC staff, July 23, 2003. (internal citation).

⁷ As evidenced by the ITC discussion quoted above, the term "MPC" is applied variously to products of ultrafiltration, precipitation, enzymatic action, and blending. However, for purposes of this submission the term "MPC" is limited to products produced by membrane filtration and drying.

through membrane separation in the manufacture of cheese. The proposed rule starts down this path but does not go far enough. Specifically, pursuant to the proposed rule, "*milk*" would mean

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, reconstituted milk, and dry whole milk. Water in a sufficient quantity to reconstitute concentrated and dry forms may be added. For the purposes of this part, wherever the term "*milk*" appears in the individual standards for cheeses and related cheese products, ultrafiltered milk as described in paragraph (f) of this section, may be used.

70 Fed. Reg. at 60,769. "*Nonfat milk*" would be defined as

skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added. For the purposes of this part, wherever the term "*nonfat milk*" appears in the individual standards for cheeses and related cheese products, ultrafiltered nonfat milk as described in paragraph (g) of this section, may be used.

Id. "*Ultrafiltered milk*" would mean raw or pasteurized milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein:whey protein ratio of the milk and resulting in a liquid product," and "*ultrafiltered nonfat milk*" would mean raw or pasteurized nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein:whey protein ratio of the nonfat milk and resulting in a liquid product." *Id.*

1. UF milk, in both liquid and dry forms, is an appropriate ingredient in the making of cheese.

- A. FDA's proposed rule is flawed in that it fails to consider the option of allowing both fluid and dry UF milk

In the preamble to the proposed rule, FDA identified the substantive options that it considered in formulating the proposed rule:

- (1) denying the two petitions,
- (2) proposing to permit the use of all fluid forms of filtered milk,
- (3) proposing to permit the use of all fluid and dried forms of filtered milk, and
- (4) proposing to permit the use of fluid UF milk.

See 70 Fed. Reg. 60,755.

Remarkably absent from the FDA's analysis was a fifth, and obvious option: proposing to permit the use of **all fluid and dried forms of UF milk**. Making FDA's omission even more puzzling are two facts. The first is the inclusion of exactly this option in its cost benefit analysis. *See* 70 Fed. Reg. 60,763 ("Option 2: Allow fluid and dry UF milk in standardized cheese production"). The cost benefit analysis found that Option 2 provided even greater benefits with regard to increasing shelf-life, decreasing transportation costs, balancing seasonal imbalances, and offsetting the volatility of fresh milk prices, than milk or fluid UF milk. *See* 70 Fed. Reg. at 60,763. The second is the fact that both the proposed and current definitions of milk and nonfat milk include the dry form of all products included in the definitions, except for UF milk. Thus

dry concentrated milk, dry reconstituted milk, dry whole milk, and dry nonfat milk are all permitted. What makes dry UF milk somehow different is never explained..

According to the Administrative Procedure Act ("APA"), a reviewing court must "hold unlawful and set aside agency actions, findings, and conclusions found to be... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law..." 5 U.S.C. § 706(2). An agency rule is arbitrary and capricious if, among other things, it fails "to consider an important aspect of the problem" or "offer[s] an explanation for its decision that runs counter to the evidence before the agency". *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. 29, 43 (1983). An agency "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual*, 463 U.S. at 43 quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962).

In considering whether an agency acted in an arbitrary and capricious manner, a court must review the administrative record to "ensure that agency decisions are founded on a reasoned 'evaluation of the relevant factors.'" *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989). "The agency must make findings that support its decision, and those findings must be supported by substantial evidence." *Burlington Truck Lines Inc. v. United States*, 371 U.S. 156, 167 (1962).

Here, FDA's failure to even consider allowing the use of both fluid and dry UF milk in cheesemaking, especially in light of the Agency's favorable evaluation of that option in its cost

benefit analysis, is contrary to the facts and, if implemented, would warrant setting the rule aside as arbitrary and capricious.

