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## II. Reopening of Comment Period and Request for Comment

The original comment period for the NPR closed on December 9, 2019.<sup>2</sup> The agencies received public comments requesting an extension of the comment period, noting that the commenters did not have sufficient time to analyze fully the agencies' notice of proposed rulemaking during the original 30-day comment period. To give these, and similarly situated, commenters additional time, the agencies are re-opening the comment period through January 23, 2020, until which time interested parties may submit public comments on the rule amendments proposed and the questions presented in the NPR.

Dated: December 20, 2019.

### Jonathan V. Gould,

*Senior Deputy Comptroller and Chief Counsel, Office of the Comptroller of the Currency.*

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, December 20, 2019.

### Margaret McCloskey Shanks,

*Deputy Secretary of the Board.*

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on December 19, 2019.

### Annamarie H. Boyd,

*Assistant Executive Secretary.*

By order of the Board of the Farm Credit Administration.

Dated at McLean, VA, this 20th day of December, 2019.

### Dale L. Aultman,

*Secretary.*

December 12, 2019.

### Mark A. Calabria,

*Director, Federal Housing Finance Agency.*

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**BILLING CODE** 4810-33-P; 6210-01-P; 6714-01-P; 8070-01-P; 6705-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 133

[Docket No. FDA-2008-P-0086]

### Cheeses and Related Cheese Products; Proposal To Permit the Use of Ultrafiltered Milk; Reopening the Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule published in the **Federal Register** of October 19, 2005, entitled "Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk." The proposed rule would amend our regulations to provide for the use of fluid ultrafiltered (UF) milk in the manufacture of standardized cheeses and related cheese products. We are reopening the comment period to receive new information and further comment on current industry practices regarding the use of fluid UF milk and fluid UF nonfat milk in the manufacture of standardized cheeses and related cheese products, and the declaration of fluid UF milk and fluid UF nonfat milk when used as ingredients in standardized cheeses and related cheese products.

**DATES:** FDA is reopening the comment period on the proposed rule published on October 19, 2005 (70 FR 60751). Submit either electronic or written comments by March 30, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 30, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 30, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2008-P-0086 for "Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed

<sup>2</sup> See 84 FR 59970 (November 7, 2019).

confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Daniel Reese, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of October 19, 2005, we proposed to amend our regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products. Specifically, the proposed rule, if finalized, for standardized cheeses and related cheese products, would (1) Amend the definitions of “milk” and “nonfat milk” in § 133.3 (21 CFR 133.3) to provide for ultrafiltration of milk and nonfat milk; and (2) define ultrafiltered milk and ultrafiltered nonfat milk in § 133.3 as raw or pasteurized milk or nonfat milk that is passed over one or more semipermeable membranes to partially remove water, lactose, minerals, and water-soluble vitamins without altering the casein-to-whey protein ratio of the milk or nonfat milk and resulting in a liquid product. FDA also proposed that the name of such treated milk be “ultrafiltered milk” or “ultrafiltered nonfat milk,” as appropriate. Consequently, when this type of milk is used, it would be declared in the ingredient statement of

the finished food as “ultrafiltered milk” or “ultrafiltered nonfat milk.”

This proposal was issued in response to citizen petitions from the American Dairy Products Institute and the National Cheese Institute, the Grocery Manufacturers of America, Inc., and the National Food Processors Association. Interested persons were originally given until January 17, 2006, to comment. We subsequently reopened the comment period to seek further comment on two specific issues raised by the comments concerning the proposed ingredient declaration (72 FR 70251, December 11, 2007); the reopened comment period was scheduled to end on February 11, 2008. In the **Federal Register** of February 11, 2008 (73 FR 7692), we extended the comment period until April 11, 2008.

In the **Federal Register** of August 14, 2017 (82 FR 37815), we announced the availability of a guidance for industry entitled “Ultrafiltered Milk in the Production of Standardized Cheeses and Related Cheese Products.” In the guidance, we notified manufacturers who wish to use UF milk or UF nonfat milk in the production of standardized cheeses and related cheese products of 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, provided that the physical, chemical, and organoleptic properties of the cheese or cheese product are not affected. We also stated our intent to exercise 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; however, we encouraged industry to identify these ingredients as “ultrafiltered milk” and “ultrafiltered nonfat milk” to the extent feasible and appropriate. We further explained that we intend to exercise enforcement discretion until we have completed a rulemaking process amending our regulations with respect to the issues covered by the guidance or announced our determination not to proceed with such a rulemaking.

##### **II. Additional Issues for Consideration**

To inform our decision on whether to proceed with the rulemaking initiated in the October 19, 2005, proposal, we seek new information and public comment on current industry practices regarding the use of fluid UF milk and fluid UF nonfat milk in the manufacture of standardized cheeses and related cheese products, and the declaration of fluid UF milk and fluid UF nonfat milk in the labeling of these products when used as ingredients. Of particular interest, we

seek comment on the following questions:

1. We would like to understand whether there is variable use of fluid UF milk or fluid UF nonfat milk in the production of standardized cheeses and related cheese products. For example, if a company uses fluid UF milk in the production of a standardized cheese, does the amount of fluid UF milk remain constant, or does the amount vary depending on certain factors (such as the cost of fluid UF milk)? Please explain whether the amount of fluid UF milk or fluid UF nonfat milk varies for specific standardized cheeses and related cheese products and the factors that influence the variability. To maintain the essential characteristics of the standardized cheese or cheese product, is the amount of fluid UF milk or fluid UF nonfat milk limited to a range (*i.e.*, a minimum and maximum amount)? Please identify the specific standardized cheese or cheese product and provide any ranges or amounts and explain your reasoning.

