January 17, 2006

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

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

The International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) submit these comments regarding the Food and Drug Administration's (FDA) proposal to amend its regulations to provide for the use of fluid ultrafiltered milk in the manufacture of standardized cheeses and related cheese products. IDFA is the Washington, D.C. – based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA comprises three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). These comments are filed on behalf of the National Cheese Institute which has 90 member companies that manufacture 80% of the cheese consumed in the U.S. The National Milk Producers Federation, based in Arlington, VA, develops and carries out polices that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 33 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of nearly 50,000 dairy producers on Capitol Hill and with government agencies.

IDFA and NMPF are joined in these comments by the Grocery Manufacturers Association, the Food Products Association, the American Dairy Products Institute, and the Wisconsin Cheese Makers Association.

EXECUTIVE SUMMARY

IDFA and NMPF applaud the agency for recognizing that the basic nature and the essential characteristics of cheese are maintained when fluid ultrafiltered (UF) milk is used in the cheesemaking process. We greatly appreciate

the depth of FDA's technical review of this issue and the agency's focus on the scientific merit of the cheese industry's petition. We strongly support FDA's proposal to amend its regulations to allow for the use of liquid UF milk in the manufacture of standardized cheese and cheese-related products. We believe that authorizing the use of UF milk in this way is scientifically justified and will provide benefits to industry and consumers alike. We are also particularly pleased that FDA has chosen to explicitly define the UF milk process in the proposed definitions. FDA should continue to assure, through definition, that liquid UF milk is not a product of recombining ingredients or rehydrating a dry product. FDA should reject any attempt to allow for this type of change to the definition of UF milk.

However, we take serious issue with the agency's proposed requirement for special ingredient labeling of outsourced UF milk when used in the cheesemaking process. 1/ Specifically, we believe the proposed requirement for labeling of outsourced UF milk on the ingredient label is not justified by established FDA precedent, provides no benefit to consumers, is impracticable to implement, and would result in consumer deception. Indeed, we believe the single change that FDA should make in the final rule is to remove the proposed special labeling requirement or otherwise provide for an exemption from ingredient labeling.

IDFA and NMPF believe that the proposed ingredient labeling requirement for outsourced UF milk is inconsistent with established law and policy in a number of ways. Underpinning all of these points is 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. The parts of the milk that are removed during ultrafiltration are removed anyway during the traditional cheesemaking process. Ultrafiltration is just another technique for producing the same finished food. To the consumer, the two products are identical, and the labeling should be identical as well. This position is further supported by the following:

- There is no valid basis for the distinction in the proposed rule between outsourced UF milk that is brought into the cheesemaking plant and milk that undergoes ultrafiltration inside the cheesemaking plant itself. Outsourced UF milk should, therefore, be exempt from ingredient labeling.
- The collective declaration for "milk" is broad enough to encompass outsourced UF milk because the use of outsourced UF milk does not affect the basic nature, essential characteristics, or nutritional profile of the finished cheese product. FDA should focus on the finished product in

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1/ As used in these comments, "outsourced UF milk" refers to UF milk purchased from a supplier as well UF milk filtered by a cheese manufacturer at an offsite facility owned by the same manufacturer.

determining whether ingredient labeling would be meaningful, which in this case it would not be.

- An ingredient labeling requirement for outsourced UF milk in packaged cheese is not legally enforceable. There is no way to test the final product to determine if outsourced UF milk was used, whether ultrafiltration was conducted inside the cheese plant, or whether regular milk was used with traditional forms of filtration. The end products are indistinguishable.
- The proposed ingredient labeling requirement is inconsistent with international standards, with no scientific basis for doing so. In an earlier proposed rule last year, designed to modernize food standards, FDA established international harmonization as one of the main principles to govern food standards development. We support this effort at harmonization with international standards as it relates to labeling of liquid UF milk.

IDFA and NMPF believe that the points described above provide persuasive reasons why FDA should delete from the final rule the proposed ingredient labeling requirement for cheese made with outsourced UF milk. Nevertheless, if FDA believes that the law requires a special ingredient declaration for outsourced UF milk, then IDFA and NMPF believe that FDA should grant an exemption from ingredient labeling in the final rule, as expressly provided for under Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). Such an exemption would be justified under either the "consumer deception" or "impracticability" criteria, or both, as listed in the statute. In particular:

- Consumers would be misled by special ingredient labeling for outsourced UF milk in packaged cheese because the label would suggest a difference in the finished product, where none exists. FDA has, in the past, expressed strong concern about special labeling on food products that does not convey to consumers a meaningful difference in the finished product.
- IDFA 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. This new set of empirical data provides a sound and objective basis for FDA to rely on in granting the exemption envisioned by the statute.
- The special ingredient labeling requirement would be so impracticable to implement that the cost of doing so would outweigh any benefits from using outsourced UF milk in cheesemakng. In fact, many cheese

manufacturers would simply not be able to use UF milk in their cheesemaking.

- The key value of using outsourced UF milk in cheesemaking is that it could be used "interchangeably" with regular milk, or in combination with regular milk, depending on the day-to-day availability of milk supplies. This value would be completely undermined if companies needed to keep track of which batches of cheese contained regular milk only, and which batches contained outsourced UF milk.
- The cost of tracking the presence of UF milk while the cheese is a work-in-progress would be prohibitive. Moreover, cheese manufacturers would have no way to test their finished products for UF milk to determine if the correct label is attached to the cheese.
- Keeping track of expanded label inventories would also be a logistical nightmare. At a minimum, companies would need to triple the number of labels to account for the three labeling possibilities: one for cheese made solely with regular milk, one for cheese made solely with UF milk, one where UF milk is used in combination with milk. This labeling challenge grows exponentially when cheese products, such as shredded cheese, are made from multiple cheese varieties. For example, in a product containing six cheese varieties, there would be 216 label variations for a single product!
- Finally, there are significant added expenses, including those associated with segregating cheese from different sources, additional warehouse expenses needed to maintain larger inventories, and decreased overall efficiency.

For all of these reasons, IDFA and NMPF believe that an exemption from the ingredient labeling requirement would be fully justified. In analogous cases, FDA has found that impracticability issues, similar to those described above, warranted an exemption. We believe that FDA could reasonably incorporate such an exemption into the final rule on the use of outsourced UF milk in standardized cheese as a "logical outgrowth" of the proposed rule. Perhaps most importantly, granting such an exemption would have no impact on public health or on consumers because the finished products are identical.

FACTUAL BACKGROUND AND AGENCY PRECEDENT

A central step in the cheesemaking process is separation of the whey constituents from the cheese curd. In traditional cheesemaking, this step was accomplished by whey syneresis, where the whey is drained from the curd following precipitation of milk proteins. For over twenty years, modern filtration technologies

have been widely used to accomplish part or all of the separation process. Of these technologies, the most commonly used process is ultrafiltration.

At the time that ultrafiltration was initially embraced, cheese plants filtered milk inside the cheese plant for immediate use in the cheesemaking process. FDA has not objected to this practice and has agreed that milk filtered in this manner is permissible as part of the "alternate make" procedures in the cheese standards, which allow the use of "any procedure" resulting in cheese with the same characteristics as cheese produced using processes outlined in the standards. 2/ In the mid-1990s, it became apparent that manufacturing efficiencies could be obtained by filtering milk in central facilities outside of the cheese plant. In 1996, FDA determined that it had no objection to the filtration of cheese milk at a central facility (operated by T.C. Jacoby & Company, Inc.), for subsequent shipment to a cheese plant (Bongards Creamery). In response to a request for labeling guidance submitted by T.C. Jacoby & Company, operator of the central filtration facility, FDA applied the "alternate make" rationale to the use of cheese produced with outsourced UF milk:

> We recognize that cheesemaking technology has changed tremendously in the last 30 years. Cheddar cheese is one of the standardized cheeses for which "alternate make procedures" have been provided . . . . Under alternate make procedures, Cheddar cheese may be prepared by any procedure which produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional cheesemaking process . . . *Additionally, we are of the opinion at this time that the retentate that results when milk is subjected to processing in an ultrafiltration system may be declared as "milk" in the ingredient statement on the label of the Cheddar cheese produced at Bongards Creamery*, provided that the Cheddar cheese manufactured from this retentate is at least nutritionally equivalent to and has the same physical and chemical properties, as the cheese prepared by the procedures specifically set forth in the applicable standard (emphasis added). 3/

2/ *See, e.g.,* 21 C.F.R. § 133.113 (cheddar cheese standard); 70 Fed. Reg. 60751, 60754 (Oct. 19, 2005) ("[T]he ingredient milk may undergo an additional step of ultrafiltration prior to being introduced into the cheese vat in a single within-batch and within-plant production line.").

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

FDA's labeling position necessarily rested on a determination that the pertinent "ingredient" for purposes of cheesemaking was "milk"—in other words, ultrafiltration was viewed as part of the cheesemaking process. This interpretation is factually well-grounded because ultrafiltration is used in cheesemaking to accomplish virtually the same effect as whey syneresis (i.e., removal of whey constituents).

FDA's position on ingredient labeling remained unchanged for nearly a decade, even while the agency was reconsidering whether use of outsourced UF milk fell within the existing cheese standards. Between 1997 and 1999, USDA asked FDA for guidance concerning the scope of FDA's 1996 determination regarding outsourced UF milk. In response to USDA's request, FDA decided that continued use of milk filtered at a facility outside the cheesemaking plant would require an amendment to the standard of identity regulations for cheese products. 4/ At the same time, FDA advised that it would not object to the use of outsourced UF milk in cheese for six months or while a petition to amend the standards to expressly allow for its use was under consideration, and did not impose any ingredient labeling requirements. 5/ A few months later, NCI, the Grocery Manufacturers of America (GMA) and the National Food Processors Association (now FPA) submitted a petition to clarify the regulatory status of outsourced UF milk in cheesemaking. FDA's response to USDA left in place the longstanding industry practice of labeling outsourced UF milk as "milk." The industry petition detailed the widely held view that outsourced UF milk is permitted under the alternate make procedures and should be declared as "milk" in finished cheese products regardless of where it is produced.

In reliance on the correspondence and industry petition described above, the cheese industry has expanded the use of UF milk for cheddar and mozzarella cheeses, the most common types of cheese products. The ability to centralize production has resulted in significant benefits, particularly for small cheesemakers who cannot afford to install ultrafiltration equipment in every plant, farmers who desire a convenient way to ship cheese milk over long distances, and consumers who benefit from resulting efficiencies. The industry has not, however, created the expensive and cumbersome systems that would be needed to label outsourced UF milk differently from in-plant filtered milk.

4/ Letter to F. Schonrock, USDA, from J. Foret, FDA Office of Food Labeling (Oct. 21, 1999) ("Based on our review of the available information and on our interpretation that the standards for cheeses, as written, do not allow for the use of UF milk, we conclude that the use of UF milk in standard cheeses cannot be accommodated outside of rulemaking.")