B. A reasoned analysis of available facts supports allowing UF milk, in both liquid and dry forms, in cheesemaking

To limit, as the proposed rule contemplates, the expansion of the definition of milk solely to "liquid UF milk" and "liquid UF nonfat milk," is not supported by sound science. UF milk, in both liquid and dry (MPC) forms, can be used in cheese manufacture such that the "essential characteristics" of the particular cheese are maintained, if not enhanced.

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. Standardization is achieved by either (1) the addition or removal of fat as cream; or (2) the addition of casein (in the form of skim milk, condensed skim milk ("condensed skim") or SMP). See Affidavit of Nana Farkye, Ph.D. ("Farkye Aff.") at ¶ 14.⁸

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.⁹ 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. However, given the variation in protein in milk

⁸ The Farkye Affidavit is attached hereto as Appendix 1.

⁹ Shakeel-ur Rehman *et al.*, 2003. (Exhibit B to Farkye Aff.).

(for the U.S. milk protein content ranges from 2.9% to 3.3%) as well as NFDM, standardization with SMP leads to the introduction of variable total solids into the cheese plant. In essence a variable ingredient (SMP) is being added to a variable raw material (cheese milk). The additional lactose added by the SMP can also lead to a number of quality issues. The level of lactose in the milk can influence the amount of lactose in the cheese, as it becomes increasingly difficult to remove it without extensive washing of the cheese curd (not a typical processing step for most cheese varieties). Excess lactose retention can cause "mechanical openness", flavor defects and negatively impact the function of the cheese for further processing into processed cheese products. Similarly, condensed skim has a 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. MPC provides a fixed amount of protein and total solids, and the specific amount used can be adjusted in accordance with the variation of protein and total solids in milk. In such a process MPC would perform in exactly the same manner as UF nonfat milk. Farkye Aff. at ¶ 15.

While FDA notes that certain "scientific literature suggests that fluid UF milk, especially at low concentration factors, can be used in different cheeses (including soft, semi-hard, hard, and direct-acidified cheeses and process cheese) without affecting the physical, chemical or organoleptic properties of the cheese", the same can be said for MPC.

Scientific studies indicate that MPCs have been used successfully in pizza cheese, and when used in certain processes can increase the calcium content of the cheese or minimize browning during the baking stage.¹⁰ MPCs have also been used with positive results in the manufacture of reduced-fat cheddar cheese.¹¹ These studies also 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 with 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. Farkye Aff. at ¶ 17. *See also Conditions of Competition for Milk Protein in the U.S. Market*, Investigation No. 332-453, USITC Pub. 3692 (May 2004). (Enrichment of cheese with MPCs can increase yields and improve the overall quality of certain cheeses.)

¹⁰ Shakeel-Ur-Rehman, N.Y. Farkye, *et al.*, *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 (2003) (Exhibit C to Farkye Aff.).

¹¹ Shakeel-Ur-Rehman, N.Y. Farkye, and B. Yim, *Use of Dry Milk Protein Concentrate in Pizza Cheese Manufactured by Culture or Direct Acidification*, J. Dairy Sci., 86: 3841 at 3847 (2003) (Exhibit D to Farkye Aff.).

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 economical 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.¹²

- 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. In fresh, soft high-moisture cheeses that generally contain higher levels of lactose than hard cheeses, the use

¹² We note that FDA determined that pursuant to 21 C.F.R. 25.32(p) "this action is of the type that does not individually or cumulatively have a significant effect on the human environment" (70 Fed. Reg. at 60,767), and accordingly, did not conduct any environmental assessment ("EA") or environmental impact statement ("EIS") in connection with the proposed rule. First, the exception cited by FDA does not fairly cover the breadth of the proposed rule. Second, even if this class of agency action does not ordinarily require an EA or an EIS, FDA fails to appreciate that the disposal of whey in the cheesemaking process presents a significant environmental issue. Measures to reduce the amount of whey disposed, such as permitting the use of both liquid and dry UF milk in cheesemaking, would be of benefit to the environment. The National Environmental Policy Act requires an agency to, among other things, prepare a "detailed statement" on the environmental impact of a major Federal action "significantly affecting the quality of the human environment." 42 U.S.C. § 4332. NEPA also requires a detailed statement regarding "alternatives to the proposed action." 42 U.S.C. § 4332(c)(iii). The matters addressed in the proposed rule are not simply ones of food content and labeling, but could also have significant environmental effects. The environmental complexities (and opportunities) arising out of the options considered by the proposed rule should not be rejected out of hand by FDA.

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

Farkye Aff. at ¶ 18.

In sum, all of the advantages identified by the FDA arising from use of liquid UF milk would also be achieved to a greater degree through the use of MPC -- giving manufacturers greater flexibility while still preserving the basic nature and characteristics of cheese; providing better retention of milk proteins and greater cheese yields; helping management of seasonal imbalances in milk supplies and cheese demand; reducing costs of bulk milk distribution; and conforming with international Codex standards, which also permit use of UF milk in all forms in cheese. *See* 70 Fed. Reg. 60,757.¹³

FDA should follow its own general principles uniformly and not contrive imaginary distinctions between milk products. Accordingly, the definitions of "milk" and "nonfat milk" within § 133.3 should include UF milk in both dried and liquid forms.

2. The expansion of the definition of milk should not be limited to UF milks.

Following a similar analysis, sound science supports the expansion of the definition of milk beyond liquid and dry UF milk. Take, for example, microfiltered ("MF") milk. Both ultrafiltration and microfiltration processing start with milk and separate out certain milk components. Many of these components are already manipulated by cheese manufacturers under

¹³ FDA notes that the Codex standard would encompass "fluid UF milk" in the manufacture of cheese, but the Codex standard goes much further and allows use of "milk and/or products obtained from milk" which would also include dried UF milk, MPCs and other ingredients. *See* 70 Fed. Reg. at 60,757.

the present rules, but in a far less efficient process. As noted by FDA, cheese producers seek to maximize the amount of protein in their cheese "without adding components that later need to be removed." 70 Fed. Reg. at 60,759. As discussed in Section 1 above, by adding condensed milk or SMP to achieve higher protein levels, cheesemakers then have to remove excess lactose and minerals that also result from the addition of those ingredients. *See also*, Farkye Aff. at ¶ 15. Use of MF milk would allow cheesemakers to achieve more precisely desired composition and characteristics in the first instance, thereby avoiding the need to later remove unwanted ingredients that would result from use of NFDM or other nonfiltrated products. Both ultrafiltration and microfiltration simply allow for a more precise and efficient separation process, allowing the cheesemaker greater control over his production and end product.

One of the significant advantages which the use of microfiltered milk promises is the ability of the cheesemaker to adjust his or her casein:whey protein ratio on the front end of cheesemaking, thereby creating a more efficient process and reducing the amount of whey protein produced as a by-product of the cheesemaking process. *See* Farkye Aff. at ¶ 18(d). It is advantageous to remove and process the whey protein (as WPC or WPI) prior to, rather than after, cheesemaking. This can be particularly true where color or specific cultures and enzymes are added in the cheesemaking process and which are also present in the whey. The industry grapples with the issue of colored whey in the manufacture of WPC products. As discussed above, MF does not affect the composition of the final product but rather simply changes the order in which various milk ingredients are removed in the cheesemaking process.

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.

See Farkye Aff. at ¶ 19.

Consequently, Fonterra would urge that FDA revise the definition of "ultrafiltered milk" so as to ensure that any filtered milk product is included and in particular that the proposed definitional requirement that the casein:whey protein ratio be as in naturally occurring milk be deleted.

Such a definition would be consistent with FDA's endorsement of the international harmonization of regulatory requirements. Specifically, in its proposed rule addressing food standards' modernization, the Agency stated that "[w]ith the rising trend in globalization and increased accessibility of U.S. goods to other nations' markets, efforts to harmonize U.S. food standards with international food standards will facilitate international trade and foster competition." (70 Fed. Reg. 29,212, 29,214, 29,223). Moreover, in the current rulemaking publication, FDA cites the need to achieve consistency with international trade standards in support of its decision to propose allowing the use of UF milk in cheese manufacturing. The

Codex Alimentarius Commission's standard of identity for cheese not only permits the use of ultrafiltration technology, but more broadly provides that cheese must contain "milk and/or products obtained from milk," Codex General Standard for Cheese, A-6-1978, amended 2003. Under Codex Standard 206-199, a "milk product" is "a product obtained by any processing of milk." In conformance with this Codex standard, cheese manufactured in many countries outside of the United States - cheese with which U.S. cheesemakers must compete - is produced with processes utilizing not only wet and dry UF milk, but microfiltered milk and other milk retentates.

3. The proposed labeling requirement for UF milk and UF nonfat milk is not justified.

Virtually hidden in the preamble to the proposal is FDA's statement that "Consequently, when this type of milk is used, it would be declared in the ingredients statement of the finished food as "ultrafiltered milk" or "ultrafiltered nonfat milk." If this labeling requirement were to apply to all cheeses made with ultrafiltered milk, *i.e.*, both cheese which is produced in a plant where the ultrafiltration is on-site, as well as cheese produced in plants where ultrafiltered milk is trucked in, then it represents an unjustified change in FDA's labeling policy. If, to the contrary, it is meant to apply only to cheese produced from ultrafiltered milk which is filtered off-site, then it is an illogical and unjustified discrimination that creates two different labels for products which are in all respects identical.

If the intent is the former, that is to apply this labeling requirement to cheese produced from milk filtered on-site, then it is contrary to FDA's current labeling policy. Specifically, FDA

has held that under the alternate make procedure allowed in certain cheese standards, the use of milk filtered inside a cheese plant is an allowable "procedure" that results in a cheese with the same characteristics as cheese produced using the processes outlined in the relevant standard of identity. As such, the cheese produced by such an alternate make procedure is properly labeled with milk as the ingredient - as the Agency points out repeatedly in the preamble to this proposed rule, the alternate make provisions apply to procedures, not ingredients. Consequently, in order to qualify as a product produced under an alternate make procedure, the cheese must necessarily be comprised only of ingredients which are allowed by the underlying standard of identity for that cheese - a status not currently held by UF milk. Clearly, if FDA is intending by this proposal to create a new labeling requirement for cheese produced with UF milk filtered on-site, it is doing so without any explanation, which is contrary to the Administrative Procedure Act's requirement that "courts hold unlawful and set aside Agency action findings and conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). As discussed above, the failure to provide a reasoned explanation for a change such as this has been held by the courts to be grounds for overturning agency action.

On the other hand, if the proposal is to be read as creating a labeling requirement for cheese produced with UF milk filtered off-site, but not for cheese produced with identical UF milk filtered on-site, then such a distinction is arbitrary and capricious on its face. Historically FDA has recognized that such products are produced from "milk." For example, in response to a 1996 request for labeling guidance submitted in conjunction with the approval of the filtration of

cheese milk at a central facility for subsequent shipment to a cheese plant, FDA offered the following advice:

From the information that you provided us, it is our understanding that the Cheddar cheese produced from the retentate that results when milk is subjected to processing in an ultrafiltration system is nutritionally equivalent to the Cheddar cheese prepared by the procedures set forth in the standard...Based on this understanding, we would not object at this time to the use of this retentate in the manufacture of Cheddar cheese...*Additionally, we are of the opinion at this time that the retentate that results when milk is subjected to processing in an ultrafiltration system may be declared as "milk" in the ingredient statement on the label of the Cheddar cheese...*provided that the Cheddar cheese manufactured from this retentate is at least nutritionally equivalent to and has the same physical and chemical properties, as the cheese prepared by the procedures specifically set forth in the applicable standard (emphasis added).

