



IDFA
International
Dairy Foods Association



August 13, 2020

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

RE: Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk; Reopening the Comment Period; Docket No. FDA-2008-P-0086; 84 Federal Register 71834 (Dec. 30, 2019)

The International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) submit these comments regarding the Food and Drug Administration's (FDA) proposed rule to provide for the use of fluid ultrafiltered milk in the manufacture of standardized cheeses and related cheese products.

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate \$159 billion in wages and \$620 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy companies and cooperatives to food retailers and suppliers, all on the cutting edge of innovation and sustainable business practices. Together, they represent 90 percent of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. Delicious, safe and nutritious, dairy foods offer unparalleled health and consumer benefits to people of all ages.

The National Milk Producers Federation, established in 1916 and based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce two-thirds of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies like FDA. NMPF provides a forum through which dairy farmers and their cooperatives formulate policy on national issues that affect milk production and marketing.

Background

In response to a citizen petition submitted in 2000, in the *Federal Register* of October 19, 2005, FDA proposed to amend its regulations to provide for the use of fluid ultrafiltered (UF) milk in the manufacture of standardized cheeses and related cheese products. FDA also proposed that when this

milk is used, it would be declared in the ingredient statement as “ultrafiltered milk” or “ultrafiltered nonfat milk.” We submitted comments in January 2006 and again in April 2008 (in response to the reopening of comment period) on the agency’s proposal. In our comments, we supported the agency’s proposal to allow the use of fluid UF milk in standardized cheeses but explained why the proposed ingredient labeling for outsourced UF milk was inconsistent with established law and policy in a number of ways. We submitted extensive information showing that the proposed UF milk ingredient labeling requirement for standardized cheese would be impractical to implement due to the logistical and cost burdens imposed on industry, cause consumer deception, and lead to unfair competition with foreign products. We explained why ingredient labeling was not compelled under the law. We also outlined why, if FDA continued to view UF milk as a different ingredient than milk when used in cheesemaking, the agency could grant an exemption from labeling under the statute.

In August 2017, FDA issued a guidance document, notifying cheese manufacturers of the agency’s intent to exercise enforcement discretion on the use of fluid UF milk in standardized cheeses. The agency also announced its intent to exercise enforcement discretion with respect to the labeling of UF milk, in recognition of the costs and logistics involved in label changes. IDFA and NMPF greatly appreciate this guidance and the agency’s decision to exercise its enforcement discretion on both of these accounts. This action has been incredibly beneficial to industry and consumers alike.

Now, to inform its decision on whether to proceed with the 2005 proposed rule, the agency once again is seeking information on current industry practices regarding the use of fluid UF milk and the declaration of fluid UF milk on product labels in the ingredient statement. We write to reinforce the position taken and information provided in our two previous sets of comments to this docket. We also write to request that FDA expand the proposed rule to allow the use of fluid microfiltered (MF) milk in standardized cheeses.

Overview

FDA is considering whether, when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients, the labeling of standardized cheeses and cheese products may alternatively declare “milk or milk and ultrafiltered milk” or “nonfat milk or nonfat milk and ultrafiltered nonfat milk” in the ingredient statements. We continue to oppose this approach and maintain that when UF milk is used in cheese making, it should be declared as “milk.” Our position is based on the simple fact — which FDA has already recognized in proposing to allow for the use of UF milk in standardized cheese — that the use of ultrafiltration in the cheesemaking process “has no material effect on the final cheese product.” Simply, *when used in cheesemaking*, milk and UF milk are indistinguishable. To label cheese products otherwise would be false and misleading. Accordingly, to require “ultra-filtered milk” in the ingredient statement of a standardized cheese would be contrary to established law. Moreover, our industry has been under substantial economic pressures in recent years, which have been compounded by the COVID-19 pandemic. Against this legal and economic backdrop, there is no basis to impose significant costs on cheesemakers through such a labeling requirement, particularly when the industry has relied upon FDA’s existing policy regarding the use and labeling of UF milk in cheese for many years. Indeed, we are concerned that any decision to require separate labeling for UF milk would be arbitrary and capricious.

