

Revisions made at the Suggestion of OMB
or in Response to Comments from OMB

March 8, 2005

3-8-05

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration 21

CFR Part 101

[Docket No. 2004N-0456]

RIN 0910-AF23

Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on whether to amend certain provisions of the agency's nutrition labeling regulations concerning serving size. FDA is issuing this ANPRM in response to recommendations of the Obesity Working Group (OWG), which was created by the Commissioner of the FDA to develop an action plan to address the Nation's obesity problem. Comments on whether, and if so, how to amend the agency's serving size regulations will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by *[insert date 75 days after*

date of publication in the Federal Register].

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0456 and/or RIN number 0910-AF23, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2004N-0456 and/or RIN number 0910-AF23 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> 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: Lori LeGault, Center for Food Safety and

Applied Nutrition (HFS-840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1791.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Serving Size Regulations

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet. Section 403(q)(1)(A)(i) (21 U.S.C. 343(q)(1)(A)(i)) of the act requires that most foods under FDA's jurisdiction bear nutrition information based on a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure appropriate to the food. The NLEA also required that FDA issue regulations that establish standards to define serving size.

Deleted: , in section 2(b)(1)(B).

To implement the serving size requirements of the NLEA, FDA underwent extensive notice-and-comment rulemaking (56 FR 60394, November 27, 1991 (the 1991 serving size proposed rule); 58 FR 2229, January 6, 1993 (the serving size final rule); and 58 FR 44039, August 18, 1993 (the serving size technical amendments)). Consistent with the act, the serving size regulations established a system to define "serving size" that was composed of two basic elements: (1) Reference amounts customarily consumed per eating occasion (reference amounts or RACCs) for specific food product categories; and (2) procedures for determining serving sizes for use on product labels derived from the reference amounts. The second element was

necessary because the RACCs are provided primarily in metric units (based on data from nationwide food consumption surveys that are expressed in grams); however, the act requires that serving sizes be expressed in common household measures that are appropriate to the particular food.

In § 101.9(b)(1) (21 CFR 101.9(b)(1)), we defined the term "serving" or "serving size" to mean:

an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

In § 101.12(b) (21 CFR 101.12(b)), we established RACCs (upon which label serving sizes are to be determined) for 129 food product categories representing the general food supply and 11 categories for infant and toddler foods [In the previous draft we referred to 129 categories combining both the general food supply and infant/toddler. We seem to be off by one category]. The general principles and factors that FDA considered in arriving at the RACCs are described in § 101.12(a). Among these principles, FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount so that consumers could make nutritional comparisons of like products in the marketplace.

The RACCs represent the amount of food customarily consumed per eating occasion for each product category, and were derived primarily from data obtained from the 1977–1978 and 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture (USDA) (58 FR at 2236–2237). We reviewed food

consumption data for the foods in each product category and considered three statistical estimates, i.e., the mean (average), the median (50th percentile), and the mode (most frequent value). Following the procedures detailed in the 1991 serving size proposed rule (56 FR at 60403-60406), we determined the reference amount that was most likely to represent the amount customarily consumed for each product category.

In § 101.9(b), we established procedures for converting RACCs into appropriate label serving sizes. Among these provisions is § 101.9(b)(6), where we defined the criteria for products to be labeled as single-serving containers. (See 58 FR at 2232-2235 for FDA’s evaluation of comments.) Most products packaged and sold individually that contain less than 200 percent of the applicable RACC must currently be labeled as a single serving. An exception to this rule occurs for products that contain between 150 percent and 200 percent of the RACC and that have a RACC of 100 grams (g) or 100 milliliters (mL) or larger. In this case, the product may be labeled as one or two servings, at the manufacturer’s option.

For example, the RACC for carbonated beverages is 240 mL (i.e., 8 fluid (fl) ounces (oz)). Containers of carbonated beverages that weigh 360 mL (i.e., 12 fl oz, 150 percent of 240 mL) or less must be labeled as a single serving. Containers weighing between 360 mL and 480 mL (i.e., 16 fl oz, 200 percent of 240 mL) may be labeled as a single serving or as [“about 2” Where did we get this language from?] servings per container. For products packaged and sold individually that contain 200 percent or more of the RACC, it is the manufacturer’s option to label the product as a single-serving container if the entire content of the package can reasonably be consumed at a single-eating occasion. For example, the RACC for muffins is 55 g. If a single large muffin weighs 110 g (200 percent of 55 g), there are two options for the serving size declaration: “1 muffin (110 g)” or “1/2 muffin (55 g).”

Deleted: However, the serving size for a product labeled as two servings is based on the household measure closest to the RACC and not on the weight of 1/2 package. ¶

B. The Report of the FDA Obesity Working Group [This heading is found in the other ANPRM as well, yet the general information provided is different for each. Perhaps we should make the two sections consistent where possible.]

Formatted

In August 2003, the Commissioner of the FDA created the Obesity Working Group (OWG) and charged it to develop an action plan covering the critical dimensions of the obesity problem in America to help consumers lead healthier lives through better nutrition. The OWG was composed of professionals across FDA who provided expertise and knowledge in a range of scientific and other disciplines. The OWG met eight times; received briefings from several invited experts from other government agencies; held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups); and solicited comments on obesity-related issues, directing them to the docket established in July 2003 (Docket No. 2003N-0338).

To accomplish its work, the OWG organized several subgroups (i.e., [messages since the meaning of this subgroup is not obvious, please either elaborate or delete], education, food label, restaurants/industry, therapeutics, research, and stakeholder investment); each designed to focus on a particular aspect of the Commissioner's charge. All of the subgroups, in turn, met separately and developed respective analyses and recommendations. The final report issued by the OWG centered on the scientific fact that weight control is primarily a function of the balance of calories eaten and calories expended; and therefore, focused on a "calories count" emphasis for FDA actions (Ref. 1) [In these footnotes can we be more specific and provide page range?].

One aspect of the Commissioner's charge was for the OWG to "develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity." To address this issue, among other actions, the OWG recommended that FDA reexamine its regulations on serving sizes

by soliciting comment on: (1) whether to require food packages that can reasonably be consumed at one eating occasion to declare the whole package as a single serving, (2) which, if any, RACCs of food categories need to be updated, and (3) whether to provide for comparative calorie claims for smaller portions of identical foods

II. Agency Request for Information

FDA's research on consumers' use of the Nutrition Facts panel (NFP) has indicated that consumers' ability to quickly read and understand the NFP is an important factor in determining whether consumers use the NFP and whether the NFP is helpful to them. In focus groups, participants indicated that they cared about nutrition and reported using the NFP, but also said that they did not want to spend a lot of time reading labels and did not always consider nutrition when deciding what to eat. They were interested in calories, but were also concerned about saturated fat, total fat, cholesterol, carbohydrates and sodium.

Most participant comments indicated that they incorrectly thought a serving size was a recommended portion size, rather than a standardized unit of measure. Some participants said that typical serving sizes, as a recommended portion, are unrealistic and pointed out that some people need to eat different amounts, depending on their age, body type, and lifestyle. In the 2002 Health and Diet Survey (Ref. 2), respondents were asked how they used the NFP. The most common answers were: (1) To see if the product was high or low in a specific nutrient, (2) to decide how much to eat, and (3) to help in meal planning. To address these issues, we request comments on the following questions:

Deleted: understand

Deleted: not

- How can FDA make serving size information on the NFP easier for consumers to use when deciding what foods and how much of these foods they should eat?
- Do consumers recognize the differences between serving sizes on food labels and

servings recommended in dietary guidance? If so, what do consumers think the differences are? What information on a label would help make this distinction clearer? For example, should the serving size and/or servings per container on the food label be made more prominent? If so, how?

- Are there some alternative, simpler ways to help consumers determine their nutrient intake based on what they eat? If so, please describe. What are the advantages and disadvantages of these options?

A. Updating RACCs

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. Because there is evidence that the U.S. population is eating larger portion sizes than they did in the 1970s and 1980s (Refs.3 through 6), the OWG recommends that FDA determine whether to update the RACCs, and if so, how to update the RACCs. Changes to the RACCs, in most instances, would require changes to the serving size on products, which in turn would require changes to the nutrient values listed on the nutrition label.

Newer food consumption data are available from the 1999–2000 and the 2001–2002 National Health and Nutrition Examination Surveys (NHANES) (Ref.7), and these data provide a more current indication of the amount of food being consumed by individuals. However, we do not want consumers to confuse the serving size on the food label (which is required by the act to be based on the amount customarily consumed) with an amount that is recommended for consumption. For example, if data show that consumers are drinking larger amounts of carbonated beverages and FDA increases the RACC, which will likely increase the serving size on the food label, additional educational efforts may be required to reinforce to consumers that a larger serving size on

the container is not a “recommended” serving size.

We request comments on these issues and specifically on the following questions:

- Should we analyze more recent food consumption data to determine which, if any, RACCs of food categories have changed over the past decade and would need to be updated? If so, should we use the most current data available from the 1999-2000 and 2001-2002 NHANES to determine changes to the RACCs? Why or why not? Are there other food consumption data sources that are available or could be provided to the agency that we should consider?

- If we revise the RACCs, what criteria should be used as the basis for change? For example, would a percentage (e.g., 20 percent, 25 percent, or 30 percent) increase or decrease from current RACCs be a valid rationale for change?

- Would consumers think that an increase in serving size on food labels means more of the food should be eaten? What additional education efforts should be provided to consumers to avoid such a conclusion?

Deleted: n assumption

B. Single-Serving Containers

Several comments to the OWG docket strongly opposed the practice of individually packaged foods that appear to be single-serving containers, declaring two or more servings on the label—such as sodas and snack packs. In addition, as noted in the OWG report, FDA initiated eight focus groups around the country and, among other questions, asked consumers about serving size information on small packages. Examples of food labels were presented for a 20 fl oz soda and an individually packaged large muffin. In general, focus group participants thought that having multiple servings listed on the label for these products was misleading and confusing. Many participants did realize that if the entire package of food is eaten,

the number of servings should be multiplied by the amount of the nutrient of interest; though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

To address this issue, we ask for comments on the following questions:

- Should FDA initiate rulemaking to require packages that can reasonably be consumed at one eating occasion to provide the nutrition information for the entire package? If so, what criteria should FDA use to determine which multi-serving products would require nutrition information for the entire package? Should it be based on the total amount in the container, the type of food, or something else?

