

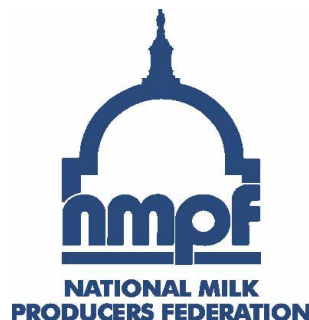


International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association



June 3, 2009

BY FIRST CLASS U.S. MAIL AND ELECTRONIC DELIVERY

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**Re: Follow up to our January 7, 2009 meeting with CFSAN
concerning labeling of ultrafiltered milk in cheese.**

Dear Dr. Bernard:

We are writing to follow up on our January 7, 2009 meeting with Mike Landa, you, and others within the Center to discuss our industry's significant concerns that labeling externally produced fluid ultrafiltered milk (UF milk) 1/ as an ingredient in cheese would be impracticable. 2/ Near the end of our meeting, we briefly outlined the regulatory pathways that are available, based on past FDA practice, for crafting an exemption from ingredient labeling in the event the agency agrees with us that labeling UF milk as an ingredient in cheese is impracticable. This letter expands on that discussion as time was not available to do so that day. 3/

In brief, impracticability assessments lead to a fork in the regulatory road, with two primary pathways: (1) include the ingredient within a collective term (e.g.,

1/ Our use of the term UF milk here refers only to fluid UF milk and does not concern dried forms. We use external UF milk to mean milk that is filtered outside of a cheese plant (e.g., at a facility on or near a dairy farm) and then transported as a form of milk for use in making cheese.

2/ Our previous submissions and the materials from our January 7 meeting addressed in extensive detail why labeling of UF milk in cheese is impracticable. We do not repeat those arguments here, but refer you to those earlier materials in the rulemaking record.

3/ As with our presentation at the January 7, 2009 meeting, we have no objection to the agency including this letter in the administrative record for the UF milk rulemaking proceeding.

declare UF milk as “milk”) or (2) declare the ingredient in “and/or” labeling (e.g., declare “milk and/or ultrafiltered milk”). In this letter, we underscore why the collective term approach is the best option for labeling UF milk, and why “and/or” labeling would itself be impracticable, defeating the purpose of a labeling exemption. ^{4/}

Background

Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires a food label to declare the common or usual name of each ingredient whenever the food is made of two or more ingredients. Section 403(i) also permits FDA to establish exemptions from the ingredient labeling requirement by regulation to the extent that compliance with the requirement is impracticable, or results in deception or unfair competition. The agency has used different types of exemptions to address different types of impracticability, ranging from a total exemption from labeling (as FDA allowed in the case of incidental additives), to collective terms like “milk,” to “and/or” labeling.

This exemption authority is most reasonably viewed as a tool to resolve the specific challenges that caused a labeling requirement to be impracticable in the first place. FDA has approached past impracticability assessments in a very factual, case-by-case way, ultimately leading to a reasonable fit between the facts presented by each ingredient and the labeling approach chosen.

Labeling of UF milk in cheese presents its own very unique set of facts and issues. As explained more fully below, UF milk is part of a well-developed and dynamic commercial system for getting cheese milk to cheese plants, which make cheese that is in turn used in countless other downstream products. The highly variable and intermittent (though quite important) use of UF milk, together with the considerable downstream effects that are unique to the cheese industry, make it unlikely that industry will be able to use “and/or” labeling in the way such labeling is typically intended—to cover a particular manufacturer’s use of technical ingredients in relatively small amounts in products that are often sold as such and not repackaged or further processed. The way that external UF milk is used fits very well with a collective term like “milk.” A collective term would be consistent

^{4/} We maintain that, as set out in our earlier submissions, the agency has a clear legal basis to determine that, in cheese, UF milk is not a separate ingredient from milk. The agency has already determined that UF milk has the same basic nature as milk in cheese (*see* note 11 *infra*), consistent with the principles for a common or usual name in 21 C.F.R. § 102.5(a). Industry views UF milk as an in-process form of milk used when it is more efficient than milk to deliver to cheese plants.

