

*In re: Milk in the Northeast Marketing Area,* )  
*et al.* )  
) **Docket Nos. AO-14-A73, et al.**  
**(Fluid Milk Product Definition)** )  
) **DA-03-10**  
)

**Comments of  
The National Milk Producers Federation**

***Introduction***

The National Milk Producers Federation (NMPF) is the voice of America’s dairy farmers, representing over three-quarters of America’s 64,000 commercial dairy farmers through their memberships in NMPF’s 34 member cooperative associations. NMPF submitted a proposal that was published in the hearing notice, and participated in the hearing, held on June 20-23, 2005. NMPF now offers its comments in response to the recommended decision published in this docket. See 71 Fed. Reg. 28590 (on May 17, 2006).

The Federal order hearing at issue was requested to correct technical problems that had grown up over time in defining and valuing milk-based beverages. NMPF’s proposal (No. 7 in the hearing notice) aimed to help modernize this language with minimal disruption to the industry generally, and to support and clarify USDA’s prior administrative intent. It sought neither to fundamentally expand nor contract the category of Class I products. NMPF supports those elements of the recommended decision which make appropriate technical corrections, and urges USDA to make these corrections more comprehensive. NMPF also opposes the exemption of yogurt drinks and kefir from Class I as fundamentally unsound.

In support of these comments, NMPF requests that the Secretary take official notice of Food and Drug Administration Docket No. 00P-0685, regarding the National Yogurt Association's "Petition to Revoke Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend Standards for Yogurt and Cultured Milk", including the advance notice of proposed rulemaking (68 Fed. Reg. 39873-39877) and the original petition referenced in that notice and found at (<http://www.fda.gov/ohrms/dockets/98fr/00p-0685-cp00001.pdf>)

With respect to the recommended decision, NMPF supports:

- using a 2.25% protein standard to define fluid milk products (FMP's);
- including all nonfat dairy ingredients in defining FMP's;
- pricing MPC's used to produce FMP's on the same basis as nonfat dry milk;

However, NMPF opposes:

- excluding casein and caseinates from the pricing of Class I FMP's;
- the recommended broad latitude of the Department to define products as FMP's even when they fall outside the compositional standards
- any changes to the definition of "meal replacement" based on the current record;
- the exemption of "kefir" and "yogurt containing beverages" from the FMP definition.

### **NMPF supports the protein standard of 2.25% and protein accounting**

USDA's adoption in the recommended decision of 2.25% protein content as a threshold for fluid milk products (FMP's) is the correct response to evolving processing technology and new product formulations. Protein is the component that is most characteristic of, and contains the primary value of, skim milk. The other, larger, component is lactose, a dairy sugar whose marginal economic value in milk is zero, and

whose carbohydrates are often considered to have a similarly null (or negative) marginal nutritional value.<sup>1</sup> Dairy protein content is the soundest basis for assessing a beverage's economic and functional similarity to milk, and therefore, to defining it as a fluid milk product.

NMPF supports the specific protein threshold of 2.25% because for average milk it equivalent to the current 6.5% nonfat solids standard. This also makes the 2.25% protein level essentially neutral in its effect on products containing un-modified skim milk ingredients. That is, it does not represent an expansion of the present fluid milk product definition. Rather, it is a reform of milk equivalent accounting.

Nonfat solids accounting for milk-equivalents of products whose protein-to-other-milk-solids ratio has not been modified is a reasonable continuation of current practice.

If dairy ingredients have been protein-modified (including ingredients containing more or less than their natural protein content) it is most equitable to account for milk-equivalents consistently on protein. Basing milk-equivalents on the higher of the protein or nonfat solids basis would result in unfair double counting, while basing them on the lower-of would result in unfair undercounting.

It is clear from the hearing testimony (Transcript 1203-1210, and Exhibit 35) of Todd Wilson of the Dallas Milk Market Administrator's office that USDA clearly supports the practice of protein accounting for such products. The *de facto* practice of that office, based in part on the 1999 Federal order reform final decision (64 Fed. Reg. 16131), has been to calculate the milk equivalents of milk protein concentrates on the basis of actual protein content. A recent administrative ruling (decision of Administrative Law Judge

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<sup>1</sup> While processed lactose has positive economic uses, its marginal economic value in milk is effectively zero. Similarly, for most U.S. consumers, that marginal health value of an additional 100 grams of carbohydrates is zero or even negative.

Marc R. Hillson in re: HP Hood, LLC, et al., 2004 Docket No. AMA-M-4-2, dated October 26, 2005) has made it clear that an order amendment is necessary to effect that approach more broadly and consistently.

### **NMPF supports counting all dairy ingredients in defining fluid milk products**

NMPF supports USDA's recommendation to include all nonfat dairy ingredients in defining fluid milk products. Technological improvements in alternative dairy ingredients, including milk protein concentrates (MPC's), casein, caseinates, and whey ingredients, have made each a more viable substitute for milk, skim milk, and skim milk powders in the formulation of milk substitutes. As a result, all should be recognized as contributing to a product's definition as a fluid milk product.

Up to now, MPC's, casein, caseinates, and whey ingredients have been excluded from defining and pricing fluid milk products under the Federal orders. This administrative precedent was set when these ingredients either did not exist or were, in effect, sufficiently denatured that they made poor ingredients for a fluid milk product.

New technologies now make it possible to use these ingredients in beverages whose form and use would make them Class I fluid milk products. New methods of fractionation have simplified the concentration of milk proteins; and new processing techniques are increasing the variety and flexibility of whey ingredients. This is evidenced by the expanded range of dairy products, including "milk protein concentrates", "whey protein concentrates", "whey protein isolates", and non-standard "skim milk powders", whose production is now being reported by the National Agricultural Statistics Service.<sup>2</sup> It

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<sup>2</sup> *Dairy Products*, USDA/NASS, found at:  
<http://usda.mannlib.cornell.edu/reports/nassr/dairy/pdp-bb/2006/dary0706.pdf>  
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is also demonstrated in expanding imports of dairy ingredients whose low tariff rates were established when their trade volumes were small or nonexistent. However, obsolete precedent has forced USDA to treat them as non-dairy ingredients, in violation of basic principles of classification.

