

Ref. 8



APR 6 2005

Clay Hough
General Counsel and Senior Vice President
Regulatory Affairs
International Dairy Foods Association
1250 H Street, N.W.
Suite 900
Washington, D.C. 20005

Dear Mr. Hough:

This is in response to your letter dated October 15, 2004, to the Food and Drug Administration (FDA) regarding the use of ultrafiltered (UF) milk in Swiss cheese. Your letter was in further reference to FDA's letter dated February 23, 2004, to North American Milk Products, in which FDA requested additional information to demonstrate that the basic nature and essential characteristics of Swiss cheese are not altered by the use of UF milk as an ingredient. In your current submission, you provided analytical data, including those taken from published literature, that show that Swiss cheese made using fluid UF milk has the same chemical, nutritional, and sensory characteristics as Swiss cheese made in accordance with the current standard of identity in Title 21 of the Code of Federal Regulations (21 CFR) section 133.195. In light of these data, you asked that the agency consider granting regulatory discretion for the use of fluid UF milk in Swiss cheese.

We thank you for providing the data and factual information we requested to demonstrate that the basic nature and essential characteristics of Swiss cheese are maintained in the use of fluid UF milk in the making of Swiss cheese. FDA has reviewed the information you submitted and agrees that fluid UF milk may be used in Swiss cheese without adversely affecting the essential chemical characteristics, nutritional properties, or sensory attributes of Swiss cheese. Therefore, based on our review of the information provided, we do not object to the use of fluid UF milk as an ingredient in the manufacture of Swiss cheese at this time.

The following provides details about the ingredient, fluid UF milk, its processing, and its use in Swiss cheese. While you refer to the ingredient as "filtered" milk, the data submitted previously by Mr. Robert Fassbender (letter dated November 26, 2003, to Felicia Satchell) and Mr. Dean Sommers (letter dated December 3, 2003, to Felicia Satchell) as well as the data included in your current submission (Johnson 2004 and published literature) specifically refer to the ingredient as "UF" milk and/or clearly describe the process of ultrafiltration in the making of Swiss and other cheeses. Therefore, the agency's review in response to your current submission is limited to the use of fluid UF milk only and does not include other types of filtered milks. For example, we did not review your submission for the use of milk processed by microfiltration as an ingredient in the making of Swiss cheese. Providing for the use of fluid UF milk, but not other types of filtered milks, in the manufacture of Swiss cheese is also consistent with the agency's previous decision to grant regulatory discretion for the use of fluid UF milk in Cheddar and mozzarella cheeses.

With respect to the process that will be employed to obtain the ingredient fluid UF milk, ultrafiltration, which retains macromolecules and particles larger than about 0.001-0.02 micrometers (Reference: Cheryan M. 1998. Ultrafiltration and Microfiltration Handbook, second edition. CRC Press LLC, Boca Raton, Florida), results in the partial loss of lactose, minerals, water-soluble vitamins, and water present in milk while the casein to whey protein ratio of milk is unaffected. In addition, as you noted, fluid UF milk typically is used in amounts of 5 to 7 percent of the volume of liquid milk in the cheese vat.

With respect to labeling, fluid UF milk that is used as an ingredient in Swiss cheese should be declared as "ultrafiltered milk" (or "ultrafiltered skim milk," as appropriate) in the ingredient statement of the finished food, Swiss cheese. Although we did not make this labeling declaration a condition as part of our enforcement discretion in the case of Cheddar and mozzarella cheeses, the agency's thinking and policy with respect to the declaration of fluid UF milk have evolved since that time. Milk that has undergone ultrafiltration is distinctly different from the starting ingredient milk. Ultrafiltration is a mechanical filtration process that typically results in the loss of some of the water, lactose, minerals, and water-soluble vitamins that are present in milk. ~~The resulting ultrafiltered milk, therefore, is~~ distinctly different from the starting ingredient milk and, therefore, cannot be called simply "milk." Rather, in accordance with 21 CFR 102.5, it must be described by a term that adequately and accurately describes its basic nature or characterizing properties. While an appropriate term to describe such ultrafiltered milk could be a name that identifies all the substances in milk that have been either reduced or removed (for example, "lactose, minerals, and vitamins reduced concentrated milk"), we believe that such a name would be cumbersome for the purposes of ingredient labeling. However, an alternative adequate and accurate descriptor is "ultrafiltered milk." A recently issued temporary marketing permit for the use of fluid UF skim milk in cottage cheese notes the agency's determination that this ingredient is appropriately declared on the finished food label as "ultrafiltered skim milk" (See 69 FR 71418, December 9, 2004).

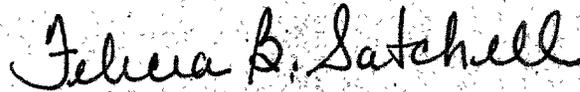
Finally, as you may be aware, the publication of a proposal to amend 21 CFR 133.3 to provide for the use of fluid UF milk in standardized cheeses and related cheese products is an A-list activity in CFSAN's FY2005 Program Priorities. Accordingly, we intend to publish a proposal on this issue during this fiscal year. We encourage you and the manufacturers you represent to provide comments on this proposal when it is published. During this rulemaking process and pending issuance of a final

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rule permitting fluid UF milk as an ingredient in standardized cheeses and related cheese products, based on the information you have provided, the use of fluid UF milk as described above in the manufacture of Swiss cheese is not an enforcement priority for FDA at this time.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,



Felicia B. Satchell

Director

Food Labeling

and Standards Staff

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition