

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 90N-0165]

RIN 0905-AD08

Food Labeling; Serving Sizes

AGENCY: Food and Drug Administration
HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its nutrition labeling regulations to: (1) Define serving size on the basis of the amount of food customarily consumed per eating occasion; (2) establish reference amounts customarily consumed per eating occasion (reference amounts) for 139 food product categories; (3) provide criteria for determining label serving sizes from the reference amounts; (4) require the use of both common household and metric measures to declare serving sizes; (5) define a "single-serving container;" (6) require that the use of claims such as "low sodium" be based on the reference amount; (7) permit the declaration of serving size in U.S. measures (ounces (oz), fluid ounces (fl oz)); and (8) permit the optional declaration of nutrient content per 100 grams (g) or 100 milliliters (mL). This action is in response to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION

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SUPPLEMENTARY INFORMATION:

I. Background

A. Proposed Regulation, Nutrition Labeling and Education Act of 1990, and Institute of Medicine's Report on Nutrition Labeling

In the **Federal Register** of July 19, 1990 (55 FR 29487), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. In the same issue of the **Federal Register** (55 FR 29517), FDA published a technical supporting proposal entitled "Food Labeling;

Serving Sizes" (hereinafter referred to as the 1990 proposal).

The 1990 proposal on serving sizes stated that in view of the many comments that the agency had received stating the need for more realistic and consistent serving sizes, FDA had concluded that reasonable and standardized serving sizes should be established. The agency proposed to amend the nutrition labeling regulations to: (1) Define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) require the use of both U.S. and metric measures to declare serving size; (3) permit the declaration of serving (portion) size in familiar household measures; (4) permit the optional declaration of nutrient content per 100 g or 100 mL; (5) define "single-serving containers" as those that contain 150 percent or less of the standard serving size for the food product; and (6) establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on the 1990 proposal.

On September 26, 1990, the National Academy of Sciences' Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s" (hereinafter referred to as the IOM Report) (Ref. 1) The IOM report was written under contract to the Public Health Service, U.S. Department of Health and Human Services (DHHS) and the Food Safety and Inspection Service, U.S. Department of Agriculture (USDA). On October 5, 1990, FDA published a notice in the **Federal Register** (55 FR 40944) announcing the availability of the IOM report and requesting that interested persons comment on the implications of the report for the agency's July 19, 1990 proposals on food labeling. The report made several recommendations related to serving sizes.

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L., 101--535). The 1990 amendments added section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)). Section 403(q) of the act specifies, in part, that: " * * * the serving size * * * is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or * * * if the use of the food is not typically expressed in

a serving size, the common household unit of measure that expresses the serving size of the food.

The 1990 amendments also require, in section 2(b)(1)(B), that FDA adopt regulations that: " * * * establish standards * * * to define serving size or other unit of measure for food, * * * "

While the requirements of the 1990 amendments that pertain to serving size are similar in many respects to FDA's 1990 proposal, differences exist, and questions about the exact meaning and the implementation of those provisions have been raised.

On February 26 1991(55 FR 8084), FDA announced a public meeting to discuss several issues arising from the comments on the serving size proposal, the 1990 amendments, and the IOM report. The meeting was held on April 4, 1991 (hereinafter referred to as the 1991 public meeting), and provided an opportunity for the public to submit oral and written comments on the issues identified in the notice.

B. The 1991 Serving Size Regulation

FDA carefully considered the serving size provisions of the 1990 amendments, the comments that it received in response to the **Federal Register** documents on serving size and at the 1991 public meeting, and the recommendations related to serving size contained in the IOM report. As a result, the agency decided to repropose the serving size regulation for two major reasons. First, FDA wished to take advantage of the explicit legal authority provided by the 1990 amendments to regulate the serving sizes used on the nutrition label. Secondly, the agency decided to make a number of changes in response to the comments received on the **Federal Register** documents and at the public meeting on serving sizes and to explain its reasons for agreeing or not agreeing with the comments.

To implement the 1990 amendments, FDA issued a proposed rule in the **Federal Register** of November 27, 1991 (56 FR 60394; corrected at 57 FR 8179, March 6, 1992) (hereinafter referred to as the 1991 serving size proposal). In that document, FDA proposed to: (1) Modify the definition of serving size in the 1990 proposal to be consistent with that in the 1990 amendments; (2) adopt regulations that provide standards for defining serving sizes; and (3) require the use of both common household and metric measures to declare serving sizes. The proposed standards had two basic elements: (1) Reference amounts of food that are customarily consumed per eating occasion for 131 product categories; and (2) procedures for determining serving sizes for use on

product labels from the reference amounts. The second element was necessary because while the reference amounts are defined primarily in metric units, under the act the serving sizes must be expressed in common household measures that are appropriate to the particular food.

In addition, in response to the many requests for changes in other aspects of the 1990 proposal and on its own initiative, the agency proposed to: (1) Revise the definition for single-serving containers to increase the upper limit from "150 percent or less" to "less than 200 percent;" (2) revise the basis for evaluating label claims such as "low sodium" to include both the declared serving size and the reference amount; (3) permit the optional declaration of serving size in U.S. measures; and (4) permit the optional declaration of nutrient content per 190 g, 100 mL, 1 oz, or 1 fl oz. Interested persons were given until February 25, 1992, to submit comments to the agency on the 1991 serving size proposal.

On January 3, 1992 (57 FR 239), FDA announced a public hearing to discuss all of the agency's proposed food labeling regulations that implement the 1990 amendments. The hearing was held on January 30 and 31, 1992 (hereinafter referred to as the 1992 public hearing). Some of the presentations and written comments submitted in response to this hearing discussed issues related to serving sizes.

This final rule responds to the written comments received on the 1991 serving size proposal and the written comments and presentations given at the 1992 public hearing on issues related to serving sizes.

II. Review of Comments

FDA received about 700 comments on the 1991 serving size proposal. Approximately 50 percent were from domestic food industries and trade organizations; about 35 percent were from consumers and consumer organizations; about 10 percent were from health professionals, health and other professional organizations, and academia; about 5 percent were from Federal, State, and local government and less than 1 percent was from foreign industries and governments.