We also note that in the more than 20 years that have passed since IDFA initially submitted our citizen petition, research and advances in cheesemaking and milk filtration and its application for use in a wide variety of cheeses have evolved to include the use of microfiltered milk (MF milk). Therefore, IDFA and NMPF are requesting the use of both fluid UF and MF milk in the manufacture of standardized cheeses and related cheese products.

We expand on these points and respond to the specific questions the agency has proposed below.

Use of Fluid Ultrafiltered Milk in Cheese

In our 2006 and 2008 comments, we provided comprehensive information to the agency regarding the use of fluid UF milk in cheesemaking, including when and why it is used. We also provided detailed information regarding the labeling of this ingredient, including the legal basis for labeling this ingredient “milk” when used in cheesemaking. Moreover, we provided extensive information regarding the costs and burdens associated with a requirement to label the ingredient as “ultra-filtered milk.” Our previous submissions answered many of the questions the agency has raised with this reopening of the comment period. Therefore, we urge the agency to review those comments again, and we hereby incorporate them by reference into this submission.

Below, we repeat the agency’s questions in the most recent *Federal Register* notice in *italics* and then provide our response.

- 1. We would like to understand whether there is variable use of fluid UF milk or fluid UF nonfat milk in the production of standardized cheeses and related cheese products. For example, if a company uses fluid UF milk in the production of a standardized cheese, does the amount of fluid UF milk remain constant, or does the amount vary depending on certain factors (such as the cost of fluid UF milk)? Please explain whether the amount of fluid UF milk or fluid UF nonfat milk varies for specific standardized cheeses and related cheese products and the factors that influence the variability. To maintain the essential characteristics of the standardized cheese or cheese product, is the amount of fluid UF milk or fluid UF nonfat milk limited to a range (i.e., a minimum and maximum amount)? Please identify the specific standardized cheese or cheese product and provide any ranges or amounts and explain your reasoning.*

UF milk is used intermittently by some cheese producers. UF milk is used variably for the following reasons:

- Availability of Local Fresh Milk Supplies. Many cheese plants are located in areas of the country with limited or no nearby fresh milk supplies. UF milk is an efficient way to get milk from its source to cheese plants that are located far away.
- Price Compared to Fresh Milk. The cost of UF milk varies, just like the cost of fresh milk and other milk ingredients. The transportation of UF milk tends to be more cost efficient than the transportation of fluid milk because water unnecessary to the cheesemaking process is removed by filtration before shipment.
- Reduced Environmental Impact. Filtration provides a cost-effective way to transport milk from dairy-rich regions to areas in need of a supplemental milk sources. Because the milk is

transported in a concentrated form, more milk can be shipped with fewer loads, saving fuel, equipment, and other resources. There is no need to ship excess water that will simply be removed in the cheesemaking process. This makes UF milk not only cost-effective, but a milk source that promotes sustainability.

- Fluctuations in Fluid Milk Composition. For seasonal and other reasons, the composition of fluid milk can fluctuate. Whole fluid milk, for example, tends to have a lower fat and protein content in summer and a higher fat and protein content in winter. ¹/ Low protein is associated with low buffering capacity in milk and the resulting cheese is susceptible to defects such as too much acid or a soft body. UF milk serves to stabilize cheese quality and consistency when raw milk protein drops. UF milk is the best source of milk proteins for cheesemaking, as other alternatives all increase the lactose level in the cheese vat, which negatively impact the cheese (i.e. high milk lactose can cause excessive acidity in cheese, residual sugar can cause defects such as gas and browning).
- Availability and Price Compared to Other Milk Ingredients. UF milk is one of several dairy inputs that can be used to supplement cheese milk and to help reach a desirable protein-to-fat ratio, which must be carefully controlled to protect cheese quality. UF milk is used when it is more cost efficient or available as compared to other milk ingredients included under the collective naming regulations, such as concentrated milk, reconstituted milk, and dry milk.
- Depletion of In-House Resources. Although some cheese plants have the capability to filter milk in house, at times, typically due to supply shortages, they may need to augment with outside UF milk resources.

