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Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products: Guidance for Industry

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U.S. Department of Health and Human Services
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I. Introduction

The purpose of this guidance is to advise manufacturers who wish to use ultrafiltered milk (UF milk) or ultrafiltered nonfat milk (UF nonfat milk) in the production of standardized cheeses and related cheese products. More specifically, this guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion regarding the use and labeling of UF milk and UF nonfat milk in these cheeses, when used in addition to the dairy ingredients specified in the standards of identity in 21 CFR part 133.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

Mechanical filtration technologies available for milk processing include ultrafiltration. For purposes of this guidance, we consider filtration to be a process whereby milk is passed over a series of semipermeable membranes with varying pore sizes. The portion of milk that passes through the membranes is referred to as the "permeate," and the portion that does not pass through the membranes is referred to as the "retentate." Ultrafiltration retains macromolecules and particles larger than about 0.001–0.02 micrometers. In dairy processing, ultrafiltration is typically used to retain all protein components of milk, including casein and whey proteins, while some of the lactose, minerals, and water soluble vitamins present in milk are lost along with water.

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

For purposes of this guidance, UF milk means raw or pasteurized milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein:whey protein ratio of the milk and resulting in a liquid product. (Additional specifications on UF milk are discussed in FDA's 2005 proposed rule, "Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk," 70 FR 60751 (October 19, 2005).) UF nonfat milk is defined similarly, except that raw or pasteurized nonfat milk is used.

Our regulations specify the standards of identity for cheeses and related cheese products in part 133 (21 CFR part 133). The general provisions within part 133, in part, define "milk" and "nonfat milk" that may be used in the manufacture of cheeses and related cheese products. The definitions for "milk" and "nonfat milk" in § 133.3(a) and (b), respectively, list different forms of milk and nonfat milk, including concentrated, reconstituted, and dried forms, that may be used in the making of cheeses and related cheese products. Fluid or dried filtered forms of milk obtained through mechanical filtration of milk or nonfat milk are not included within these definitions. Therefore, while current regulations permit the use of concentrated, reconstituted, and dried forms of milk and nonfat milk as basic dairy ingredients (i.e., the only difference in these ingredients is the amount of water), they do not provide for the use of fluid or dried filtered milk or fluid or dried filtered nonfat milk as basic dairy ingredients in standardized cheeses and related cheese products.

Consistent with our general labeling provisions in 21 CFR 101.4, ingredients used in standardized cheeses are required to be declared by their common or usual name in descending order of predominance by weight.

III. Discussion

In the *Federal Register* of October 19, 2005 (70 FR 60751), we issued a proposed rule that would amend our regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products. We tentatively concluded that the proposed rule, if finalized, would promote honesty and fair dealing in the interest of consumers and, to the extent practicable, achieve consistency with existing international standards of identity for cheeses and related cheese products. We explained our tentative conclusion that fluid UF milk can be used in standardized cheeses while preserving the basic nature and maintaining the essential characteristics of the food, while providing for greater flexibility in cheesemaking. However, we also noted in the proposed rule that, "[p]roviding for the use of fluid UF milk does not preclude a standardized cheese from meeting the existing requirements within the applicable individual standard(s) of identity in part 133. Rather, the use of fluid UF milk would be optional and any cheese made using fluid UF milk would have to meet all the requirements, including the physical and chemical characteristics, specified in the applicable individual standards of identity" (70 FR 60751 at 60757).

The comment period for the 2005 proposed rule was reopened on December 11, 2007 (72 FR 70251) and extended until April 11, 2008 (73 FR 7692 (Feb. 11, 2008)). However, due to competing priorities, as of August 2017, we have not completed the rulemaking.

Recently, we have become aware of issues regarding domestically produced UF milk in the international marketplace. In brief, due to recent developments in some export markets, the United States dairy industry is experiencing an oversupply and pricing challenges with domestically produced UF milk (Refs. 1 and 2). Additionally, we have received requests to exercise enforcement discretion while the rulemaking is pending, in part to mitigate the impact on U.S. companies producing UF milk (Ref. 3).

FDA believes that food standards should provide for flexibility in manufacturing procedures and ingredients, provided that the basic nature and essential characteristics of the food are preserved. Given the oversupply of UF milk and the pending rulemaking, through this guidance, we are announcing our intent to exercise enforcement discretion regarding the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products under 21 CFR part 133, in addition to the other required dairy ingredients, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected.

FDA is also announcing its intent to exercise enforcement discretion with respect to the labeling of standardized cheeses and related cheese products, when, in addition to milk or nonfat milk, fluid UF milk or fluid UF nonfat milk is used as an ingredient, but is not declared in the ingredient statement, provided that milk or nonfat milk is declared in the ingredient statement. We are exercising enforcement discretion with respect to the labeling of fluid UF milk and fluid UF nonfat milk in recognition of the costs and logistics involved in label changes, although we encourage industry to identify the ingredients as "ultrafiltered milk" and "ultrafiltered nonfat milk" to the extent feasible and appropriate.

We intend to exercise enforcement discretion until we have completed a rulemaking process amending our regulations with respect to the issues covered by this guidance, or announce in the *Federal Register* our determination not to proceed with such a rulemaking.

IV. References

We have placed the following references on display with the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of August 8, 2017, FDA had verified the Web site address for the references we make available as hyperlinks from the Internet copy of this guidance, but we are not responsible for any subsequent changes to Non-FDA Web site references after August 8, 2017.

1. Letter from Senator Amy Klobuchar, Senator Al Franken, Representative Collin Peterson, and Representative Tim Walz, to President Donald J. Trump, accessed on the Web at https://www.klobuchar.senate.gov/public/index.cfm/2017/4/klobuchar-franken-peterson-walz-urge-administration-to-support-minnesota-dairy-farmers-through-strong-enforcement-of-our-trade-laws-with-canada.

2. Congressional Research Service, "New Canadian Dairy Pricing Regime Proves Disruptive for U.S. Milk Producers," dated April 20, 2017, accessed on the Web at https://www.everycrsreport.com/reports/IN10692.html.

3. Letter from Michael D. Dykes, D.V.M., President and CEO, International Dairy Foods Association, to Stephen Ostroff, M.D., Deputy Commissioner for Foods and Veterinary Medicine, Food and Drug Administration, dated June 22, 2017.