Letter from M. Col, FDA Office of Food Labeling, to T.C. Jacoby, T.C. Jacoby and Co., Inc. (Oct. 21, 1996).

We would note that while this advice was given by FDA in the context of its then approval of the use of off-site filtered milk as an acceptable "alternate make" procedure, and that the Agency's position on the correctness of this underlying position has subsequently been modified, the labeling advice would appear to remain valid. Moreover, there is simply no basis for distinguishing between UF milk brought into a cheesemaking plant and milk that is ultrafiltered within a cheesemaking plant. Likewise, there is no valid basis for distinguishing for labeling purposes (or for that matter, any other purpose) between UF milk brought into a plant in liquid form, and UF milk brought into a plant in dry form.

Indeed, by regulation, FDA has provided that an ingredient name should be "a specific name and not a collective (generic) name" unless a generic name is approved by FDA (21 C.F.R. § 101.4(b)). FDA's regulations provide further that:

The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. *The name shall be uniform among all identical or similar products* and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods (emphasis added).¹⁴

The application of these principles leads to the conclusion that UF milk, whether liquid or dry, should continue to be characterized as "milk" in the ingredient line. This is true for two fundamental reasons. First, the basic nature of outsourced UF milk, whether liquid or dry, is the same as UF milk produced on-site; and second, the finished product produced by the utilization of these alternatives is, as detailed above, identical.

4. The Cost Benefit Analysis supports expanding the definition to include UF milk in both dry and liquid forms.

While FDA's cost benefit analysis supports an expansion of the definition of milk to allow fluid and dry UF milk in standardized cheese production,¹⁵ it understates the benefits of

¹⁴ 21 C.F.R. § 102.5(a). While this regulation applies specifically to the common or usual name of finished food products, the statute uses the "common or usual name" terminology for both finished foods and food ingredients.

¹⁵ The FDA identified in its regulatory analysis several options that it considered in developing the proposed rule (*see* Fed. Reg. 60,755); however, the FDA did not consider an option that would allow the use of all fluid and dried forms of UF milk, although that option was extensively considered in the cost benefit analysis, as was allowing all milk or milk products obtained from milk to be used in cheese, in concert with the Codex standard.

fluid UF use, and significantly understates the benefits of dry UF (MPC) use, while overstating the costs. First, the FDA cost benefit analysis neglects basic economic relationships that show that reducing costs of production of cheese manufacture will lower the price of cheese and raise the price of raw milk to farmers. Thus both consumers and farmers would gain from allowing UF milk in cheese manufacturing. Second, based on the FDA's own evidence and reasoning the benefits of permitting dry UF milk to be used in cheese manufacturing would reduce costs of cheese production substantially more than permitting fluid UF alone. Benefits of allowing dry UF milk would spread upstream to farmers and downstream to consumers. These gains are substantial and suggest a reduction in cheese prices and increases in cheese production and an increase in milk solids used for cheese. Contrary to FDA's expressed concerns, there is little or no risk of an increase in government costs of the price support system. Indeed, by raising the price of milk the potential cost of the government price support program would more likely fall. Finally, given projections of dairy non-fat-solids prices from both USDA and the Food and Agricultural Policy Research Institute ("FAPRI"), there should be little additional pressure for dairy imports.

At the outset, FDA's analysis does not incorporate the fundamental principal that removing a restriction does not require the formerly prohibited practice to be used if it is unprofitable. Thus, if the use of UF milk were expected to be unprofitable, firms would not adopt the new practice even if the rule restricting the practice is removed. Consequently, the effect of removing a constraint must improve the net benefits for firms previously constrained.