- Should such products be required to include an additional column within the NFP to list the quantitative amounts and % Daily Value for the entire package, as well as the preexisting columns listing the quantitative amounts and % Daily Value for a serving that is less than the entire package (i.e., the serving size derived from the RACC)? Alternatively, should the nutrition information only be declared for the entire package as a single serving?

- If the nutrient amount per serving size (derived from the RACC) and per package were listed side-by-side in separate columns, how would this affect consumers' ability to understand the label?

The current cutoff criteria for single serving containers (200 percent of the RACC (or 150 percent for products that have a RACC of 100 g or 100 mL or larger)) does not appear to be appropriate across the board for all food categories. As previously noted, participants in focus groups said they thought that having multiple servings listed on the label of a 20 fl oz soda (250 percent of the RACC) was misleading and confusing.

- Should the current cutoff criteria to define single-serving containers be

changed? Should criteria vary for different types of products? Explain why or why not. What criteria should be used to designate which package sizes should be required to list nutrition information for the entire package?

- In addition to the three statistical estimates previously mentioned (i.e., the mean, median, and mode), food consumption surveys allow calculation of intake estimates for individuals who eat a greater amount of food than average (e.g., those in the 90th and 95th percentiles). Should package sizes falling at these amounts (e.g., 90th or 95th percentile), as reported from nationwide food consumption surveys, be used as cut points at or below which nutrition information should be included for the entire package? If so, the RACC tables in § 101.12(b) would have to be modified to include a column for the amount specific to each product category as a cut point for when a product must be labeled as a single-serving container. Is this a viable option? If not, how can single-serving containers be defined?

Regulations can have unintended consequences, such as reformulation by the manufacturer to avoid the new labeling requirements.

Deleted: secondary effects

- If FDA requires that manufacturers list the nutrient content for the entire package for packages up to specified sizes, are manufacturers likely to repackage products in larger sizes to avoid this requirement? If so, what are the likely impacts of this repackaging?

C. Comparison of Calories in Foods of Different Portion Sizes

As noted in the OWG Report, the Federal Trade Commission has suggested that FDA consider “allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes.” Our current regulations for

comparative nutrient content claims, including calorie claims, require that all such comparisons be based on a uniform amount of food, i.e., per RACC for individual foods or per 100 g for meals and main dishes. Consequently, the current regulations (§ 101.60(b)) require that comparisons reflect actual nutrient differences in the same quantity of similar foods (e.g., “Reduced calorie chocolate ice cream, 25% fewer calories than the leading brand of chocolate ice cream. The leading brand contains 150 calories per 1/2 cup serving. Our ice cream contains 100 calories per 1/2 cup serving”). The current regulations do not permit claims that compare the amount of calories based on different sized portions of the same food.

Nevertheless, as noted in the OWG report, “using the food label to promote consumption of smaller portions may have merit [particularly] if consumers understand that (1) the calorie reduction is solely a function of the reduction in portion size and (2) the smaller portion size is actually less than what they usually consume.” Thus, we solicit comments regarding the appropriateness of label claims based on the amount of calories in a specified portion of a product (i.e., the amount of food specified by the claim, e.g., one 15 g cookie) vs. claims based on the RACC and specified in the labeled serving size of a product (i.e., the amount specified in the Nutrition Facts panel, e.g., two 15 g cookies). We ask for specific comments on the following questions:

- Because all currently approved comparative claims are based on the difference in the amount of the nutrient in a uniform amount of food such as per RACC, or per 100 g, will it be confusing to consumers to have claims made only on the basis of the difference in the amount of calories in two different labeled servings (i.e., the serving size specified in two different Nutrition Facts panels, e.g., an 8 fl oz can vs. a 12 fl oz can of soda) or two different portions (i.e., amounts specified by the claim, e.g., one 15 g cookie vs. two 15 g cookies) of the

same food? Explain why or why not.

- If a claim is made based only on the difference in the amount of calories in two different serving sizes or portions of the same food, what words should be used to ensure that consumers understand that comparisons are made only on this basis (i.e., the difference in the amount of product) and that there is not a difference based on product reformulation, e.g., “the caloric savings is based on a smaller than normal portion?”

- Should the size of the compared servings, portions, or packages be part of the claim (e.g., “this 8 fl oz bottle of juice has 33 percent fewer calories than our 12 fl oz bottle”)? Explain why or why not.

- Should these types of claims be limited to products that are identical except for the specified serving or portion size?

- Will such claims be misleading if the claim is based on the number of calories that are in an amount of food other than what is specified in the Nutrition Facts panel (e.g., claims based on half a “labeled serving” —one cookie, compared to the amount specified in the Nutrition Facts panel—two cookies)?

- Should this claim be limited to single-serving containers, or is it appropriate on multi-serving packages? Explain why or why not.

- If claims are permitted on multi-serving packages, should these claims be limited to products that have portioned pieces, such as cookies or slices of bread, or should they be allowed on products that are not portion controlled, such as pies or bulk sodas? For example, might this claim be extended to “bulk” products such as pizza suggesting that if you cut a smaller slice, you will get a caloric savings?

- What comparative terms are appropriate? Because “reduced” has always been used to signal some type of reformulation (i.e., special processing, alteration,

Comment: I understand this term is defined by regulation—can that be said rather than the more informal “has always been”?

formulation, or reformulation to lower the nutrient content), is it appropriate to use the term “reduced” on products that have not been so altered? Is “less than,” which has been used more broadly to signal differences in nutrient levels derived through a variety of means, a more appropriate term?