5/ *Id.*

In the past year, however, FDA began to change its position on the ingredient labeling issue. In granting a request that the agency extend its position on Cheddar and Mozzarella cheese to Swiss cheese as well—i.e., exercise enforcement discretion and allow outsourced UF milk in the production of Swiss cheese—the agency also advised, in an April 6, 2005 letter to IDFA, that specific labeling of the milk as "ultrafiltered" would be required on the ingredient line. 6/

FDA is now seeking to codify this new position in the proposed rule, by proposing to require that all varieties of cheese made with outsourced UF milk, including Swiss cheese, declare ultrafiltered milk on the ingredient line. 7/ These comments explain why outsourced UF milk should continue to be labeled as "milk" in the ingredient line for all cheese products. FDA may not have realized the practical significance of the ingredient labeling issue, but it has far-reaching

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6/ Letter to Clay Hough, IDFA, from F.B. Satchell, Director, Food Labeling and Standards Staff (Apr. 6, 2005).

7/ *See* 70 Fed. Reg. 60751, 60754 (Oct. 19, 2005) (proposed rule regarding standards of identity for cheese products). However, FDA provided no explanation or analysis in the proposed rule to support this conclusion. Thus, FDA did not meet the requirements of the Administrative Procedure Act (APA), which provides that courts should "hold unlawful and set aside agency action, findings, and conclusions of law found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). As the Supreme Court made clear in *Motor Vehicle Manufacturer's Association v. State Farm Mutual Automobile Insurance Company*, FDA must provide a "reasoned analysis" to support its decision to require labeling of UF milk. *Motor Vehicle Mfrs. Ass's v. State Farm Mut. Auto. Ins. Co*, 463 U.S. 29, 57 (1983). The need for a reasoned explanation is magnified where, as here, FDA's position on ingredient labeling is not internally consistent. Additionally, FDA is obligated to explain how its thinking has "evolved" on this issue. As the Supreme Court stated in *State Farm*, "[w]hile the agency is entitled to change its view . . ., it is obligated to explain its reasons for doing so." *Id.* at 56. FDA's statement, "milk that has undergone ultrafiltration is distinctly different from the starting ingredient milk . . . and, therefore cannot be called simply 'milk,'" does not adequately explain this "evolution" in thinking. Letter to Clay Hough, International Dairy Foods Association, from F.B. Satchell, Director, Food Labeling and Standards Staff (Apr. 6, 2005). At a minimum, FDA is required under the APA to provide an explanation as to how it came to the contrary conclusion that outsourced UF milk should be declared in the ingredient statement for finished cheese products. Second, FDA should elucidate the reasons for its determination that UF milk processed outside a cheese plant is an ingredient, whereas UF milk processed inside a cheese plant is not.

consequences and, ultimately, would undermine any benefits that could otherwise result from the ability to use outsourced UF milk in cheese products.

THE LABELING OF STANDARDIZED CHEESE MADE WITH OUTSOURCED UF MILK

IDFA and NMPF disagree with the agency's proposed requirement that standardized cheese products made with outsourced UF milk be labeled as containing "ultrafiltered milk" in the ingredient statement. Accordingly, we are requesting that FDA remove the ingredient labeling requirement from the final rule. We believe that the ingredient labeling requirement is not dictated by the agency's governing statute, or its existing labeling regulations and policies. In addition, the labeling requirement is not consistent with international standards and would create an uneven playing field for U.S. cheese manufacturers. Finally, the labeling requirement is both impracticable and misleading to consumers, and, as such, qualifies for an exemption from ingredient labeling.

I. The Proposed Labeling Requirement is Not Consistent with Current Law and Agency Policy

A. There Is No Valid Basis for the Distinction in the Proposed Rule between UF Milk Brought into the Cheesemaking Plant and Milk that Undergoes Ultrafiltration Inside the Cheesemaking Plant.

FDA currently allows cheese manufacturers to prepare many types of standardized cheese by methods specifically set out in the regulations, "or by any other procedure which produces a finished cheese having the same physical and chemical properties." 8/ As is provided in the regulations, in traditional cheesemaking, milk is used as a starting material and the water-soluble constituents of the whey (i.e., water, lactose, whey proteins, and vitamins and minerals) are wholly or partially removed from the cheese curd through a draining procedure known as "whey syneresis."

Over the years, cheese manufacturers have developed an alternative procedure whereby milk is filtered to remove the water-soluble constituents just prior to its introduction into the cheese vat. Because the constituents that UF milk may be lacking are the very ones that invariably are removed from regular milk during the cheesemaking process, when cheese is produced using UF milk, it has the same physical and chemical properties as cheese produced by other milk products. Thus, whether the water-soluble constituents are removed during the draining procedure known as whey syneresis or during filtration of the milk, the

8 / *See, e.g.,* 21 C.F.R. § 133.113(a)(1).

end result is exactly the same—a finished cheese with the same chemical properties, sensory attributes, and nutritional value.

Because the end product is the same, cheese manufacturers are able to use UF milk in the manufacture of cheese under the "alternate make" provisions of the regulations and declare the ingredient as "milk," so long as the milk is filtered inside the cheese plant. However, under FDA's proposed rule, UF milk which is filtered at another location is a distinct ingredient which must declared on the ingredient statement. There is no valid basis for this distinction between UF milk produced in an outside plant and milk filtered inside the cheese plant. Indeed, under FDA's proposal, even a cheese manufacturer which produces its own UF milk at a plant separate from its cheese plant would be forced to declare UF milk in the ingredient statement. No matter where it is filtered, UF milk is the same product, it serves the same role in the cheesemaking process, and it produces the same cheese as traditional cheesemaking.

Just as milk filtered inside the cheese plant is considered "milk" for purposes of the ingredient statement, milk filtered outside the cheese plant should also be considered "milk." In fact, in 1996, FDA applied the principles of "alternate make" to the use of UF milk and concluded that UF milk from outside the cheese plant was to be considered "milk" for labeling purposes in the finished cheese product. FDA stated:

> From the information that you provided us, it is our understanding that the Cheddar cheese produced from the retentate that results when milk is subjected to processing in an ultrafiltration system is nutritionally equivalent to the Cheddar cheese prepared by the procedures set forth in the standard . . . Based on this understanding, we would not object at this time to the use of this retentate in the manufacture of Cheddar cheese . . . . *Additionally, we are of the opinion at this time that the retentate that results when milk is subjected to processing in an ultrafiltration system may be declared as "milk" in the ingredient statement on the label of the Cheddar cheese* . . . provided that the Cheddar cheese manufactured from this retentate is at least nutritionally equivalent to and has the same physical and chemical properties, as the cheese prepared by the procedures specifically set forth in the applicable standard (emphasis added). 9/

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

Thus, FDA clearly understood that because ultrafiltration accomplishes the same outcome as whey syneresis, it is part of the cheesemaking process. While liquid UF milk may sometimes be manufactured outside of the cheese plant, it is identical to that used as part of the cheesemaking process inside a cheese plant. As such, no specific labeling is justified.

This is true regardless of where the filtration of the milk takes place. Indeed, existing regulations recognize that the manufacturing process for a food can take place in more than one location. As such, the regulations exempt in-process food components from ingredient labeling requirements. Specifically, 21 C.F.R. § 101.100(d) exempts from the labeling requirements "food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed . . . ." 10/ Because outsourced ultrafiltered milk has been a practice of the trade, the proposed labeling requirement for UF milk produced outside the cheese plant is inconsistent with established FDA regulations. Instead, FDA should look to its own prior precedent and recognize the role that UF milk serves in the cheesemaking process; and, that there is no valid basis to distinguish between milk which undergoes filtration inside the cheese plant and milk which undergoes filtration outside the cheese plant.

B. The Collective Declaration for "Milk" Applies to UF Milk.

By regulation, FDA has provided that an ingredient name should be "a specific name and not a collective (generic) name," unless a generic name is approved by FDA. 11/ FDA's regulations further provide that—

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

10/ 21 C.F.R. § 101.100(d).

11/ 21 C.F.R. § 101.4(b).

that distinguishes it from different foods (emphasis added). 12/

The common or usual name of a food may be established by common usage or by regulation. 13/

Applying these principles to the use of outsourced UF milk in cheese, there is a clear legal basis for continuing to identify the UF milk as "milk" in the ingredient line. This conclusion is based on the essential characteristics of UF milk as used in cheese and FDA ingredient labeling precedent.

1. Basic Nature of Outsourced UF Milk as Used in Cheese.

FDA should recognize the unique circumstances surrounding the use of UF milk in cheese that may not extend to other foods in which UF milk is used. FDA has previously stated that its decision to require the inclusion of ingredient labeling of UF milk is based on the agency's determination that UF milk differs from regular milk because the ultrafiltration process typically results in "some loss of water, lactose, minerals, and water-soluble vitamins." 14 According to FDA officials, these differences make UF milk "distinctly different" from regular milk and, therefore, create a need for specific ingredient labeling.

While it is true that the ultrafiltration process results in "some loss of water, lactose, minerals, and water-soluble vitamins," that difference is completely irrelevant in the cheesemaking process. This is because the same constituents that UF milk may be lacking are the very ones that invariably are removed from regular milk during the cheesemaking process. As used in cheese, UF milk has the same "basic nature" and "characterizing properties" as milk used in traditional cheesemaking. When milk is used as a starting material in traditional cheesemaking, water-soluble constituents of the whey (i.e., water, lactose, whey proteins, and vitamins and minerals) are wholly or partially removed from the cheese curd through a draining procedure known as "whey syneresis." These same milk constituents are wholly or partially removed in the filtration process, in which milk is separated into (1) a "permeate" that contains the water-soluble constituents

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12/ 21 C.F.R. § 102.5(a). Although these principles address the common or usual name of finished food products for consumer use, they are reasonably applied to food products that are used as ingredients since the statute uses the "common or usual name" terminology for both finished foods and food ingredients.

13/ *Id*. § 102.5(d).

14 / Letter to Clay Hough, IDFA, from F.B. Satchell, Director, Food Labeling and Standards Staff (Apr. 6, 2005).

(i.e., water, lactose, some whey proteins, and vitamins and minerals), and (2) a retentate that is used to make cheese.

Thus, whether the water-soluble constituents are removed during whey syneresis or during filtration, the end result is exactly the same—a finished cheese with the same chemical properties, sensory attributes, and nutritional value. Accordingly, because there is nothing in the finished cheese product that reasonably identifies whether UF milk or regular milk were used, regular milk and UF milk are comparable products under these conditions of use and should be labeled with the same common or usual name.

2. Finished Product Focus.

Consideration of the function of outsourced UF milk in finished cheese is appropriate because FDA historically has looked to the finished product when assessing similar ingredient labeling issues. For example, FDA has determined that dry milk, concentrated milk, and similar products may be declared as "milk" in foods generally because these ingredients are nutritionally and functionally equivalent in finished products. 15/ Specifically, when proposing to amend the definition of milk for use in cheese, the agency stated "[t]he Commissioner believes that, technologically, alternate forms of milk, nonfat milk, and cream, i.e. concentrated, dried, and reconstituted forms, can be used to produce the same cheese as produced from fluid cow's milk." 16/ Similarly, FDA has provided that incidental additives, such as processing aids, need not be declared as ingredients where the additives have no technical or functional effect in the finished food and are present at insignificant levels.

Although the finished product may not be controlling in all instances, it is a relevant consideration here. This is especially true in the cheese context where, by FDA's own conclusion, an ingredient such as outsourced UF milk is substantially equivalent to milk when used as a constituent of cheese. 17 / Thus, in assessing whether outsourced UF milk must be identified as such when used in cheese, FDA should evaluate the issue from the perspective of the finished product.

15/ 41 Fed. Reg. 1156, 1157-58 (Jan. 6, 1976).

16/ 43 Fed. Reg. 42127, 42128 (Sep. 19, 1978). FDA also stated that reconstituted, dried or concentrated milk may be declared as "milk" in the ingredient statement. 48 Fed. Reg. 2736, 2738 (Jan. 21, 1983). "This method of ingredient declaration is not deceptive because differences in the form of the dairy ingredients used (i.e. , liquid, concentrated, or dried) have no perceptible effect on the final product." *Id*.

17 / *See* 70 Fed. Reg. 60751, 60756 (Oct. 19, 2005).

3. Industry Practice.

FDA's regulations provide expressly that the common or usual name of a food (and thus, a food used as an ingredient) may be established by common usage or regulation. Industry has long used UF milk in Cheddar and Mozzarella cheesemaking without "ultrafiltered milk" labeling. The fact that FDA did not condition its use of discretion for Cheddar and Mozzarella cheeses on special labeling for UF milk confirmed that the common or usual name of UF milk as used in cheese is "milk," due to the nature of the cheesemaking process.

4. Other Dairy Precedent.

FDA has not required process-based labeling in other dairy contexts, such as with whey products. For example, the name "whey protein concentrate" is prescribed by regulation regardless of the process used to produce the ingredient, including ultrafiltration. 18/ Indeed, the preamble to the final rule affirming whey protein concentrate and other whey ingredients as generally recognized as safe (GRAS) expressly stated, without identifying any concerns from a common or usual name perspective, that FDA did not intend to limit the processing methods that can be used to produce these ingredients. We are aware of no circumstances where FDA has suggested that whey ingredients produced through filtration must be labeled using "ultrafiltered whey" or similar terminology.

5. FDA classification of UF milk as "milk."

Furthermore, in other contexts, FDA has determined UF milk to be reasonably classified as "milk." For example, in a recently finalized Compliance Policy Guide interpreting the Federal Import Milk Act (FIMA), FDA found that UF milk is "milk" for purposes of the FIMA permit process. 19/ This finding was based on food safety considerations and provides additional support for IDFA's position.

In short, because final cheese products are essentially indistinguishable, regardless of whether they are made using UF milk or regular milk, we believe that special ingredient labeling for UF milk, when used in cheese, is unwarranted. The physical properties of UF milk and key characteristics of the cheesemaking process provide a compelling basis for why the common or usual name, for ingredient labeling purposes, of UF milk as used in cheese is "milk."

18/ 21 C.F.R. § 184.1979; 46 Fed. Reg. 44434, 44437 (Sept. 4, 1981).

19/ FDA Compliance Policy Guide, Imported Milk and Cream—Federal Import Milk Act, CPG 7119.05 (Rev. Apr. 2005).

C. Ingredient Labeling of Outsourced UF Milk in Processed Cheese is Not Enforceable.

As discussed previously, cheese manufactured with outsourced UF milk is the same product in finished form as cheese manufactured without UF milk. There is no meaningful difference between the two products. In fact, when examining the finished product, there is no way to distinguish cheese made from outsourced UF milk from either cheese made from milk undergoing filtration within the cheese plant, or cheese not made with UF milk at all. As such, FDA will not be able to examine or test the finished product to determine if it contains outsourced UF milk which, under the proposed rule, would need to be declared on the ingredient statement. Therefore, FDA will not be able to enforce the labeling requirement and determine whether those cheese products which do in fact contain outsourced UF milk, but do not declare its presence on the ingredient statement, are misbranded.

D. The Proposed Rule is Inconsistent with International Standards.

Through section 410(c) of the FDA Modernization Act of 1997 (21 U.S.C. § 383(c) and FDA's international harmonization policy (60 Fed. Reg. 53078 (1995)), FDA has endorsed the international harmonization of regulatory requirements. Moreover, in its proposed rule addressing Food Standards Modernization, 20/ FDA specifically proposed harmonization of U.S. standards with international food standards. 21/ In support of this proposal, FDA stated that "[w]ith the rising trend in globalization and increased accessibility of U.S. goods to other nations' markets, efforts to harmonize U.S. food standards with international food standards will facilitate international trade and foster competition." 22/ Most importantly, in support of its decision to allow the use of UF milk in cheese manufacturing, FDA cited the need to achieve consistency with international standards. 23/

Nonetheless, by requiring UF milk to be declared on the ingredient statement for cheese, FDA is proposing a rule that is inconsistent with

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20/ 70 Fed. Reg. 29214 (May 20, 2005).

21/ 70 Fed. Reg. 29214, 29235 (stating "Consistent with § 130.6 of this chapter, the food standard should be harmonized with international food standards to the extent feasible.").

22/ 70 Fed. Reg. 29214, 29223.

23/ 70 Fed. Reg. 60751, 60757 (Oct. 19, 2005).

international standards. The Codex Alimentarius Commission's standard of identity for cheese permits the use of ultrafiltration technology, but does not consider UF milk to be an ingredient separate from milk. 24/

Consistent with the Codex standards, cheese manufactured outside the United States is frequently manufactured with outsourced UF milk. However, because FDA could not determine if imported cheese was made with outsourced UF milk, there would be no incentive for foreign cheese manufacturers to comply with the ingredient labeling requirement. This would place U.S. cheese manufacturers at a competitive disadvantage within our own country. Moreover, because of the added costs of compliance with the labeling requirement, U.S. manufacturers would need to pass those costs on to consumers worldwide, which would place U.S. cheese companies at a competitive disadvantage for overseas sales as well. As such, it is important for FDA to remove the ingredient labeling requirement from any final rule in order to level the international playing field.

II. If FDA Nevertheless Maintains that Current Law Demands a Special Ingredient Declaration for Outsourced UF Milk in Standardized Cheese, then FDA Should Grant an Exemption in the Final Rule.

Although we do not believe it necessary to trigger special ingredient labeling when UF milk is used in standardized cheese, if FDA continues to maintain that current law demands special ingredient labeling in this circumstance, IDFA and NMPF request that FDA grant an exemption, by regulation as provided for in the statute, as part of the ongoing UF milk/cheese standard of identity rulemaking process.

The statutory provision governing ingredient labeling is Section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act), under which a food fabricated from two or more ingredients is deemed misbranded unless its label bears "the common or usual name of each such ingredient." In appropriate circumstances, however, the statute permits exemptions from this rule. Pursuant to this statutory provision, to the extent that compliance with the statutory ingredient labeling requirement noted above "is impracticable, or results in deception…," the statute provides that "exemptions shall be established by regulations." 25/ Providing special ingredient labeling on cheese products made with UF milk is both "impracticable" and results in "consumer deception." We believe, therefore, that such an exemption would be warranted in this circumstance.

24/ Codex General Standard For Cheese A-6-1978, amended 2003.

25/ 21 U.S.C. § 343(i)(2); 403(i)(2) FDC Act.

FDA has the authority to grant this exemption to cheese manufacturers in the context of the final rule because it is a "logical outgrowth" of the proposed rule. The "logical outgrowth" doctrine allows an agency's final rule to differ from the proposed rule in those instances where interested parties have had sufficient notice and opportunity to comment during the rulemaking process. 26/ As the D.C. Court of Appeals has noted: "[n]otice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the final rule and thereby enhance the quality of judicial review." 27/ Here, because FDA's proposed labeling requirement is included in the proposed rule, 28/ all interested parties have had an opportunity to submit comments on the proposed requirement. Any change to the proposed labeling requirement would be "reasonably anticipated" 29 / by all interested parties, and thus such a change would be fully consistent with the Administrative Procedure Act. Granting cheese manufacturers an exemption to the labeling requirement for outsourced UF milk in the final rule would stem directly from the labeling provision in the proposed rule, 30/ and thus would be a "logical outgrowth" of that proposed rule.

26/ *See Envtl. Integrity Project v. Envtl. Protection Agency*, 425 F. 3d 992, 996 (D.C. Cir. 2005).

27/ *Int'l Union, United Mine Workers v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

28/ 70 Fed. Reg. 60751, 60756-57 (Oct. 19, 2005).

29/ *Northeast Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004) (stating that a final rule is a 'logical outgrowth' of a proposed rule if interested parties "should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.").

30/ It is perfectly acceptable for the agency to grant an exception to its proposal on labeling. *See Am. Iron & Steel Inst. v. EPA*, 886 F. 2d 390, 400 (D.C. Cir. 1989) (stating "one logical outgrowth of a proposal is surely . . . to refrain from taking the proposed step"). Here, granting an exemption is the equivalent of refraining from taking a proposed step.

A. Consumer Deception.

1. Basis for concern that consumers may be misled by special ingredient labeling for outsourced UF milk.

It is a general principle of food labeling that similar or identical products should bear a uniform common or usual name. If cheese made with traditional milk is identified as having "milk," but the exact same cheese made with outsourced UF milk is identified as having "ultrafiltered milk," consumers may reasonably be misled into thinking that there is a difference between the two cheese products, when that is not the case. Indeed, as described earlier, there is no apparent basis for distinguishing between cheese made with outsourced UF milk and cheese made with regular milk because the final cheese products have the same basic nature, essential characteristics and nutritional profile. If there is no attribute in the finished product for the consumer to know something material about, then there is no valid reason to require labeling of an intermediate step in the cheesemaking process, and to do so would invariably mislead consumers.

FDA has previously stated that including a label statement that implies a difference where none exists may be misleading to consumers. In 2002, when the state of Oregon was considering a ballot initiative to require special labeling on genetically engineered foods, FDA intervened by sending a letter to the Governor of Oregon. 31/ In that letter, FDA stated that "mandatory labeling to disclose that a product was produced through genetic engineering does not promote the public health in that it fails to provide material facts concerning the safety or nutritional aspects of food and may be misleading to consumers." 32/ Notably, FDA listed the following circumstances in which it would consider mandatory labeling to be appropriate:

- the food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food;
- an issue exists for the food regarding how the food is used or consequences of its use;
- the food has significantly different nutritional properties; or

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31/ Letter to Governor John A. Kitzhaber, MD, from Lester M. Crawford, D.V.M., Ph. D., FDA Deputy Commissioner (Oct. 4, 2002).

32/ *Id*.

- a new food includes an allergen that consumers would not expect to be present in the food based on the food's name. 33/

None of these circumstances ring true with the proposed ingredient labeling of outsourced UF milk on standardized cheese products: (a) the finished cheese product made with outsourced UF milk is not significantly different from its traditional counterpart; (b) there are no differing consequences from its use; (c) the finished cheese product has the same nutritional properties; and (d) there are no allergen-related issues. Accordingly, mandatory ingredient labeling on cheese products made with outsourced UF milk would run contrary to FDA policy and would not reveal a material fact to consumers.

