Kraft Foods

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

Re: Docket No. 2000P-0586; Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk; 70 Fed. Reg. 60751 (Oct. 19, 2005)

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) is the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells, especially Kraft cheese. Today, Kraft brands are found in more than 99% of all U.S. households and over 155 countries around the world. As a major U.S. producer of cheese and cheese products, Kraft has a substantial interest in making sure that the cheese standards stay up-to-date as production methods become more efficient.

Introduced about four decades ago, ultrafiltration is a technology that improves cheese-making efficiency. It is used to remove those parts of the "whey" portion of milk (such as lactose) that are otherwise removed by the traditional cheese-making process. Most, but not all, of the U.S. cheese standards have "alternate make" provisions that expressly permit the use of this technology inside the cheese plant.

In response to a petition filed five years ago by several leading trade associations, including the National Cheese Institute (NCI), FDA has now proposed to add a sentence to the definition of "milk" so that "milk" and "ultrafiltered milk" (UF milk) may be used interchangeably in all standardized cheeses. This proposal would allow use of ultrafiltration in making cheese covered by standards without "alternate make" procedures. More significantly, the proposal clearly provides for the use of "outsourced" UF milk: i.e., milk filtered outside of the cheese plant, either by a third party or by the cheese manufacturer at a facility separate from the plant that produces the cheese. Changing the definition as proposed would bring all the standards into line with current industry practice, a step Kraft supports.

FDA also has proposed to require that outsourced UF milk be labeled as an "ingredient" distinct from milk (i.e., as "ultrafiltered milk" or "ultrafiltered nonfat milk") on the finished cheese label. To apply the proper finished product label, industry would need to establish complex systems for tracking use of outsourced UF milk throughout the production

process. The result would be increased inventories for in-process materials, finished products, and labels, all designed solely to segregate cheese made with outsourced UF milk from other cheese. A requirement to preserve the identity of outsourced UF milk would make it impossible to use UF milk and milk interchangeably, effectively contradicting and undermining the rest of the agency's proposal.

The proposed labeling requirement would impose these and other burdens without any well-founded reason. Certainly, all cheese is made from milk, whether the ultrafiltration process to remove whey occurs entirely at the cheese plant or partially in a separate facility to reduce shipping costs and improve efficiency. The physical, chemical, organoleptic, and nutritional properties of cheese are the same regardless of whether the cheese is made with milk filtered inside a cheese plant, outsourced UF milk, or milk that has not been filtered at all. FDA has long agreed that ultrafiltration at the cheese plant triggers no need for special labeling. For these and other reasons, Kraft considers outsourced UF milk used for making cheese to be a transient or "in-process" form of the ingredient "milk" that should be declared as "milk" on the ingredient line of finished cheese products.

In fact, the labeling proposal would be detrimental to both consumers and the dairy industry. We respectfully suggest that FDA should be most concerned about the consumer confusion created by requiring different labels for cheeses that are indistinguishable—confusion confirmed by our consumer research as well as that conducted by NCI. For the cheese industry, the practical implications of the proposal would be significant, but without a measurable change in the finished product, the labeling requirement would be largely unenforceable, especially for imported products. We are particularly concerned that the proposal would require costly changes to systems that are already in place and would eliminate benefits that are already being realized, based upon reasonable interpretations of the law and agency precedent. These changes would increase, not reduce or stabilize, the cost of cheese to both manufacturers and consumers, contrary to the agency's economic analysis.

Kraft is both a major purchaser and manufacturer of cheese, so we are in a position to share with the agency implications of the proposed rule that may not have been apparent when the proposal was drafted. We urge FDA to recognize outsourced UF milk for what it is—an "in-process" form of the ingredient "milk." Even if FDA continues to believe that outsourced milk is a distinct ingredient, we ask that the agency allow it to be declared collectively as "milk" to prevent consumer confusion, enforceability issues, and the unnecessary complexity an additional labeling requirement would introduce into the production process.[1]

[1] *See, e.g.*, Federal Food, Drug, and Cosmetic Act (FFDCA) § 403(i)(2). For example, FDA allows dairy ingredients like concentrated milk to be declared as simply "milk" in cheese because "differences in the form of the dairy ingredients used (i.e., liquid, concentrated, or dried) have no perceptible effect on the final product." 48 Fed. Reg. 2376, 2377-78 (Jan. 21, 1983). For similar reasons, even if FDA believes UF milk is

Regulatory History of Ultrafiltration in Cheese-making

The starting point for all varieties of cheese is milk. Milk, therefore, is part of the basic nature of cheese and substantially contributes to its essential characteristics. The cheese-making process, however, selectively concentrates only certain components of milk, such as major milk proteins and fat; the water-soluble constituents of the "whey" portion of milk (i.e., water, lactose, whey proteins, and some vitamins and minerals) are wholly or partially removed from coagulated cheese curd through a draining procedure known as whey syneresis. Ultrafiltration is a process that allows the dairy industry to use modern filtration technologies to remove the same milk constituents as whey syneresis, but at an earlier phase of the cheese-making process. Ultrafiltration of cheese milk merely rearranges the steps of the cheese-making process, and cheese made with milk that has been ultrafiltered has the same physical, chemical, organoleptic, and nutritional properties as cheese made in the traditional way. Incidentally, in our processes, outsourced UF milk is used in relatively small amounts (e.g., typically 12% to 20% of the milk used in making cheese) to supplement the local milk supply on an as needed basis.

FDA and industry have long agreed that milk filtered inside of a cheese plant is permitted as part of the alternate make provisions of the cheese standards. In other words, milk filtered inside of a cheese plant is simply viewed as a transient or "in-process" form of the ingredient milk, and in-plant UF milk is labeled on the ingredient line of finished cheese products as "milk." Ultrafiltered milk has been used in cheese-making and declared in this way since the late 1970's in this country and perhaps a decade longer, stretching back to the 1960's, in Europe.

To the best of our knowledge, FDA's first formal opinion on the status of outsourced UF milk was in response to a request from an operator of a central filtration facility. This operator, T.C. Jacoby & Company, Inc. (Jacoby), intended to filter milk close to farms in the Southwest for subsequent delivery to a cheese plant in Minnesota (Bongards Creamery) and use in standardized cheddar cheese. Jacoby asked FDA whether outsourced UF milk must be labeled in bulk and in the end cheese product, pointing out that the cost of labeling the end cheese product would be prohibitive.[2] In response, FDA replied that it did not object to the use of Jacoby's outsourced UF milk in cheddar cheese or to the declaration of this milk as "milk" in the ingredient line of the finished product.

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an ingredient distinct from milk, the agency should allow it to be declared as "milk" in the ingredient line of finished cheese.

[2] Letter from T. Jacoby, Jr. to Elizabeth J. Campbell, FDA (May 1, 1996)("Bongards makes process cheese, and they have many labels, all of which would have to be changed if they are required to label. The costs associated with this labeling would be prohibitive.").

FDA's decision was consistent with longstanding agency policy to accommodate emerging technologies where there is a reasonable basis for doing so. In fact, FDA's response to Jacoby relied on a clearly stated legal rationale—the alternate make provisions of the cheese standards—of general applicability to all cheese operations, not simply the cheese facility addressed in the letter:

> 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 cheese making process . . .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 by Bongards Creamery on the limited basis described in your May 1, 1996 correspondence. However, if it is found that the resultant cheese differs from that produced traditionally, use of the retentate in the cheese would necessitate a petition to amend the definition and standard of identity for the cheese.
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> 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.[3]

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

In 1999, in response to questions raised by USDA,[4] FDA reexamined this interpretation, and ultimately asked NCI for a petition to amend the standards so that the permitted uses of ultrafiltration would be clear.[5] The agency, however, continued to permit use of outsourced UF milk in cheddar and mozzarella cheese, and to allow its labeling as simply "milk," while an NCI petition to amend the standards was pending. Thus, FDA historically has not objected to the labeling of outsourced UF milk as "milk" on the ingredient line of finished cheddar and mozzarella cheese. In early 2005, FDA did take the position that outsourced UF milk intended for use in Swiss cheese must be labeled as distinct from milk, although the agency continued to recognize that Swiss cheese prepared with outsourced UF milk is physically, chemically, and organoleptically equivalent to Swiss cheese made in the traditional way.[6] NCI has asked FDA to withdraw or stay this position until the labeling of UF milk is resolved through rulemaking.

With this proposal, FDA attempts to resolve the ambiguity surrounding outsourced UF milk by amending the standards to provide for its explicit use in standardized cheese. In taking this action, the agency acknowledges that outsourced UF milk provides many benefits.[7] General benefits of UF milk include greater flexibility in cheese-making, better processing efficiencies (e.g., by allowing more milk solids to be processed per batch with the same equipment, relative to cheese made with unfiltered milk), and more uniform product quality. Benefits specific to outsourced UF milk include better management of seasonal imbalances in milk supplies and cheese demand and reduced costs associated with milk distribution, resulting in savings that can be passed along to consumers in the form of more stable cheese prices. Of the many benefits of outsourced UF milk, one of the most important is the ability to use such milk intermittently as the need arises, as can occur when local supplies of milk are not adequate. For example, a cheese plant in the Midwest may not always have an adequate supply of local milk, but UF milk can be supplied as needed from remote locations because it can be easily and efficiently hauled over long distances.

Outsourced UF Milk Used in Cheese Is Milk for Ingredient Labeling Purposes

FDA is proposing to treat outsourced UF milk as an ingredient that must be declared in finished cheese as "ultrafiltered milk" or "ultrafiltered nonfat milk," as appropriate.

4 Letter from F. Tracy Schonrock, USDA, to John Foret, FDA (Mar. 1, 1999).

5 Letter from John Foret, FDA, to F. Tracy Schonrock, USDA (Oct. 21, 1999).

6 *See* Letter from F. Satchell, FDA, to C. Hough, IDFA (Apr. 6, 2005)(explaining that "the agency's thinking and policy with respect to the declaration of fluid UF milk have evolved" since FDA's 1999 determination not to require labeling of outsourced UF milk as an ingredient distinct from milk).

7 70 Fed. Reg. 60751, 60757 (Oct. 19, 2005).

This approach would trigger an identity preservation requirement for outsourced UF milk, negating the important benefits described above and conflicting with the basic role of UF milk in cheese-making as simply an alternative form of milk.

Although FDA does not use the term "outsourced UF milk," the agency draws a clear distinction between the ingredient status of milk filtered inside a cheese plant and milk filtered outside a cheese plant:

> [T]he alternate make provision of current cheese standards allows manufacturers to appropriately process the basic ingredient milk during the cheese-making process. For example, the 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 for cheese making. In such a process, the ingredient that is introduced into the cheese-making process is milk. However, fluid UF milk purchased or brought in from another plant, even within the same company, that is then introduced into cheese making is considered an alternate ingredient because the ultrafiltration process is used solely for the production of an ingredient that is subsequently used in cheese making. Therefore, in this case, the ingredient is fluid UF milk, not milk.[8]

Under the reasoning suggested by FDA, the ingredient status (and therefore, ingredient labeling requirements) for UF milk used in cheese would be based solely upon the location of the ultrafiltration equipment. If the filtration equipment is inside the cheese plant, the pertinent ingredient is "milk," but if some of the milk is filtered outside of the cheese plant, that portion of the cheese milk is "ultrafiltered milk" (or "ultrafiltered skim milk"). We respectfully suggest that such a position is not justified by the facts or existing law.

As described previously, ultrafiltration is used in cheese-making simply to remove the whey constituents that would otherwise be removed by other steps in the cheese-

[8] 70 Fed. Reg. 60751, 60754 (Oct. 19, 2005). FDA's proposal contains very little explanation of the justification or scope of the proposed labeling requirement. In light of this discussion in the preamble, as well as other precedent, we understand the agency's position to be that UF milk is an "ingredient" distinct from milk (and thus must be labeled as "ultrafiltered milk") only when it is prepared by an outside facility. Indeed, the agency's reasoning demonstrates that there would be no sound legal or factual basis for classifying UF milk prepared inside the cheese plant as an ingredient distinct from milk because it is simply a transient form of milk produced as a necessary part of the cheese-making process. Thus, there is no legal basis for characterizing either in-plant or outsourced UF milk as a distinct "ingredient" in cheese for labeling purposes.

making process. Ultrafiltration, therefore, is as much a part of the cheese-making process as whey syneresis. Regardless of where the filtration occurs, in all cases, the starting and characterizing material is milk; the filtration technologies are identical; the resulting in-process materials are functionally equivalent; and the finished cheese products have the same physical, chemical, nutritional, and organoleptic qualities. In sum, the only difference is the location of the ultrafiltration equipment.

The Federal Food, Drug, and Cosmetic Act (FFDCA) recognizes that the same ingredient may be processed in two plants as part of a single process, but without becoming a "new" ingredient. FDA's regulations implementing section 405 of the Act[9] exempt foods that are shipped in an "in process" or unfinished form from any and all labeling requirements. This broad exemption implicitly recognizes that in-process articles of food do not have any independent legal identity and, thus, no product identity or other labeling requirements (including identification as an "ingredient" in the finished foods in which they are incorporated) can apply. UF milk intended for use in cheese is an unfinished item because it simply represents a portion of the cheese milk from which the whey constituents have been removed prior to introduction into the cheese vat. This efficient removal of whey constituents is an early part of the cheese-making process; it does not become a different process simply because it occurs in more than one plant. Therefore, outsourced UF milk is shipped pursuant to the exemption for unfinished items and is, as used in cheese-making, an in-process form of the ingredient milk.

Identification of Outsourced UF Milk as an Ingredient Distinct from Milk Would Mislead Consumers

Identification of UF milk as an ingredient different from milk would mislead consumers because cheese prepared with outsourced UF milk is substantially the same as both cheese made with in-plant filtered milk and cheese made traditionally. It is entirely reasonable to assume that consumers will view products made with distinct ingredients as different in meaningful ways, especially where the ingredients are central to the product's identity. Research Kraft fielded has confirmed this reasonable assumption: a substantial number of consumers do in fact consider the presence of UF milk to signal a meaningful change in composition of the finished product, even though none has occurred. A report of this research is provided in Attachment 1.

[9] 21 C.F.R. 101.100(d); FFDCA § 405; 21 U.S.C. § 345 ("The Secretary shall promulgate regulations exempting from *any labeling requirement of this Act* . . . food which is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment . . .") (emphasis added).

To understand how consumers view a distinct ingredient declaration for UF milk in cheese, Kraft fielded consumer research with 300 Primary Grocery Shoppers. Study participants had eaten cheese in the past month and had purchased cheddar cheese within the past 6 months. Each participant was exposed to current cheddar cheese packaging, which declares "milk" as the primary dairy ingredient, and revised packaging that declares both "milk" and "ultrafiltered milk" as ingredients. Consumers were then asked a series of questions about the two products. The first set of questions focused on whether the consumers viewed the two products as the same or different; the questions then probed as to whether the differently labeled products were the same or different with respect to quality, healthfulness, and taste. In all, the online interviews lasted about five minutes each and were conducted between November 10th and November 14th, 2005.

The results showed that most consumers (80%) believe a cheese product made with "ultrafiltered milk" is different from the cheese made with simply "milk." In addition, a notable percentage of consumers believe the products will be specifically different with respect to healthfulness (48%), quality (42%), and taste (32%). It is remarkable that so many consumers perceive these cheese products to be different in material ways, when the underlying products are in fact the same, as were the starting materials (milk) and the in-process materials (UF milk and/or milk from which whey constituents have been separated). The use of different labeling schemes for these products creates a false and misleading impression of meaningful differences where there are none.

Identification of Outsourced UF Milk as an Ingredient Distinct from Milk Is Impractical

In addition to examining the likely effects on consumers, we carefully evaluated the effect on our cheese supply chain of FDA's proposal to require identification of outsourced UF milk as an ingredient distinct from milk. Kraft's $6 billion cheese business is among the largest and most diverse in the world, so it presents a good case study for examining the practical implications of this proposal. After a thorough assessment, we conclude that the complex and costly systems necessary to implement the proposed labeling change would be not only impractical, but commercially infeasible for our business.

Our cheese manufacturing sector spans all facets of the supply chain, including production of natural cheeses from milk, UF milk, and other ingredients; production of natural cheese products from raw material cheeses (e.g., conversion of cheese into chunks or shredded cheese); production of process cheeses from a variety of cheese and other ingredients (e.g., cheese trim remaining from natural cheese processes as well as virgin cheese); and distribution of cheese products to retailers, food service operators, and other food manufacturers for use in finished food products. It is not uncommon for finished cheese products, such as process cheese or shredded cheese blends, to contain 4 different types of cheese (e.g., a 4-cheese "Mexican style" blend of shredded cheese).

Many "finished" products are used in the production of other foods. For example, a shredded cheese may be used by another food manufacturer in a frozen entrée or by a foodservice operator who prints brochures identifying all ingredients. These customers must be notified in advance of all ingredient changes so that labels and labeling can be adjusted accordingly. Thus, the proposed labeling requirement affects not only retail cheese products, but all foods in which cheese is used as an ingredient. FDA's proposal makes no mention of these downstream implications, which leads us to believe the agency may not have considered their impact when developing the proposal.

As shown in Attachment 2, Kraft operations are supported by a network of more than 30 suppliers of raw materials (including Kraft-owned plants) that presently supply more than 140 cheese styles to approximately 25 "conversion" facilities. A cheese style is a particular type of cheese, such as cheddar, which may be further divided by flavor (e.g., mild, sharp), usage (e.g., for slicing or chunking), or other properties (e.g., moisture or fat content). A conversion facility is any plant that converts bulk cheese into finished goods, such as natural cheese sold to consumers in blocks, slices, or chunks; shredded cheese (including blends of two or more types of shredded cheese); and process cheese.