About 20 oral presentations at the 1992 public hearing discussed issues related to serving sizes. A written transcript of the meeting is on file with Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. FDA also received written comments that discussed issues related to serving sizes in response to

the notice of the public hearing. Issues discussed at the hearing mostly reiterated the issues discussed in written comments on the 1991, serving size proposal. Therefore, a separate evaluation has not been done for the comments received in response to the 1992 public hearing. FDA will respond to these comments together with all comments received in response to the 1991 serving size proposal.

Consumers overwhelmingly supported the provisions in the 1991 serving size proposal and again emphasized the need for realistic and standardized serving sizes. Health professionals and nutritional or health professional organizations generally supported the provisions in the 1991 serving size proposal. Many industry and trade associations supported the general approach that FDA took in the 1991 serving proposal. However, they often disagreed with specific aspects of the procedures used to determine reference amounts, specific reference amounts, or some other specific aspects of the 1991 serving size proposal. International comments again emphasized the need for international harmonization of food labeling (e.g., these comments usually recommended the use of 100 g (or mL) as the basis for the nutrition information).

The agency will describe the comments on serving sizes in more detail and respond to them by topic in the discussion of the final regulation that follows.

III. The Final Regulation

A. Legal Authority

1. A manufacturer contended that the 1990 amendments did not mandate that FDA establish, by regulation, specific serving sizes for each food. The comment objected to FDA taking away its right to set serving sizes within the broad parameters of being reasonable, fair, and consistent. The comment stated that the 1990 amendments authorized FDA to establish standards or guides that the manufacturer must follow when the manufacturer sets the specific serving size. A trade association stated that FDA's proposed "device" of reference amounts does not qualify as standards because when reference amounts are applied using the proposed procedures, they amount to specific serving sizes. Another industry comment stated that some reference amounts were expressed in common household measures (e.g., cups, tablespoon (tbsp.)), and therefore, label serving sizes in common household measures will be the same as the reference amount. This, the comment

argued, disqualifies these reference amounts from being standards.

FDA disagrees with the comments. First, FDA did not establish "specific serving sizes" for each food. The agency established a system that consists of the two basic elements described above. A manufacturer uses these elements to determine the serving size most appropriate for specific products. The fact that a manufacturer has relatively limited discretion within that system does not represent an infirmity in the system. Section 403(q)(1)(A)(i) of the act establishes the fundamental principle for determining serving size. This principle is much more specific than as one comment suggested that the amount be reasonable, fair and consistent. The act requires that the serving size be an amount of the food that is customarily consumed.

The legislative history in section 2(b)(1)(B) of the 1990 amendments is silent as to what type of standards that Congress contemplated in that section. It merely directs the agency to establish them (H Rept. 101-538, 101st. Congress. 2d sess. 18 (1990)), (See also the House report at page 7: "In order to make this information meaningful, the bill requires the FDA to issue standards providing that uniform serving size information and information concerning the number of servings be furnished on the food label." Thus, the question as to whether the standards that FDA proposed are adequate and consistent with the act really becomes a question of whether the serving size that results from applying that standard represents an amount customarily consumed. Significantly, none of these comments claimed that it does not. Consequently FDA concludes that the two element system that it proposed in the 1993 serving size proposal constitutes a standard for determining serving sizes that is consistent with the act.

2. An industry comment stated that the 1990 amendments give FDA the legal authority to use any unit of measure (not necessarily a serving based on customarily consumed amounts) that it deems most appropriate for expressing the nutrient content of foods. The comment stated that food consumption surveys, such as the Nationwide Food Consumption Survey (NFCS) conducted by USDA, do not provide "real" consumption values because there are too many varieties of different foods, different uses of the same foods, different foods for the same use, and other variables, and because there is too much diversity in individual consumption to establish any sort of meaningful or representative consumption standard. The comment

asserted that as long as competitive products are given the same serving size value, it is not that important whether there is valid supporting data. The comment recommended the use of "reference nutrition units" that would eliminate the idea that the serving size represents what people really eat. Under the system suggested by this comment, all foods would be given a reference point that represents a reasonable quantity of food for a given category, and all competitive foods would be given the same reference point.

FDA disagrees with the comment that the 1990 amendments allow the agency to use any unit of measure that it deems most appropriate for expressing the nutrient content of foods. Section 403(q)(1)(A)(i) of the act clearly defines serving size as an amount of food customarily consumed. As discussed in the 1991 serving size proposal (56 FR 60394 at 60490), FDA is well aware of the high variability in the amounts customarily consumed by individuals, as well as other factors such as many different uses of the same food and many different foods for the same use. These issues complicate the process for determining reference amounts. However, FDA continues to believe that by using data from national food consumption surveys, such as the NFCS, and by following the principles and procedures that it described in the 1991 serving size proposal, a reasonable" reference amount that represents the amount of food customarily consumed within each product category can be determined for the major usage of the food.

FDA also disagrees with the comment that stated that as long as competitive products are given the same serving size value, valid supporting data are not important. FDA does not believe that the only intent of the 1990 amendments is to establish the same serving size for competitive products. FDA believes that the intent is also to ensure that nutrition information will be based on a meaningful quantity of food, the amount customarily consumed. Competitive foods often differ in characteristics (e.g., density) that affect the amount customarily consumed. For example, ready-to-eat breakfast cereals compete with one another, but their densities (g per cup) differ widely from less than 20 g per cup to over 120 g per cup. Food consumption data show that the amount customarily consumed, depends on the density of the cereal. Therefore, the same serving size should not be used for all ready-to-eat breakfast, cereals. In this case using, the same serving sizes for competitive products could be misleading to consumers.

B. Definition of Serving Size

In accordance with the 1990 amendments, FDA proposed in § 101.9(b)(1) to define "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 the same section, FDA proposed to define "portion" to mean "an amount of a food that is not typically expressed in a serving size, i.e., a food customarily used only as an ingredient in the preparation of other foods (e.g., 1/4 cup flour or 1/4 cup tomato sauce)."