2. (a) We invite comment on why manufacturers may sometimes produce their particular brands of standardized cheeses and related cheese products with fluid UF milk or fluid UF nonfat milk and sometimes without fluid UF milk or fluid UF nonfat milk. Please explain your reasoning.

At present, due to the existing enforcement discretion, manufacturers do not make *brand* based decisions regarding the use of UF milk. Should FDA require ultrafiltered milk to be declared in the ingredient statement, however, then some manufacturers may only produce certain brands with fluid UF milk. These decisions would be based factors such as logistical complexity (e.g., use of trim, production of blends, use in process cheese, number of suppliers), customer preference (e.g., private label, foodservice, use in further manufacturing such as lasagna or pizza), and/or consumer demand or lack thereof. Some companies are likely to decide that they will not use ultrafiltered milk in particular brands, requiring their suppliers to discontinue use of an environmentally sustainable practice.

¹ Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture, Raising the Minimum Nonfat Solids Standard to the National Average in Raw Milk: A Study of Fluid Milk Identity Standards at 29 (Aug. 2003) (stating that in 2001, “the monthly averages for true protein content of farm milk in April through August were below the annual average and for January-March and September-December were above it.”). *See also id.* at 8 and 10.

(b) Given that manufacturers may sometimes choose to produce these products with or without fluid UF milk or fluid UF nonfat milk, we are interested in how ingredient labeling of these standardized cheeses and related cheese products could be addressed.

IDFA and NMPF maintain that the proper ingredient labeling of cheese products that contain fluid UF milk is to identify the ingredient as “milk.” FDA’s appears to be approaching the labeling question from the position that a container of fluid milk and a container of UF milk are different from each other. IDFA and NMPF agree that as a factual matter UF milk differs from fluid milk in that the “whey stream” has been removed and with it the contents of the whey stream, namely, water, lactose, whey proteins, and certain vitamins and minerals. *However, in the course of traditional cheesemaking, the whey stream is ALWAYS removed, so that the “milk” used in cheesemaking is “fluid milk without the whey stream”—the exact same product as UF milk.* The question, therefore, is not whether fluid milk and UF milk are the same or different in general; rather, the proper question is whether fluid milk, *as used in cheesemaking*, is the same or different from UF milk, and the answer is clear: they are the same. Accordingly, because the “milk” ingredient in cheese (milk without the whey stream) is the very same as UF milk (milk without the whey stream), the proper labeling for the ingredient is “milk.”

(c) Our understanding is that fluid UF milk and fluid UF nonfat milk, when used as ingredients in cheese, are always used in lesser amounts by weight than milk and nonfat milk in order to avoid affecting the physical, chemical, and organoleptic properties of the cheese. For example, a manufacturer might use milk and fluid UF milk, but our understanding is that the amount of fluid UF milk will be less than that of milk. As such, milk would be the predominant ingredient and declared first in the ingredient statement, per FDA's regulations that require ingredients to be declared by their common or usual names in descending order of predominance by weight (21 CFR 101.4(a)). Fluid UF milk, if used, would be declared thereafter.

Cheesemaking and milk filtration technology have advanced so that it is possible to produce cheese solely from fluid UF milk. As a practical matter, manufacturers do not frequently produce cheese solely from outsourced UF milk for economic reasons. Namely, to produce cheese solely from fluid UF milk, the UF milk would be concentrated to a lesser degree than UF milk that will be blended with milk in the cheese vat. The lesser the concentration, the more water is present, the higher the transportation costs. Nonetheless, a cheesemaker with the ability to procure UF milk close to the cheese plant could find it worthwhile to purchase and produce cheese solely with outsourced fluid UF milk. Further, depending on the concentration level used, UF milk may be used in combination with fluid milk, but be the predominate ingredient. Therefore, a labeling scheme that presupposes “milk” as the predominant ingredient would not be accurate.