Conversion plants use a variety of cheese inputs, all of which are coded throughout the supply chain to the finished good. A requirement to preserve the identity of outsourced UF milk would significantly increase the number of codes and amount of physical product that must be segregated and tracked.

For example, our conversion plants use roughly 1750 codes to produce more than 1200 stock-keeping units (SKUs). These codes include more than 250 cheese usage codes, which track different forms of natural cheese (e.g., slices, chunks, shredded), process cheeses, and other cheese products (e.g., hard cheeses for grating). Of these, more than 25 codes are used just for different types of cheese trim, which are the pieces of cheese remaining after bulk blocks of cheese are cut into the desired weight and form for the finished product. Trim is typically further processed into items such as cheese spread and pasteurized process cheese.

Conversion plant codes also include more than 1500 "work in progress" (WIP) codes, which help trace in-process items throughout production. For instance, a typical process cheese formula like Kraft American Singles has 7 steps in the manufacturing process, including grinding of various raw material cheeses (e.g., raw material barrels, trim from ready-to-eat conversion plants, and material from other steps in making process cheese), blending non-cheese ingredients (e.g., emulsifiers, cream, salt), cooking, cooling, packaging, and palletizing. Each step is considered WIP and has a separate code for tracking pounds and value of materials and for maintaining quality control traceability. A typical process cheese conversion plant has more than 55 formulas, so 55 formulas times 7 WIP step codes results in 385 codes, without consideration of UF milk labeling.

A requirement to identify UF milk as distinct from milk would add cost and complexity at every level of our business. At any given time, as much as 50% or more of our raw material cheese might be made with outsourced UF milk. Use of UF milk is frequently intermittent, based on seasonal requirements tied to local availability of milk—indeed, a major advantage of UF milk is greater flexibility in managing seasonal variations. The proposed labeling requirement, if implemented with our current system, would compel our supply chain to preserve the identity of many raw material cheeses that are currently commingled. We conservatively estimate that, as a result, our various codes for raw materials, trim, and WIP would increase substantially, as much as 75% or more. In other words, where today we may have more than 1700 codes for various inputs, nearly 3000 total codes may be needed if the proposed ingredient labeling requirement is finalized without change. The increased number of codes might nearly double the number of SKUs, from 1200 currently to more than 2100, also placing a significant additional workload burden on retail grocery stores.

The additional codes and other steps needed to maintain the identity of cheese made with outsourced UF milk would result in significant costs. Initial costs would be incurred to modify our tracking systems to accommodate the additional codes,[10] update specifications, update our quality control programs, and increase storage capacity for the increased amount of finished goods. Ongoing costs would be triggered by the need for increased inventory of raw materials, packaging, and finished goods. For example, we estimate that twice to three times as many labels would need to be maintained as compared to our current practice.[11] Additional ongoing costs would include a need for more frequent line changeovers at plants and the added expense of managing additional price changes, packaging materials, and finished goods planning and forecasting.

Significant investments would be especially needed in the planning systems for linking raw materials and finished goods (i.e., linking finished good packaging and SKU planning with raw material cheese production). Presently, our supply chain functions primarily

[10] All codes are traced using advanced software and tracking technologies. Technologies commonly used in the cheese industry include Manugistics (production and demand forecasting), E-sync (a materials management tool), Prism (a payment and inventory management system), Quest (forecasting), Schedule X (final capacity assessments), and Matrics (inventory management, including packaging). An identity preservation requirement for outsourced UF milk would require significant adjustments to these and other management systems.

[11] The proposed labeling requirement is likely to create a need for more than twice the number of existing labels because many cheese products contain more than one cheese. Thus, although a single-cheese item would usually require two labels, one with UF milk and one without, a multiple-cheese product like a 4-cheese "Mexican-Style" blend of shredded cheese could have many more variations. Each of the four cheeses might or might not be subject to the UF milk labeling requirement, potentially exploding the number of labels required for the finished product.

in a "top down" fashion because sales create demand for finished goods, which in turn trigger orders for packaging and raw materials. A labeling requirement for UF milk complicates this process considerably because an interactive planning loop would need to be created to match the demand for finished goods to the appropriate raw materials and packaging.

Based on a preliminary and conservative assessment, we estimate the cost of identifying outsourced UF milk in cheese as an ingredient separate from milk to be in the neighborhood of 23 million dollars. To avoid this cost, Kraft would seriously consider not using outsourced UF milk. This decision, however, would also have economic consequences because outsourced UF milk plays an important role in the cheese supply chain. Many cheese plants, particularly in the Midwest, turn to dairy farms in other parts of the country, like New Mexico or California, because farms in the Midwest can no longer consistently meet the local demand for cheese milk. These dairy farms use ultrafiltration to transport milk in a cost-effective manner, helping to keep cheese plants in the Midwest economically viable. Without this reliable supply, cheese plants that must do without outsourced UF milk would be forced to source other milk at much higher costs. The labeling proposal thus presents an unattractive choice: dedicate substantial resources to preserving the identity of UF milk, or incur the added cost and inefficiency associated with using all unfiltered milk. The solution is to allow outsourced UF milk to be used interchangeably with other types of milk, consistent with longstanding industry practice.

The cost increase is especially troubling because the proposed labeling would provide no benefits to consumers or the cheese industry. There is no benefit to consumers because the use of UF milk is not material information: finished cheese products are the same regardless of whether the whey constituents are removed through filtration (whether inside or outside the cheese plant) or whey syneresis. Indeed, the proposal is a detriment to consumers because it leads them to believe otherwise identical products are different; it also adds unnecessary length and complexity to the ingredient list. For industry, there is no benefit because a labeling requirement would effectively negate the purpose and advantages of outsourced UF milk.