Additionally, the labeling requirement would further confuse consumers when they seek to compare standardized cheeses with non-standardized cheeses. Although both products could be produced with outsourced UF milk, only the standardized cheese would declare its presence on the ingredient statement. Consumers could be misled into thinking that the non-standardized cheese is somehow different because it supposedly does not contain a particular ingredient. While non-standardized cheeses do differ from standardized cheeses, those differences are not the result of using outsourced UF milk. UF milk is not a material attribute in either product of which consumers need to be aware.

2. New consumer studies document that a large percentage of consumers are misled by special ingredient labeling for outsourced UF milk.

In response to FDA's proposed rule, IDFA commissioned consumer research specifically designed to determine whether the labeling requirement will result in the kind of deception described above. 34/ The study, a copy of which is attached, used an internet-based methodology. The study had 672 respondents who are responsible for grocery shopping in the household and who consume packaged cheese at least once per month. For label evaluation, interviews were divided into two groups, with 336 respondents in each group. The online interviews were conducted between December 1, 2005 and December 7, 2005. The sample size provided results at the 95% confidence level across groups.

Using a pre-established questionnaire, respondents were asked to compare a traditional ingredient label displaying "milk" versus an ingredient label

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33/ *Id.*

34/ The study, entitled "Ultrafiltered Milk Label Evaluation," was conducted by DDW Data Development Worldwide, and was commissioned by IDFA/ NCI.

displaying either "Ultrafiltered Milk" (version #1) or "Milk and Ultrafiltered Milk" (version #2). 35/ Within each interview, respondents were then asked whether they felt the products were the "same" or "different" in several ways, including whether the products were the "same" or "different" with respect to taste, healthfulness, and quality.

The research results are striking: a high percentage of consumers perceived a difference between cheese labeled as containing "ultrafiltered milk" and cheese labeled as containing "milk" – when, in fact, the final cheese products are identical. 36/ When consumers were asked to compare a cheese package labeled as containing "milk" with a cheese package labeled as containing "ultrafiltered milk," 52% of consumers believed that the two products were different. Once consumers were directed to the ingredient statement for the products, the percentage rose even further, as approximately three-quarters of the consumers perceived a difference between the two products.

Moreover, many consumers believed those differences would pertain to taste, healthfulness, and quality:

- More than one-third of consumers surveyed believed that the taste of products labeled as containing "ultrafiltered milk" would be different from those labeled as containing "milk" (without actually tasting the product).

- Nearly half of consumers thought there was a difference in the healthfulness of the two products (even though the Nutrition Facts Panels were identical).

- One-third of consumers surveyed perceived a difference in quality between cheese labeled as containing "ultrafiltered milk" and cheese labeled as containing "milk."

35/ Two separate ingredient labels were used ("Ultrafiltered Milk" and "Milk and Ultrafiltered Milk") because UF milk could be used alone or combination with regular milk as long as the finished cheese product is the same.

36/ FDA has stated that the agency will use a "reasonable consumer" standard in evaluating whether food labeling is misleading. 67 Fed. Reg. 78002, 78003 (Dec. 20, 2002). FDA has adopted the Federal Trade Commission's viewpoint that a representation is considered "from the perspective of a consumer acting reasonably under the circumstances: 'the test is whether the consumer's interpretation or reaction is reasonable.'" *Id.* (citing Deception Policy Statement, Cliffdale Assoc. Inc, 103 F.T.C. 110,177 (1984)).

These findings are dramatic and document, for the first time, the significant consumer confusion that would result from special ingredient labeling of outsourced UF milk in packaged cheese.

In addition to the IDFA study, one of IDFA's member companies conducted its own consumer research and found similar results. In that study, 80% of consumers believed that a product labeled as containing "ultrafiltered milk" was different from a product labeled as containing "milk." Similarly, nearly a third of consumers in that study believed that the two products differed as to taste, nearly half believed that the two products differed as to healthfulness, and more than 40% believed that the products were different in quality. A copy of that study will be submitted separately to this docket.

Thus, based on this new research, the proposed ingredient labeling requirement would mislead a high percentage of consumers into thinking that there is a material difference between cheese produced with outsourced UF milk and cheese produced with regular milk, where no such difference exists. Accordingly, because the proposed labeling requirement would result in consumer deception, FDA should grant an exemption to the statutory labeling requirement as provided in Section 403(i) of the Act.

B. Impracticability

The special labeling requirement for the UF milk ingredient in cheese would also be completely impracticable for the cheese industry to implement in a cost-effective way. IDFA requested information from its members regarding the proposed labeling requirement, and the respondents made it clear that if they need to maintain additional sets of labeling, any potential savings from the use of outsourced UF milk would be more than offset by these added costs. The common denominator in all of the responses was that complying with the proposed labeling requirement would be so logistically burdensome and costly as to reach the point of impracticability. In fact, if cheese manufacturers were to be required to declare the presence of UF milk on the ingredient statement, they simply would not be able to use outsourced UF milk in their cheesemaking processes.

Thus, FDA should grant an exemption to the proposed labeling requirement because compliance is impracticable. The labeling requirement is particularly onerous because cheese manufacturers do not use outsourced UF milk on a consistent basis. Instead, outsourced UF milk use is intermittent and is driven by regional milk availability and economic considerations. The proposed labeling requirement would necessitate additional labels, inventory, personnel, and system changes, as well as result in lost efficiency. Finally, granting an exemption from

the labeling requirement to cheese manufacturers is in keeping with FDA precedent and, most importantly, would not disadvantage consumers.

1. Cheese Manufacturers Do Not Use Outsourced UF Milk on a Consistent Basis; Instead, Outsourced UF Milk and Conventional Milk Are Used Interchangeably in the Cheese Manufacturing Process.

In cheese manufacturing, UF milk supplements a cheese manufacturer's milk supply when it is economically practical or necessary. Thus, outsourced UF milk is not used on consistent basis. For example, a manufacturer may be in the middle of producing an order and run out of outsourced UF milk. Then, out of necessity, it would need to change from a blend of outsourced UF milk and milk, to milk only. At that time, the manufacturer would be obligated to change over to different packaging with a different label. Conversely, a cheese manufacturer may find that fresh milk is not regionally available. The manufacturer then would utilize outsourced UF milk in its manufacturing processes. Not only do cheese manufacturers use milk and outsourced UF milk interchangeably, but they do not differentiate whether or not the dairy component in a particular process was a result of a specific filtration process. Instead, manufacturers produce cheese based on specifications and desired chemical and physical properties in the finished product, not on the processing technique. Cheese manufacturers currently do not have information technology systems in place to track and measure the presence of outsourced UF milk. Therefore, given the use of outsourced UF milk, knowing the make-up of a particular vat of cheese for labeling purposes would be extremely difficult.

This only serves to produce additional complications as the cheese is further processed. For example, after cheese is cut into exact weight and packaged, there is remaining cheese left over. These pieces of cheese, called "trim," are often further processed into cheese spread, shredded cheese, or processed cheese product. Frequently, further processing involves combining trim from one block of cheese with trim from other blocks of cheese. Because outsourced UF milk may or may not have been used in each block of cheese, tracking the presence of UF milk in the finished cheese product is a logistical nightmare.

Shredded cheese is another example of how complicated it is to know the exact source of raw materials for the product and to ensure that the proper label is affixed to the final cheese product. Shredded cheese can be produced by combining trim from several different productions of a particular cheese type, causing the labeling burden explained just above. Additionally, shredded cheese packaging can contain more than one type of cheese. For example, a package of "Italian" cheese blend might contain mozzarella, parmesan and Romano cheeses.

Each cheese type could be labeled in three different ways on the package, depending upon the presence and quantity of outsourced UF milk. 37/ Thus, because there are three different cheese types, which can be produced any one of three different ways, there are 27 different label variations for a single package of shredded "Italian" cheese. 38/ Not only would it be a tremendous burden to produce all the label variations, but maintaining stocks of each possible label, tracking the presence of outsourced UF milk, and guaranteeing that the correct label is on the cheese package is simply impracticable.

While it would be difficult for a single supplier to account for every instance that outsourced UF milk is used, it is even more difficult for those cheese manufacturers who combine their products with cheese products produced elsewhere. It is not uncommon for cheese manufacturers to obtain cheese for further manufacturing from different suppliers and then co-mingle them at the point of final processing. In this circumstance, food manufacturers may be unaware of whether supplied products have been made from UF milk. Suppliers often do not provide this information, and to do so through labeling would mean more logistical difficulties and added costs. Finally, the cheese processor would have no way to test product from a supplier to determine if outsourced UF milk was used and thus ensure that the correct label was affixed to the finished good.

2. It Would Be an Enormous Burden on Cheese Manufacturers to Produce, Maintain, and Coordinate the Various Labels that Would be Required under the Proposed Rule.

In order to comply with the proposed labeling requirement, cheese manufacturers will, at a minimum, need to triple their label inventory. A given cheese manufacturer will need labels for: (1) cheese produced without outsourced UF Milk; (2) cheese produced with outsourced UF milk; and (3) cheese produced only with outsourced UF milk in combination with regular milk. Those cheese manufacturers which provided information to IDFA stated that they have between 500 and 3,800 different SKUs which would be impacted by the labeling change.

37/ A given cheese manufacturer will need labels for: (1) cheese produced without outsourced UF Milk; (2) cheese produced only with outsourced UF milk; and (3) cheese produced with outsourced UF milk in combination with regular milk.

38/ A shredded cheese blend of six types of cheese, such as an "Italian" blend of mozzarella, provolone, parmesan, fontina, romano, and asiago would be even more complicated, necessitating 216 label variations. The cheese manufacturer would not be able to use outsourced UF milk because of the impracticability of monitoring its presence in the finished cheese product.

Because of the need to triple the number of labels, the proposed labeling requirement would create the need for a total number of between 1,500 and 11,800 SKUs for these manufacturers. 39/ The need to increase the number of labels affects other areas as well:

- Increased costs to create, produce and store the labels;
- Additional time and personnel to ensure the labels are packaged on the appropriate cheese product and that the correct product is received by the customer;
- Expanded cheese inventories to accommodate customer preferences;
- Logistical problems and increased inefficiencies driven by multiple product codes for the same item; and
- The need for new information technology systems to link demand for finished goods with both specific packaging and raw material planning.

Given the use of outsourced UF milk in the cheese manufacturing process, these constraints are extremely burdensome, and make compliance with the proposed labeling requirement impracticable.

Costs of Producing More Labels. Packaging costs under the proposed labeling requirement would increase in a number of different ways. First, the cost to produce a new plate for packaging and labeling is approximately $200 per plate. Given the number of SKUs involved, one cheese manufacturer estimated that the initial cost of artwork and plate development to produce new packaging would be approximately $985,000. A different cheese manufacturer estimated that its costs for creating new labels would be $1.73 million. One of the largest cheese manufacturers predicted its costs would increase by as much as $2.7 million. Those manufacturers who produce cheese sold under other brand names would face additional challenges as their business requires customer approval for changes to customer labeling.

These figures do not reflect the cost of carrying additional packaging inventory. One cheese manufacturer responded that its current film and label inventory costs about $1.7 million. Those costs would at a minimum double, if not triple, under the proposed labeling requirement, costing that one company an

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39/ These numbers will vary for cheese manufacturers depending upon whether or not they produce mostly raw material cheese or finished cheese products, and depending upon their use of outsourced UF milk.

additional $1.7 million to $3.4 million. A different cheese manufacturer believes that its label inventory could triple from its current level of $4.5 million. Similarly, another producer also estimates that the value of its label inventory would also triple: an estimated increase of $12 million. Because manufacturers would have on hand more labels with more variations, the risk of obsolete packaging would also increase. These costs would range from approximately $100,000 to $2 million. Furthermore, if the proposed labeling requirement were to take effect, cheese manufacturers would need additional storage space for label inventory. One cheese manufacturer estimated that warehouse costs would increase by $70,950 per month, or $840,000 annually.

Additionally, because manufacturers would have multiple versions of the same product depending on the use and the level of outsourced UF milk, some cheese manufacturers would be ordering labels in smaller quantities. Where a cheese manufacturer formerly ordered 75,000 impressions, under the proposed rule, the manufacturer would order 3 runs of 25,000 impressions. Packaging costs are tied to run size: the smaller the run, the higher the cost. Thus, packaging costs would increase.

Inventory Constraints. The proposed labeling requirement also would reduce cheese manufacturers' ability to fill an order for a specific type of cheese on short notice. The customers of cheese manufacturers rarely purchase all of their supply for any given SKU from only one manufacturer. Nonetheless, they expect all of the product manufactured for their brand to be uniform in all aspects, including the ingredient statement. Therefore, manufacturers would need to increase their raw material inventory. Assuming that cheese manufacturers would need to double their inventory levels to account for multiple labeling requirements, one cheese manufacturer reported that its raw material inventory costs would increase by $470,000. A different manufacturer estimated that its raw material cheese inventory costs would be $5.2 million. This manufacturer's inventory of finished goods would cost an additional $5.8 million.

Moreover, if one cheese manufacturer uses or does not use outsourced UF milk, all other suppliers to a private label customer must segregate specific batches of a product, or decline the business altogether, in order to avoid a conflict with the customer's demand. It is extremely costly to keep product segregated, and yet passing such costs on to a typical private label customer is not an option due to competitive pricing.

The Need for Additional Personnel. Due to the increased need for packaging inventory management, cheese manufacturers would need to hire additional personnel to serve as purchasing agents, to monitor cheese production, to input new product codes into the system, and more. The addition of multiple product codes will further complicate the inventory systems of the customers of

cheese manufacturers because the current inventory systems do not allow for the merging of multiple product codes to reflect the true level of a finished cheese product. Some cheese manufacturers believe they would need to hire four additional employees, others will need to hire as many as 17 new employees. Several manufacturers estimated that they would need to double their number of schedulers/inventory planners. The cost of these additional personnel in salaries and benefits ranges from $240,000 per year to over $900,000.

Administrative and Logistical Problems. Simply hiring more personnel would not solve the many complications that the proposed labeling requirement would produce. According to several cheese manufacturers, it would be a tremendous burden to try to ensure that the proper label or packaging is placed on every case of finished goods the manufacturer produces. Each manufacturer not only would need to ensure that the correct packaging or labeling was used for each run, but that each plant has a sufficient inventory of the packaging and labels. Overall, the proposed labeling requirement would affect the following logistical and administrative areas:

- Information technology systems for raw material planning, forecasting and inventory management;
- Information technology systems for finished goods planning, forecasting, and production;
- Information technology systems to coordinate packaging, raw materials, finished goods to account for the use of UF milk;
- Line changeovers at plants due to the use of UF milk;
- Management of price changes, additional finished goods, and additional packaging materials.

Many customers of branded items require the cheese manufacturer to supply specifications of the cheese for their records. But due to how UF milk is used in the cheesemaking process, the manufacturer would not be able practically identify to customers which version of the cheese they would be receiving. Private label customers would also not accept variations in packaging for a single cheese product. Thus, manufacturers would need to be able to link demand for a given finished cheese product with the production run for that product to ensure that the proper ingredients are used, as well as the proper packaging. Creating such a system is estimated to cost one cheese manufacturer $5.4 million.

Most importantly, manufacturers would need to dramatically increase their internal coding in order to accurately track customer required labeling and

raw material input. One cheese manufacturer estimated a figure of $3,000 per code to reflect the costs associated with complying with the proposed labeling requirement. This cost basis includes increased time for coding, invoicing and inventory reconciliations, scheduling for production runs (to change over to different labels), short production runs, increase material waste (because of needing to change runs), and potential product shortages due to inability to substitute product. Thus, as a cheese manufacturer's current number of codes can be expected to triple under the labeling requirement, and with each code costing $3,000, the costs are prohibitive. One cheese manufacturer currently has 8,000 different codes. Consequently, under the proposed labeling requirement, this manufacturer faces costs of $72 million for this change alone.

Decreased Efficiency. Under the proposed labeling requirement, operational efficiencies would also decline. Currently, many manufacturing plants run 24 hours a day, 7 days a week. Not only would plants lose up to an hour a day changing packaging to reflect the different use of milk products in each vat of cheese, but additional time would be spent auditing labels and pallet tags to ensure that each cheese product was properly labeled. As previously discussed, cheese produced with outsourced UF milk is indistinguishable from cheese produced only from milk. Thus, there is no way for cheese manufacturers to test the final product to be certain that the labeling and packaging is correct. Instead, they will need to rely on their operating systems and internal product control systems to ensure that each product is properly labeled.

In sum, in addition to the cost of label changes, cheese manufacturers would also suffer significant added costs of system changes to process new specifications and codes, the costs of managing inventories, and the costs of scheduling line changes. Overall, operational efficiencies would decline, costs would rise, and these costs eventually would be passed along to the consumer, with no resulting increased value to the consumer, given the absence of food safety and nutritional benefits. The bottom line is that special labeling for outsourced UF milk is simply impracticable, given how the marketplace works and current systems are set up. As such, cheese manufacturers would need to reconsider their use of outsourced UF milk for cheese manufacture. Given that outsourced UF milk is used when economically practicable, lack of use would disrupt the supply of cheese and cost increases would be passed to consumers.

3. Granting an Exemption to Cheese Manufacturers Will Not Disadvantage Consumers.

The lack of ingredient labeling for outsourced UF milk in cheese would not disadvantage consumers. As has already been discussed, cheese which contains outsourced UF milk is nutritionally equivalent to cheese which does not. In fact, when cheese is produced using outsourced UF milk, it has the same physical and

chemical properties as cheese produced by other milk products. Moreover, it is not possible to distinguish between cheese produced by outsourced UF milk and cheese which is produced by regular milk. Granting an exemption to the labeling requirement would not disadvantage consumers because the use of outsourced UF milk in cheese has no bearing on the taste, quality, or chemical composition of the finished product. Consumers who use the ingredient label to avoid certain foods for health related reasons will still receive adequate information about the basic nature of the cheese product and will be able to make informed purchasing decisions.

4. Granting Cheese Manufacturers an Exemption to the Proposed Labeling Requirement is Consistent with Previously Granted Exemptions.

Presented with similar circumstances in the past, FDA has established exemptions by regulation to ingredient labeling requirements, based on findings of "impracticability." For example, in 1999, the agency amended its ingredient labeling regulations to permit the use of "and/or" labeling for various fish species used in the production of surimi and surimi-containing products. Just as FDA did with surimi, the agency should find that special labeling for outsourced UF milk in cheese products is "impracticable."

In the case of surimi, the agency recognized "the impracticability of maintaining different label inventories to reflect any and all possible formulation combinations." 40/ As discussed above, it would be completely impracticable for cheese manufacturers to maintain different label inventories to reflect any and all possible formula combinations. This is especially evident in the case of packaged shredded cheese containing a blend of various cheeses. When three different cheese types produce the shredded cheese blend, there are 27 possible labels for the package because each type of cheese could be produced with regular milk, with UF milk, or with UF milk combined with regular milk. If six different cheese types are used, the number of label variation skyrockets to 216 for a single shredded cheese package! Just as the fish types used in surimi are "functionally interchangeable," so too are the cheeses made from outsourced UF milk, and those made without outsourced UF milk. In both cases it will be impracticable for the manufacture to track which type of ingredient is present in the finished product.

Moreover, in the case of surimi, the agency was "persuaded by the arguments presented in the petition that the use of a more flexible ingredient labeling requirement will not disadvantage consumers because the specific source of fish protein has little bearing on the economic value, taste, or quality of the finished

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40/ 64 Fed. Reg. 17295, 17297 (Apr. 9, 1999).

food." 41/ FDA recognized that, "consumers who use the ingredient label to avoid certain foods for health-related reasons will still receive adequate information about the basic nature of the food and will be able to make informed purchase decisions." 42/ This argument applies to cheese as well. Consumers will not be disadvantaged because the use of outsourced UF milk has no material effect on the nutritional profile of the finished cheese product and consumers will still receive the very same nutrition information on the Nutrition Facts Panel, whether or not there is special ingredient labeling of outsourced UF milk.

There are other FDA precedents as well. In 1993, FDA granted a Section 403(i)(2) exemption for wax or resin coatings on fresh produce. 43/ In that circumstance, FDA considered the constant change of produce items in retail and the inability of packers to adhere to a constant pattern of wax or resin use. Accordingly, the agency concluded "that specific ingredient declaration of waxes and coatings on fresh produce is impracticable and that the proposed exemption permitting use of collective terms by the retailer is appropriate." 44/

Accordingly, as in these previous cases where FDA has exercised its exemption authority, there are significant impracticability concerns that accompany the requirement to specially label outsourced UF milk in cheese. We believe, therefore, that an exemption from ingredient labeling is warranted for use of outsourced UF milk in cheese due to impracticability.

CONCLUSION

In sum, FDA should remove the proposed requirement for ingredient labeling of outsourced UF milk from the final rule. As proposed, the labeling requirement is inconsistent with prior FDA interpretations, as well as FDA issued

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41/ *Id.*

42/ *Id.*

43/ 58 Fed. Reg. 2850 (Jan. 6, 1993).

44/ *Id.* In 1993, FDA again found an exemption to be justified under Section 403(i)(2) of the Act. In its final rule amending the juice labeling declarations, FDA granted a one-year exemption from the percent juice labeling requirements. 58 Fed. Reg. 49190 (Sept. 22, 1993). The agency considered the substantial cost burden to the industry and the substantial noncompliance that would occur because of a lack of capacity of package and label suppliers to provide sufficient quantities of new labels. Again, due to these impracticability concerns, FDA found an exemption to be warranted.

regulations. Both outsourced and in-plant produced UF milk undergo further processing to produce the same cheese. As such, there is no valid distinction between the two, and outsourced UF milk should not be subject to special ingredient labeling. Instead, the collective declaration "milk" should apply to UF milk as it is used in cheesemaking. This is consistent with FDA regulations, policy, industry practice, and international standards.

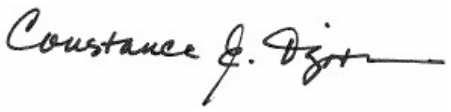
Moreover, compliance with the proposed labeling requirement is impracticable and will result in consumer deception. Thus, if FDA nevertheless maintains that current law demands a special ingredient declaration for UF milk in standardized cheese, then FDA should grant an exemption to this requirement in the final rule. We have provided in these comments, significant new data and information, including consumer research documenting that a high percentage of consumers are confused and misled by special ingredient labeling of UF milk. We have also provided substantial economic and feasibility-related information showing that the proposed ingredient labeling requirement would be impracticable.

