



"The Cooperative of Choice in the Southeast"

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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**

Southeast Milk, Inc (SMI) submits these comments regarding the Food and Drug Administration's (FDA) proposal to amend its regulations to provide for the use of fluid ultrafiltered (UF) milk in the manufacture of standardized cheeses and related cheese products. SMI is a Florida based cooperative of 294 members marketing 2.94 billion pounds of milk annually. These comments are submitted on behalf of SMI member – owners who began marketing fluid ultrafiltered milk in 2004 and will market in excess of 168 million pounds of milk in the form of fluid ultrafiltered milk in 2005.

SMI appreciates the depth of FDA's technical review of the issue of fluid UF milk and applauds the agency for recognizing that the basic nature and essential characteristics of cheese are maintained when fluid UF milk is used in the cheesemaking process. We strongly support FDA's proposal to amend its regulations to allow the use of fluid ultrafiltered milk in the manufacture of standardized cheese and cheese related products. We believe this action is not only scientifically sound but will offer benefits to both the dairy industry and the consumer.

SMI does take issue with the agency's proposed requirement for special labeling of UF milk when used in the cheesemaking process if the UF milk is sourced from a facility apart from the cheesemaking facility. We feel that the labeling requirement would be overly burdensome on the industry, would not benefit the consumer and would actually cause deception to occur, and is not justified by established FDA precedent. SMI believes that the final rule should have the label requirement removed or otherwise provide an exemption from ingredient labeling.

BACKGROUND

UF milk has been commercially available since 1996 for the use in standardized cheese and cheese products. FDA approved the use of UF milk from a facility in Lake Arthur, NM for use in cheddar cheese in October of 1996. 1/ In response to a request for labeling guidance from Mr. Ted Jacoby, marketing agent for the UF facility in New Mexico, FDA applied the "alternate make" rationale to the use of cheese manufactured with outsourced UF milk and further defined the UF retentate as "Milk":

1/ Letter from M. Cole, FDA Office of Food Labeling, to T.C. Jacoby, T.C. Jacoby and Company, Inc. (October 21, 1996).

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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 of the label of the Cheddar cheese produced at Bongards Creamery, provided that the 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.

The Food Safety Branch of FDA similarly defined the UF retentate as **"Concentrated Raw MILK for Pasteurization"** when it assigned product code 39 to this "milk" for Interstate Milk Shippers purposes. 2/

FDA did not waver from this definition until earlier in 2005 when FDA requested ingredient labeling as "Ultrafiltered Milk" when addressing a request for "regulatory discretion" in the use of UF milk in Swiss cheese manufacture. 3/ For nearly ten years, FDA allowed the use of UF retentate in Cheddar and Mozzarella cheese manufacture and allowed the retentate to be labeled "MILK". An industry was developed during this time to provide UF milk to the market and cheese manufacturers modified their plants to use this accepted "milk" in their processing system. SMI entered the UF business with a multi-million dollar facility based on the longstanding FDA practices in place in 2003.

THE LABELING ISSUE

SMI disagrees with FDA's proposed requirement that standardized cheese products made with "outsourced" UF milk be labeled as containing "ultrafiltered milk" in the ingredient declaration. We are requesting that FDA remove the ingredient labeling requirement from the final rule. SMI believes that the ingredient labeling requirement is not required by FDA's governing statute or its existing labeling regulations and policies. The labeling requirement is both impracticable from an industry standpoint and misleading to consumers, qualifying for an exemption from ingredient labeling.

2/ IMS List, Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers, US Department of Health and Human Services, Public Health Service, FDA

3/ Letter to Clay Hough, International Dairy Foods Association, from Felicia Satchel, Food and Drug Administration (April 6, 2005)

The Proposed Label Requirement is NOT Consistent with Current Law or Agency Policy.

1. There is no valid basis for the distinction in the proposed rule between UF milk brought into the cheese plant (outsourced UF milk) and milk that undergoes ultrafiltration within the cheese plant.

FDA currently allows cheese manufacturers to prepare 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." 4/ Traditional cheesemaking uses a process of draining the curd whereby some of the water soluble constituents of the whey (water, lactose, whey proteins, vitamins and minerals) are removed. This process is termed "whey syneresis". The process of ultrafiltration does exactly the same thing to the milk; removing water soluble constituents prior to cheesemaking that would be removed in the whey syneresis process anyway. The end product is the same and cheese manufacturers are able to use UF milk in the manufacture of cheese under the "alternate make" provision in 21CFR, Section 133.113(a)(1) and declare the ingredient "milk" so long as the milk is filtered inside the cheese manufacturing plant. FDA's proposed rule would require UF milk that is ultrafiltered at another location to be declared as "ultrafiltered milk" on the ingredient statement. There is NO valid basis for distinction between UF milk that is outsourced from another facility and milk filtered within a specific cheese plant. UF milk, regardless of where it is filtered, serves the same role in cheesemaking and produces the same finished cheese as traditional cheesemaking.

2. Just as milk filtered inside the cheese plant is considered "Milk" for purposes of the ingredient statement, milk filtered outside the plant should also be considered "milk". FDA clearly understood this and applied the principles of "alternate make" and concluded that the ingredient declaration should be "milk" when UF was first allowed. 5/
3. Existing regulations recognize that the manufacturing process for a food can take place in more than one location. The regulations exempt "in-process" food components from labeling requirements. 21CFR Section 101.100(d) exempts from labeling requirements "food which is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity as an establishment other than where originally processed or packed....". 6/

Outsourced UF milk is an "in-process" food component and the proposed FDA label requirement is inconsistent with established FDA regulations.

4/ 21 C.F.R. Section 133.113(a)(1)

5/ Letter to T.C. Jacoby, T.C. Jacoby and Company from M.Cole, FDA Office of Food Labeling (October 21, 1996).

6/ 21C.F.R. Section 101.100(d)

The Collective Declaration for “Milk” Applies to UF Milk

FDA has provided by regulation, that an ingredient name should be “a specific and not a collective (generic) name” unless a generic name is approved by FDA. 7/ FDA’s regulation 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 that distinguishes it from different foods. 8/

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

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. It is our understanding that the cheese industry has long used UF milk in Cheddar and Mozzarella cheesemaking without the need for “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 speaks volumes to confirm that the common or usual name of UF milk as used in cheese is “milk” due to the cheesemaking process.

Ingredient Labeling of Outsourced UF Milk in Manufactured Cheese is Not Enforceable

Cheese manufactured with outsourced UF milk is the same product in finished form as cheese manufactured with “in plant” UF milk or cheese manufactured without UF milk. There is no meaningful difference in the products. When examining the finished product, there is no way to distinguish cheese made with UF milk from cheese not made with UF milk. FDA will not be able to test the finished product to determine if in fact, it contains UF milk and would require labeling under the proposed rule. FDA will NOT be able to enforce the labeling requirement nor determine if the cheese is misbranded by containing UF milk.

7/ 21 C.F.R. Section 101.4(b)

8/ 21 C.F.R. Section 102.5(a)

THE EXEMPTION ISSUE

While we feel that an ingredient declaration is unnecessary, we want the record to reflect the need for a special label exemption should FDA persist in demanding that UF milk be labeled as Ultrafiltered milk in the ingredient declaration.

The statute provides that if a statutory label requirement "is impracticable or results in deception", and exemption may be established. 9/

The complexity of the logistics for cheese companies to segregate, track and maintain inventories of cheese makes labeling impracticable. Many cheese companies source multiple ingredients and interchange them depending on economics in their plant. We have been told by many of our UF milk customers that if labeling is required, they would discontinue the use of UF milk since the economic and logistical burden would more than offset any potential gains they may receive from using UF milk in their plants.

Data will also be submitted to the record by others that show a high degree of confusion by consumers when to identical pieces of cheese bear different ingredient label declarations.

Both of these conditions would justify a special exemption for labeling UF milk in cheese.

CONCLUSION

SMI's UF Facility is a "balancing" plant for the Southeast US market. Our customers utilize the UF milk interchangeably 100% with other ingredients since we do not have a year-round supply. Our plant will be out of business under the proposed rule, at a significant cost to the member-owners of SMI and create additional economic hardship to the dairy industry in the Southeast US.

FDA should remove the proposed requirement for ingredient labeling for outsourced UF milk from the final rule. As proposed, the labeling requirement is inconsistent with prior FDA interpretations as well as FDA issued regulations. Both outsourced and in-plant produced UF milk undergo further processing to produce the same cheese. 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 all UF milk as it is used in cheesemaking. This action is consistent with FDA regulations, policy, and industry practice.

Compliance with the proposed regulation requiring labeling is impracticable and will result in consumer deception should the cheese industry comply with the proposed regulation.

Southeast Milk, Inc. urges FDA to delete the proposed ingredient labeling requirement from the final rule or otherwise contain explicit exemption language for such labeling.

Please contact me if you need further clarification or if we can be of assistance with information that may be of benefit to the Agency as it revisits this proposed rule.

Sincerely,



Calvin Covington
Chief Executive Officer