This has created perverse incentives to use dairy-based “non-dairy ingredients” that are inferior or intrinsically more expensive or both. This can be done in order to reduce the officially recognized dairy ingredient content below the current 6.5% nonfat solids standard, and so exempt the product from Class I pricing on its recognized milk content. In this way, a small amount of casein, whey, MPC, etc., can reduce the cost of a large amount of milk from Class I to Class II. This high marginal subsidy to these ingredients distorts product formulation and ingredient markets, and should be eliminated, as recommended by USDA.

The recommended decision claims that NMPF has “no basis to accurately conclude that adoption of a true protein standard would not alter any current product’s classification.” In fact, ingredient and nutrition labeling allows for a general assessment of many products’ potential for reclassification based on a protein threshold. After looking at many product labels, assessing the sources of protein based on the ingredient list, and calculating the protein content based on nutrition labeling, we were unable to determine that any product whose composition would define it as Class II, based on USDA practice at the time of the hearing, but which would be moved to Class I. In addition, in 20 hours of hearing, only General Mills identified a single yogurt drink produced by them and subject to reclassification; and that product had been formulated specifically to avoid Class I pricing. No other example of a product that would be reclassified based on this change was offered. Finally, NMPF discussed this issue with numerous processors of formulated

dairy beverages and found no other product that would be subject to reclassification. All of this evidence reinforces our contention that reforming fluid milk product accounting by the adoption of a protein standard would generally have a neutral effect on the classification of beverages.

Based on these considerations, NMPF concurs with USDA's recommended inclusion of all milk-derived proteins in defining fluid milk products based upon the 2.25% protein threshold.

### **NMPF supports Class I pricing of milk protein concentrates in FMP's**

NMPF supports USDA's recommendation to price milk protein concentrates (MPC's) contained in fluid milk products on the same basis as milk, including Class I pricing for wet ultra-filtered milk and Class IV-to-Class I up-charges for dry MPC's. Accounting for the milk equivalent of MPC's on a protein basis is entirely consistent with the adoption of the protein standard for FMP's.

The occasional exemption of MPC's from Class I pricing has been based upon obsolete technology (discussed above) and is disruptive of Federal order principles of form and use. It should be clearly and permanently be revoked.

The basis for pricing wet MPC's and up-charging dry MPC's is straight-forward, once the principle of protein accounting of milk equivalents is adopted. The increase in volume is reconstitution, which would be up-charged at the difference between Class I and IV, minus any applicable credit; other milk equivalent use is fortification, with no additional charge. Since dry MPC's are Class IV products, this application is consistent and equitable. According to the order reform final decision (64 Fed. Reg. 16133 n), such

products as wet MPC's are concentrated milk, so they may be priced based on their final use. Administration of this does not require conforming amendments.

For all the fundamental reasons stated above, and for all the same reasons that MPC's should be used in defining fluid milk products (discussed above), NMPF strongly supports the Class I pricing of the protein-based milk equivalent of MPC's used to produce Class I fluid milk products.

**NMPF strongly opposes exemption of casein/caseinates from Class I pricing in FMP's**

NMPF opposes USDA's recommendation to exempt casein and caseinates from Class I pricing when used to produce Class I fluid milk products.

Treating casein and caseinates differently than nonfat milk and MPC's will create market distortions, and could drive very substantial Class I use to these exempted Class IV ingredients. Processors put great emphasis on low ingredient costs, and considerable pressure will be put on dairy ingredient suppliers to devise exempted ingredients that can fill in for non-exempt ones, or to be replaced with imports. Manufacturing processes could be altered to take advantage of the functional advantages of casein and caseinates. All of this would lead to uneconomic decisions in formulation, marketing, and consumer purchasing. This may be avoided by pricing casein, caseinates, and a full range of other dairy protein products as Class I when used to produce fluid milk products.

There is no substantive difference between casein and caseinates, on one hand, and skim milk and MPC's, on the other, that would justify distinct treatment with respect to classification. Dry casein and caseinates are Class IV products: "Class IV milk shall be all skim milk and butterfat...used to produce...(a)ny milk product in dried form", including nonfat dry milk, MPC's, casein, and caseinates. (7 CFR 1000.40 (d))

Moreover, the Food and Drug Administration has not defined a standard of identity for casein, calcium caseinate, or sodium caseinate. Among these, only “edible dry casein (acid)” has been defined for grading by the Agricultural Marketing Service. (7 CFR 58.2800) This means that there is no standard for purity for most of these products upon which to base the exemption, and no evidence for such a standard has been offered for the record. Milk itself contains casein as an ingredient; so a casein exemption without proper qualification would exempt nearly 90% of the fluid skim milk, if taken to the extreme. The administrative imposition of limits would invite administrative appeal by unhappy processors and users, imposing an undue burden on the administration of the orders.

The final order reform decision states, “As used in parts 1000 through 1135, the term concentrated milk means milk that contains not less than 25.5 percent, and not more than 50 percent, total milk solids. It may include milk that has been condensed or milk that has been filtered using such methods as reverse osmosis and ultra-filtration. Concentrated milk may be pasteurized and it may be homogenized.” (64 Fed. Reg. 16133 n) Based on this principle and the dry product classification above, wet casein and caseinates are “concentrated milk” and should also be treated identically with concentrated skim milk and wet MPC’s.

Casein and caseinates should also be treated the same as skim milk and MPC’s with respect to pricing milk used to produce a Class I fluid milk product. The continuing evolution of fractionation technologies, is making the practical distinction between MPC’s and casein/caseinates blurry and will eventually make it meaningless, based on recombination with filtered non-casein protein.

As a result, NMPF believes that the classification of wet caseins or caseinates, as well as wet MPC’s, should follow their final use in fluid milk products.



The upcharge for the use of dry ingredients also should be the same as that for nonfat dry milk, with the exception that the milk equivalents should be calculated on a protein basis, as USDA recommends for MPC. That is, any Class IV ingredient used in the reconstitution of a Class I fluid milk product should be up-charged (and credited) just as if a volume of nonfat milk, containing the equivalent pounds of protein, were used.