Accordingly, IDFA and NMPF urge FDA to delete the proposed ingredient labeling requirement for outsourced UF milk from the final rule or to include in the final rule an explicit exemption for such labeling.

* * * *

Please contact us if either IDFA or NMPF can assist the agency with additional information or perspectives that may be helpful as the agency revisits its proposed labeling requirement.

Sincerely,



Constance E. Tipton
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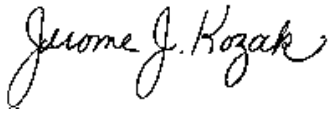

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President and CEO
National Milk Producers Federation

Data Development **Worldwide**

Ultrafiltered Milk Label Evaluation

– Final Report –

Prepared for:

The National Cheese Institute

December 2005

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Table of Contents

Background and Objectives

- The FDA recently proposed to allow the use of Ultrafiltered (UF) Milk in cheese. However, the FDA proposal would require that if UF Milk is used, the content must be declared on the label. The ingredient list would then state the use of “Ultrafiltered Milk” instead of simply “Milk.”

- The goal for this research is to understand how consumers of packaged cheese products would perceive items stating the presence of “Ultrafiltered Milk”.

- Specifically, this report seeks to investigate whether consumers differentiate products based on the inclusion of “Ultrafiltered Milk” on the label.

Methodology

- **Who:**
  - 672 respondents who are responsible for grocery shopping in the household and consume packaged cheese at least once a month.
    - For label evaluations, interviews were divided into two groups to ensure equal exposure to proposed ingredient labels.
      - 336 respondents evaluated an ingredient label detailing “Ultrafiltered Milk”.
      - 336 respondents evaluated an ingredient label detailing “Milk and Ultrafiltered Milk”.
      - For both groups, the proposed label was evaluated against a traditional label containing just “Milk”.
- **What:**
  - 5 minute online interview.
- **When:**
  - Interviews were conducted between December 1 and December 7, 2005
- **Significance Testing:**
  - Is conducted at the 95% confidence level across groups, indicated as:
    - A/B - Significantly higher than column indicated.
      - Note that no significant differences were found at this level of confidence.

Methodology

- Questionnaire:
  - Two versions of ingredient labeling for a packaged cheese product were measured across unique sample groups.
    - In each version, respondents were asked to compare a traditional ingredient label displaying “Milk” versus an ingredient label displaying either:
      - Version #1: “Ultrafiltered Milk”
      - Version #2: “Milk and Ultrafiltered Milk”
  - Within each interview, respondents were then asked whether they felt the labels were the “Same” or “Different” regarding:
    - Overall perception;
    - Ingredients;
    - Inclusion of Ultrafiltered milk content;
    - Taste;
    - Healthfulness; and
    - Quality.

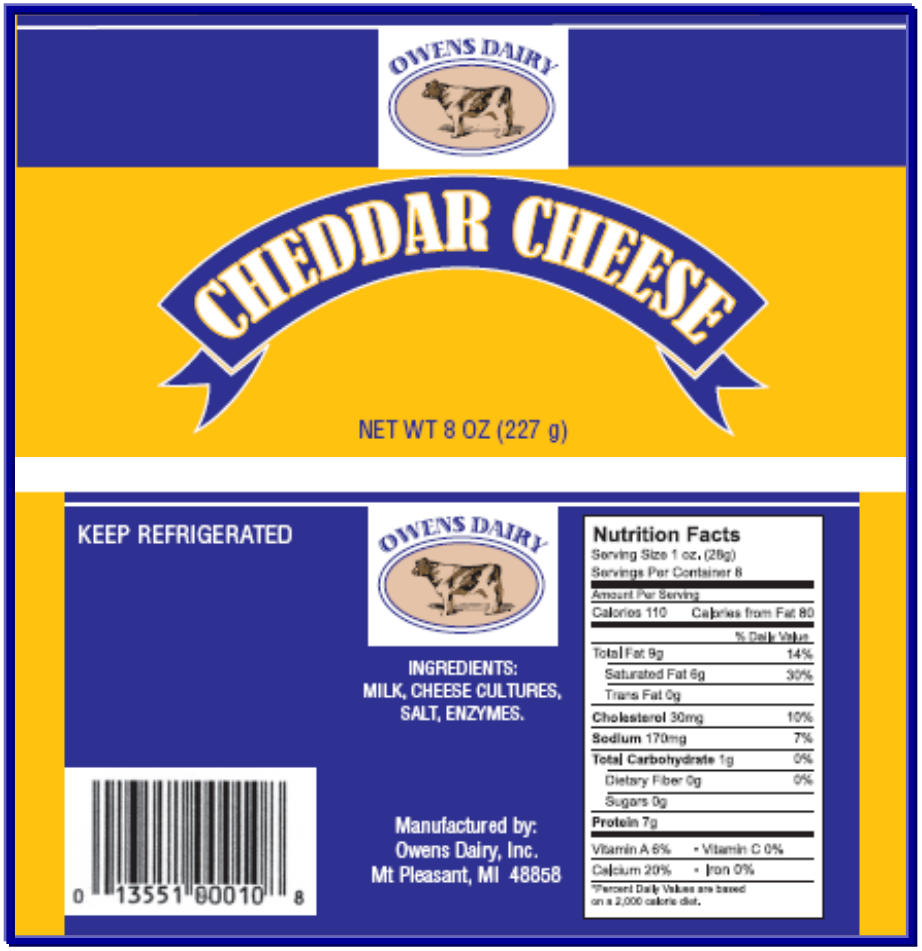
Version #1: Packaged Cheese Labels Evaluated
"Milk" vs. "Ultrafiltered Milk" Labels

Packaged Cheese Product 1

Packaged Cheese Product 2

Version #2: Packaged Cheese Labels Evaluated
"Milk" vs. "Milk and Ultrafiltered Milk" Labels

Packaged Cheese Product 1



Packaged Cheese Product 2

Summary of Findings

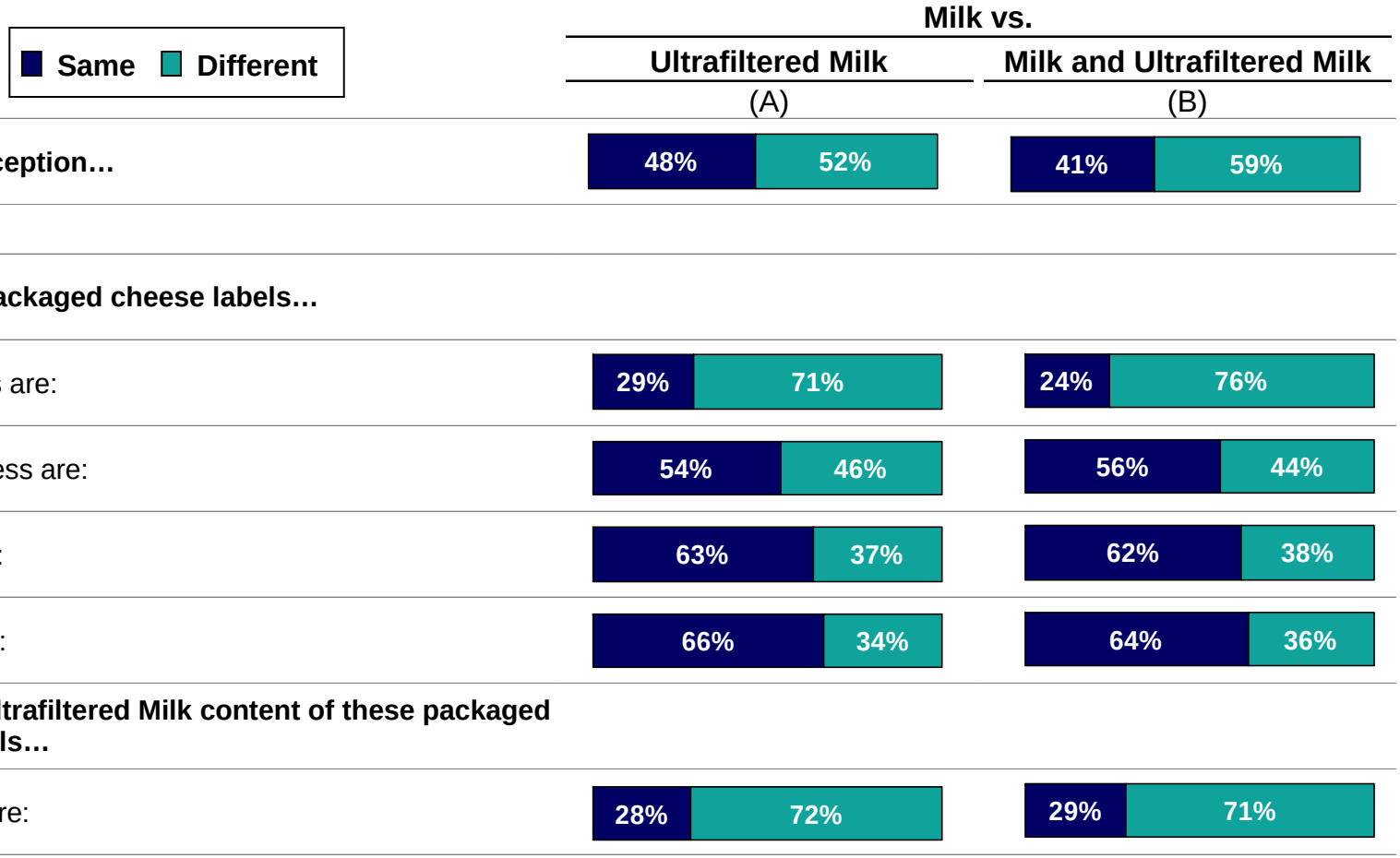
Summary of Findings

- Overall, there is a high level of confusion when distinguishing a packaged cheese made with Milk versus a packaged cheese made with Ultrafiltered Milk (or Milk and Ultrafiltered Milk).
  - When exposed to these labels, at first glance, consumers are almost just as likely to say that the products are different as they are to say that they are the same.
- This confusion is most likely driven by consumers specifically identifying that there are differences in ingredients between labels.
  - When prompted to the ingredients, approximately three quarters of consumers believe that the ingredients are different.
- In addition to the differing overall perceptions of the products, many also believe that the healthfulness, taste, and quality of the product made from Milk is different from the product made from Ultrafiltered Milk.
  - Approximately, half of consumers view the healthfulness of these products as different.
  - And more than one-third believe the taste and quality would be different.
- Most of all, when consumers' attention is specifically directed to the Ultrafiltered Milk content, almost three-quarters believe that there would be differences between a product made from Milk and a product made from Ultrafiltered Milk.