Over 75 percent, of the approximately 80 comments that addressed the definition of serving size agreed with FDA's proposal for the definition of serving size. These comments pointed out that the act explicitly states that the serving size shall be an amount customarily consumed in terms of a common household measure appropriate to the food, and that thus FDA's proposed definition is consistent with the requirements of the act. Approximately 25 percent of the comments received on this issue disagreed with FDA's proposal. The reasons for the disagreement and the definitions suggested in these comments, are discussed below.

3. Several comments stated that FDA should use the serving sizes in the diabetic exchange list as the serving sizes for nutrition labeling of food because they are already in use, and because people are familiar with the serving size contained in the exchange list.

FDA disagrees with these comments. Section 493(q)(1)(A)(i) of the act defines serving size as, "an amount customarily consumed." Thus, the act links serving size to the amount consumed. Serving sizes contained in the diabetic exchange list are not based on amounts

customarily consumed by the American public. They are tailored to meet a special dietary need of a subpopulation that has a unique health problem. They are inappropriate to use as serving sizes for the nutrition labeling of products for the general population because the serving sizes for a population with a medical problem do not necessarily reflect the consumption practices of the general healthy population. For example, to facilitate achievement of medical goals of this subpopulation, the

serving sizes in the exchange lists are based on the calorie content and the energy-producing macronutrient content of specific foods and may not, as required by the act, reflect amounts of food customarily consumed by average consumers. The 1991 serving size proposal discussed in detail the reasons why FDA cannot use the serving sizes contained in the diabetic exchange list for the nutrition labeling of food (56 FR 60394 at 60399). None of the comments provided any basis for finding that that discussion was wrong. Therefore, FDA has not modified the definition of "serving size" in response to these comments."

4. International, comments and several U.S. manufacturers opposed nutrition information based on serving sizes. Some pointed out that the European Community directive requires that all nutrition information be on a 100 g or 100 mL basis, the comments argued that requiring nutrition information on a per serving basis offers little consistency with nutrition labeling in other countries and creates a significant trade barrier.

FDA recognizes that many foreign countries use 100 g or 100 mL as the basis for nutrition labeling. However, the act requires that the nutrition information be provided on a per serving basis. The act also defines serving size as an amount customarily consumed which is expressed in a common household measure that is appropriate to the food. The 100 g or 100 mL does not represent an amount customarily consumed for many foods. In addition g and mL are not common household measures in the United States. Therefore, FDA cannot use 100 g or 100 mL as the basis for the primary serving size. However, partly to facilitate the utility of the serving size in the international community, FDA is requiring in new § 101.9(b)(7) that the equivalent metric quantity be declared on the label in addition to the serving size in a common household measure end is permitting, in new § 101.9(b)(10)(mL) a voluntary listing of a second column of values on a per 100 g or 100 mL basis.

5. Several industry and consumer comments suggested using 1 oz for the serving size rather than customarily consumed amounts. The comments contended that: (1) A uniform 1-oz serving size allows nutrition comparisons of all foods; (2) nutrition information per oz allows calculation of the nutrient content of food per serving of an individual's choice; and (3) the word "serving" is confusing and should be eliminated. Another consumer comment argued that few people

measure out a serving of a product as noted on packages. Most people just pour an amount that they feel is reasonable or desirable. Therefore, it is not necessary to have standard serving sizes. Rather, FDA should use 1 oz as the basis for nutrition information.

As discussed above, section 403(q)(1)(A)(i) of the act requires that serving sizes be in amounts customarily consumed. Because 1 oz is not an amount customarily consumed for many products, FDA cannot use 1 oz as the basis for nutrition information for all products.

6. Some consumer comments suggested defining serving size as the amount consumed by adult females. The comments stated that females need smaller amounts of food to maintain good nutrition and health. The comments were concerned that if serving sizes are based on the amount consumed by adult males, the quantity will be too large for females. Another consumer comment suggested that FDA define serving size as the amount consumed by a "middle consumption group between youth and men." The comment contended that if the serving size is set at a middle consumption level, it would be "easier to decrease for youth and increase for men."

FDA believes that these comments misunderstand the purpose of a serving size on product labels. The serving size declared on the product label is not an amount recommended for consumption. It is, by statute, the amount customarily consumed. FDA believes that promoting recommended servings can best be addressed through public education. The agency's promulgation of nutrition labeling regulations will be followed by a consumer education program to assist consumers in using the nutrition information on the label, including how nutrition information based on labeled serving size should be adjusted on the basis of an individual's actual or recommended serving size. FDA is currently planning for these activities.

The general food supply is consumed by the general population which is defined, for regulatory purposes, as all persons 4 years of age or older. Therefore, serving sizes should reflect the amounts customarily consumed by the general population and not by any selected age or sex group (e.g., adult male or female) within the general population.

7. An industry comment stated that the phrase "per eating occasion" should be deleted from the definition of serving size because small amounts of food consumed, such as for tasting during food preparation, could be counted as an eating occasion.

FDA does not believe that the issue raised by this comment presents a problem. The term "eating occasion" in food consumption surveys usually refers to meals and snacks. Even if the small amounts of food consumed during tasting are included in determining the amount of food customarily consumed per eating occasion, the general principles and factors (e.g., use of the mean, median, and modal consumed amount per eating occasion) considered by FDA in arriving at the reference amounts ensure that such infrequently reported small amounts would not affect the determination of the amount customarily consumed per eating occasion. Furthermore, deletion of the term "per eating occasion" would leave the definition of serving size open-ended, which would likely result in more inconsistencies among serving sizes. Therefore, FDA is retaining the term "per eating occasion" as part of the definition for serving size.

8. A consumer comment stated that because different units are used for serving size (e.g., oz, tbsp.) and nutrition information (e.g., g), the current nutrition information is not useful to estimate the percent of a nutrient (e.g., fat) in the product. The comment stated that expressing both serving size and nutrition information in g would facilitate computation of the percentage of a nutrient in the product. The comment, therefore, suggested that FDA mandate that the nutrition information of all products be provided on a per 100-g basis, instead of common household measures.

