



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2016-N-2938]

Reference Amount Customarily Consumed for Flavored Nut Butter Spreads and Products That Can Be Used To Fill Cupcakes and Other Desserts, in the Labeling of Human Food Products; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive comments, particularly data and other information, on the appropriate reference amount customarily consumed (RACC) and product category for flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored), and products that can be used to fill cupcakes and other desserts, such as cakes and pastries. We are taking this action in part because we have recently issued a final rule updating certain RACCs, and we have also received a citizen petition asking that we either issue a guidance recognizing that “nut cocoa-based spreads” fall within the “Honey, jams, jellies, fruit butter, molasses” category for purposes of RACC determination; or amend the regulation to establish a new RACC category for “nut cocoa-based spreads” with an RACC of 1 tablespoon (tbsp.). We also are taking this action in response to a request to amend our serving size regulations to establish an RACC and product category for cupcake filling.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2016-N-2938 for “Reference Amount Customarily Consumed for Flavored Nut Butter Spreads (e.g., cocoa, cookie, and coffee flavored), and Products That Can Be Used To Fill Cupcakes and Other Desserts, in the Labeling of Human Food Products; Request for Information and Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cherisa Henderson, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1450.

SUPPLEMENTARY INFORMATION:

I. Background

A. Flavored Nut Butter Spreads (e.g., cocoa, cookie, and coffee flavored)

Under section 403(q)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(1)(A)(i)), food that is intended for human consumption and offered for sale must bear nutrition information that provides a serving size that reflects the amount of food customarily consumed (i.e., the RACC) and is expressed in a common household measure that is appropriate to the food (unless an exception applies). We established RACCs for specific product categories in a final rule that appeared in the Federal Register on January 6, 1993, entitled "Food Labeling; Serving Sizes" (58 FR 2229, "1993 final rule"). In the 1993 final rule, FDA provided nine general principles and factors for establishing RACCs in 21 CFR 101.12(a)

to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

The 1993 final rule included a reference (Ref. 1) to a memorandum to the file entitled “List of products for each product category,” which listed “Nutella” as an example of a product in the product category “Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and non-dairy whipped toppings” (see 58 FR 2229 at 2268). The conclusion that “Nutella” belongs in the “Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and non-dairy whipped toppings” category with an RACC of two tbsp. was based on a consumer survey conducted in 1991 that showed a significant number of respondents used “Nutella” as a dessert topping, particularly for ice cream.

In the Federal Register of March 3, 2014, we published a proposed rule entitled, “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (79 FR 11990, “2014 proposed rule”). The 2014 proposed rule proposed to update and modify certain RACCs for previously established product categories and establish RACCs for new products and product categories. The 2014 proposed rule provided no specific discussion with respect to “Nutella.” After publication of the proposed rule, on March 4, 2014, we received a citizen petition that requested we either: (1) Issue guidance recognizing that “nut cocoa-based spreads” fall within the “Honey, jams, jellies, fruit butter, molasses” category for purposes of RACC determination or (2) amend § 101.12 to establish a new product category for “nut cocoa-based spreads” with an RACC of one tbsp. (Docket No. FDA-2014-P-0263.) Based on the information provided, which included data pertaining specifically to “Nutella,” we understand

that the petition intended “Nutella” to be incorporated into a category described as “nut cocoa-based spreads.” The petitioner submitted results of a consumer usage survey that the petitioner had commissioned through a marketing research firm. The survey included 722 mothers who purchased “Nutella” in the past 3 months. The survey found that, on average, 74 percent of “Nutella” use was associated with spreading the product on bread, including toast and in making sandwiches, and that two percent of use was as a topping for ice cream. The petition also included the results of an analysis of the National Health and Nutrition Examination Survey (NHANES) 2003-2010 consumption data for individuals aged 4 years or older (n = 43). The reported mean, median, and mode consumption amounts from this analysis for “Nutella,” including similar products used as chocolate-flavored hazelnut spreads, were 22.6 grams (g) (about 1 tbsp.), 18 g (1 tbsp.), and 18 g (1 tbsp.), respectively.