with both FDA precedent and the commercial framework, while providing meaningful information to consumers.^{5/}

1. “And/or” labeling of UF milk as an ingredient in cheese is impracticable

FDA has permitted “and/or” labeling for four sets of ingredients: (1) fats and oils; (2) various baking ingredients, including leavening agents, yeast nutrients, and dough conditioners; (3) firming agents; and (4) surimi. Labeling was impracticable in these cases because manufacturers needed flexibility to change ingredients due to factors like variable market conditions such as availability or price (fats and oils, surimi) or variable formulation needs that require recipe adjustments to minor, technical ingredients (firming agents, leavening agents, yeast nutrients, dough conditioners). In all four cases, manufacturers requested, and FDA granted, the flexibility needed for very specific situations.

“And/or” labeling made sense for these ingredients because it resolved the labeling challenges at issue. With “and/or” labeling, each manufacturer could decide for itself whether that kind of flexibility was needed, and then use one label for each product. Significantly, downstream effects were not identified by the agency as the basis of impracticability in any of the four “and/or” exemptions FDA has granted to date.^{6/} The identity of the specific ingredients also had at least some relevance for consumers. Ingredients such as vegetable oils or fish of different species begin with different foods. Olive oil is different from palm oil, which is different from cottonseed oil or beef fat. Pollock is not cod. Calcium carbonate and baking soda are different chemicals, not different forms of the same ingredient.^{7/}

^{5/} In this letter, we focus on the “impracticability” problem with “and/or” labeling, however, at the January 7 meeting, we also raised other problems with “and/or” labeling that remain relevant, even though we do not address them further here.

^{6/} The petitioners for “and/or” labeling of firming agents did raise a possible effect on private label distributors as a possible problem. However, FDA, in the final rule, based its decision on the economic benefits of flexibility for manufacturers to take advantage of price fluctuations. *See* 48 FR 8053-54. In any event, the one layer of downstream effects raised by the firming agents petitioners does not compare meaningfully to the multiple and expanding layers of downstream effects affecting countless products that would result from labeling UF milk in cheese.

^{7/} We note that UF milk in cheese is also different from the use of high fructose corn syrup (HFCS) and sugar as sweeteners in soft drinks, which the agency considered for “and/or” labeling. The downstream effects of labeling UF milk in cheese are much more extensive and wide-ranging than for bottled soft drinks. Soft drinks are not typically commingled or incorporated into numerous other products. Moreover, many consumers know what HFCS is, know that it is different from cane sugar, and have an opinion about it. The same is not true of UF milk. The particular ingredient identity of UF milk is less relevant than for HFCS. This is supported by the agency’s position that cheese made with ultrafiltered milk through alternate make need not be labeled.

UF milk in cheese is different from these other examples. As discussed at the January 7 meeting, UF milk is an efficient and sustainable way to get cheese milk to cheese plants. Cheese is unusual – and unlike any of the ingredients for which FDA has granted “and/or” labeling – in that it is repeatedly packed and repacked, broken and commingled, processed into other types and forms of cheeses, and added to many, many other foods. Although cheese may be sold to consumers as such (e.g., as a block of “cheddar cheese”), it is also a significant ingredient in countless other foods. If one were to diagram the supply chain of cheese, it would look like a tree, with the bulk cheese as the trunk, and branching off to multiple products at each layer of the supply chain. As a result, though UF milk is only used in a fraction of total cheese produced in the United States, a requirement to label UF milk in cheese would be felt well beyond cheese manufacturers.