FDA understands the consumers' desire for information on the percentage of fat in the product. However, the act mandates that the primary unit for the serving size should be a common household measure that is most appropriate to the specific product. Therefore, serving sizes will continue to be expressed in common household measures (e.g., cups, tbsp., oz). However, FDA notes that it is also requiring metric equivalents of the household measures (e.g., 1 cup (55 g)). Therefore, nutrition information on a per 100-g basis is not necessary to facilitate such computation. Consumers who desire information on the percentage of a nutrient in the product should be able to calculate this number from the metric equivalent of the serving size and the amount of the nutrient, expressed in g.

9. A trade association stated that industry makes no distinction between the terms "serving" and "portion." The comment contended that FDA's definition is not consistent with the industry's usage of "portion." Limiting

the term "portion" for use with products that are used primarily as ingredients (e.g., flour, tomato sauce) creates more confusion in terminology and contributes nothing to nutrition labeling.

FDA agrees with this comment. Because foods such as flour and tomato sauce are not served by themselves but as part of other foods, conceptually the term "serving" may not be as appropriate as the term "portion" as defined in the 1991 serving size proposal. However, FDA acknowledges that many manufacturers use "serving" and "portion" interchangeably. These terms are also used interchangeably in the literature (Ref. 37). FDA also recognizes that consumers are not likely to distinguish between the two terms, and that the use of two different terms on the label could be confusing. For these reasons, FDA is deleting the definition of "portion" from new §101.9(b)(1).

C. Definition of Single-Serving Container

FDA proposed in § 101.9(b)(6) to define a single-serving container as a product that is packaged and sold individually containing less than 200 percent of the applicable reference amount. (Section 101.9(b)(6) of the 1991 serving size proposal had a typographical error and slated "packaged or sold individually" instead of "packaged and sold individually.") The agency proposed to require that the entire content of such products be labeled as one serving. In addition, the agency proposed that packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single eating occasion.

FDA received many comments on issues related to the definition of a single-serving container. About half of the comments agreed with the proposed definition. The other half, mostly industry comments, opposed or had reservations on some aspects of the proposed definition.

10. The majority of the comments disagreeing with the proposal objected to the proposed upper limit of "less than 200 percent." These comments argued that FDA provided insufficient reasons for increasing the upper limit from 150 percent to 200 percent of the reference amount, placing considerable importance on a few new single-serving products, such as buffet cans of canned fruit with pop-tops and king-sized candy bars. The comments stated that FDA ignored many other products on

the market for which the 200 percent cutoff level would be unreasonably high. Examples given included 6 oz cans of tuna, 10 oz cans of canned fruits, 9 oz cans of canned vegetables, and 15 to 16 oz cans of ready-to-serve soup or entrees (e.g., chili with beans, spaghetti). These comments recommended that the upper limit be lowered to 150 percent of the reference amount. Several other comments recommended that FDA allow manufacturers to decide whether a package containing 150 to 200 percent of the reference amount is a single serving.

FDA originally proposed 150 percent of the standard serving size (equivalent to the reference amount in the 1991 serving size proposal) for the upper limit (55 FR 29487, July 19, 1990). Several comments and presentations at the 1991 public meeting on serving sizes argued that single-serving packages that are larger than 150 percent of the "standard serving sizes" are not uncommon in the market and may be increasing in number. The agency had also learned, from its own observations in the marketplace, of a trend towards larger "single-serving" packages (e.g., snacks). Therefore, in the 1991 serving size proposal, FDA proposed to change the upper limit for the single-serving container from "less than or equal to 150 percent" to "less than 200 percent"

After careful examination, of all comments for and against the 200 percent upper limit, the agency concludes that 200 percent of the reference amount is a more reasonable cutoff level for most products than 150 percent. If FDA lowered the upper limit for single-serving containers to 150 percent of the reference amount as the comments suggested, many foods that are clearly intended for one serving (e.g., 1.8 oz. snacks, 1.7 oz candy bars) could be labeled as 2 servings. The agency does not believe that such a result would represent the amount that people customarily consume; therefore, representing such foods as two servings would be confusing and misleading to consumers.

However, FDA agrees with the comments that the 200 percent cutoff level may be too high for some products (e.g., canned fruits and vegetables, soups, and entrees). The reference amounts of these products are very large compared to many other products, and examination of food consumption data showed that the average variability (defined as the standard deviation as a percent of the mean) in the amount customarily consumed for foods having a reference amount of 100 g (or mL) or larger is about two-thirds of the

variability for foods having a reference amount less than 100 g (Ref. 38). In other words, it is much less likely that a person will consume approximately twice the reference amount of a food with a reference amount of 190 g or more than it is that he or she would consume twice the reference amount of a food with a smaller reference amount. The agency has therefore concluded that for those products that have reference amounts of 100 g (or mL) or larger, 150 percent is a more reasonable cutoff for a single-serving container. Therefore, FDA is revising § 101.9(b)(6) to allow manufacturers to determine whether there are 1 or 2 servings in packages that contain more than 150 percent but less than 200 percent of the reference amount if the food in the package has a reference amount of 100 g (or mL) or larger.

The agency, however, also concludes that regardless of the package size, a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as "singles" or "the perfect size for one") must be labeled as one serving. Otherwise, the labeling will be misleading under section 403(a) of the act.

11. An organization of nutrition professionals recommended changing the upper limit for single-serving containers to include 200 percent of the reference amount, so that 16 fl oz soft drinks would be required to be labeled as one serving. An organization of health professionals urged FDA to require that snack foods provide nutrition information for the entire contents of the package, regardless of the declared serving size. The organization stated that such a requirement would reflect "more accurately consumption patterns for these products."

FDA does not believe that it is appropriate to change the definition of a single-serving container so that certain sizes of a selected class of products can be labeled as a single serving or to set a different requirement for a selected class of products without food consumption data or a scientifically sound basis that supports such a different requirement. The comments did not present any food consumption data or other scientific basis that would justify the suggested changes in the definition of single-serving containers. Therefore, FDA has not adopted these recommendations.