- Currently all comparative calorie claims are limited to reductions of at least 25 percent. Should these comparisons (e.g., reduced or fewer calories) continue to be limited to reductions of at least 25 percent, and if not, what justification is there that a smaller reduction of calories would be meaningful and significant? Please provide data.

- What other requirements may be necessary to ensure that the claim is not confusing or misleading to consumers?

- If manufacturers are permitted to make such label comparisons of different portion sizes of food, what is the likely change in the distribution of package sizes that will become available to consumers?

Deleted: s

- What other labeling changes, if any, would encourage a broader range of package sizes?

III. Future Analysis of Benefits and Costs

If the agency proposes regulatory changes based on the initiatives outlined in this ANPRM, we will estimate the costs of labeling changes and other potential costs (such as the costs of reformulating products) should the regulations create incentives for new products. The comments on this ANPRM may identify other costs as well. The benefits of the regulatory options depend on how consumers respond to the changes in label serving sizes or package sizes. We will use the information from comments to help determine ways to estimate the possible consumer responses to

various changes. The comments will also contribute to our estimates of the effects of regulatory options on small entities.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Report of the Working Group on Obesity, “Calories Count” (Internet address: <http://www.cfsan.fda.gov/~dms/owg-toc.html>), March 12, 2004.
2. Food and Drug Administration, Center for Food Safety and Applied Nutrition, “2002 Health and Diet Survey—Preliminary Topline Frequencies (Weighted),” March 2004.
3. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, “Portion Distortion! Do You Know How Food Portions Have Changed in 20 Years?” (Internet address: <http://hin.nhlbi.nih.gov/portion/index.htm>).
4. Young, L.R. and M. Nestle, “Expanding portion sizes in the US marketplace: Implications for nutrition counseling,” Journal of the American Dietetic Association, Vol. 103, No. 2, pp. 231-234, February 2003.
5. Smiciklas-Wright, H., D. C. Mitchell, S. J. Mickle, Goldman JD, A Cook, “Foods commonly eaten in the United States, 1989-1991 and 1994-1996, Are portion sizes changing?” Journal of the American Dietetic Association, Vol. 103, No. 1, pp. 41-47, January 2003.
6. Nielsen, S. J. and B. M. Popkin, “Patterns and Trends in Food Portion Sizes, 1977-1998,” Journal of the American Medical Association, Vol. 289, No. 4, pp. 450-453, January 22/29, 2003.

7. U.S. Department of Health and Human Services, National Center for Health Statistics, NHANES 1999–2000 Data Files (Internet address: http://www.cdc.gov/nchs/about/major/nhanes/NHANES99_00.htm) and NHANES 2001–2002 Data Files (Internet address: <http://www.cdc.gov/nchs/about/major/nhanes/nhanes01-02.htm>).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

Revisions Recommended by OMB

March 14, 2005

3-14-05
FROM OMB

Follow-up Responses

Calories

Please submit the revised draft in ROCIS.

Serving Size

We suggest the following edits. Please let us know by COB, Wednesday if FDA is amenable to these edits. If not, we should schedule a conference call for Thursday.

- P.8: Recommend the following edits:

How should we analyze more recent food consumption data to determine which, if any, RACCs of food categories have changed over the past decade and would need to be updated? Should we use the most current data available from the 1999-2000 and 2001-2002 NHANES to determine changes to the RACCs? Are there other food consumption data sources that are available or could be provided to the agency that we should consider?

Deleted: Should

Deleted: If so, s

Deleted: Why or why not?

- P.9: Recommend adding the following question or similar at the end:

We previously stated in the preamble to the Serving Size rule under Part 101 (58 FR 2229 at 2235): "Section 403(q)(1)(A)(i) of the act, which states that a serving size is the amount customarily consumed, effectively requires the use of food consumption data as the primary basis for determining serving sizes." However, considering the issues raised above, should the agency reconsider its definition of "serving" and "serving size" or how the agency interprets "customarily consumed"?

- P.11: It seems just as or more likely that if manufacturers were forced to identify a "negative" attribute such as the amount of calories in an entire package, they would have an incentive to lower the size of the package. In fact, this should be an *intended* consequence of the rule. Recommend adding the following language:

These labeling regulations can have indirect effects, such as reformulation by the manufacturer,

- If FDA requires that manufacturers list the nutrient content for the entire package for packages up to specified sizes, are manufacturers likely to repackage products in larger sizes to avoid this requirement? If so, what are the likely impacts of this repackaging?
- Conversely, manufacturers may have an incentive to lower the size, and therefore the total calories, of single serving packages. Would this be an option that manufacturers would consider? If so, what would be the likely consequences of this reformulation?

Deleted: R

Deleted: unintended

Deleted: consequences

Deleted: to avoid the new labeling requirements

FDA Response to Revisions
Recommended by OMB

March 16, 2005

Response to OMB Suggested Edits

3-16-05
FROM FDA

Calories

The revised draft has been submitted.