***Defining the milk equivalent of fractional protein.*** The Class I pricing of casein and caseinates is as straight-forward as is that of MPC's, with a single, easily clarified exception. The Class I pricing of serum (non-casein) proteins requires the same clarification.

One traditional basis for defining milk equivalents is to calculate the milk used to produce a product. This can result in double-counting, such as when the same hundred pounds are used to produce 4.5 lbs. of butter and 8.7 lbs. of nonfat dry milk; if we add 100 pounds of milk used to produce 4.5 lbs. of butter plus 100 pounds used to produce 8.7 lbs. of nonfat dry milk, we could arrive at the incorrect conclusion that 200 pounds of milk were used. To avoid this double-counting, products are converted to milk equivalents based on their share of some component, such as butterfat, total solids, or protein.

One hundred pounds of skim milk contains about 2.8 lbs. of casein and about 0.4 lbs. of other protein. It took one hundred pounds of skim milk to extract 2.8 lbs. of casein. However, if the milk equivalent of casein was inflated to 100 pounds of milk for each 2.8 lbs. of casein, and we then made some other calculation of milk used to produce the 0.4 pounds of serum protein, the result would be more than 100 pounds; that would be inequitable for pricing. There would be double-counting: once for the 100 pounds used to produce the casein, and again for the same hundred pounds used to produce the other protein.

Instead, a sound basis for establishing the basis for fractionated milk proteins is to convert them on an overall milk protein basis. For example, the casein from 100 pounds of skim milk (2.8 pounds) is the protein-based equivalent of 87.5 pounds of skim milk, while the serum protein from 100 pounds of skim milk (0.4 pounds) is equivalent to the other 12.5 pounds. All the proteins are accounted for and their milk equivalents add up to the original 100 pounds. This approach is consistent with the current, correct milk accounting in Federal order administration (Transcript 1203-1210), and avoids potential double-counting of the same milk used to produce several differentiated proteins. This allows for consistent accounting for all proteins used in fluid milk reconstitution, without confusion over protein fractions.

The clear application of current Federal order practice to the definition of casein and caseinates as Class I milk ingredients in fluid milk products removes any doubt about the propriety of treating casein and caseinates on the same basis as nonfat milk and MPC's.

USDA has recommended that "whey" ingredients be exempted from Class I pricing when used to produce a fluid milk product. "Whey" should be clearly defined in Federal order administration, as they are by FDA and USDA, as "the fluid obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking" (21 CFR 184.1979, 7 CFR 58.805) Other "whey" products are similarly constrained to be the direct product of cheesemaking. (21 CFR 184.1979a, 1979b, and 1979c) That is, "whey" cannot be the product of an alternative cheese make procedure in which the non-casein proteins are separated prior to the coagulation in the cheese vat or to other separation, distinct from the cheese-making process.

This definition should be acknowledged in the final decision, and the intent of its application should be made clear, so that if the "whey" definition is changed for other

purposes, it should be maintained for the purposes of Federal order classification and pricing.

USDA would be justified in treating all such proteins as Class IV products. However, USDA may decide that such proteins are to be considered as Class III products, based on their derivation from an alternative cheese make procedure. In either case, their use in reconstitution should invoke an upcharge from Class IV to Class I, in order to preserve a neutrality of treatment for finished ingredients. This is appropriate for several reasons. First, the protein parity values of dry dairy ingredients tend to converge. Next, reconstitution up-charges are generally based on Class IV prices that are set months after the Class IV product was originally made; this means that the connection between the upcharge and the original Class IV price is limited, and no exact accounting is necessary. Also, a Class III to Class I up-charge procedure is made very difficult by the absence of a whey protein value in the Class III protein price; the Class IV protein equivalent price more accurately follows the value of serum (and whey) proteins than does the Class III protein value. Finally, no changes in conforming language are necessary; this decision can be made administratively, with support from supporting language in the final decision in this proceeding.

All dairy ingredients, except whey properly defined, should be priced in Class I fluid milk products, and their reconstitution upcharge should follow the present Class IV to Class I calculation in order to avoid distorted incentives in the use of dairy ingredients.

*Defining the milk equivalent of “clean” non-casein proteins.* In order to price non-casein proteins at Class I when used to reconstitute a fluid milk product, a clear procedure must be established. When they are produced as a by-product of Class IV casein or caseinate production, they could be treated as Class III or Class IV intermediate

products, and be upcharged on a milk equivalent in reconstitution, based on their total protein content.

The evolution of protein fractionation technology should generally invalidate the exemption of protein fractions from Class I pricing. If proteins can be fractionated without denaturing, they can also be recombined into a fluid milk product with the same protein profile as milk. Indeed, two of the first five ingredients in HP Hood's Carb Countdown™ Reduced Fat Chocolate Dairy Beverage are calcium caseinate and whey protein concentrate, just such a recombination of fractionated dairy proteins to approximate a complete dairy protein. The natural and undesirable outcome of exempting casein and non-casein proteins from Class I pricing is that they will be separated and recombined in order to be charged at the Class IV price.

Based on the discussion regarding the treatment of milk protein concentrates (MPC's) in the preamble to the recommended decision, NMPF has concluded that the modifications that we recommend require no additional language changes, since upcharges to any modified bulk fluid or dry Class IV ingredient can be provided for exactly as the recommended decision provides for MPC's. Other dairy ingredients are "nonfluid milk ingredients"; and bulk fluid modified dairy ingredients can be accounted for in just the same way as ultra-filtered milk.

***Regulatory burden on reconstitution of dry ingredients:*** At hearing, Ms. Taylor, from Leprino Foods, raised concerns about the regulatory burden placed on processors who would use milk protein concentrates and other dry dairy ingredients to formulate fluid milk products. (Transcript, pages 982-983) In fact, Federal order language currently allows for Class I transfers of "nonfluid milk ingredients that are reconstituted for fluid use." (See 7 CFR 1000.76(d)) This allows a formulated fluid milk product plant to buy

Class I powder at a fixed price each month, and hold it in inventory. As written, it would also allow for such minimal regulation of a plant reconstituting any Class IV dairy ingredient. As long as such a plant has no other milk receipts or the Class I powder receipts fully account for the milk used to produce Class I fluid milk products, it has no obligation to or from the Federal order pool, except to verify receipts and report its Class I sales. This even offers ingredient makers the opportunity to provide added value to their customers, in the form of regulatory burden avoidance.