2. (a) We invite comment on why manufacturers may sometimes produce their particular brands of standardized cheeses and related cheese products with fluid UF milk or fluid UF nonfat milk and sometimes without fluid UF milk or fluid UF nonfat milk. Please explain your reasoning.

(b) Given that manufacturers may sometimes choose to produce these products with or without fluid UF milk or fluid UF nonfat milk, we are interested in how ingredient labeling of these standardized cheeses and related cheese products could be addressed.

Our understanding is that fluid UF milk and fluid UF nonfat milk, when used as ingredients in cheese, are always used in lesser amounts by weight than milk and nonfat milk in order to avoid affecting the physical, chemical, and organoleptic properties of the cheese. For example, a manufacturer might use milk and fluid UF milk, but our understanding is that the amount of fluid UF milk will be less than that of milk. As such, milk would be the predominant ingredient and declared first in the ingredient statement, per FDA’s regulations that require ingredients to be declared by their common or usual names in descending order of predominance by weight (21 CFR 101.4(a)). Fluid UF milk, if used, would be declared thereafter.

Based on our understanding, we are considering whether, when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients, the labeling of standardized cheeses and cheese products may alternatively declare “milk or milk and ultrafiltered

milk” or “nonfat milk or nonfat milk and ultrafiltered nonfat milk” in the ingredient statements. We invite comment on this consideration and whether such declarations would indicate that fluid UF milk or fluid UF nonfat milk may be an ingredient, but not as predominant as milk or nonfat milk, and also enable manufacturers to avoid relabeling costs if they use varying amounts of fluid UF milk or fluid UF nonfat milk. Please discuss whether such declarations would be informative (or, conversely, potentially misleading to consumers) and please explain your reasoning.

3. We also are interested in issues related to the costs of printing different product labels and the logistics involved in label changes when fluid UF milk and fluid UF nonfat milk are sometimes used as ingredients in the production of a manufacturer’s standardized cheese or cheese product. For example, what impacts, if any, would a label statement of “milk or milk and ultrafiltered milk” or “nonfat milk or nonfat milk and ultrafiltered nonfat milk” have on labeling costs? How would these costs compare if fluid UF milk and fluid UF nonfat milk are declared only when used in the standardized cheese or cheese product? Please explain your reasoning.

4. Ultrafiltered milk is being used in a greater number of food products than in the past. There are dairy products in the marketplace, which appear to have gained consumer acceptance, where “ultrafiltered milk” has appeared in the statement of identity or declared in the ingredient statement on the product label. Are there any situations where retailers or consumers would not purchase standardized cheeses or cheese products labeled as containing “ultrafiltered milk” as an ingredient? Please describe such situations and provide any recent consumer data or market analyses you may have to explain your reasoning.

Dated: December 19, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG–100956–19]

RIN 1545–BP16

#### Source of Income From Certain Sales of Personal Property

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed regulations modifying the rules for determining the source of income from sales of inventory produced within the United States and sold without the United States or vice versa. These proposed regulations also contain new rules for determining the source of income from sales of personal property (including inventory) by nonresidents that are attributable to an office or other fixed place of business that the nonresident maintains in the United States. Finally, these proposed regulations modify certain rules for determining whether foreign source income is effectively connected with the conduct of a trade or business within the United States.

**DATES:** Comments and requests for a public hearing must be received by February 28, 2020.

**ADDRESSES:** Submit electronic submissions via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (indicate IRS and REG–100956–19) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (“Treasury Department”) and the IRS will publish for public availability any comment received to its public docket, whether submitted electronically or in hard copy. Send hard copy submissions to: CC:PA:LPD:PR (REG–100956–19), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

#### FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations Brad McCormack, (202) 317–6911 or Anisa Afshar, (202) 317–4999; concerning submissions of comments and requests for a public hearing, Regina L. Johnson, (202) 317–6901 (not toll free numbers).

#### SUPPLEMENTARY INFORMATION:

## Background

These regulations (the “proposed regulations”) contain proposed amendments to 26 CFR part 1 revising the rules under section 863 of the Internal Revenue Code (the “Code”) for determining the source of gross income from sales of certain property, and under section 864 for treating foreign source income as effectively connected with the conduct of a trade or business within the United States. Conforming revisions are made to current regulations that reference section 863. The proposed regulations also provide guidance under section 865(e)(2) and (3) regarding the source of income from the sale of personal property, including inventory property, within the meaning of section 865(i)(1) (“inventory”), by nonresidents.

The Tax Cuts and Jobs Act, Pub. L. 115–97 (2017) (the “Act”), enacted on December 22, 2017, amended section 863 of the Code, which provides special rules for determining the source of income, including income partly from within and partly from without the United States. Specifically, section 14303 of the Act amended section 863(b) to allocate or apportion income from the sale or exchange of inventory property produced (in whole or in part) by a taxpayer within and sold or exchanged without the United States or produced (in whole or in part) by the taxpayer without and sold or exchanged within the United States (collectively, “Section 863(b)(2) Sales”) solely on the basis of production activities with respect to that inventory. Before the Act, section 863(b) provided that income from Section 863(b)(2) Sales would be treated as derived partly from sources within and partly from sources without the United States without providing the basis for such allocation or apportionment.

Current § 1.863–3 provides rules for allocating or apportioning gross income from Section 863(b)(2) Sales. Those rules provide several methods for determining the amount of gross income from Section 863(b)(2) Sales that is attributable to production activity and the amount of gross income attributable to sales activity, with different rules then applying to source the portion of the income derived from production activity versus sales activity. *See* current § 1.863–3(b). Current § 1.863–3(f) provides rules for gains, profits, and income that are treated as derived partly from sources within the United States and partly from sources within a possession of the United States (generally referred to herein as a “U.S. territory”).