12. Several industry comments requested that the definition of a single-

serving container be eliminated, and that nutrition information on all containers be based on the reference amount. The comments requested that the agency, if it chooses to retain the single-serving container definition, allow dual labeling of nutritional values for single-serving containers (i.e., per reference amount and per entire contents of the container). The comments expressed concern that the single-serving container definition would result in different nutrition information on the labels of the same food product found in different sized containers. The comments argued that: (1) Consumers would be confused by such information, and (2) consumers would not be able to compare nutritional values of different brands of the same food because they come in different single-serving sizes. Therefore, these comments contended that FDA should allow manufacturers to voluntarily provide a second column of values based on the reference amount. A few of the comments that supported dual labeling also preferred that the required nutrition information be based on the reference amount, not on the entire contents of the container. However, a large number of consumers requested that FDA require that nutrition information on single-serving products be provided for the entire contents of the container.

FDA recognizes "that the proposed rule could result in different nutritional values appearing on the labels of the same food product contained in different container sizes. Whether this would be confusing to consumers was discussed at the 1991 public meeting. In the notice of public meeting, the agency specifically requested views and data on whether differences in the listing of the nutritional content of the same food in different container sizes would be confusing to consumers. No data on this issue were presented at the meeting or in written comments. Comments on the 1991 serving size proposal again claimed that different nutrition information on the same food found in different-sized containers would be confusing to consumers. However, the comments did not submit any data to support their claim. Considering the strong consumer support for the nutrition information based on the entire contents of the container, and in the absence of any data showing that the nutrition information based on the entire contents of the container would be confusing to consumers, the agency has concluded that the definition of single-serving container should be retained, and that nutrition information

of the single-serving containers should be based on the entire contents of the container.

With regard to the requests for dual labeling of single-serving containers, the agency does not believe that it is appropriate under the act. Because, by definition, a single-serving container has a number of servings of 1, nutrition information based on the reference amount would have a fractional number of servings (e.g., 1.4 servings). Consumers repeatedly complained about fractional number of servings on a single-serving container and asked that FDA require manufacturers to provide nutrition information based on the entire contents of the single-serving containers. Thus, there is strong evidence in the record to conclude that presenting a second column of nutrition information based on the reference amount on the single-serving containers will be confusing to consumers. The agency also notes that such information will clutter the label on the already limited space devoted to nutrition labeling. In considering whether to grant this request, FDA considered permitting dual labeling with the number of servings left blank. However, such labeling would fail to include a material fact—how many servings are being provided. Thus such an approach is not acceptable under the act. Therefore, for these reasons, FDA is rejecting this request.

13. A manufacturer expressed confusion about the definition of single-serving containers. While the preamble of the 1991 serving size proposal specifically stated that no lower limit for the definition of a single-serving container is being established, proposed § 101.9(b)(2)(i) stated, "If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, serving size shall be one unit." The comment interpreted this provision to mean that the lower limit for single-serving containers is 67 percent of the reference amount. The comment also requested clarification on how to label single-serving containers that contain less than 100 percent of the reference amount.

The comment confused a single-serving unit of products in discrete units (e.g., muffin, sliced bread, apple) in a multiunit, and thus multiserving, container with a single-serving container. For products in discrete units that come in multiserving containers, new § 101.9(b)(2)(i) describes the procedure to convert the reference amounts in new § 101.12(b) to label serving sizes in common household measures. Products in discrete units come in many different sizes. To promote uniformity in the serving sizes

of similar products, FDA proposed in the 1991 serving size proposal that a unit that weighs at least 67 percent or more, but less than 200 percent, of the reference amount be called a single-serving unit. (The lower limit of the single-serving unit in the final regulation has been changed from 67 percent or more to more than 50 percent (see section III.E.1. of this document).) This provision (new §101.9(b)(2)(i)) applies to products in discrete units that come in multiserving packages (e.g., sliced products, small candy bars), but it does not apply to single-serving containers.

A single-serving container is a product that is packaged and sold individually and that contains less than 200 percent of the reference amount. As discussed in the 1991 serving size proposal (56 FR 60394 at 60398). FDA did not consider that a lower limit for the single-serving containers was necessary because the agency proposed to base the qualification for claims on the reference amount and the label serving size. The use of the reference amount for the claim evaluation would prevent a single-serving container from qualifying for a descriptor based on the package size alone. Therefore, concern about the potential manipulation of single-serving container sizes to qualify for a "low" claim (e.g., a 1/2 oz. bag of potato chips making a "low sodium" claim) was eliminated. Because there is no lower limit for a single-serving container, a product that is packaged and sold individually and that contains less than the upper limit of the single-serving container must be labeled with the entire contents of the package being one serving. For example, if a muffin that weighs 45 percent of the reference amount is packaged and sold individually, it is a single-serving container product, and the nutrition information is to be provided per the entire content of the container, i.e., one muffin. The agency notes, however, that if a number of these muffins are packaged in a multiserving container, the label serving size for this multiserving container would be the number of muffins that most closely approximates the reference amount, i.e., in this case two muffins.

To avoid any potential confusion, FDA has modified new § 101.9(b)(2) to clearly state that single-serving containers are exempted from the general rule set forth in that section. The modified provision reads: "Except as provided in paragraphs (b)(3), (b)(4), and (b)(6) of this section, " * * * serving size declared on a product label shall be determined from the 'Reference Amounts Customarily Consumed Per

Eating Occasion' * * * ." Single-serving containers are discussed in § 101.9(b)(6).

14. An industry comment did not object to a manufacturer voluntarily listing a product as a single serving if it is slightly greater than 200 percent of the reference amount, provided that this claim was preapproved by FDA. A nutrition professional organization also recommended preapproval of the single-serving status of a package that contains 200 percent or more of the reference amount.

FDA finds no basis to conclude that preapproval is necessary. Because the regulation requires that the serving size for single-serving containers or units (single-serving products) be the entire contents of the container or unit, FDA expects that the manufacturer's decision to declare products that contain 200 percent or more of the reference amount as a single serving will be self-limiting. As the size of the single-serving product increases, the nutrition information will show proportionately larger amounts of nutrients. Although a larger size of single-serving product will show larger amounts of nutrients having positive connotations (e.g., calcium, fiber), most foods also contain nutrients having negative connotations (e.g., calories, fat, sodium). Therefore, single-serving products that are good sources of nutrients with positive connotations will also show larger amounts of nutrients with negative connotations. FDA thus does not anticipate that there will be abuse of this option. In addition, the agency can control obvious abuses of this option under section 403(a) of the act.