It is worth emphasizing, as NCI did in its petition, that outsourced UF milk is widely used in today's marketplace, so labeling changes at this time would actually reduce or eliminate currently realized benefits. Of particular concern are the many changes that would affect existing systems and businesses built around outsourced UF milk. The agency's economic analysis indicates FDA did not realize the dairy industry already has invested large amounts of money in equipment and designed supply systems to capture the benefits of ultrafiltration at a central facility. The investments made to date were based upon reasonable interpretations of existing "alternate make" provisions and the rules on "in-process" ingredients, which do not require labeling. Guidance and enforcement policy in place before the agency's thinking about

labeling recently "evolved"[12] did not lead industry to predict the possibility of a labeling requirement triggering a need to back-track high-cost systems.

Identification of Outsourced UF Milk as an Ingredient Distinct from Milk Poses Enforcement and Commercial Concerns

FDA has long taken reasonable steps to accommodate new and emerging technologies. In the case of UF milk, which has been widely used in this country for nearly thirty years, the agency's flexibility has allowed U.S. producers to realize the productivity benefits attainable in other countries. For example, producers in the European Union have used UF milk technologies for about forty years.

The creation of a burdensome labeling system would force the U.S. industry either to adopt costly tracking measures or to incur the higher cost of obtaining enough unfiltered milk to make cheese. Foreign companies that import cheese into the United States would be largely unaffected because the labeling requirement is not enforceable simply by examining or testing the cheese product. The finished cheese products are the same whether in-plant UF milk, outsourced UF milk, or no UF milk is used, so there is simply no way to tell upon inspection whether a product is labeled properly. Accordingly, the unenforceable nature of this requirement places the U.S. cheese industry at a competitive disadvantage as compared to foreign producers. Similarly, the proposed requirement would be nearly impossible to enforce domestically because the only way to detect use of outsourced UF milk without labeling would be to observe the violation as it occurs in the cheese plant.

The proposed requirement would likewise create the potential for confusion with respect to cheese purchased on the open market, in commodity exchanges that cannot be controlled in the same way that ongoing purchases by contract can. Specifically, traders of cheese on the Chicago Mercantile Exchange are not required to disclose use of outsourced UF milk. Therefore, if FDA's labeling rule is finalized as proposed, unsuspecting buyers might purchase cheese without realizing that labeling is required, and the resulting uncertainty could harm the liquidity of the exchange.

[12] *See* Letter from F. Satchell, FDA, to C. Hough, IDFA (Apr. 6, 2005)(explaining that "the agency's thinking and policy with respect to the declaration of fluid UF milk have evolved" since FDA's 1999 determination not to require labeling of outsourced UF milk as an ingredient distinct from milk).

Summary and Next Steps

FDA is proposing to amend the cheese standards in a way intended to result in meaningful benefits to the cheese industry and U.S. consumers. By providing for the explicit use of outsourced UF milk in standardized cheese, FDA anticipates greater flexibility in cheese manufacturing, greater product uniformity, more efficient distribution systems, reduced distribution costs, better management of seasonal demands and imbalances, and reduced or stabilized prices for consumers. In reality, however, the added labeling requirement would negate these important benefits.

Consumer confusion would result because cheese products that are the same would be labeled in different ways with respect to milk, the key cheese ingredient. In addition, the systems needed to maintain the separate identity of inputs such as milk, in-plant UF milk, and outsourced UF milk are simply impractical and would lead to a competitive disadvantage for U.S. producers. The most likely result of FDA's proposal as currently written is that industry would seriously consider abandoning outsourced UF milk and resort to less efficient means of production. This result would lead to increased cheese prices, frustrating the intent of FDA's proposal.

In our view, the most logical solution is for FDA to reconsider its position that outsourced UF milk is a distinct "ingredient" and instead recognize this material for what it is—simply an in-process form of milk used in cheese-making. For all forms of milk used in cheese-making, including fluid milk, in-plant filtered milk, or outsourced UF milk, the starting material and key characterizing ingredient is always milk. There is no reasonable basis for characterizing UF milk as a distinct ingredient simply because the ultrafiltration equipment that makes it useful in cheese-making is located outside of the cheese plant.[13]

[13] This analysis is necessarily specific to the cheese-making process because UF milk and milk function identically in the production of cheese (i.e., as a source of characterizing milk proteins and other milk constituents not removed by whey syneresis). It may not apply where UF milk is truly used as an ingredient as opposed to an alternative source of an in-process form of milk.

A second approach would be for the agency to allow UF milk in cheese to be declared collectively as "milk." FDA has authority to provide for collective ingredient labeling declarations of this type, and has in the past exercised this authority where more specific declarations would result in consumer deception, be impractical, or result in unfair competition.[14] The proposed requirement to declare outsourced UF milk as an ingredient different from milk would satisfy these criteria.

Thank you for your consideration. Please let us know if additional information would be useful.

Respectfully submitted,

Sheryl A. Marcouiller
Chief Counsel, Food Law
Kraft Foods Global, Inc.

[14] *See, e.g.,* FFDCA § 403(i)(2).

Attachment 1

UF Milk Ingredient Assessment

Prepared for Kraft

Prepared by Synovate

Job number 5B24 (MSA #05-6867)

Date November 2005

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Background

– The Cheese and Dairy Sector of Kraft is reviewing a potential FDA labeling requirement to separate out-sourced “ultrafiltered” milk as an ingredient. Quantitative research is of interest to understand how category users will view the product, that is, is it the same or different, with the potential change in labeling.

Methodology

- A 5-minute, custom Internet methodology utilizing the Synovate Consumer Opinion Panel (SCOP) was utilized for this research. A sample of 300 Primary Grocery Shoppers who are also both past month cheese eaters and past 6 month Cheddar cheese purchasers are the basis of the analysis.

- Each respondent was exposed to both the current and the new package front and back panel. Respondents were then asked their opinion on whether or not the product was the same or different in several steps. They were then asked whether the quality, healthfulness and taste of the product was the same or different.

- The study was in the field from November 10th through November 14th, 2005.