(d) Based on our understanding, we are considering whether, when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients, the labeling of standardized cheeses and cheese products may alternatively declare “milk or milk and ultrafiltered milk” or “nonfat milk or nonfat milk and ultrafiltered nonfat milk” in the ingredient statements. We invite comment on this consideration and whether such declarations would indicate that fluid UF milk or fluid UF nonfat milk may be an ingredient, but not as predominant as milk or nonfat milk, and also enable manufacturers to avoid relabeling costs if they use

varying amounts of fluid UF milk or fluid UF nonfat milk. Please discuss whether such declarations would be informative (or, conversely, potentially misleading to consumers) and please explain your reasoning.

As explained above, the labeling proposals under consideration would not be accurate. They do not account for the fact that UF milk may be the predominate ingredient or may be the only dairy ingredient in the product. Furthermore, these proposals do not take into account a combination of whole and nonfat milk in the making of cheese, or the use of reduced fat milk. For example, a cheesemaker may use whole milk and nonfat UF milk; or it may use milk, nonfat milk, and nonfat UF milk. There is no “one-size-fits-all” label declaring UF milk that encompasses all of the possibilities. Thus, the labeling proposals under consideration would not enable manufacturers to avoid relabeling costs, as manufacturers would continue to be required to maintain various sets of labels for the products they produce and track the use of various ingredients used in these products.

More importantly, these labeling proposals would be misleading to consumers. As we have discussed in our comments previously submitted to this docket, any labeling scheme that requires UF milk to be specifically declared in the ingredient statement of a cheese product is misleading. For purposes of cheesemaking, there is no difference between cheese produced with outsourced fluid UF milk, cheese produced with in-plant fluid UF milk, and cheese produced from milk. Yet, these products would be labeled differently with the first product declaring fluid UF milk and the other two stating only “milk.” IDFA previously commissioned an internet-based consumer study that documented, in very clear terms, that a high percentage of consumers mistakenly attribute important differences—including differences in taste, healthfulness and quality—to UF milk labeled products. Similar results were found in a second study conducted separately by one of IDFA’s member companies. Why wouldn't consumers be misled by two products that are identical but the labeling different? Consumers are naturally misled when a label suggests a difference when, in fact, there is none.

We also submit that consumers would be misled by the proposed labels because they state that UF milk may be present. That may not be the case. For example, for logistical reasons, a manufacturer that sources cheese from several different suppliers may be forced to declare UF milk on all product labels, rather than separately track the suppliers that use it. Therefore, even if some of the finished cheese will never contain UF milk, the product label would suggest that it could. This also would be false and misleading.

Notably, consumers have been enjoying cheese produced with fluid UF milk for decades. Cheesemakers always have been permitted to use in-plant UF milk in standardized cheeses under the “alternate make” provisions in the standards. Further, FDA first exercised enforcement discretion for the use of outsourced fluid UF milk in cheddar cheese in 1996. And outsourced fluid UF milk has been permitted in all standardized cheeses for the past three years. In all cases, the use of UF milk has been identified to consumers as “milk.” There is no evidence to suggest that consumers have been misled or harmed by this practice.

Finally, we note that FDA could only impose the type of “and/or” labeling under consideration if the agency finds separate ingredient labeling for ultrafiltered milk to be “impracticable” under Section 403(i)

of the Federal Food, Drug, and Cosmetic Act. If that's the case, then the agency should provide an exemption from ingredient labeling under the statute altogether, rather than proceed with the labeling options under consideration.

3. We also are interested in issues related to the costs of printing different product labels and the logistics involved in label changes when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients in the production of a manufacturer's standardized cheese or cheese product. For example, what impacts, if any, would a label statement of "milk or milk and ultrafiltered milk" or "nonfat milk or nonfat milk and ultrafiltered nonfat milk" have on labeling costs? How would these costs compare if fluid UF milk and fluid UF nonfat milk are declared only when used in the standardized cheese or cheese product? Please explain your reasoning.