In considering whether labeling UF milk in cheese is impracticable, FDA will want to consider all of the relevant factors. The need to use UF milk in some cheeses as a result of market conditions (e.g., price and availability of milk) is just one reason why labeling of UF milk in cheese is impracticable. Labeling UF milk in cheese is also impracticable because the need for UF milk is decided at the very beginning of a diverse and complex supply chain. For example, consider the supply chain for the cheddar cheese ingredient in a pizza product. A bulk cheddar cheese manufacturer sells its bulk cheddar to numerous manufacturers of varied cheese products, such as shredded cheese, cheddar cubes, cheddar slices, cheddar cheese powders, and processed cheeses. One of the purchasers of the bulk cheddar cheese breaks and commingles it with cheese from multiple suppliers to create a shredded cheddar cheese product. The shredded cheese manufacturer, in turn, sells the shredded cheddar cheese to numerous manufacturers of varied products containing cheese, such as pizzas, burritos, soups, frozen dinners, cheese crackers, stuffed jalapenos, or salad dressings. One of the purchasers of the shredded cheddar cheese also sources shredded cheddar, mozzarella and Monterey jack cheeses from multiple suppliers to make a Three Cheese Pizza product. If there were a UF milk labeling requirement, every product in the supply chain would have to track whether any supplier in the chain used UF milk.

Impracticability that is driven by a multiple-layer supply chain is not resolved by “and/or” labeling because early decisions made to benefit a cheese plant’s particular circumstances will affect all of the downstream products. Consider the example of a packaged cracker product made with a process cheese spread. The manufacturer of the finished cracker product may buy the cheese spread from one or more process cheese suppliers, which in turn will make the spread from cheddar and other cheese varieties purchased from several cheese manufacturers. The decision to use UF milk is made at the beginning of this supply chain. If the process cheese plant has five cheddar cheese suppliers, and just one

uses external UF milk, or expects it *might* use external UF milk (it might be difficult to predict in any given year), then a unique labeling requirement for UF milk will be felt all the way through the supply chain. This would be true even though a manufacturer who uses UF milk will probably use only a few tanker loads daily (as discussed in the meeting, one cheese plant in California that uses UF milk regularly might receive only 5 tankers of UF milk of 250 total milk tankers daily). It would be true even though another supplier, who might not expect to use UF milk but cannot rule it out, may go for a year or more without using it, but feels it must adopt “and/or” labeling to be safe. And it would be true even though a third supplier might filter milk inside the cheese plant, making exactly the same cheese, but without the labeling consequences.

The situation presented by UF milk has not been addressed in previous “and/or” decisions. It is difficult to predict exactly how industry would react to “and/or” labeling, but at least two scenarios seem likely:

- Some cheese suppliers either depend heavily on occasional shipments of UF milk, or will think they might need to allow for that possibility. These suppliers would probably use “and/or” labeling, and all of their downstream customers (their direct accounts, and their accounts, and so on) would need to carry the labeling through to all labels of cheese-containing products, even though it is quite unlikely that any given product would actually contain cheese made with UF milk. This scenario makes “and/or” labeling the practical equivalent of a “may contain” statement because the facts would permit no other conclusion for many products. FDA, however, has expressly rejected as “useless” for consumers labeling that doesn’t tell consumers whether a particular ingredient will ever be present in a product. In allowing “and/or” labeling for fish protein used in surimi, FDA suggested that “and/or” necessarily means that an ingredient will sometimes be present in the product.^{8/} As a practical matter, then, “and/or” labeling would impose substantial additional supply-related costs, but without giving consumers useful information.^{9/}

^{8/} FDA rejected a proposal to allow “may contain” labeling for surimi, explaining that “FDA believes that the statement that a food may contain a particular fish species would be useless to consumers because the statement would not advise them whether the product would ever contain the fish species named. On the other hand, “and/or” labeling informs the consumer that one or more of the fish species declared is sometimes present in the product. Therefore, the agency is not granting the request to allow the use of the term “may contain” in the declaration of fish species in fish protein.” Final Rule, *Food Labeling: Declaration of Ingredients*, 64 FR 50445, 50446 (Sept. 17, 1999)