On March 10, 2016, we received a comment in response to the 2014 proposed rule in which a report prepared by a scientific consulting firm analyzed the NHANES data from 2003 through 2012 among participants aged 1 year and older for “Nutella” and other similar products used as chocolate-flavored hazelnut spreads (n = 92) (Ref. 2). The comment stated that the results showed that the mean, median, and mode consumption amounts were 28.6 g, 18 g (about 1 tbsp.), and 12 g, respectively. The comment included a report of an online survey designed to estimate the amount of “Nutella” typically consumed in an eating occasion. The comment asserted that the survey was administered to a representative sample of the U.S. population aged 18 to 80 years, with an average age of 27.3 years. Four hundred and thirty respondents consumed “Nutella” in the year before the survey was administered, and these respondents reported 824 eating occasions. Based on the categorical consumption amount selections weighted by the frequency of such amount consumed, the comment concluded that median

consumption per eating occasion was 18.5 g (about 1 tbsp.), that the mean consumption per eating occasion was 32.6 g, and that almost half of the eating occasions (46.9 percent) involved using the product as a spread with bread or toast, as compared to use with crackers or cookies (17.2 percent), use by itself (13.9 percent), use as a spread for fruit (10.8 percent), use as a spread over pancakes or waffles (8.2 percent), and other uses (3 percent). The report concluded that the median consumption amount from both analyses was one tbsp., consistent with the RACC of one tbsp. that we had established for sweet spreads for bread such as honey, jams, and jellies.

Following the receipt of the citizen petition and comment, in the Federal Register of May 27, 2016, we published a final rule entitled, “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (81 FR 34000) (“2016 final rule”). The 2016 final rule updated and modified certain RACCs for previously established product categories and established RACCs for new products and product categories. The preamble to the 2016 final rule explained in the response to the comment on nut cocoa-based spreads that the primary usage of hazelnut spread, which was a reference to nut cocoa-based spreads such as “Nutella” discussed in the comment, is as a spread for bread instead of as a dessert topping (81 FR 34000 at 34029 to 34030). However, with respect to specific assertions raised in the March 10, 2016, comment, we responded that, while we recognize a need for an RACC for hazelnut spread outside of the dessert product category,” and agreed that the primary usage of hazelnut spread is as a spread for bread instead of as a dessert topping because the proposed rule was silent about an RACC for hazelnut spread, and because we intended to provide the opportunity for public comment on this specific issue, we intended to consider whether to move hazelnut spread to a

different appropriate product category in a future rulemaking” (81 FR 34000 at 34029). This notification of request for comments represents the first step of our evaluation of the appropriate RACC and product category for flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored), which we consider to include “nut cocoa-based spread” as described in the citizen petition and comment to the 2014 proposed rule.

B. Products Used as a Filling for Cupcakes and Other Desserts

In response to the 2014 proposed rule, one comment requested that we establish an RACC for icing intended for use as cupcake filling. In the preamble to the 2016 final rule, we said that we recognize a need for an RACC for this specific food product as well as for other types of cake or pastry fillings,” but we further explained that, because the proposed rule was silent about an RACC for cupcake filling, and because we intended to provide the opportunity for public comment on this specific issue, we intend to establish an RACC for this product category in future rulemaking” (81 FR 34000 at 34029). This notification of request for comments represents the first step of our evaluation of the appropriate RACC and product category for products used as a filling for cupcakes and other desserts.

II. Other Issues for Consideration

We invite interested persons to comment on the appropriate RACC and product category for flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored), and products used as fillings for cupcakes and other desserts, such as cakes and pastries. In responding to the specific questions identified in this notice, please provide additional data and information that you believe we should consider. Please thoroughly explain your reasoning and provide data and other information to support your comments and responses to these questions. If you submit data, please also provide information regarding the type of survey or study conducted, research

methodology, sampling frame, results of statistical analyses, and any other information needed to interpret the data.

We are particularly interested in responses to the following questions:

- What additional data and information are available to determine the customary consumption amounts of and appropriate product category for flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored)?
- What is the major intended use of flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored)?
- What other products on the market, if any, are similar to flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored)? What product characteristics make these products similar? What dietary usage makes these products similar? Which product categories do flavored nut butter spreads (e.g., cocoa, cookie, and coffee flavored) compete with or take market share and volume from? What data and information are available regarding the customary consumption amounts and product category for these similar products?
- What additional data and information are available regarding the customary consumption amounts and product category of products used as fillings for cupcakes and other desserts, such as cakes and pastries?
- What is the major intended use of fillings for cupcakes and other desserts, such as cakes and pastries?
- What other products on the market, if any, are similar to cupcake filling, such as cakes and pastries fillings? What product characteristics make these products similar? What dietary usage makes these products similar? Which product categories do fillings for cupcakes and other desserts, such as cakes and pastries, compete with or take market

share and volume from? What data and information are available regarding the customary consumption amounts and product category for these similar products?

III. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>.

1. Park, Y., Memorandum to the File, List of Products for Each Product Category, October 8, 1992.
2. Ferrero Inc., Comment to the Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Proposed Rule. August 1, 2014.

Dated: October 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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