We have previously submitted detailed information regarding the logistics and costs associated with label changes and the estimated costs that would be incurred if manufacturers were required to declare outsourced UF milk on product labels. Please see our 2006 and 2008 comments.

In our previous comments we explained how a labeling requirement would place a considerable burden on cheese processors who convert cheese from suppliers into other products such as shreds, blends, and process cheese, as there may be multiple suppliers for each of the various cheese inputs. These complexities would remain with the proposed labeling statements under consideration. But even if we were to assume a manufacturer only needed to change its labels once and that it would not have to manage multiple labels, changing every single product label would be a significant cost.

Yet there is no reason to impose such a cost on the cheese industry, particularly when cheesemakers have just recently had to update their labels to reflect the updated Nutrition Labeling requirements and are in the process of updating their labels to reflect required bio-engineered food labeling disclosures. We note that the Administration has instructed FDA to consider rescinding, modifying, waiving, or providing exemptions from regulations and other requirements that may inhibit economic recovery from the COVID19 pandemic.² Now is not the time to impose costly labeling requirements without a corresponding benefit to the public interest.

Indeed, the absence of a basis for requiring labeling of UF milk is concerning because the Administrative Procedure Act's ("APA") arbitrary and capricious standard requires agencies to provide a "reasoned analysis" for rulemaking decisions.³ Moreover, in light of the agency's long standing enforcement discretion with respect to labeling and the use of outsourced UF milk in cheese, any decision to require labeling would raise questions about compliance with APA standards. First, as the Supreme Court recently explained, "*State Farm* teaches that when an agency rescinds a prior policy its reasoned analysis must consider the 'alternative[s]' that are 'within the ambit of the existing [policy]'."⁴ Thus, the final rule must consider the possibility of continuing to permit cheesemakers to label UF milk as "milk."

² Executive Order on Regulatory Relief to Support Economic Recovery (May 19, 2020).

³ Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 57 (1983).

⁴ Dep't of Homeland Sec. et al. v. Regents of the Univ. of Cal. et al., No. 18-587, slip op. at 23 (U.S. Jun. 18, 2020) (quoting Motor Vehicle Mfrs. Ass'n. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U. S. 29, 51 (1983))

Second, the Supreme Court also advised that “[w]hen an agency changes course . . . it must ‘be cognizant that longstanding policies may have ‘engendered serious reliance interests that must be taken into account.’”⁵ Cheesemakers have relied upon the agency’s current policy, which allows ultrafiltered milk to be declared as “milk,” for many years. Any decision to require labeling for UF milk in cheese must take this reliance into account.

In sum, there are several reasons why FDA should not require separate labeling for UF milk in standardized cheeses: (1) There is a legal basis for declaring UF milk as “milk;” (2) A separate labeling requirement would be misleading to consumers; (3) A separate labeling requirement would be costly to industry; (4) The agency’s current policy does not require separate labeling, demonstrating both that this is a feasible option and that consumers are not harmed; and (5) Industry has substantial reliance interests in the current policy. We see no reason to require separate labeling for UF milk in cheese, much less one that outweighs the reasons against such an approach as outlined above and in our previous comments.

4. Ultrafiltered milk is being used in a greater number of food products than in the past. There are dairy products in the marketplace, which appear to have gained consumer acceptance, where “ultrafiltered milk” has appeared in the statement of identity or declared in the ingredient statement on the product label. Are there any situations where retailers or consumers would not purchase standardized cheeses or cheese products labeled as containing “ultrafiltered milk” as an ingredient? Please describe such situations and provide any recent consumer data or market analyses you may have to explain your reasoning.

We anticipate consumers and retailers (particularly those with private label brands) may not purchase standardized cheese products labeled as containing UF milk. These customers may not like the confusing declaration “milk or milk and ultrafiltered milk” on the ingredient label, preferring a “simple” ingredient statement; they may mistakenly believe that the cheese is different from other cheeses; or retailers may simply fear that consumers will reject this product. Therefore, if the agency adopts the labeling scheme under consideration, in some instances cheese manufacturers would continue to need to produce two sets of labels for their products – one for those produced only with milk and one for those sometimes produced with milk and UF milk. Quite simply, the “and/or” labeling under consideration would not allow the cheese industry to go to only one label, and all of the impracticalities associated with having to produce two types of products would be incurred.