The recommended provisions for the treatment of casein and caseinates, on the one hand, and MPC's, on the other, seems to leave a large grey area of undefined actual and potential dairy ingredients. One reading of this is that dairy ingredients with complete milk proteins are to be upcharged when used in Class I products, but that any product with even the slightest modification to the proportions of protein will be treated as a non-dairy ingredient with respect to pricing (though not with respect to defining fluid milk products). If this reading is correct, these recommendations offer considerable opportunity to ingredient processors to produce a product that resembles an MPC or nonfat milk, but has the slightest bit of fractional protein removed in order to exempt the ingredient from an upcharge. (This can be done by filtration very slightly different from that used to produce MPC's, and presumably, with very little difference in cost.)

Such a large grey area demands clarification. The clearest and best means of clarifying this is to upcharge all dairy ingredients (except properly-defined "whey") as NMPF proposes.<sup>3</sup>

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<sup>3</sup> NMPF opposes the exemption from upcharge for casein and caseinates. However, if this exemption is imposed upon the fluid milk product definition, then casein and caseinates should be defined narrowly enough that their exemption does not become a blanket exemption for the universe of dairy ingredients containing anything less than complete dairy proteins.

Casein, caseinates, and “clean” dairy proteins generally should be priced and upcharged on their milk equivalent, as calculated on a total protein basis.

### **NMPF opposes overly subjective criteria for defining FMP’s**

NMPF opposes the recommendation that the Department have broad latitude to define products as FMP’s when they fall outside the compositional standards discussed above. Such “bright line” criteria as compositional standards are a crucial objective complement to more subjective “form and use” criteria. The proper venue for this application of USDA judgement and discretion is in this rulemaking proceeding, and such future proceedings as may be made necessary by changes in markets and technology.

Clear quantitative standards provide important guidance to the industry. They allow processors to formulate products with well-understood ground rules. In fact, the presence of clear guidelines is crucially important to new product development. Certain parties have made many spurious arguments about Federal orders stifling new product innovation. Fuzzy Federal order definitions might finally give substance to those arguments, to the detriment of all involved.

Also, firm objective standards establish a clear legal basis for enforcement. A product’s standing with respect to a compositional standard is unarguable, while a subjective exceptional classification on “form and use” principles alone may be viewed as arbitrary and so compromise administration and enforcement.

Setting aside the legality of the proposed latitude, it will certainly not be an efficient use of USDA staff time. Rather than saving time by avoiding incremental Federal order amendment hearings, staff will become embroiled in a series of administrative

appeals that will undermine the credibility of the system, even with the most consistent and determined efforts.

Certainly, changing technologies and markets could render some part of this definition obsolete at a future date. This argues for a very forwarding-looking approach to issues in this proceeding, so that the resulting language fits as well as possible for as long as possible, and broadly subjective discretion is not necessary.<sup>4</sup>

At such time that the rules presently under development become inadequate – as the current rules have – a new hearing can and should be called to consider amendments. While the rule-making similarly depends upon the judgement of the Department, it provides a broader basis for considering the ultimate classification of any products in question, and establishes grounds for review and reclassification of previously classified products.

Significantly, there did not appear to be any testimony at hearing in support for this broad discretion.

NMPF supports the use of the 2.25% protein standard as an absolute minimum for fluid milk products, and discourages USDA from relying on an overly subjective – and possibly indefensible – standard.

### **NMPF opposes recommended changes to the meal replacement exemption**

NMPF opposes USDA's recommendation to change the meal replacement exemption from the fluid milk product definition and supports maintaining the current language. The new definition does not establish a clear line between meal replacements

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<sup>4</sup> Such forward looking would anticipate, for example, expanded “clean” fractionation of dairy proteins, the prospect of category expansion to exploit exemptions originating from this rulemaking, possible changes in related regulations by other agencies, and the likelihood of legal challenge to insufficiently clear regulatory language.

and fluid milk products. Its use of a marketing channel to define a product is a bad precedent, and is also not adequately defined to work.

The “health care industry” qualification on the recommended meal replacement exemption is too vague to be useful. “Health care industry” could be defined to include any or none of the following: pharmacies, health and nutrition stores, large drug stores, grocery stores. It might or might not distinguish between the dairy case and other sections of a large drug store or a supermarket. It might be limited to hospitals and nursing homes, in which case any dairy beverage, or any dairy beverage for which the slightest claim as a “meal replacement” might be so defined if sold to a hospital and nursing home. This could include any modified milk product, such as “skim deluxe”.

Generally, the definition of a product on the basis of its marketing channel creates inequitable pricing distortions that lead to uneconomic decisions on the part of processors, distributors, retailers, and consumers. For example, consider a product defined by its manufacturer as a “meal replacement” which might receive a Class II classification on the basis of its sale in the pharmacy department of a large chain drug store. The retailer might sell more product in that dairy case, but that would raise his price from the processor; a distributor might sell more product through convenience and grocery stores, but that would raise his price from the processor; the processor could sell more product through those channels, but that would increase its obligation to the pool. The consumer may prefer a Class I product, but that product is more expensive because of the break given to the “meal replacement”.

In addition, the use of marketing channels to define classification creates problems in inventory classification and record-keeping. It also invites fraud, by establishing a definition that rests on a thin and nearly inexplicable difference in final disposition.



It appears from the proposed language that formulas for “infant feeding” and for “dietary use (meal replacement)” are subject to the same conditions. This means, presumably, that “the health care industry” must be defined in the same way for both. Infant formulas sold through supermarkets could not then be exempt from Class I unless adult meal replacement drinks sold there are, as well. This is one reason why packaging has been so important to this exemption.