^{9/} FDA’s regulations authorizing “and/or” labeling exemptions state that the applicable ingredients, even if not present in the product, “may be listed if they are sometimes used in the

- In some parts of the industry, customers will insist that suppliers supply only cheese without UF milk, to avoid the associated inefficiencies or for other reasons. The suppliers of these customers would be left with two inefficient choices: (1) stop manufacturing or using any cheese made with UF milk, or (2) establish dual inventories and tracking for cheese containing UF milk (and, for cheese manufacturers, reconfigure plants and business models). The first choice may not be feasible for reasons of supply or plant capacity—for example, the local milk supply might not be adequate, or a particular plant may not have adequate capacity to fill orders without using external UF milk. The second choice results in similar costs as if no labeling exemption were granted.

We recognize there are situations in which a labeling proposal is worth the added cost. For example, a labeling requirement may be justified if it will benefit public health or safety, or will otherwise provide meaningful information such as convey a nutritional benefit that, on balance, outweighs the costs. In the case of labeling UF milk in cheese, however, the benefits to consumers are unclear at best. “And/or” labeling does not tell consumers whether a product contains UF milk or not, only that it “may contain” UF milk. Moreover, UF milk does not pose any safety or allergen risk separate from milk, so “and/or” labeling does not provide any safety benefit over no labeling of UF milk.

2. A collective term for UF milk and milk in cheese is consistent with FDA precedent

Unlike “and/or” labeling, use of a collective term that encompasses both UF milk and milk would permit the industry to maintain a single label, resolve the impracticability challenge, and provide meaningful information for consumers. FDA’s findings in the proposed rule for UF milk in standardized cheese are consistent with the agency’s previous reliance on collective terms to address impracticability.

In permitting use of the collective term “milk” for milk, concentrated milk and dried milk used in certain cheeses, [10](#)/ FDA considered that:

[T]he sources of milk solids in processed cheese products vary from day to day depending on factors such as availability and price, and there is

product.” See 21 CFR 101.4(b)(14), (16)-(19) and (23). This standard would not be met for a cheese product in which no UF milk is ever used.

[10](#)/ 21 C.F.R. § 101.4(b)(3)-(4).

no detectable difference in the finished products through such variations in the sources of milk solids. [11/](#)

The agency determined that a collective term could be used where the collective term is “reasonable and meaningful to consumers.” [12/](#) In later extending the use of the collective terms for milk and dairy ingredients to all non-standardized foods, the agency stated:

The Commissioner is aware that some consumers prefer foods made using fresh milk or fluid skim milk, rather than foods made using other forms of milk, such as dried milk.... However, since most food products made using concentrated milk or dry whole milk have the same nutritional value and the same taste as foods made using fluid milk, the Commissioner concludes that consumers will not be deceived by declaration of these ingredients by the class name “milk.” [13/](#)

Similarly, FDA determined in the proposed rule to allow use of UF milk in cheese because “the use of fluid UF milk is consistent with the basic nature of cheese in that the starting ingredient is milk.” [14/](#) The proposed rule limits the use of UF milk to uses in standardized cheeses that do not affect the physical or chemical characteristics of cheese. [15/](#) Consumers are protected and would not be deceived by use of UF milk in cheese because UF milk cannot be used in a way to change the cheese, and because it poses no safety or allergen risk separate from milk itself. Given these limitations in the proposed rule, it is difficult to imagine how the failure to declare UF milk would harm or deceive consumers, particularly since under the proposal, firms may continue to ultrafilter milk to make cheese without any special labeling, so long as the ultrafiltration takes place in-plant under an alternate make procedure.

In addition to relying on collective terms to cover various forms of milk, FDA has also allowed collective labeling to help manage the challenges of complex downstream effects. In permitting collective terms for waxes and resins on fruits

[11/](#) Final Rule, *Certain Cheese Products; Labeling Requirements*, 37 FR 13339, 13340 (July 7, 1972). The collective terms were later re-codified out of the individual cheese standards of identity to apply to labeling of milk or dairy product ingredients in any food.