Serving Size

You suggested that we modify language on P. 8. We do not think that rephrasing the question as you requested is appropriate. To clarify, the question we intended to ask on P.8 is not how we should analyze the food consumption data, but whether or not we should analyze this data to determine which, if any, RACCs of food categories have changed. Furthermore, keeping the language as originally drafted is more in line with the additional question you recommended adding to P.9 (with which we agree). Similar to your suggested question, the original language on P. 8 does not presume FDA should analyze data to determine which RACCs have changed.

We suggest the following language:

~~Should we analyze more recent food consumption data to determine which, if any, RACCs of food categories have changed over the past decade and would need to be updated? If so, should we use the most current data available from the 1999-2000 and 2001-2002 NHANES to determine changes to the RACCs? Are there other food consumption data sources that are available or could be provided to the agency that we should consider?~~

Deleted: How s

Deleted: S

You also suggested that we modify the language on P.11. The original draft of the language on P.11 should not have contained any reference to reformulation. The questions should deal solely with “repackaging” (i.e., changing package size) and not reformulation of the product (i.e., changing the ingredients). Furthermore, as this is an ANPRM, and does not contain any codified language, the reference to “these regulations” is inappropriate. We are not suggesting any codified language, nor are we referring to the present language. As such, we suggest the following language:

Deleted: are

~~New regulations can have indirect effects, such as the repackaging of a product by the manufacturer.~~

Deleted: These labeling

Deleted: reformulation

- If FDA requires that manufacturers list the nutrient content for the entire package for packages up to specified sizes, are manufacturers likely to repackage products in larger sizes to avoid this requirement? If so, what are the likely impacts of this repackaging?
- Conversely, manufacturers may have an incentive to lower the size, and therefore the total calories, of single serving packages. Would this be an option that manufacturers would consider? If so, what would be the likely consequences of this repackaging?

Deleted: reformulation

Revision Recommended by OMB/
FDA Response to Recommended Revision

March 18, 2005

3-18-05

OMB suggested the following language (p. 8):

How should we consider more recent food consumption data such as 1999-2000 and 2001-2002 NHANES to determine which, if any, RACCs need to be updated? Are there other food consumption data sources that are available or could be provided to the agency that we should consider?

FDA discussed this, and we believe the following language more appropriately states the question we want to ask and clarifies the earlier wording (p. 8):

How do recent food consumption data, such as data from the 1999-2000 and 2001-2002 NHANES, factor into the determination of which, if any, RACCs need to be updated? Are there other food consumption data sources that are available or that could be provided to the agency for our consideration?

Revisions made at the Suggestion of OMB
or in Response to Comments from OMB

Resubmitted Revised Version

March 21, 2005

REVISED VERSION
FOLLOWING OMB
COMMENTS RESUBMITTED
MAR 21 2005

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004N-0456]

RIN 0910-AF23

Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on whether to amend certain provisions of the agency's nutrition labeling regulations concerning serving size. FDA is issuing this ANPRM in response to recommendations of the Obesity Working Group (OWG), which was created by the Commissioner of the FDA to develop an action plan to address the Nation's obesity problem. Comments on whether, and if so, how to amend the agency's serving size regulations will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by *[insert date 75 days after date of publication in the Federal Register]*.

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0456 and/or RIN number 0910-AF23, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N-0456 and/or RIN number 0910-AF23 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* 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: Lori LeGault, Center for Food Safety and Applied Nutrition (HFS-840), Food and Drug Administration, 5100 Paint

Branch Pkwy., College Park, MD 20740, 301–436–1791.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Serving Size Regulations

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535), together with FDA’s implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet. Section 403(q)(1)(A)(i) (21 U.S.C. 343(q)(1)(A)(i)) of the act requires that most foods under FDA’s jurisdiction bear nutrition information based on a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure appropriate to the food. The NLEA also required that FDA issue regulations that establish standards to define serving size.

To implement the serving size requirements of the NLEA, FDA underwent extensive notice-and-comment rulemaking (56 FR 60394, November 27, 1991 (the 1991 serving size proposed rule); 58 FR 2229, January 6, 1993 (the serving size final rule); and 58 FR 44039, August 18, 1993 (the serving size technical amendments)). Consistent with the act, the serving size regulations established a system to define “serving size” that was composed of two basic elements: (1) Reference amounts customarily consumed per eating occasion (reference amounts or RACCs) for specific food product categories; and (2) procedures for determining serving sizes for use on product labels derived from the reference amounts. The second element was necessary because the RACCs are provided primarily in metric units (based on data

from nationwide food consumption surveys that are expressed in grams); however, the act requires that serving sizes be expressed in common household measures that are appropriate to the particular food.

In § 101.9(b)(1) (21 CFR 101.9(b)(1)), we defined the term "serving" or "serving size" to mean:

an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

In § 101.12(b) (21 CFR 101.12(b)), we established RACCs (upon which label serving sizes are to be determined) for 129 food product categories representing the general food supply and 11 categories for infant and toddler foods. The general principles and factors that FDA considered in arriving at the RACCs are described in § 101.12(a). Among these principles, FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount so that consumers could make nutritional comparisons of like products in the marketplace.

The RACCs represent the amount of food customarily consumed per eating occasion for each product category, and were derived primarily from data obtained from the 1977–1978 and 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture (USDA) (58 FR at 2236–2237). We reviewed food consumption data for the foods in each product category and considered three statistical estimates, i.e., the mean (average), the median (50th percentile), and the mode (most frequent value). Following the procedures detailed in the 1991 serving size proposed rule

(56 FR at 60403-60406), we determined the reference amount that was most likely to represent the amount customarily consumed for each product category.