The recommended decision found “that packaging is not a legitimate criterion for considering some meal replacement products as Class II products and others in Class I.” Indeed, packaging is a more legitimate criteria than marketing channels. The current requirement that “meal replacement” be “packaged in hermetically-sealed containers” represents an imperfect but clear and substantial barrier to redefining a product as “meal replacement” for the sake of Class pricing. Hermetically sealed containers with a shelf-life of 6 months or more are a substantial packaging cost, roughly commensurate with the difference in Class prices for a single-serving package. This helps define the product as distinct from other fluid milk products, and will generally ensure that the exemption is not being exploited specifically to avoid paying the Class I value to the pool.

A meal replacement definition similar to that originally proposed by O-AT-KA Milk Products Cooperative, Inc., in the original notice of hearing (70 FR 19013) might establish a clearer objective compositional definition of a meal replacement; however, evidence in support of that proposal was never presented and so its consideration must await a future proceeding.

If the same conditions applied to “meal replacement” were not intended for “infant feeding”, then the separation should be made clear.

The FDA definition of “special dietary use” (21 CFR 105) provides some meaningful foundation for the current definition, as does the physical and financial constraint of hermetically-sealed containers (which are also defined by FDA, at 21 CFR 113). Overall, the current meal replacement definition is considerably weakened by the recommended decision, and the record in the current proceeding is inadequate to produce an improved definition. NMPF advocates retaining the status quo in this provision until a more effective definition of “meal replacement” under the Federal orders can be established through separate rulemaking.

### **NMPF strongly opposes the exemption of yogurt and “kefir”**

NMPF strongly opposes the exemption of “kefir” and “yogurt containing beverages containing 20 percent or more yogurt by weight” from the fluid milk product definition. This recommendation is thoroughly inconsistent with the underlying principle of “form and use”, and it is unworkable in practice.

The Agricultural Marketing Agreement Act provides for “classifying milk in accordance with the form in which or the purpose for which it is used”. (7 USC 608c(5)) This is the “form and use” criteria which have long been applied to the classification of fluid milk products. Plain and flavored drinkable yogurts, yogurt drinks, and kefir are nearly identical to plain and flavored milks in *form*, including physical composition, nutritional content, and their liquid state. Exhibit 25 demonstrates yogurt is nearly identical with milk in composition and nutrition. Yogurt makers produced beverage products to expand their markets; that is, to expand into the beverage market. By marketing them as a beverage, they are redefining the form and use of yogurt; and as such, they are redefining drinkable yogurt as a fluid milk product.

Similarly, they are identical in that they are *used* as beverages. The dictionary defines “beverage” as “a drinkable liquid” (Merriam-Webster Online, found at [www.m-w.com](http://www.m-w.com)). Drinkable yogurts are, of course, drunk – that is, used as a drink – and as Ms. Ledman (a proponent of the exemption) testified, for example, are a substitute for the milk that her children normally drink with their cookies. (See Transcript, p. 542)

Other traditional criteria for dairy product classification also identify yogurt and fluid milk as similar products: Yogurt drinks depend upon the same fresh fluid milk supply as other fluid milk products; they cannot be stored without refrigeration; and they are shipped from factory to consumer at the full weight of the milk used to produce them, limiting their geographic market or requiring substantially higher costs.

The exemption of kefir and yogurt beverages from the fluid milk product definition is an arguably arbitrary violation of Federal order principles of form and use. Yogurt is nearly identical to fluid milk in its composition, including its nutritional profile. (Exhibit 25) All other major dairy products are very different from milk in their composition. Only yogurt is fundamentally milk in its finished form. Spoonable yogurt is defined as Class II only because of its semi-solid form. Drinkable yogurt and yogurt drinks present no such distinction from milk; they are beverages. That is to say, they are fluid milk products, they compete directly with fluid milk, and producers face all the same challenges in supplying an adequate and wholesome supply of milk to produce them.

The recommendation to exempt yogurt appears to depend heavily on data presented by General Mills and Dannon, which purported to show that milk and yogurt drinks do not compete in the same market space.

Dannon’s numbers were asserted in the testimony of Jim Box, without presentation of underlying data. These consisted of two types of “data”.

The first was represented as the price elasticities of demand for three very specific products: “-0.64 for Frusion”, a yogurt-containing beverage, “-0.93 for LNF Smoothie”, another yogurt-containing beverage, and “-1.17 for La Creme cup yogurt”, a spoonable yogurt. Dannon also presented an “average” for Dannon’s products of -0.98. Mr. Box then made a point of the substantial difference between the typical elasticity for fluid milk of about -0.2 and those for these specific products.

These data are irrelevant to the issue at hand for a couple of reasons. First, the -0.2 demand elasticity typically estimated for fluid milk is for fluid milk as an aggregated category. That is, if the price of ALL fluid milk rises by 10%, the estimated -0.2 demand elasticity indicates that consumption of ALL fluid milk will go down by 2%. By contrast, Mr. Box presents numbers for individual products, whose quantity demanded is much more price-sensitive than an entire category. For example, if the price of a Dannon Le Crème cup yogurt rises by 10%, Mr. Box’ number indicates that the quantity demanded will drop by 11.7%; but some of those lost sales are taken up by Yoplait products or store-brand yogurts. For the category as a whole, this number would be much lower. In fact, all that Mr. Box has shown is that his “yogurt-containing beverages” are less price sensitive than his cup yogurt. (Exhibit 24, pages 14-15)

The other reason that these demand elasticity numbers are irrelevant is that all three of the products identified are currently Class II products, according to Mr. Box’ testimony. (Transcript, 699-700) So they offer no illumination on the competition between Class I yogurt-containing beverages and other fluid milk products.