[12/](#) *Id.*

[13/](#) Final Rule, *Food Labeling and Label Declaration of Ingredients Requirements*, 41 FR 1156, 1158 (January 6, 1976).

[14/](#) Proposed Rule, *Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk*, 70 FR 60751, 60756 (October 19, 2005). The agency distinguished UF milk from other forms of filtration, such as microfiltration, “that are specific individual components of milk and are no longer milk.”

[15/](#) *See id.* at 60757.

and vegetables, the agency considered that, in addition to a need for flexibility of ingredients based on seasonal, product, and market conditions, [16/](#) ingredient labeling was impracticable because multiple lots of fresh fruit and vegetables from different areas and different suppliers are frequently commingled. [17/](#) The industry in that case was structured in such a way that it would be seriously impeded in its ability to meet demands and specifications of customers if industry could not commingle product. The agency concluded that the increased costs of ingredient labeling could not be justified if consumer needs could be met through alternative labeling provisions, which in that case included use of collective terms.

FDA specifically selected the use of collective terms for waxes and resins on fruits and vegetables to address the needs of downstream retailers, whose needs could only be met through commingling: “[t]he agency is proposing to permit retailers to use appropriate collective names because of the constant change of produce items in marketing areas.” [18/](#) Similarly, the agency permitted packers and repackers to use the collective terms because of the impracticability posed by commingling. “The agency finds...that the loss of specific lot identification because of commingling of variously coated produce while in bulk storage at the wholesale distributor level makes specific ingredient declaration impracticable.” [19/](#)

Downstream labeling effects are also a key issue for the cheese industry. As described previously, cheese is repeatedly packed and repacked, broken and commingled, processed into other types and forms of cheeses, and added to a large number of other foods. Commingling practices, such as the use of trim and rework to make process cheese, reflect an efficient industry structure. Use of a collective term will allow industry to meet processing and consumer needs without unreasonable costs.

Summary and Path Forward

External UF milk is a key form of cheese milk that is used by cheese plants in small, but variable and meaningful, amounts at the very beginning of a lengthy supply chain. If the agency agrees that labeling UF milk in cheese is impracticable, we ask the agency to choose an exemption from ingredient labeling that addresses the impracticability. The collective term “milk” is consistent with FDA precedent, the commercial framework, and the enforcement policy that has been in place for milk and UF milk in cheese for the past ten years. It addresses the impracticability; “and/or” labeling does not.

[16/](#) Final Rule, Food Labeling; Declaration of Ingredients, 58 FR 2850, 2860 (Jan. 6, 1993).

[17/](#) *Id.*

[18/](#) Proposed Rule, Food Labeling; Declaration of Ingredients, 56 FR 28592, 28613 (June 21, 1991)

[19/](#) 58 FR at 2861.

Dr. Susan Bernard

June, 3, 2009

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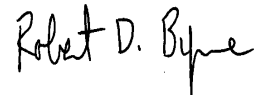
The agency does not need to amend the collective term “milk” in 21 C.F.R. § 101.4(b) – which applies to the ingredients included in that term when used in any food – in order to grant a collective term exemption for UF milk and milk in cheese. The proposed rule addresses use of UF milk in cheese products. An amendment to the general provisions of the cheese standards in 21 CFR Part 133 would be appropriate for a collective term limited to the use of UF milk and milk in cheese. Regardless of its placement, a collective labeling allowance should apply to all types of cheese, including standardized and non-standardized products.

We appreciate the opportunity to present our views and we look forward to continuing to work with the agency on this issue. Please let us know if we can provide you with further information that would be of help.

Sincerely,



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cc: Felicia B. Billingslea, CFSAN, Director, Food Labeling and Standards
Michael M. Landa, FDA, Acting Chief Counsel