More importantly, the existence of products in the marketplace that are labeled as “ultrafiltered milk” or contain ultrafiltered milk as an ingredient underscores why cheese made with or from UF milk should be labeled as containing “milk.” Because they either are ultrafiltered milk or contain ultrafiltered milk, these other products are different from their counterparts. Fluid UF milk sold as a beverage contains more protein and calcium and less sugar than “milk.” Ice cream made with UF milk has more protein, less sugar, and fewer calories than ice cream made without UF milk. In contrast, cheese made with

⁵ Id. at 24 (citing Encino Motorcars, LLC v. Navarro, 579 U. S. ___, ___ (2016) (slip op., at 9) (quoting FCC v. Fox Television Stations, Inc., 556 U. S. 502, 515 (2009))).

ultrafiltered milk is the exact same product as cheese made without UF milk. For purposes of cheesemaking, UF milk and milk are the same and should be identified as “milk.”

If our labeling survey in 2005 showed that consumers would perceive cheese labeled as containing UF milk to be different than cheese labeled as only containing milk, then we would expect those results to be magnified today. In particular, we suspect that consumers may believe that a cheese made with UF milk would have enhanced nutritional properties, resulting in a healthier cheese. Thus, the existence of other products in the marketplace reinforces that to avoid misleading consumers, when used in cheese, ultrafiltered milk should be identified as “milk.”

Use of Fluid Microfiltered Milk in Cheese

In the 20 years since the citizen petition was filed and in the 15 years since FDA issued its proposed rule to allow for the use of fluid UF milk in standardized cheeses, milk filtration and cheesemaking technology have both evolved. In particular, both UF milk and microfiltered (MF) milk produce cheese with the same finished characteristics as cheese produced with milk. Accordingly, IDFA and NMPF respectfully request that FDA expand the proposed allowance for the use of UF milk to encompass fluid MF milk as well.

All milk membrane filtration processes separate the components of milk based on size. The largest pore size is microfiltration and the next smaller is ultrafiltration. However, there is no rigid definition of these two types of membrane filtration: there is overlap between the small pore size for microfiltration and the large pore size for ultrafiltration. The difference is that based on the orientation of the components, microfiltration retains fat, bacteria, and casein proteins, whereas lactose, and whey proteins can pass through. In contrast, ultrafiltration retains all milk proteins and fat (lactose can pass through).

For cheesemakers, there are several advantages for concentrating cheese milk by membrane filtration, including: increased cheese yield, increased productivity, more consistent process, less seasonal variation, and avoiding problems caused by excessive lactose if skim milk powders are used. In addition, milk-derived whey has significant advantages over cheese-derived whey. In particular, milk-derived whey has a superior flavor and is clearer (due to lower fat content); it has fewer off-flavors (no cheese starter culture or rennet enzymes from the cheesemaking process are present); and there are no color issues from colored cheeses (many international markets only want uncolored whey for use in products like infant formula). Therefore, both cheesemakers and dairy producers have a common interest in an allowance for fluid MF milk in cheese.

As the agency is aware, cheesemaking is essentially a concentration process where the milk protein casein and fat are concentrated, and water, whey, and lactose are partially removed. This is the same process as producing MF milk. Therefore, it is not surprising that the Center for Dairy Research at the University of Wisconsin has conducted research and determined that use of MF milk in cheesemaking in combination with other milk inputs does not affect key attributes of the finished product. Indeed, the same fat, moisture, total protein, salt, milk-solids-not-fat, fat in dry matter, and nutritional properties were achieved when cheese was produced with MF milk.⁶

⁶ Reale, E., S. Govindasamy-Lucey, M. E. Johnson, J. J. Jaeggi, M. Molitor, Y. Lu and J. A. Lucey. 2020. Impact of the depletion of whey proteins from unconcentrated milk using microfiltration on the yield, functionality and nutritional profile of Cheddar cheese. *Journal of Dairy Science* (in press).