The other Dannon data were answers to survey questions regarding one of Dannon’s several lines of yogurt drinks. Like some of the General Mills survey results, discussed below, this is a strangely specific survey, regarding hypothetical purchases of

one specific size of one line of products – the Drinkable Danimals XL are a 5.75 ounce version of their 3.1 ounce Danimals line for children. Consumers who buy any kind of yogurt for children aged 3 to 11 were asked what this product would replace if they bought it. (That is, they did not necessarily buy this product.) Since only 1.1% said it would replace milk, Mr. Box offered the conclusion that drinkable yogurts, as a category, only take 1% of their sales from fluid milk, and therefore don't compete with fluid milk. He ignored that 64% said that it would replace another yogurt product. (Exhibit 24, pages 20-21) Again, all of those asked were already buying yogurt for children; so this tells us nothing about the substitution that had already been made between milk and drinkable yogurts by these consumers. In addition, the type of substitution demonstrated by Ms. Ledman's testimony (Transcript 542) – drinkable yogurt for milk and cookies – is not consciously identified as substitution for milk as much as for the cookies, though in such a case it clearly substitutes for both. Such cases would logically fall within the 29% of respondents that would hypothetically replace other food with this particular yogurt-containing beverage, so that as much as 94% of this "substitution" could be from fluid milk. And this is, presumably, a carefully selected survey result.

General Mills' data was drawn selectively from surveys conducted by NPD. NMPF finds the two charts presented in exhibit 26 to be problematic. Chart 5, entitled "When Consumers Eat" shows the breakdown of fluid milk and yogurt smoothie consumption by mealtime. This chart was represented by proponents as showing very different mealtime patterns for the two products, but despite an apparent selectiveness in presentation by General Mills, it fails to show this.

None of the underlying data was provided and only the most general description of the methodology was offered. (Transcript 795-798) The products are not clearly defined,

so that the possibility that flavored fluid milk is consumed in a pattern nearly identical to yogurt drinks is not explored. The odd and undefined category of “carried”, which one would expect to be apportioned among the other “meal events”, may be an example of selective presentation of data (see below) and would skew the results. Even in this selective result, there was 63% overlap in the panelists use of “fluid milk” and “yogurt smoothies.” That is, at least 32.8% of each product was consumed at breakfast, at least 12.2% at lunch, at least 10.1% at dinner, at least 0.9% at “snack”, and at least 6.9% at “carried”. This totals to 63% – nearly two-thirds – of each product consumed at the same meal event, including the ambiguous “carried”. If anything, Chart 5 shows a substantial similarity of milk and yogurt drinks.

Chart 4 is particularly meaningless. (Exhibit 26) As demonstrated by the complete NPD survey results offered by NMPF as Exhibit 14-f, these surveys typically involve a range of questions designed to get at an issue from many angles. The choice by General Mills of two specific questions almost certainly introduces a very substantial bias to the results. As we noted in our brief, Chart 4, specifically, is based upon a very awkward and inconclusive multiple choice question. Consumers were asked how they used fluid milk and yogurt smoothies; their only options for response (as a “base dish”, “additive”, “ingredient”, or “cooking aid”) are a strange and incomplete selection. These options did not include “as a beverage”, which would have undermined General Mills’ contention that yogurt smoothies are not a beverage. A question with this option was either not asked, or asked and discarded when the results were unfavorable to their argument.

Even with this bias in the selection of questions, there was 50% overlap in the answers to these questions. Specifically, at least 45.3% of the use of both products was as

a “base dish”, at least 0.9% was as an “additive”, at least 3.7% was as an “ingredient”, while no-one (0%) used either as a “cooking aid”.

However, there are serious questions regarding the credibility of even the numbers derived from this selective questioning. Although NMPF produced the full NPD study (Exhibit 14-f) to which it referred in testimony, General Mills chose to present only the numbers they selected from that study, even when asked to present the underlying data. (Transcript 795-798).<sup>5</sup> The evidence presented in Exhibit 14-f, which came from a similar study conducted by the same firm, shows that when questions of this type are commissioned, the underlying data report, including all results for all questions asked, should be available to the customer. General Mills did not provide greater detail on the survey that they commissioned.<sup>6</sup>

All the problems with this data deserve to be weighed by the Secretary in the final decision. The recommended decision concludes that “drinkable yogurts are marketed as a food item to supplement or even replace a meal such as breakfast or lunch” and that this “differentiates their intended use from fluid milk products consumed as beverages or as accompaniments to other mealtime snacks.” The difference between a “supplement” and an “accompaniment” is a bit too fine to serve as a basis for this decision. Moreover, the general conclusion seems to be based more on the assertions of yogurt-makers than on the substance of their evidence. This deserves very serious reconsideration.

The recommended decision also seems to give weight to the National Yogurt Association’s (NYA) noting in its brief the “while DFA and NMPF testified that

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<sup>5</sup> The response of the witness – that the court or the proposal’s opponents could pay for more data if they wanted it – did not answer these questions.

<sup>6</sup> Further, the shares of consumer use of yogurt smoothies in Chart 4 add up to 100.5%. The General Mills representative who offered this chart did not offer the underlying data, but asserted that “If I were to give you a piece of paper with the numbers on them, they would be the exact numbers that are reflected in our exhibit.” (Transcript 800)

consumers are buying low-carbohydrate milk instead of fluid milk, they did not offer similar evidence for yogurt-containing products.”

NMPF did present data on the relationship between fluid milk and low-carbohydrate milk substitutes; this was done in support of its own proposal, based on the presumption that the proponent of a change to the Federal orders bears the burden to prove the correctness of their position. The exemption of yogurt drinks from the fluid milk product definition was proposed by the Dannon Company and adopted by General Mills and NYA. They had the burden to prove a justification for their proposal. We believe that they have not met the burden of proof for this change.

Moreover, NMPF believed this proposal to be so unreasonable on its face as to not demand new research (though such research would certainly show an even greater similarity between milk and yogurt drinks than the considerable similarity that is already shown in General Mills’ selective data.) The conclusion that a yogurt beverage is not a beverage is so absurd that even some of the witnesses on behalf of the proposal declined to state it explicitly when asked. Mr. Box, on behalf of Dannon, agreed that drinkable yogurt is a beverage. (Transcript, page 716) Mr. Tipton, on behalf of a bevy of proprietary processors, avoided answering the question. (Transcript, page 1128) Only Bob Anderson, “Yoplait’s Director of Consumer Insights”, speaking on behalf of, and in the interests of, General Mills, was willing to explicitly state that drinkable yogurt is not a beverage, contrary to any dictionary definition of such. (Transcript, page 803)

Beyond the fundamental inconsistency of the yogurt drink and kefir exemptions from the fluid milk product definition, the recommended exemptions are unworkable in practice.