15. A consumer organization expressed concern that the proposed upper limit restriction may lead to the declaration of two servings for obviously single-serving products (e.g., a large candy bar, ice cream bar, frozen dinner) that contain slightly more than 200 percent of the reference amount. The comment contended that consumers would be misled by a label that gives nutrition information for half of the obviously single-serving products. The comment requested that FDA require manufacturers to disclose how many servings the package contains on the front panel of packages that contain between 200 and 300 percent of the reference amount.

FDA does not believe that it should require the number of servings on the front panel of products that contain more than the upper limit for the single-serving container. The agency is concerned that such a requirement would result in an information overload, contribute to the space problem for single-serving containers.

and clutter the label. Moreover, to have a clear, readily understandable, and usable definition for "single-serving container," FDA finds that it is appropriate to adopt less than 200 percent of the applicable reference amount as the defining level. However, the agency recognizes the comment's concern. FDA's position, as stated earlier in this section, is that regardless of the package size, a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as "singles" and "the perfect size for one") must be labeled as one serving. If it is not, the labeling of the product will be misleading under section 403(a) of the act. Therefore, FDA concludes that no action in response to the comment is necessary.

16. An industry comment stated that, in determining whether a product meets the definition of a single-serving container, it is not clear whether the exact weight of an oz (i.e., 28.35 g) or a rounded value of 30 g or 28 g should be used to calculate the percent of the reference amount from the net oz weight of the package.

The Compliance Policy Guides (7150.17) define 1 oz as 28.34952 g for metric declarations of quantity of contents on product labels (Ref. 39). Therefore, manufacturers should use 28.35 g to convert the oz weight of the package to the g weight.

To calculate the percentage of the reference amount from the net weight of the package, because it is a determination made on a weight/weight basis, manufacturers should divide the net weight of the package in g by the reference amount of the product and multiply by 100. For example, the percent of a reference amount of a product having a net weight of 1.3 oz and a reference amount of 30 g would be $[(1.3 \times 28.35)/30] \times 100$, i.e., 123 percent.

For the purpose of expressing the serving size for nutrition labeling, new § 101.9(b)(5)(iv) defines 1 oz as 28 g. Therefore, to express the serving size, manufacturers should use 28 g to convert the serving size in oz to the g-weight equivalent.

D. Reference Amounts for Serving Sizes

To comply with the act with respect to serving sizes, FDA proposed, in § 101.12 (b), reference amounts customarily consumed for 131 product categories, covering almost all food products that are regulated by FDA. FDA proposed that these reference amounts be used as the basis for

determining serving sizes for specific products. FDA set forth the methodology (general principles and procedures) by which it arrived at the 131 reference amounts. FDA also proposed general rules for determining reference amounts for several product classes, including: (1) Products that require further preparation before consumption; (2) imitation or substitute foods, altered foods, and foods for special dietary use; and (3) products consisting of 2 or more foods having individual reference amounts. This section discusses the comments received on the methodology that FDA used to determine the reference amounts, the number and names of product categories, the reference amounts for specific product categories, the reference amounts for special product classes mentioned above, and how to express or present the reference amounts.

1. Methodology for determining reference amounts

This section discusses comments that addressed the general principles and procedures for determining the reference amounts. Comments that discussed the methodologies for determining the reference amounts for specific product categories are included in section III.D.5, of this document, which discusses issues related to the reference amounts for specific categories.

17. Some comments objected to using food consumption data as the primary source in determining the reference amounts. The reasons for this objection varied. Some comments reasoned that food consumption data have many limitations, and therefore it is not possible to derive accurate estimates of the customarily consumed amounts from such data. Other objections included that: (1) Food consumption data such as the NFCS used by FDA, contain only a limited number of days of information (e.g., 3 days) and are not appropriate to use to determine "long-term" intake, and (2) reference amounts should be based on what people should eat rather than what they usually eat. The comments recommended using other sources of information such as industry's "longstanding" serving sizes, the serving sizes currently used by industry, or the serving sizes in dietary guidance documents. Some industry comments also stated that changing the currently used serving sizes would be confusing to consumers. Other comments, however, opposed the use of industry's "longstanding serving sizes" or opposed the use of any data other than food consumption data, arguing

that they do not fulfill the act's requirement that the serving sizes reflect amounts customarily consumed.

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. Without such data, it is impossible to determine the amount of food that is customarily consumed. FDA is well aware of the limitations of the available food consumption data bases. However, these data bases are still the best sources of food consumption data collected under actual conditions of use available to the agency. Thus, FDA concludes that its use of food consumption data as the primary source for the customarily consumed amounts of food for nutrition labeling purposes is appropriate.

FDA agrees with the comments that stated that sources other than food consumption data are sometimes appropriate. Thus, when food consumption data were inadequate, the agency used the other sources of information listed in § 101.12(a)(5) to determine the reference amounts.

As for the use of the "longstanding" serving sizes, in the notice for the 1991 public meeting (56 FR 8084), FDA requested comments and supporting data on the definition of a "longstanding" serving size. In response to this notice, the agency received only one comment that stated that "longstanding" serving size should include serving sizes used before 1973, as a minimum, and presented three examples of serving size used before that date. Since it had no established definition or sufficient data to define "longstanding" serving sizes, the agency took into consideration all serving sizes suggested in comments regardless of their history of use in determining the reference amounts proposed in the 1993 serving size proposal. In comments to the 1991 serving size proposal, the agency has not received any additional information or data on how to define a "longstanding" serving size. Therefore, it is unable to define "longstanding" serving sizes.