Furthermore, quantifying the aggregate expected effects of removing a restriction requires projecting the degree to which newly permitted practices are likely to be adopted. *See* Sumner and Balagtas, "Analysis of the Economics of Alternative Proposals to Permit the Use of Ultrafiltered Milk in Manufacture of Standardized Cheese and Related Cheese Products in the United States" (Jan. 8, 2006) at 2. ("Sumner/Balagtas Rept.").¹⁶

Perhaps more important, by lowering costs of production for firms that change their practices, removing a restriction transmits economic effects both upstream from the firms making the initial adjustment (towards farmers) and downstream (towards consumers). These economic linkages are the function of markets and may be analyzed by considering shifts in the marginal cost or supply functions and by tracing through demand and supply responses to implied market price changes, which the FDA's analysis fails to do. *Id.*

A. FDA's Benefit Calculation

The FDA benefit analysis of Option 1, allowing the use of fluid UF milk in standardized cheeses, develops a cost accounting matrix that attempts to calculate cost savings in cheese manufacturing from cheese yield increases, lower transport and storage costs and lower costs for coagulant usage. While the FDA must base its calculations on many assumptions, more importantly it must consider the market adjustments that would follow from a reduction in the cost of production of cheese. As noted above, these market linkages are crucial to understanding the economic costs and benefits and how they are distributed. The FDA's analysis neglects these

¹⁶ The Sumner/Balagtas Report is attached hereto as Appendix 2.

important upstream and downstream linkages. *See* Sumner/Balagtas Rept. at 3. Thus, the FDA analysis has not considered the appropriate set of economic relationships between cheese manufacturing, the market for cheese, and the market for cheese ingredients and raw milk supply. *Id.* A standard model of market equilibrium is used by Sumner and Balagtas in Appendix 2 to calculate the changes in equilibrium price and quantity in the cheese market caused by allowing fluid UF milk in cheese production, on the one hand, and both fluid and dry UF milk on the other. Based on this modeling, allowing fluid UF milk in cheese production would result in a reduction of cheese prices by about 1.3 percent and an increase of cheese production and consumption at the wholesale level of about 0.6 percent. Allowing dry UF milk as well would result in wholesale cheese prices falling by 2.5 percent, and cheese consumption and production increasing by 1.25 percent at the wholesale level. *See* Sumner/Balagtas Rept. at 5.

B. FDA's Cost Calculation

In the discussion of the costs of Option 1, the FDA notes (70 Fed. Reg. at 60,762) that replacing fluid milk used for cheese by fluid UF milk would be neutral with respect to the total quantity of milk solids demand and hence not affect the quantity of raw milk used for cheese. FDA reasons that this means that government purchases of NFDM (or butter and cheese) would also be unaffected. This reasoning is sound as far as it goes. However, it leaves out two significant effects. First and most important, under this option the FDA shows that the cost of manufacturing cheese would fall (and FDA may underestimate the amount of this fall). As noted

above, this means that the price of cheese facing commercial buyers would also fall and more cheese would be taken from the market at the lower price. More cheese means more milk solids used in cheese and the increased derived demand for milk solids in cheese means dairy farmers benefit from increased sales at a higher price. Furthermore, because total commercial use of dairy products would rise, implying a rise in the price of milk components, there would follow a reduced probability of government purchases of NFDM. *See* Sumner/Balagtas Rept. at 5-6.

A second effect relevant to government programs relates to the operation of the dairy price support program. The United States supports the price of farm-level raw milk at a legislated minimum price, currently \$9.90 per hundredweight of milk. However, this support price is implemented by a program of purchasing manufactured dairy products, specifically cheese, butter and NFDM. The relationship between the support price for raw milk and the purchase price for each of the products is guided by the so-called make allowance, which reflects the costs of converting a unit of raw milk into a unit of the manufactured dairy product. The make allowance is set administratively and may be adjusted by USDA officials. A decline in the cost of production of cheese due to permitting the use of UF milk in the manufacture of standardized cheese may be an occasion for reducing the make allowance for cheese. *See* Sumner/Balagtas Rept. at 6.