Summary of Findings

- While, ingredient labeling of “Ultrafiltered Milk” and labeling of “Milk and Ultrafiltered Milk” tend to generate similar reactions from consumers, there are some slight differences in the perceptions that they generate.
  - Overall, labeling containing “Milk and Ultrafiltered Milk” tends to be slightly more confusing than labeling solely containing “Ultrafiltered Milk”.
    - While not statistically significant, both the overall perception, and the perception of the ingredients for labeling containing “Milk and Ultrafiltered Milk” generate a higher level of differentiation than labeling containing only “Ultrafiltered Milk”.
    - However, both labels generate similar perceptions relating to healthfulness, taste and quality.

Packaged Cheese Evaluation Summary
Perceptions of Differences and Similarities



Data Development **Worldwide**

Detailed Findings

Data Development **Worldwide**

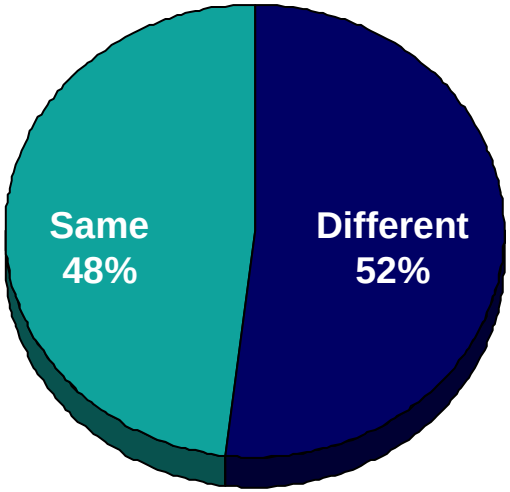
Product Evaluation

Looking at these two packaged cheese products, do you believe that these two products would be the same or different?

- Overall, at least half of consumers perceive products containing Ultrafiltered Milk in the ingredient labeling as different.
  - Those evaluating Milk versus Milk and Ultrafiltered milk are slightly more likely to differentiate the two products than those evaluating Milk vs. Ultrafiltered milk.

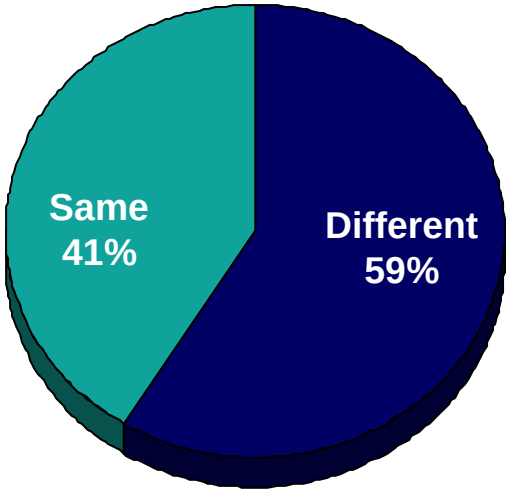
Milk vs. Ultrafiltered Milk

(A)



Milk vs. Milk and Ultrafiltered Milk

(B)

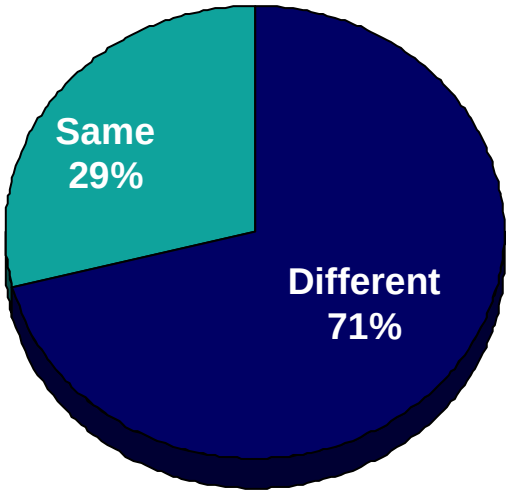


Looking specifically at the ingredients for these two packaged cheese products, do you believe that these two products would be the same or different?

- Consumers notice even greater differences in these products once they are prompted to look at the ingredient lists.
  - Around three-quarters perceive differences in the final cheese products based on the ingredient lists.

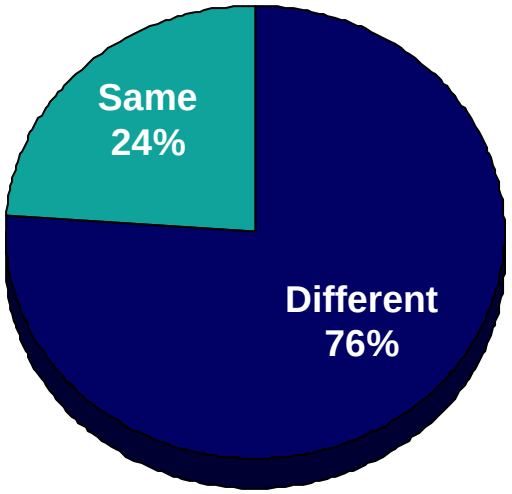
Milk vs. Ultrafiltered Milk

(A)



Milk vs. Milk and Ultrafiltered Milk

(B)



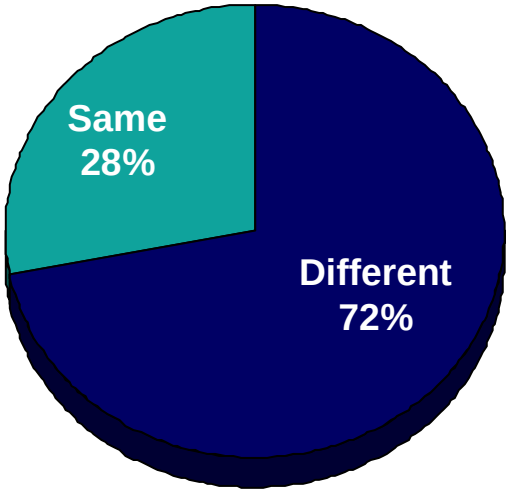
Given that one of these packaged cheese products contains Ultrafiltered Milk in its ingredients, do you believe that these two products would be the same or different?

- As with the ingredients, prompting Ultrafiltered Milk content increases product discrimination.
  - More than seventy percent believe the cheeses to be different once they are pointed to the presence of Ultrafiltered Milk.
    - Proportionally very similar to the responses related to the labels' ingredients.

Milk vs.

Ultrafiltered Milk

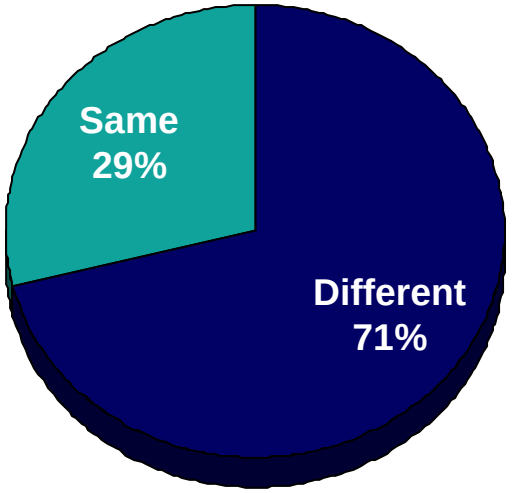
(A)



Milk vs.

Milk and Ultrafiltered Milk

(B)



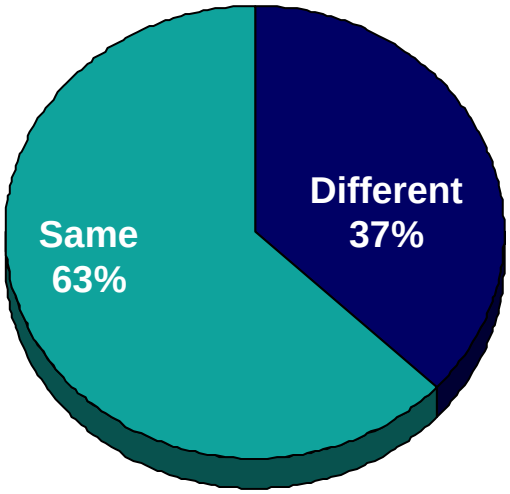
Do you believe that these two packaged cheese products would <u>taste</u> the same or different?

- More than one third of consumers believe the taste of the products would be different.

<u>Milk vs.</u>

<u>Ultrafiltered Milk</u>

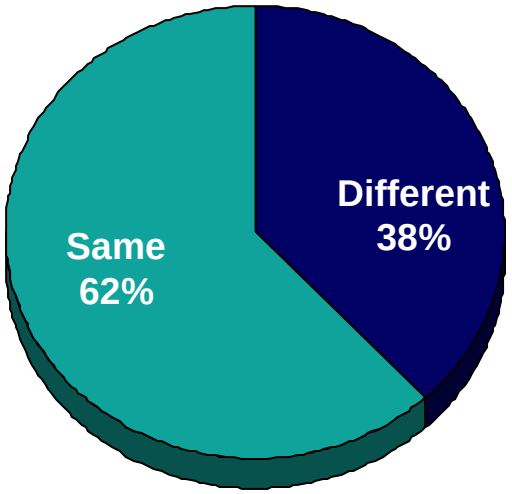
(A)



<u>Milk vs.</u>

<u>Milk and Ultrafiltered Milk</u>

(B)

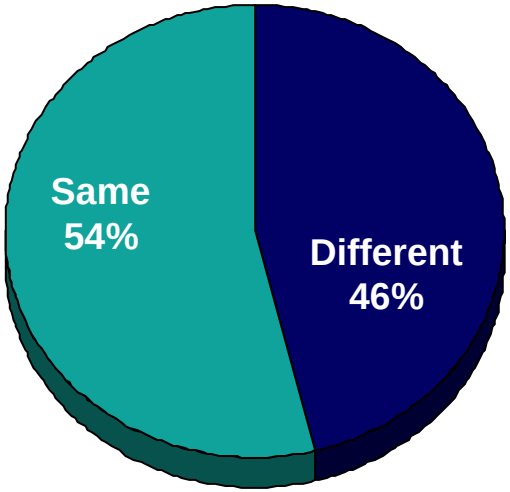


Thinking about the healthfulness of these two packaged cheese products, do you believe that these two products would be the same or different?

- Nearly half of consumers believe the healthfulness of the products would be different.

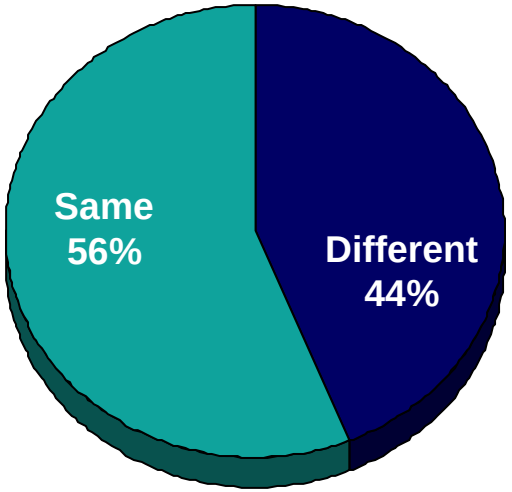
Milk vs. Ultrafiltered Milk

(A)



Milk vs. Milk and Ultrafiltered Milk

(B)



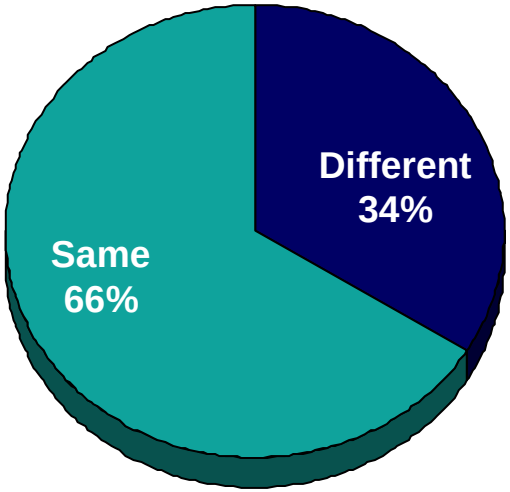
Thinking about the quality of these two packaged cheese products, do you believe that these two products would be the same or different?