Summary

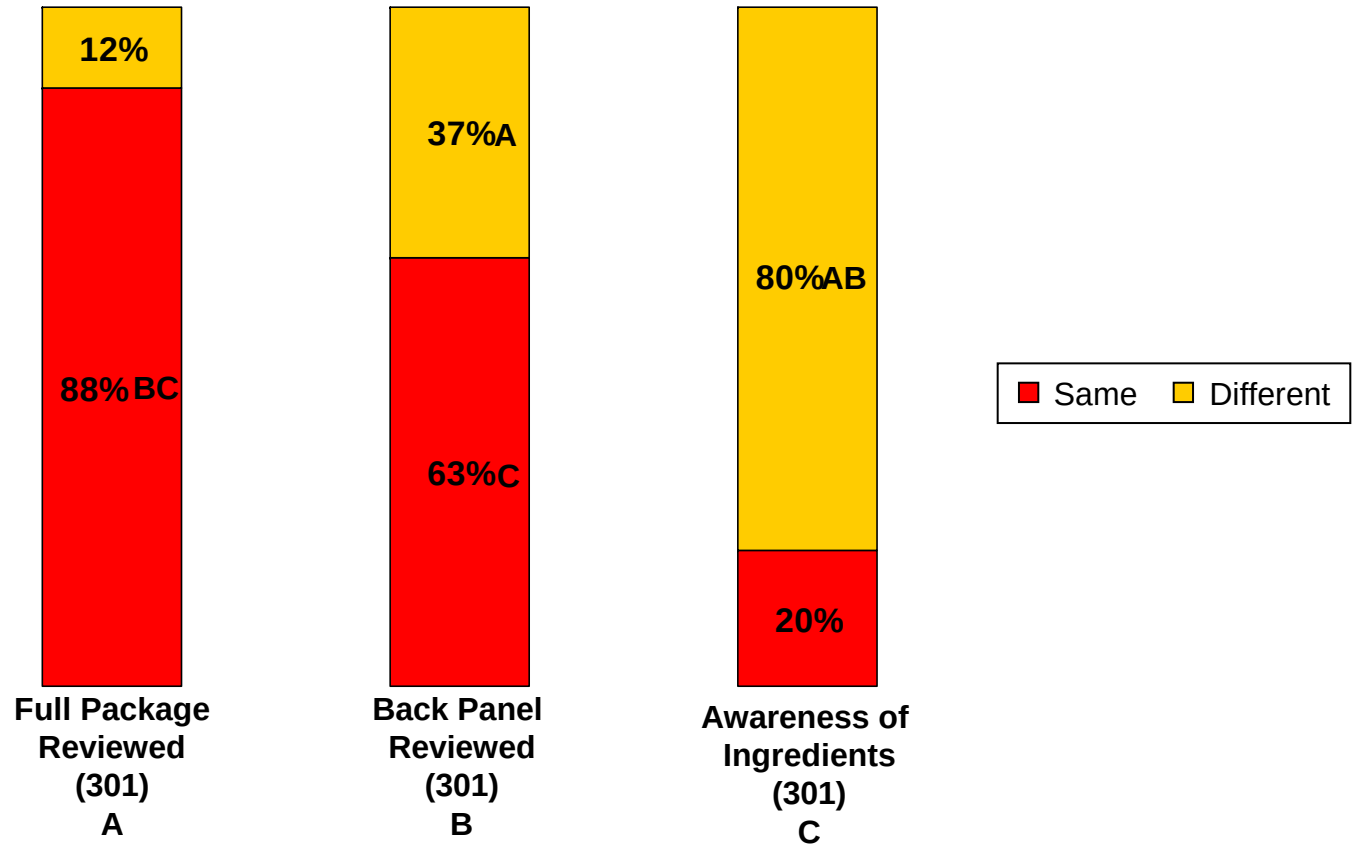
- The results from the Kraft UF Milk Internet study (n=300) show that consumers believe the products will be different based on one product including UF Milk and the other including Milk (Same 20%, Different 80%).

- A notable percentage of consumers also believe the products will be different on taste (same 68%, different 32%), healthfulness (same 52%, different 48%) and quality (same 58%, different 42%).

Detailed Findings

Overall Product Differences

Consumers believe the products would be different based on one product being made with “ultrafiltered milk” and another being made with “milk”.