C. Milk Protein Imports and Milk Protein Prices

The FDA analysis presumes that all (or almost all) dry UF milk used in the United States would continue to be imported (70 Fed. Reg. at 60,764). In fact, this does not follow, especially

if the demand by cheese manufacturers is substantial. Furthermore, current and recent period prices for milk protein in the United States, while comfortably above support, have been at or below world prices and the United States has been a commercial exporter of NFDM. Under these conditions expansion of dry UF milk production in the United States is quite feasible, and in fact is taking place. *Id.*

As noted above, Fonterra, in partnership with DFA in Portales, New Mexico and UDA near Phoenix, Arizona, is actively engaged in the production of significant quantities of MPC, as are others. We estimate that within a year to eighteen months approximately half of U.S. demand for MPC will be supplied domestically.

Moreover, forecasts are that high U.S. prices for NFDM are likely to continue. The USDA baseline projections are that the annual average U.S. all milk price will continue to rise to through 2014-15, approaching \$17/cwt (USDA Economic Research Service(c), p.60). Currently, government purchase prices for NFDM, cheese and butter are set in order to support a farm price of manufacturing milk of \$9.90 (USDA Economic Research Service (a)). The USDA projections are that milk prices will remain well above the current support price. *See* Sumner/Balagtas Rept. at 8-9.

Likewise, dairy market projections from FAPRI also show that NFDM milk prices will be above current support levels. The 2005 FAPRI projections are that the price of milk used for NFDM and butter will remain above \$11/cwt through 2014, and prices of milk used for cheese will remain higher still, well above the current support price of \$9.90/cwt. FAPRI projects that

NFDM prices will remain at \$.84/lb or higher through 2015, higher the current support price of \$.80/cwt. for NFDM. Thus, these projections all indicate that the probability of government purchases of NDFM is relatively low in the coming years, and FDA's stated concern is misplaced. *See Sumner/Balagtas Rept. at 9.*

Demand for dry UF milk products has been driven significantly by their technical advantages over NFDM. As discussed above, in cheese plants, filtered protein products with low levels of lactose offer an improvement over NFDM as way to add protein. This technical superiority means that these filtered milk protein products and NFDM are less than perfect substitutes. One implication of this is that demand for the filtered products exists even when prices of the filtered milk protein products are higher than the price of NFDM (on a comparable basis, such as \$/lb of protein). For example, in recent months, cheese plants and other food manufacturers have continued to use filtered milk products despite high prices of filtered products relative to NFDM. *See Sumner/Balagtas Rept. at 9-10.*

As we have seen, the relatively high prices of filtered milk products, and continued demand for these products despite high prices, have created incentives for U.S. dairy processors to produce the filtered products. *See Sumner/Balagtas Rept. at 10.*

It should also be noted that promulgating a regulation that would allow for the use of liquid, but not dry, UF milk, based on import concerns, would be inconsistent with the U.S.'s obligations under the General Agreement on Tariffs and Trade.

5. Expansion of the milk definition to include only liquid UF milk will harm small cheese producers.

While the FDA notes that the high cost of implementing dry UF technology may be prohibitive for small dairy processors (*see* 70 Fed. Reg. at 60,763), the cost benefit analysis fails to account for the harm that will come to small cheese producers if liquid UF milk is permitted but dry UF milk is not.

The Regulatory Flexibility Act ("RFA") requires that the FDA consider the economic impact that a proposed rule will have on small entities. Specifically, the RFA mandates that the Agency conduct an analysis describing "the impact of a proposed rule on small entities." 5 U.S.C. § 603. "The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of the general notice of proposed rulemaking for the rule." *Id.* When an agency promulgates a final rule, the required regulatory flexibility analysis must set forth in detail "the steps the agency has taken to minimize the significant economic impact on small entities," including "a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected." 5 U.S.C. § 604(a)(5).¹⁷

¹⁷ The final regulatory flexibility analysis must also contain (1) a succinct statement of the need for, and objectives of, the rule; (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (4) a description of the projected reporting, record-keeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record. *See* 5 U.S.C. § 604(1)-(4).