Contrary to the assertion by Mr. Tipton (Exhibit 32, page 10; Transcript, page 1065), “kefir” has no legal standard of identity. The Food and Drug Administration’s (FDA) cultured milk definition allows additional modifiers for cultured milk to describe traditional or generic types, and offers as one example “kefir-cultured milk.” However, it does not define “kefir” itself. (21 CFR 131.112(f))

Further, to the extent that “kefir” might be generally identified with “cultured milk”, it is identified with a category of beverages that are clearly fluid milk products, including “cultured buttermilk” and “acidophilus cultured milk”. The reclassification of kefir would call into doubt the status of these products, and so on through the gradations of fluid milk products until no product except unflavored “milk” would remain in the fluid milk product definition.

The general meaning of the word “kefir” is so unclear as to be indistinguishable from milk itself.<sup>7</sup> If kefir is exempted from the fluid milk product definition, any processor could identify any line of flavored (or unflavored) milk drinks as “kefir” and receive an exemption from Class I pricing. Since there is no legal basis for identifying kefir, its exemption would create perverse economic incentives for processors to label other products as kefir. This would further obscure the meaning of “kefir” and could unfairly release fluid processors from their obligations to the market. An exemption of kefir from the fluid milk product definition violates Federal principles of form and use, and is unworkable without an FDA standard of identity.

According to the recommended decision,

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<sup>7</sup> Sixty years ago, Merriam-Webster defined “kefir” (rhymes with “heifer”) as a “effervescent liquor” from the Caucasus. (*Webster’s Collegiate Dictionary*. G. & C. Merriam Co.: Springfield, MA. 1946) Today, Merriam-Webster defines “kefir” as a “fermented milk drink”. (found at: <http://www.m-w.com/dictionary/kefir>) Most kefir sold today in the U.S. is neither fizzy nor alcoholic.

“The only evidence provided to support excluding kefir from the fluid milk product definition was identifying kefir as a cultured product similar to drinkable yogurt. Kefir is a cultured product that, like drinkable yogurts, contains active cultures. While cultured beverages are one of the listed products in the fluid milk product definition, kefir's similarities to drinkable yogurts provide a reasonable basis to conclude that the milk used in kefir products should be classified in the same way as milk used in drinkable yogurt products. As with drinkable yogurts containing at least 20 percent yogurt, kefir should be exempt from the fluid milk product definition.” (71 FR 28602)

In fact, there was no evidence supporting kefir's exclusion from the fluid milk product definition, only an assertion that kefir is similar to drinkable yogurt and a misleading reference to the cultured milk standard. There is no compositional data, or even an ingredient label; and kefir cannot be found on the USDA nutritional database from which data on fluid milk and yogurt were introduced at hearing. (Exhibit 25. Found at: <http://www.nal.usda.gov/fnic/foodcomp/search/>)

NMPF believes that kefir should remain a fluid milk product, provided that it meets the compositional standard.

Unlike kefir, yogurt has a standard of identity; but it is so broad as to make the “yogurt containing beverage” exemption a very large loophole. The only significant compositional element in the yogurt standard is an acidity requirement. (21 CFR 131.200) However, this acidity test has been stayed (as have exclusions of preservatives, reconstituted dairy ingredients, and non-specified dairy ingredients), so that the standard's only compositional requirement is that one or more milk ingredients are “cultured” by yogurt cultures. (47 Fed. Reg. 41523) There is no standard for the volume of these cultures, or the extent to which they must act on the milk ingredients. Presumably, a miniscule (and even undetectable) exposure to these cultures might define a very large volume of fluid milk as “yogurt”, thereby exempting that volume (and 4 times that volume

of added milk, based on the recommended “20% yogurt” provision) from classification as a fluid milk product.

This standard and the accompanying standards for low fat and nonfat yogurt (21 CFR 131.203, 131.206) are also the subject of an open FDA docket, including a 2003 advance notice of proposed rulemaking (68 Fed. Reg. 39873-39877). This notice responded to a petition<sup>8</sup> filed by the National Yogurt Association (NYA). According to that petition, the current yogurt standards are “incomplete and unclear.” (Page 2) In fact, NYA asked for substantial changes in these standards, arguing that they “contain many outdated provisions” and that the current standards do not maintain the integrity of the term “yogurt.” (Page 2) This petition pointed out that the current standard does not require the presence of live and active cultures, and does not adequately distinguish yogurt from other cultured or fermented milk products.

General Mills and Dannon are both members of NYA, and their employees represent the majority of NYA’s Board of Directors (<http://www.aboutyogurt.com/industryAndResources/listings.asp>). Thus, the three primary proponents at hearing of exempting any “yogurt-containing” beverage from being defined as a beverage have collectively argued that yogurt’s standard of identity is insufficient, and that many products currently definable as “yogurt” should instead be defined as “cultured” or “fermented” milk products. To cite the petition directly:

“The current yogurt standards do not contain a coherent set of provisions that accurately represents FDA’s current enforcement policy. Therefore, the standards defeat the purpose of preventing consumer fraud by having a statement of identity to which

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<sup>8</sup> Citizen’s Petition, page 2. This petition was submitted “on behalf of the National Yogurt Association, under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act” and maintained as part of an open FDA Docket: No. 00P-0685, per 68 FR 39873. Found at <http://www.fda.gov/ohrms/dockets/98fr/00p-0685-cp00001.pdf>.

manufacturers and consumers can look to know the ingredients contained in yogurt and the procedures employed to make yogurt.” (pp 13-14, NYA Petition)

The current standards, as presently in effect, fail to provide other government agencies the certainty necessary to make effective use of the FDA “yogurt” definition for rulemaking. This is due to the regulatory uncertainty of the open docket, as well as the insufficiency of the present standard for the purposes of defining an exemption from Class I pricing.