FDA does not agree with the industry comment that changing the currently used serving sizes would be confusing to consumers, and the agency has not received any data to support these arguments. On the contrary, consumer comments overwhelmingly attest to the fact that the current system that allows a proliferation of serving sizes has been very confusing. Congress also recognized this fact. The House Report specifically states: "The Committee believes that the current information

about serving size on many foods is extremely misleading" (H. Rept 101-538, supra, 18). Establishing standard serving sizes will reduce this confusion and provide a consistent basis for serving sizes and for claims based on them. Moreover, some of the serving sizes currently in use (e.g., 2 servings on a 12-fl oz can of soft drink) are not consistent with the act because they do not reflect the amount customarily consumed.

With regard to the use of other dietary guidance materials and the claim that reference amounts should be based on what people should eat rather than what they usually eat, FDA acknowledges that it would be desirable to have serving sizes on product labels that are consistent with the serving sizes in the dietary guidance documents published by Federal agencies. However, FDA advises that the act defines serving size as an "amount customarily consumed," not an amount people should eat. The agency has made some modifications in reference amounts where the changes are consistent with the customarily consumed amounts of the products under consideration, such as those described for bread in section III.D.5. of this document. Although these changes have not deviated from the definition of serving size, they have resulted in serving sizes more in agreement with dietary guidance documents.

However, because dietary guidance documents were developed for purposes other than regulatory uses, these documents have several problems that prevent their use as the primary source in determining reference amounts. Of greatest significance is the fact that many serving sizes in the dietary guidance documents are not based on the amounts customarily consumed and, therefore, are not consistent with the definition of serving size in the act. Dietary guidance documents published by Government agencies usually list approximate amounts of food for the purpose of providing "general" guidance as to what quantity of each food group a person should consume to maintain good health. Therefore, the amount that represents a serving is often not well defined (e.g., 1 slice for bread when the weight of a slice of bread varies among different brands).

The documents also provide a measure that is not applicable for all products within a product category. For example, these documents recommend the serving size for vegetables, other than raw leafy Vegetables, as 1/2 cup. Vegetables in small pieces (e.g., green peas, cut corn) can be measured with a cup. However, many other vegetables come in a form that cannot be measured

with a cup (e.g., broccoli spears; although broccoli can be measured if it is cut in small pieces, the weight per cup would vary widely depending on the shape and size of the cut piece).

In addition, dietary guidance documents give one serving size for a broad food group. Customarily consumed amounts, however, vary for different types of food within the food group. Therefore, for nutrition labeling purposes, FDA cannot use one reference amount for the broad groups defined in these documents.

In summary, dietary guidance documents are written for purposes other than implementing the serving size requirements of the act, and thus the serving sizes in these documents do not provide the accuracy and specificity that are needed for the reference amounts that are used for nutrition labeling under section 403(q) of the act.

With regard to the comment that a food consumption data base such as the NFCS is inappropriate to determine long-term intake because the survey covered only a limited number of days, FDA notes that the comment has confused the procedures used to estimate the reference amounts with the procedures used to estimate the average daily intake of food. FDA advises that the number of days of data collection is not critical for the estimation of reference amounts, particularly if the survey included a large number of people as was done in the NFCS.

The number of days of data collection is an important issue when an estimate of the long-term intake (chronic intake) is needed, e.g., for the safety evaluation of a food or a component of food. A survey that contains a limited number of days of data may overestimate the chronic intake, by eaters, of a food that is consumed infrequently (e.g., a specific fish) but that was consumed during the survey. For example, estimates of the average daily intakes of swordfish derived from the NFCS are likely to overestimate the chronic intake of swordfish because this fish is not consumed frequently in the United States. If an uncommon food is consumed during the survey and the amount consumed is divided by the number of survey days, 3 in this example, the average daily intake estimate for long-term intake will be greatly exaggerated because even people who like sword fish are not likely to consume it once every 3 days.

However, in determining reference amounts, FDA used the amount consumed per eating occasion, which is a short-term not a long-term intake. Thus, it was not necessary to average the amount of food consumed by the

number of survey days. For the determination of reference amounts, the amount of food consumed for each eating occasion reported was counted as a separate entry. Consequently, surveys that contain 3-day data for a large number of people, like the NFCS, are appropriate for use in determining the amount of food customarily consumed per eating occasion.

18. Several comments discussed the selection of the food consumption data base used in determining the reference amounts. Most of the comments objected to using the 1987-1988 NFCS either by itself or with the 1977-1978 NFCS. The comments were concerned that, because of the low response rate, the data from this survey may not represent the amount customarily consumed as directed by the act. Some comments stated that FDA should use only the 1977-1978 NFCS. Some comments opposed using the 1985 and 1986 Continuing Surveys of Food Intakes by Individuals (CSFII) because these data bases included only selected age/sex groups (women 19 through 50 and children 1 through 5 years of age). These comments asserted that the use of the CSFII data bases resulted in an underestimation of the amount customarily consumed because men and older children, who as a group usually consume larger quantities of food than women and younger children, were not included.

A comment from a consumer organization strongly objected to FDA's use of the 1987-1988 NFCS with validation by the CSFII if data from the 1987-1988 NFCS suggested a change in consumption practices since 1977-1978 NFCS. The comment asserted that the CSFII is an inappropriate data base for validating serving sizes because the CSFII included only women ages 19 through 50 and their young children ages 1 through 5. Therefore, the comment asserted, the data base did not reflect the food consumption practices of the entire population, and the validation cannot be used for the entire population. The comment also contended that in validating the trend change in consumption, FDA did not compare the data from the CSFII to what women and young children were eating in the 1977-1978 NFCS.

A manufacturer stated that FDA should solicit consumption data from manufacturers because "the industry may well be the most efficient, accessible and accurate source of information" because "an ongoing knowledge of current consumption data * * * is vital and basic to [the] production and marketing of a product."

Because the final results of the 1987-1988 NFCS were not available in time for the 1990 proposal, FDA relied primarily on the 1977-1978 NFCS to determine the "standard serving sizes." Numerous comments on the 1990 proposal opposed FDA's use of a data base that is more than 10 years old. The comments argued that the food consumption practices have changed since the 1977-1978 NFCS, and that, therefore, estimates derived from the 1977-1978 NFCS may not reflect current food consumption practices.