FDA admits that the "proposed rule will have a significant impact on a substantial number of small entities." 70 Fed. Reg. 60,766. FDA discusses and seeks comment on "the financial burden investing in UF technology imposed on dairy processors and cheese manufacturers, particularly small entities" (70 Fed. Reg. at 60,766), but gives no consideration to the economic harm that will come to small cheese manufacturers due to the "liquid only" nature of the proposed rule.

The use of UF milk may be desirable for large scale manufacturing plants that can afford the investment in 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 equivalent to purchasing three truck loads of milk. Logistically, the plant may not have enough storage for this volume of product, which has shelf life similar to that of raw milk. *See Farkye Aff.* at ¶ 16. Alternatively, MPC does not have to be sold by the truck load, and can be sold in varying quantities as required by the purchaser. Therefore, the most economic approach is to use MPC.

FDA suggests that there will be "significantly lower hauling costs for filtered milk [that] may enable small milk processors and cheese producers to ship ingredients over larger distances" (70 Fed. Reg. 60,766), but FDA's statement misses the mark. While there may be some

reduction in shipment costs for liquid UF milk, the true reduction in shipping and storage comes from the use of MPC.

It is essential that FDA conduct this analysis in reaching its conclusions in the Final Rule. FDA's cost benefit analysis found lower transportation and storage costs for MPC milk than for either milk or fluid UF milk. *See* 70 Fed. Reg. at 60,763. Yet FDA failed to examine why an alternative was chosen that would impose not only increased costs on small cheese producers, but would put those producers at a distinct disadvantage compared to larger operations that can afford to buy truck loads of liquid UF milk. The Agency has seemingly failed to consider, let alone reconcile, this very arbitrary (and avoidable) negative impact on small cheese manufacturers that would result from the proposed rule.

Conclusion

The regulations governing the permissible milk ingredients in standard of identity cheeses are in need of revision to take into account the significant progress and innovations achieved in membrane filtration technology. Use of this technology can bring great efficiencies to dairy processing, in general, and cheesemaking in particular, without compromising the nutritional value and compositional qualities of standardized cheese. Indeed, the proposed rule acknowledges these advances and their benefits.

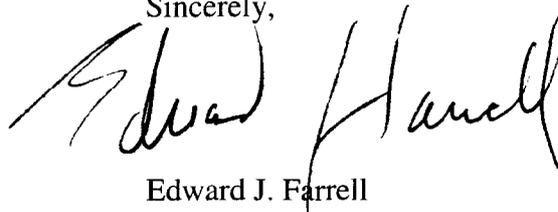
Regrettably, the proposed rule offers only a small and inadequate step in recognizing the benefits of membrane technologies in general, and of UF milk in particular, in the production of cheese. Rather than simply follow the course indicated by sound science and economic analysis

by permitting the use of UF milk, either in liquid or dry form, FDA has chosen to arbitrarily propose that only UF milk in liquid form is a permissible ingredient, while dry UF milk (or MPC) is not. FDA's proposed rule ignores the fact that liquid UF milk and dry UF milk perform identical functions in cheesemaking, and that use of dry UF milk provides logistic and economic advantages that neither nonfiltered milk, nor liquid UF milk can provide. Of particular concern is the competitive disadvantage that small cheesemakers would face if the rule is limited to fluid UF milk.

The bottom line is that UF milk in both liquid and dry forms should be accepted ingredients in standard of identity cheeses. They both offer greater efficiencies in cheese production than nonfiltered milk and their use often results in a healthier product. Use of UF milk in all forms will result in increased milk sales by dairy producers and lower prices for consumers. The FDA should abandon the tortured and unsatisfactory rule that it now proposes, and amend its regulations to allow liquid and dry UF milk in cheese.

Likewise, the FDA should be true to its endorsement of the harmonization of U.S. food standards with international standards, and consider expanding the definition of milk for standard of identity cheeses to include other products of membrane filtration such as MF milk.

Sincerely,



Edward J. Farrell