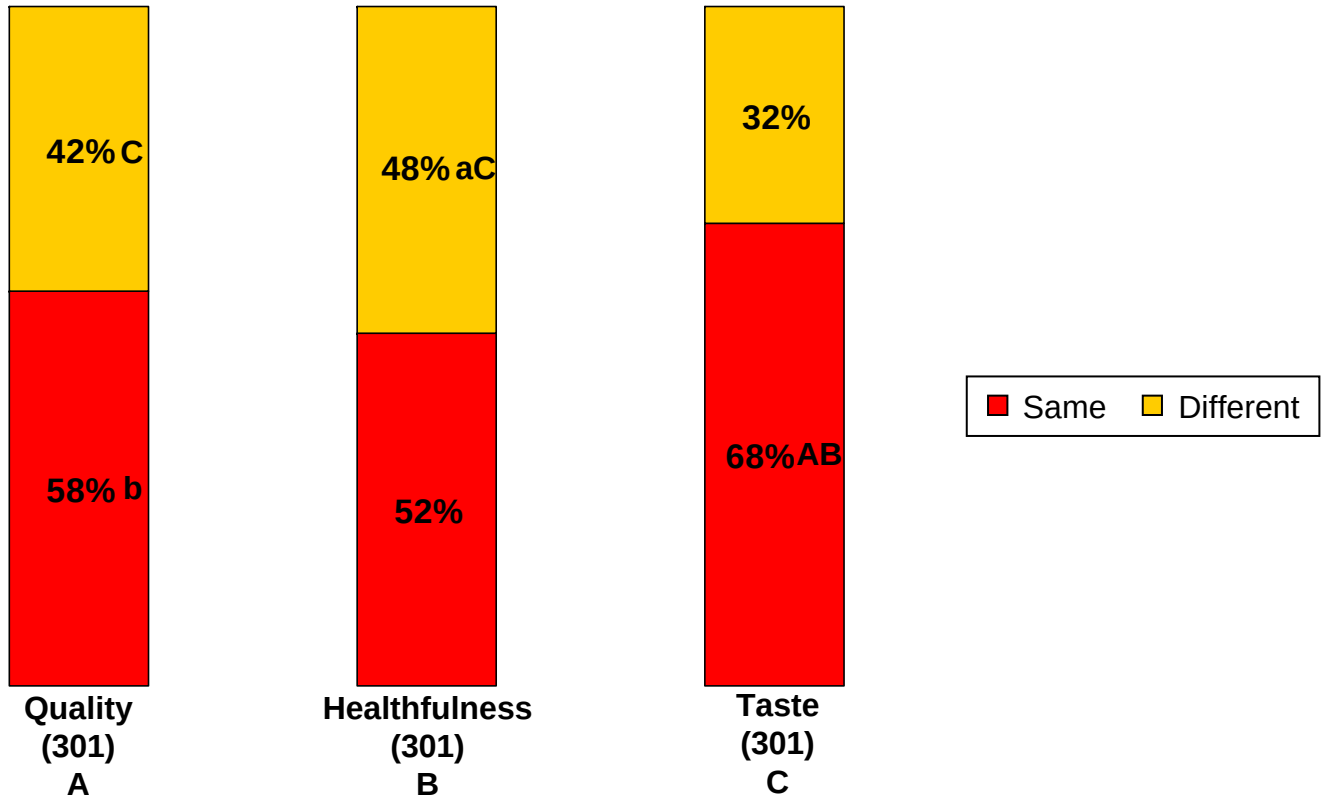


Columns tested with 95% (upper case) / 80% (lower case) significance: A/B/C
Q1. Thinking about the PACKAGES we just showed you, would you say that the PRODUCTS are the same or different?
Q2. Now that you’ve thoroughly reviewed both the nutritional facts and the ingredient list on the packages, would you say that the PRODUCTS are the same or different?
Q3. Knowing that one ingredient list includes both milk and ultrafiltered milk, while the other includes just milk, would you say that the PRODUCTS are the same or different?

Differences in Product Characteristics

A substantial number of consumers feel that the quality, healthfulness and taste of cheese with “ultrafiltered milk” would be different than the same cheese made with “milk”.

Perceptions of both quality and healthfulness are expected to be more impacted than taste.



Columns tested with 95% (upper case) / 80% (lower case) significance: A/B/C
Q4A. Would the QUALITY of the product you saw first be the same or different than the QUALITY of the product you viewed second?
Q4B. Would the HEALTHFULNESS of the product you saw first be the same or different than the HEALTHFULNESS of the product you viewed second?
Q4C. Would the TASTE of the product you saw first be the same or different than the TASTE of the product you viewed second?

Appendix

Current Package

Nutrition Facts
Serving Size 1/4 cup (28g)
Servings Per Container about 8

Amount Per Serving	
Calories 110	Calories from Fat 80
	% Daily Value*
Total Fat 9g	14%
Saturated Fat 6g	30%
Trans Fat 0g	
Cholesterol 25mg	8%
Sodium 190mg	8%
Total Carbohydrate 1g	0%
Dietary Fiber 0g	0%
Sugars 0g	
Protein 6g	
Vitamin A 6% •	Vitamin C 0%
Calcium 20% •	Iron 0%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories:	2,000	2,500
Total Fat	Less than		65g	80g
Sat Fat	Less than		20g	25g
Cholest	Less than		300mg	300mg
Sodium	Less than		2,400mg	2,400mg
Total Carb			300g	375g
Fiber			25g	30g

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FOR BEST QUALITY, USE OR FREEZE BY DATE ON FRONT. ONCE OPENED, USE WITHIN 5 DAYS. MAY BE FROZEN FOR UP TO 2 MONTHS BEFORE OPENING. REFREEZING NOT RECOMMENDED.

INGREDIENTS: CHEDDAR CHEESE (MILK, CHEESE CULTURE, SALT, ENZYMES, ANNATTO [COLOR]); POTATO STARCH, CELLULOSE POWDER, AND CALCIUM SULFATE ADDED TO PREVENT CAKING; NATAMYCIN (A NATURAL MOLD INHIBITOR)