In § 101.9(b), we established procedures for converting RACCs into appropriate label serving sizes. Among these provisions is § 101.9(b)(6), where we defined the criteria for products to be labeled as single-serving containers. (See 58 FR at 2232-2235 for FDA's evaluation of comments.) Most products packaged and sold individually that contain less than 200 percent of the applicable RACC must currently be labeled as a single serving. An exception to this rule occurs for products that contain between 150 percent and 200 percent of the RACC and that have a RACC of 100 grams (g) or 100 milliliters (mL) or larger. In this case, the product may be labeled as one or two servings, at the manufacturer's option.

For example, the RACC for carbonated beverages is 240 mL (i.e., 8 fluid (fl) ounces (oz)). Containers of carbonated beverages that weigh 360 mL (i.e., 12 fl oz, 150 percent of 240 mL) or less must be labeled as a single serving. Containers weighing between 360 mL and 480 mL (i.e., 16 fl oz, 200 percent of 240 mL) may be labeled as a single serving or as "about 2" servings per container (21 CFR 101.9(b)(8)(i)).

For products packaged and sold individually that contain 200 percent or more of the RACC, it is the manufacturer's option to label the product as a single-serving container if the entire content of the package can reasonably be consumed at a single-eating occasion. For example, the RACC for muffins is 55 g. If a single large muffin weighs 110 g (200 percent of 55 g), there are two options for the serving size declaration: "1 muffin (110 g)" or "1/2 muffin (55 g)."

B. The Report of the FDA Obesity Working Group

In August 2003, the Commissioner of the FDA created the Obesity Working Group (OWG) and charged it to develop an action plan covering the critical dimensions of the

obesity problem in America to help consumers lead healthier lives through better nutrition. The OWG was composed of professionals across FDA who provided a range of expertise in areas such as food labels; communication and education efforts; the role of industry and restaurants; and therapeutic interventions for obesity. The OWG met eight times and received briefings from several invited experts from other government agencies. In addition, the OWG held one public meeting, one workshop, two round table discussions (one with health professionals/academicians, and one with consumer groups), and solicited comments on obesity-related issues, directing them to a docket established in July 2003 (Docket No. 2003N-0338). The final report issued by the OWG centered on the scientific fact that weight control is primarily a function of the balance of calories eaten and calories expended; and therefore, focused on a “calories count” emphasis for FDA actions (Ref. 1).

A principal aspect of the Commissioner’s charge was for the OWG to “develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity.” To address this issue, among other actions, the OWG recommended that FDA reexamine its regulations on serving sizes by soliciting comment on: (1) Whether to require food packages that can reasonably be consumed at one eating occasion to declare the whole package as a single serving, (2) which, if any, RACCs of food categories need to be updated, and (3) whether to provide for comparative calorie claims for smaller portions of identical foods.

II. Agency Request for Information

FDA’s research on consumers’ use of the Nutrition Facts panel (NFP) has indicated that consumers’ ability to quickly read and understand the NFP is an important factor in determining whether consumers use the NFP and whether the NFP is helpful to them. In

focus groups, participants indicated that they cared about nutrition and reported using the NFP, but also said that they did not want to spend a lot of time reading labels and did not always consider nutrition when deciding what to eat. They were interested in calories, but were also concerned about saturated fat, total fat, cholesterol, carbohydrates and sodium. Most participant comments indicated that they incorrectly thought a serving size was a recommended portion size, rather than a standardized unit of measure. Some participants said that typical serving sizes, as a recommended portion, are unrealistic and pointed out that some people need to eat different amounts, depending on their age, body type, and lifestyle. In the 2002 Health and Diet Survey (Ref. 2), respondents were asked how they used the NFP. The most common answers were: (1) To see if the product was high or low in a specific nutrient, (2) to decide how much to eat, and (3) to help in meal planning. To address these issues, we request comments on the following questions:

- How can FDA make serving size information on the NFP easier for consumers to use when deciding what foods and how much of these foods they should eat?

- Do consumers recognize the differences between serving sizes on food labels and servings recommended in dietary guidance? If so, what do consumers think the differences are? What information on a label would help make this distinction clearer? For example, should the serving size and/or servings per container on the food label be made more prominent? If so, how?

- Are there some alternative, simpler ways to help consumers determine their nutrient intake based on what they eat? If so, please describe. What are the advantages and disadvantages of these options?

A. Updating RACCs

The serving size is critical to nutrition labeling since all of the information on

nutrient levels depends on the amount of the product represented. Because there is evidence that the U.S. population is eating larger portion sizes than they did in the 1970s and 1980s (Refs. 3 through 6), the OWG recommends that FDA determine whether to update the RACCs, and if so, how to update the RACCs. Changes to the RACCs, in most instances, would require changes to the serving size on products, which in turn would require changes to the nutrient values listed on the nutrition label.

Newer food consumption data are available from the 1999–2000 and the 2001–2002 National Health and Nutrition Examination Surveys (NHANES) (Ref.7), and these data provide a more current indication of the amount of food being consumed by individuals. However, we do not want consumers to confuse the serving size on the food label (which is required by the act to be based on the amount customarily consumed) with an amount that is recommended for consumption. For example, if data show that consumers are drinking larger amounts of carbonated beverages and FDA increases the RACC, which will likely increase the serving size on the food label, additional educational efforts may be required to reinforce to consumers that a larger serving size on the container is not a “recommended” serving size.