Whatever the merits of the NYA petition with respect to the open FDA docket, they have demonstrated that the yogurt standard is broad enough to encompass a very wide range of products, including liquid dairy products that do not fit the traditional understanding of “yogurt.” That the primary proponents of this exemption from the fluid milk products definition have raised such doubts about the yogurt standard, and that FDA has acknowledged its intention to reconsider the standard through its advance notice of proposed rulemaking, suggest the impropriety of basing the proposed and recommended exemption upon the current “yogurt” standards of identity.

The nonexistent standard of identity for kefir and a standard of identity for yogurt that is unclear in the context of the proposed exemption from Class I both raise concerns about enforceability under the Federal orders, and would seem to invite administrative appeal of any decision to define any product with any level of yogurt content as Class I. This exemption would become, after multiple time-consuming appeals, a blanket exemption of any such product.

One can easily envision the potential for a large category of yogurt-tinged drinks exploiting this loophole. These would lead to substantial distortions, including Class I revenues lost to the pool to the detriment of producers and fluid processors, mispriced beverages unfairly competing with fluid milk, and products formulated to contain nominal

“yogurt” – regardless of all other cost and consumer preference considerations. This would give added incentive to processors to further assault the integrity of the word “yogurt”, as described in NYA’s petition.

The integrity of the classified pricing system itself, however, is NMPF’s greatest concern in this hearing generally, and with respect to this issue specifically. This exemption has similar potential to undermine the fluid milk product definition as the lack of a protein standard or other exemptions of dairy ingredients.

## **Conclusion**

Federal order Class I pricing is intended to compensate producers for the difficulty of supplying fresh fluid milk to the market. In regions where the supply of milk is more limited, there is a higher Class I use percentage and a correspondingly higher compensation for producers.

Processing technology has evolved significantly since the advent of the Federal milk marketing order system. Previously, the standardization of butterfat and expanded sales of skim and lowfat milk compelled adjustments of Class I standards and valuations to maintain the integrity of the Federal order system; today, new technology that allows for standardization of lactose and development of low lactose milk substitutes requires similar adjustments.

The Class I definition must include more than just “milk” under the Federal standard of identity, although certainly some limits on the Class I definition are necessary. These limits should be clear physical standards, but should also reflect a reasonable assessment of what type of products simulate, and substitute for, milk and flavored milk. The 6.5% nonfat solids standard made sense when it prevented large sales of milk

substitutes from being exempt from Class I pricing. However, because new technology has changed the industry and the traditional 6.5% nonfat solids standard cannot distinguish between valuable protein and valueless lactose in today's market, it must be modified to recognize 2.25% protein content as the true defining test of a fluid milk product.

New technology leads to new products, as shown in the growing number of dry dairy ingredient products reported by the National Agricultural Statistics Service – milk protein concentrates, whey protein concentrates, and non-standard “skim milk powders”. Fractionation technologies continue to make various configurations of dairy proteins available to processors who have adequate incentive to use them, including Class price advantages over similar ingredients. NMPF welcomes the development of a broader range of dairy products for consumers, dependent upon these same processing technologies.

However, as new technologies have changed the possible configurations of milk components in dairy products, so has it changed the ways in which milk components must be accounted for to provide consistent classification rules. Since classified pricing is (along with pooling of producer revenue) one of the two basic principles upon which the Federal order system is built, its integrity must be maintained.

Changes in technology and the need to maintain the integrity of classified pricing have therefore demanded that we pursue changes in the accounting of dairy components in Class I use. Most of these necessary changes are embedded in the recommended decision, including adoption of 2.25% protein threshold for fluid milk products, applying all dairy protein content to that 2.25% protein test, and pricing the milk equivalent of milk protein concentrates used to produce Class I products. These are all important corrections to Federal order provisions made obsolete by new technology, and NMPF supports them.

However, these corrections are incomplete, because they have excluded casein, caseinates, and – potentially – a range of other undefined dairy proteins from pricing as Class I ingredients. NMPF urges USDA to include all dairy proteins, with the limited exception of whey proteins denatured in the cheesemaking process, to be priced as Class I when used to produce Class I fluid milk products. If this loophole is not closed in the final decision, processors will inevitably find ways to exploit it, and it will inevitably be the center of another hearing in the relatively near future. In the meantime, producer income will be lost and new inequities will arise among processors based on new pricing distortions among competing dairy ingredients. This decision cannot be a lasting one unless this is corrected.

NMPF also urges USDA to apply its judgement to effective compositional elements of the fluid milk product definition in this decision, rather than reserve future judgement on products that fall outside such a compositional definition. The uncertainty this raises for processors, including especially developers of new products, is unfair and potentially indefensible. If and when unforeseen technological innovations make new standards necessary, they would be best addressed through new rulemaking, rather than administrative fiat.

In the absence of an adequate record to achieve an effective reform of this provision, NMPF opposes any change to the “meal replacement” exemption in the current fluid milk product definition.

Finally and once again, NMPF strongly opposes the exemption of “kefir” and “yogurt-containing beverages” from the fluid milk product definition, and therefore, from Class I pricing. No meaningful justification has been demonstrated for this exemption. The only evidence offered to show that yogurt drinks do not serve the fluid milk market

were presented very selectively and still don't demonstrate that point. That the uses of "yogurt smoothies" and "fluid milk" show a two-thirds overlap in the sub-data selected as most favorable to the proponents of this exemption instead demonstrates very clearly that they do, in fact, serve the same uses. "Kefir" has no legal definition and the definition of "yogurt" is inadequate for the purposes of this rulemaking; so their exemption is likely to produce just the kind of inequitable loopholes that this hearing was convened to address. Moreover, the exemption of any "beverage" from Class I runs in direct opposition to the underlying principles involved in this hearing. This proposed exemption has the future potential to do more damage to the integrity of Federal order classified pricing than is currently undone by the positive elements of this decision, and will most likely lead to another hearing in the not-too-distant future. NMPF urges the Secretary not to permit this unwarranted exemption to these products.

Thank you for the opportunity to comment on these recommendations. I would be happy to discuss, or provide any clarification, of these comments.

Respectfully submitted,

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