- As with taste, one-third of consumers perceive the quality would be different.

Milk vs.

Ultrafiltered Milk

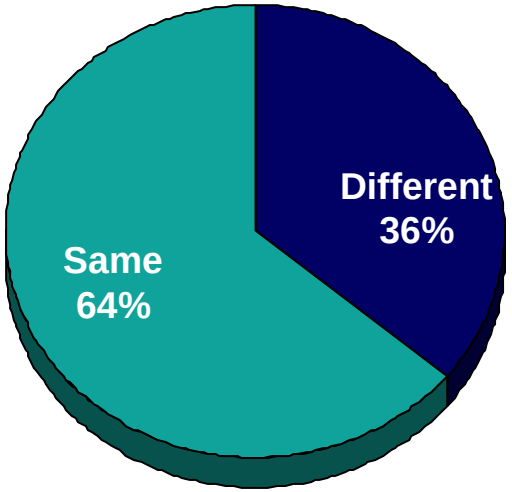
(A)



Milk vs.

Milk and Ultrafiltered Milk

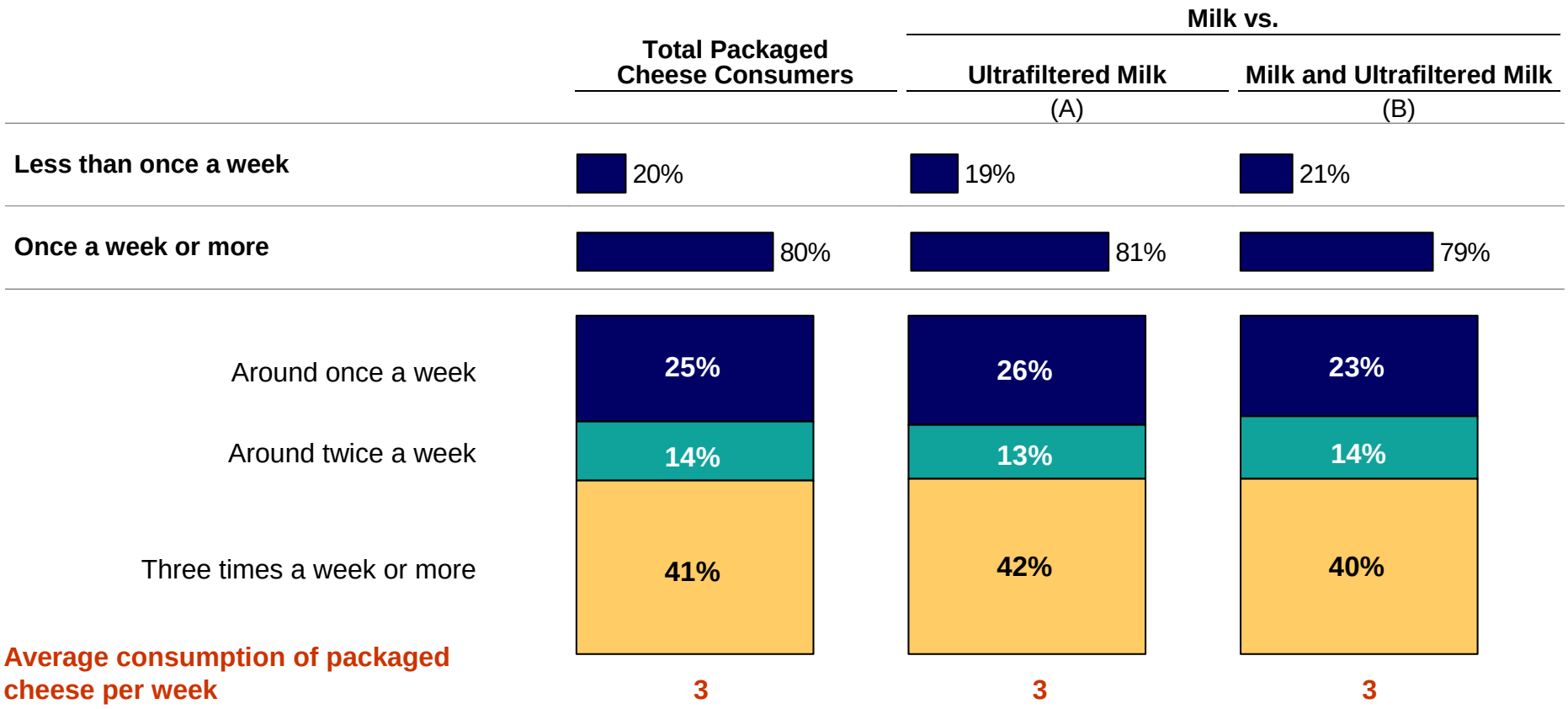
(B)



Appendix: Consumption Behavior

Weekly Consumption of Packaged Cheese

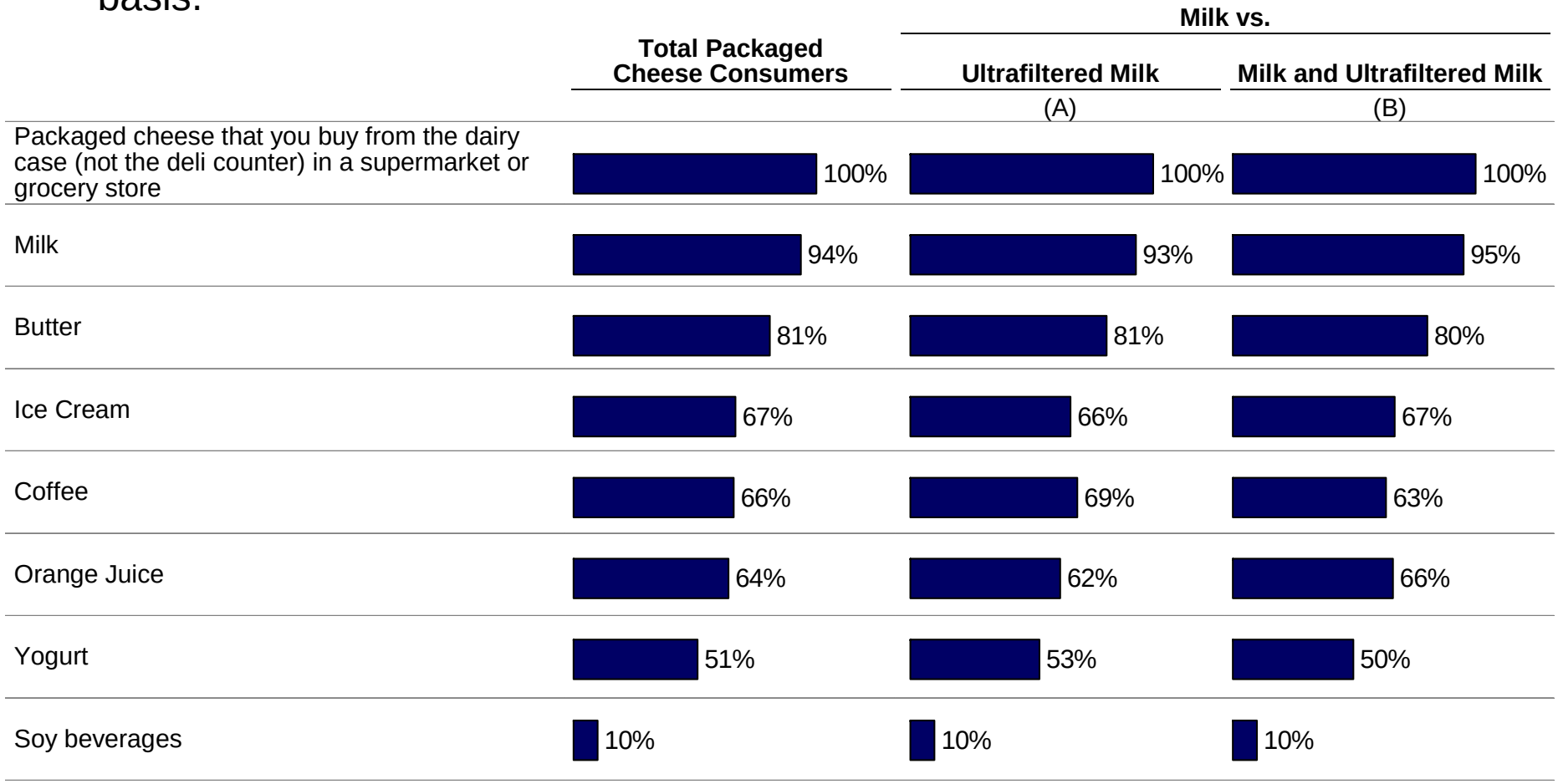
- Among packaged cheese consumers, most eat packaged cheese once a week or more.



Scr.E On average, about how many times a month do you eat packaged cheese that you buy from the dairy case (not the deli) in a supermarket or grocery store?

Items Bought on Regular Basis

- As would be expected, packaged cheese consumers are highly likely to also buy other dairy products including milk, butter, and ice cream on a regular basis.



Scr.D Which of the following food items do you buy on a regular basis?

Appendix: Demographics

Summary of Demographics

	Total	Milk vs. Ultrafiltered Milk	Milk vs. Milk and Ultrafiltered Milk
	%	(A) %	(B) %
Gender			
Male	36	38	34
Female	64	62	66
Age			
Under 35	24	24	25
35+	76	76	75
50+	44	45	44
Average Age	*48*	*48*	*47*
Marital Status			
Married	61	62	60
Not married	38	38	39
Household Composition			
1 person household	19	20	18
2 people household	34	35	34
3 or more people household	46	44	47
Presence of Children Under 18 in Household			
Have children under 18 in the household	40	40	40
Average # of Children in Household	*2*	*2*	*2*

Summary of Demographics

	Total	Milk vs. Ultrafiltered Milk (A)	Milk vs. Milk and Ultrafiltered Milk (B)
	%	%	%
Education			
High school graduate or less	21	23	20
Some college or more	78	77	79
Bachelor's degree or higher	33	32	35
Employment			
Employed	53	55	51
Not employed	46	44	48
Household Income *(among total answering)*			
Less than $50,000	55	55	55
$50,000 or more	45	45	45
Median	*$46,100*	*$46,000*	*$46,220*
Race			
White, non-Hispanic	73	73	73
Black/African American, non-Hispanic	11	12	11
Hispanic	12	12	12
Other, non-Hispanic	2	2	2
Region			
Northeast	14	14	14
South	34	33	35
Midwest	28	29	26
West	24	23	25