We request comments on these issues and specifically on the following questions:

- How do recent food consumption data, such as data from the 1999-2000 and 2001-2002 NHANES, factor into the determination of which, if any, RACCs need to be updated? Are there other food consumption data sources that are available or that could be provided to the agency for our consideration?
- If we revise the RACCs, what criteria should be used as the basis for change? For example, would a percentage (e.g., 20 percent, 25 percent, or 30 percent) increase or decrease from current RACCs be a valid rationale for change?
- Would consumers think that an increase in serving size on food labels means more of the food should be eaten? What additional education efforts should be provided to consumers to avoid such a conclusion?
- We previously stated in the preamble to the Serving Size rule under Part 101 (58

FR 2229 at 2235): "Section 403(q)(1)(A)(i) of the act, which states that a serving size is the amount customarily consumed, effectively requires the use of food consumption data as the primary basis for determining serving sizes." However, considering the issues raised above, should the agency reconsider its definition of "serving" and "serving size" or how the agency interprets "customarily consumed"?

B. Single-Serving Containers

Several comments to the OWG docket strongly opposed the practice of individually packaged foods that appear to be single-serving containers, declaring two or more servings on the label—such as sodas and snack packs. In addition, as noted in the OWG report, FDA initiated eight focus groups around the country and, among other questions, asked consumers about serving size information on small packages. Examples of food labels were presented for a 20 fl oz soda and an individually packaged large muffin. In general, focus group participants thought that having multiple servings listed on the label for these products was misleading and confusing. Many participants did realize that if the entire package of food is eaten, the number of servings should be multiplied by the amount of the nutrient of interest; though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

To address this issue, we ask for comments on the following questions:

- Should FDA initiate rulemaking to require packages that can reasonably be consumed at one eating occasion to provide the nutrition information for the entire package? If so, what criteria should FDA use to determine which multi-serving products would require nutrition information for the entire package? Should it be based on the total amount in the container, the type of food, or something else?
- Should such products be required to include an additional column within the NFP to list the quantitative amounts and % Daily Value for the entire package, as well as the preexisting columns listing the quantitative amounts and % Daily Value

for a serving that is less than the entire package (i.e., the serving size derived from the RACC)? Alternatively, should the nutrition information only be declared for the entire package as a single serving?

- If the nutrient amount per serving size (derived from the RACC) and per package were listed side-by-side in separate columns, how would this affect consumers' ability to understand the label?

The current cutoff criteria for single serving containers (200 percent of the RACC (or 150 percent for products that have a RACC of 100 g or 100 mL or larger)) does not appear to be appropriate across the board for all food categories. As previously noted, participants in focus groups said they thought that having multiple servings listed on the label of a 20 fl oz soda (250 percent of the RACC) was misleading and confusing.

- Should the current cutoff criteria to define single-serving containers be changed? Should criteria vary for different types of products? Explain why or why not. What criteria should be used to designate which package sizes should be required to list nutrition information for the entire package?

In addition to the three statistical estimates previously mentioned (i.e., the mean, median, and mode), food consumption surveys allow calculation of intake estimates for individuals who eat a greater amount of food than average (e.g., those in the 90th and 95th percentiles). Should package sizes falling at these amounts (e.g., 90th or 95th percentile), as reported from nationwide food consumption surveys, be used as cut points at or below which nutrition information should be included for the entire package? If so, the RACC tables in § 101.12(b) would have to be modified to include a column for the amount specific to each product category

as a cut point for when a product must be labeled as a single-serving container. Is this a viable option? If not, how can single-serving containers be defined?

New regulations can have indirect effects, such as the repackaging of a product by the manufacturer.

- If FDA requires that manufacturers list the nutrient content for the entire package for packages up to specified sizes, are manufacturers likely to repackage products in larger sizes to avoid this requirement? If so, what are the likely impacts of this repackaging?

- Conversely, manufacturers may have an incentive to lower the size, and therefore the total calories, of single serving packages. Would this be an option that manufacturers would consider? If so, what would be the likely consequences of this repackaging?

C. Comparison of Calories in Foods of Different Portion Sizes

As noted in the OWG Report, the Federal Trade Commission has suggested that FDA consider “allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes.” Our current regulations for comparative nutrient content claims, including calorie claims, require that all such comparisons be based on a uniform amount of food, i.e., per RACC for individual foods or per 100 g for meals and main dishes. Consequently, the current regulations (§ 101.60(b)) require that comparisons reflect actual nutrient differences in the same quantity of similar foods (e.g., “Reduced calorie chocolate ice cream, 25% fewer calories than the leading brand of chocolate ice cream. The leading brand contains 150 calories per 1/2 cup serving. Our ice cream contains 100 calories per 1/2 cup

servings”). The current regulations do not permit claims that compare the amount of calories based on different sized portions of the same food.