When the agency issued its proposed rule in 2005, the proposed definition of ultrafiltered milk included a fixed casein:whey protein ratio. Specifically, the agency proposed: “ultrafiltered milk means 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.” We believe this definition is overly restrictive and does not account for the advances in technology and research in the intervening years.

First, whey proteins are lost with the whey stream during traditional cheesemaking and only trace amounts are present in the final cheese. Second, the actual concentrations of casein and fat in milk can vary, as well as the ratio of casein to total protein, due to breed, season, stage of lactation, etc. Neither are fixed. Third, currently under the standards of identity it is acceptable to increase the concentrates of protein components through the addition of ingredients like nonfat dry milk. Thus, a focus on the casein:whey ratio is misplaced.

Moreover, microfiltration currently is being used extensively outside of the U.S. We know of at least 50-60 cheese plants in Europe currently producing cheese with MF milk and at least 15 European companies that are supplying MF milk and milk-derived whey. This creates significant advantages for European operations and results in unfair competition for U.S. businesses. These companies are not labelling MF milk and these companies do export cheese products to the U.S.

Therefore, we urge FDA to reconsider its decision to limit the use of filtered milk in cheesemaking to ultrafiltered milk. We respectfully request that FDA expand the proposed rule to include the use of fluid microfiltered milk. To account for evolving technologies, we suggest that the definitions of “milk” and “nonfat milk” at 21 CFR 133.3 include “filtered milk” and “filtered nonfat milk.” “Filtered milk” would be defined to mean “raw or pasteurized milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, water-soluble vitamins, or whey proteins, resulting in a liquid product.” When either UF or MF milk are used in cheesemaking, they would be identified in the ingredient statement as “milk.”⁷ We believe this action would be a “logical outgrowth” of the proposed rule and would not necessitate additional notice and comment rulemaking. This approach is compatible with the very broad and overlapping size ranges for these two membrane types.

Conclusion

IDFA and NMPF urge FDA to re-evaluate its tentative position on ingredient labeling for UF milk and determine either that ingredient labeling is not called for or that standardized cheese made with UF milk should be exempted from the ingredient labeling requirement. Both approaches are fully supportable and both are extensively documented in the administrative record in this rulemaking. Indeed, we believe that the administrative record in this matter shows that FDA may not and should not require UF milk ingredient labeling, and a decision to the contrary would be arbitrary and capricious.

We also urge FDA to expand the proposed allowance for the use of UF milk to encompass fluid MF milk as well.

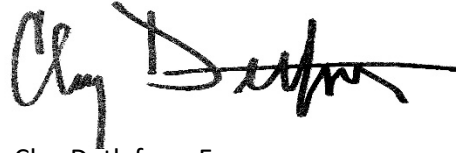
⁷ FDA could accomplish this by amending 21 CFR 101.4(b)(3) and 4) to state the following: “Skim milk, concentrated skim milk, reconstituted skim milk, ~~and~~ nonfat dry milk, and filtered milk used to make cheese and cheese products, may be declared as “skim milk” or “nonfat milk”.”; and, “Milk, concentrated milk, reconstituted milk, ~~and~~ dry whole milk, and filtered milk used to make cheese and cheese products, may be declared as “milk”.”

If IDFA or NMPF can assist the agency with additional information or perspectives, please contact us.

Sincerely,

A handwritten signature in black ink that reads "Joseph Scimeca". The letters are cursive and somewhat slanted to the right.

Joseph Scimeca, Ph.D.
Senior Vice President, Scientific and
Regulatory Affairs
International Dairy Foods Association

A handwritten signature in black ink that reads "Clay Detlefsen". The signature is highly stylized with a large, sweeping flourish at the end.

Clay Detlefsen, Esq.
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