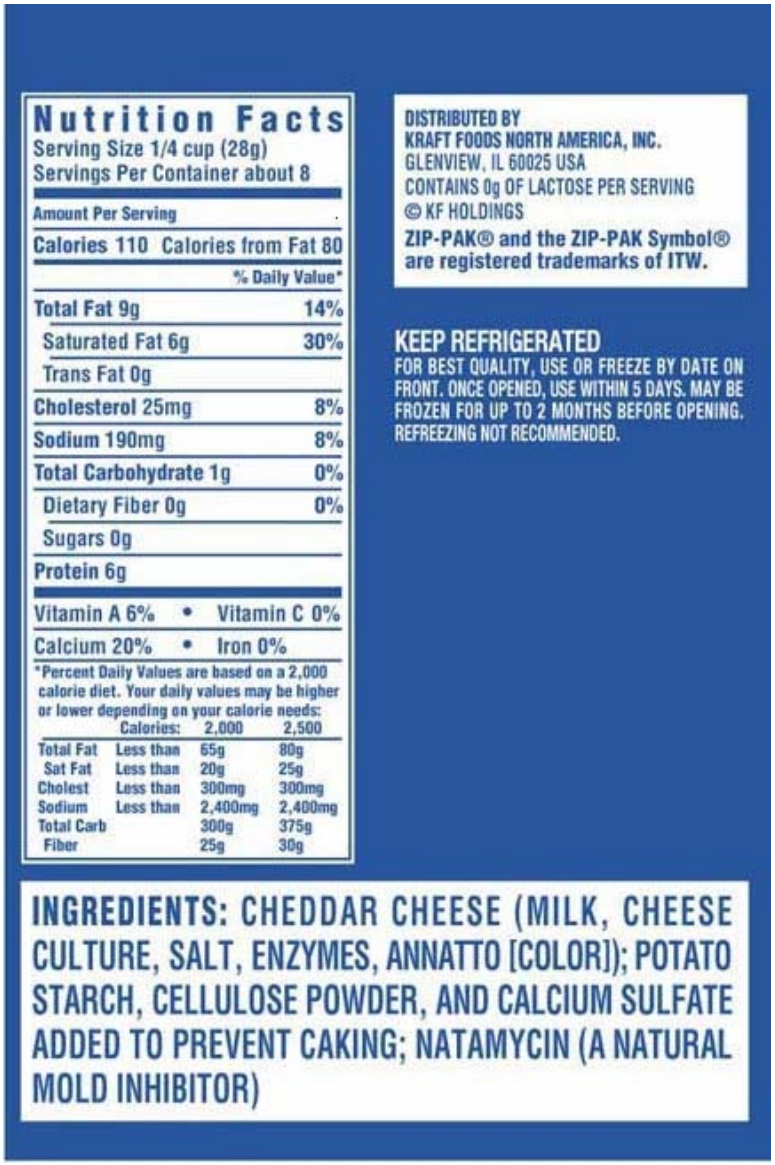
View for Question 1

Potential New Package with Ultrafiltered Milk

View for Question 1

synovate
Research reinvented

Ingredient Labels



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Ultrafiltered Milk

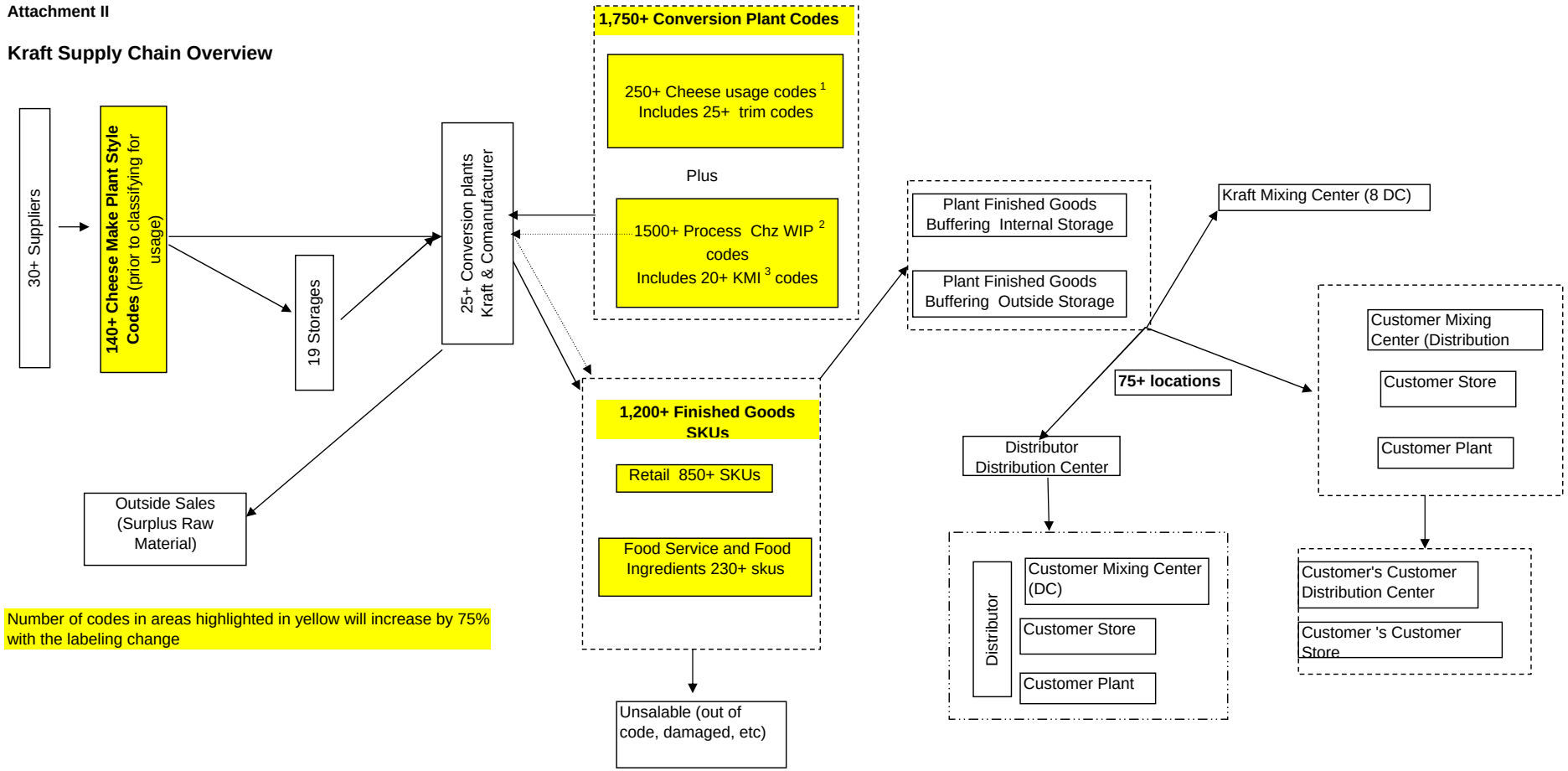
View for Questions 2 & 3

synovate
Research reinvented

Attachment 2

Attachment II

Kraft Supply Chain Overview



Number of codes in areas highlighted in yellow will increase by 75% with the labeling change

[1] Includes codes used for natural cutting, process and Italian grating Finished Goods

[2] Each output of a process cheese manufacturing process is a WIP (work in progress). 250 formulas X six WIP codes per formula = 1500 codes to produce 1200+ SKUs

[3] Kraft Manufactured Ingredient (made in one plant, used in another to make the final finished good)