Nevertheless, as noted in the OWG report, “using the food label to promote consumption of smaller portions may have merit [particularly] if consumers understand that (1) the calorie reduction is solely a function of the reduction in portion size and (2) the smaller portion size is actually less than what they usually consume.” Thus, we solicit comments regarding the appropriateness of label claims based on the amount of calories in a specified portion of a product (i.e., the amount of food specified by the claim, e.g., one 15 g cookie) vs. claims based on the RACC and specified in the labeled serving size of a product (i.e., the amount specified in the Nutrition Facts panel, e.g., two 15 g cookies). We ask for specific comments on the following questions:

- Because all currently approved comparative claims are based on the difference in the amount of the nutrient in a uniform amount of food such as per RACC, or per 100 g, will it be confusing to consumers to have claims made only on the basis of the difference in the amount of calories in two different labeled servings (i.e., the serving size specified in two different Nutrition Facts panels, e.g., an 8 fl oz can vs. a 12 fl oz can of soda) or two different portions (i.e., amounts specified by the claim, e.g., one 15 g cookie vs. two 15 g cookies) of the same food? Explain why or why not.
- If a claim is made based only on the difference in the amount of calories in two different serving sizes or portions of the same food, what words should be used to ensure that consumers understand that comparisons are made only on this basis (i.e., the difference in the amount of product) and that there is not a difference based on product reformulation, e.g., “the caloric savings is based on a smaller than normal portion?”

- Should the size of the compared servings, portions, or packages be part of the claim (e.g., “this 8 fl oz bottle of juice has 33 percent fewer calories than our 12 fl oz bottle”)? Explain why or why not.

- Should these types of claims be limited to products that are identical except for the specified serving or portion size?

- Will such claims be misleading if the claim is based on the number of calories that are in an amount of food other than what is specified in the Nutrition Facts panel (e.g., claims based on half a “labeled serving” —one cookie, compared to the amount specified in the Nutrition Facts panel—two cookies)?

- Should this claim be limited to single-serving containers, or is it appropriate on multi-serving packages? Explain why or why not.

- If claims are permitted on multi-serving packages, should these claims be limited to products that have portioned pieces, such as cookies or slices of bread, or should they be allowed on products that are not portion controlled, such as pies or bulk sodas? For example, might this claim be extended to “bulk” products such as pizza suggesting that if you cut a smaller slice, you will get a caloric savings?

- What comparative terms are appropriate? Because “reduced” has always been used to signal some type of reformulation (i.e., special processing, alteration, formulation, or reformulation to lower the nutrient content), is it appropriate to use the term “reduced” on products that have not been so altered? Is “less than,” which has been used more broadly to signal differences in nutrient levels derived through a variety of means, a more appropriate term?

- Currently all comparative calorie claims are limited to reductions of at least 25 percent. Should these comparisons (e.g., reduced or fewer calories) continue to be limited to reductions of at least 25 percent, and if not, what justification is there

that a smaller reduction of calories would be meaningful and significant? Please provide data.

- What other requirements may be necessary to ensure that the claim is not confusing or misleading to consumers?
- If manufacturers are permitted to make such label comparisons of different portion sizes of food, what is the likely change in the distribution of package sizes that will become available to consumers?
- What other labeling changes, if any, would encourage a broader range of package sizes?

III. Future Analysis of Benefits and Costs

If the agency proposes regulatory changes based on the initiatives outlined in this ANPRM, we will estimate the costs of labeling changes and other potential costs (such as the costs of reformulating products) should the regulations create incentives for new products. The comments on this ANPRM may identify other costs as well. The benefits of the regulatory options depend on how consumers respond to the changes in label serving sizes or package sizes. We will use the information from comments to help determine ways to estimate the possible consumer responses to various changes. The comments will also contribute to our estimates of the effects of regulatory options on small entities.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses but is not responsible for subsequent changes to the Web sites after this

document publishes in the Federal Register.

1. Report of the Working Group on Obesity, “Calories Count” (Internet address: <http://www.cfsan.fda.gov/~dms/owg-toc.html>), March 12, 2004.
2. Food and Drug Administration, Center for Food Safety and Applied Nutrition, “2002 Health and Diet Survey—Preliminary Topline Frequencies (Weighted),” March 2004.
3. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute, “Portion Distortion! Do You Know How Food Portions Have Changed in 20 Years?” (Internet address: <http://hin.nhlbi.nih.gov/portion/index.htm>).
4. Young, L.R. and M. Nestle, “Expanding portion sizes in the US marketplace: Implications for nutrition counseling,” Journal of the American Dietetic Association, Vol. 103, No. 2, pp. 231-234, February 2003.
5. Smiciklas-Wright, H., D. C. Mitchell, S. J. Mickle, Goldman JD, A Cook, “Foods commonly eaten in the United States, 1989-1991 and 1994-1996, Are portion sizes changing?” Journal of the American Dietetic Association, Vol. 103, No. 1, pp. 41-47, January 2003.
6. Nielsen, S. J. and B. M. Popkin, “Patterns and Trends in Food Portion Sizes, 1977-1998,” Journal of the American Medical Association, Vol. 289, No. 4, pp. 450-453, January 22/29, 2003.
7. U.S. Department of Health and Human Services, National Center for Health Statistics, NHANES 1999–2000 Data Files (Internet address: http://www.cdc.gov/nchs/about/major/nhanes/NHANES99_00.htm) and NHANES 2001–2002 Data Files (Internet address: <http://www.cdc.gov/nchs/about/major/nhanes/nhanes01-02.htm>).

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S