Since the publication of the 1990 proposal, USDA released the final data tape for the 1987-1988 NFCS. However, FDA could not use the 1987-1988 NFCS alone because this survey had an unusually low response rate. Therefore, FDA used both the 1977-1978 and the 1987-1988 survey data. In developing the reference amounts in the 1991 serving size proposal. If the 1987-1988 NFCS had a higher response rate, the new survey data would have been preferable to the 1977-1978 NFCS data for determining the reference amounts of food because of its recency. The use solely of the 1977-1978 NFCS is also not desirable because the data are almost 15 years old, and many new products have been introduced into the marketplace for which the 1977-1978 NFCS had no data. Also, changes in the customarily consumed amounts that might have occurred since the 1977-1978 NFCS could not be determined from the use of that survey alone. Therefore, FDA tentatively concluded that using both survey data bases is the most desirable approach because such an approach compensates for limitations in each of the two surveys; increases the number of available data points; provides two sets of mean, median, and modal amount consumed rather than one; and therefore strengthens the reliability of the reference amounts determined. Comments that objected to the use of the 1987-1988 NFCS did not provide any solution on how to determine the current customarily consumed amount of food that reflect changes in the food consumption practices of the U.S. population since the 1977-1978 NFCS. In addition, the comments did not provide any suggestions on how to estimate the consumption of new products introduced into the marketplace since the 1977-1978 NFCS. Thus, in order to determine the customarily consumed amount of food that is representative of U.S. food consumption, that reflects current consumption practices, and that includes new products introduced into the marketplace since the 1977-1978

NFCS, the agency concludes that the use of both the 1977-1978 NFCS and the 1987-1988 NFCS is necessary to compensate for limitations in each of the two surveys.

The comments that objected to the use of the CSFII data bases because these data may have lowered the reference amounts, misunderstood the way FDA used these data bases in determining reference amounts. When the results of the 1987-1978 NFCS suggested a change in food consumption practices since the 1977-1978 NFCS (e.g., customarily consumed amounts increased or decreased substantially), FDA used the CSFII data bases, which had a high response rate, only to confirm the validity of the trends observed, i.e., to show that the apparent trends were not an artifact of the low response rate in the 1987-1988 NFCS. As mentioned in the 1991 serving size proposal (56 FR 6093 at 60403), such a validity check to confirm the trend observed in the 1987-1988 NFCS was recommended by an expert ad hoc committee that evaluated the impact, of nonresponse in the 1987-1988 NFCS (Ref. 26). Only when the same trends were observed in the CSFII did FDA rely solely on the 1987-1988 NFCS, so that the reference amount would reflect the current consumption practices more accurately. The estimates of intakes derived from the CSFII were not used in arriving at the reference amounts proposed in the 1991 serving size proposal. Therefore, potentially lower estimates derived from the CSFII data bases had no effect on lowering reference amounts.

With regard to the objection to FDA's use of the 1987-1988 NFCS if it suggested a change in consumption since the 1977-1978 NFCS and the use of CSFII to validate that change, the agency recognizes that the CSFII included only limited age and sex groups. Although the CSFII data bases used to confirm the trends included only women 19 through 50 and children 1 through 5 years of age, these data bases were the only other recent data bases that: (1) Were produced in a study conducted about the same time period as the 1987-1988 NFCS using the same survey methodology, (2) reflected food consumption practices representative of the U.S. population groups that were studied under the actual conditions of use, and (3) had a high response rate. Therefore, the CSFII data bases were the only data bases available to the agency for the purpose of confirming the apparent trend observed in the 1987-1988 NFCS, and, as mentioned above, their use in this manner was recommended by an expert ad hoc committee that evaluated the impact of

nonresponse in the 1987-1988 NFCS (Ref. 26).

As for the assertion that FDA should have compared the data from the CSFII to what women and young children were eating in the 1977-1978 NFCS, the agency has done data analysis for women and young children in the 1977-1978 NFCS for those product categories that relied on the 1987-1988 NFCS because of consumption changes since the 1977-1978 NFCS. The results showed that the same consumption changes were observed for women and young children as for the total population since the 1977-1978 NFCS (Ref. 40). Thus, FDA concludes that it used the 1987-1988 NFCS and the CSFII data appropriately, and that it made the best use of the available food consumption data bases.

With regard to the request that FDA solicit consumption data from manufacturers, in the preamble to the 1991 serving size proposal (56 FR 60394 at 60401), FDA requested such data by stating that "[T]he agency is willing to consider any data that may give a better estimation of an amount customarily consumed of a specific product category." Many comments submitted food consumption and other data in support of the requests for changes of the reference amounts. FDA has considered all data that were submitted. It will discuss and respond to these data in section III.D.5. of this document, which discusses requests for changes in reference amounts for specific product categories. However, while some of these data have led the agency to modify the specific reference amounts in Table 2 in new § 101.12(b), the fact that they have caused the agency to make only a relatively small number of changes supports the basic validity of FDA's reliance on the 1977-1978 and 1987-1988 NFCS data.

19. A few comments stated that reference amounts should be based solely on the modal amount consumed, which represents the most frequently consumed amount, not the mean or median amount consumed.

FDA received the same suggestions in the comments on the 1990 proposal. As explained in the 1991 serving size proposal (56 FR 60394 at 60400), the mode was not useful as the sole criterion for determining the reference amount because most food groups had two or more modes, and there usually was no obvious or rational basis to choose one over the other. Therefore, FDA used all three (or more, if there was more than one mode) values that could represent an amount customarily (commonly) consumed, i.e., the mean, the median, and the mode. Following

the procedures detailed in the 1991 serving size proposal (56 FR 60394 at 60404). FDA determined the reference amount that was most likely to represent the amount customarily consumed for each product category. The new comments offered no additional data or arguments to support that using only the modal value is better than using all three values suggestive of the amount customarily consumed and no suggestions for how to select one modal value over another when there were multiple modes that were similar in frequency. Thus, FDA concludes that it is appropriate to consider all three values that provide data on which to derive the customarily consumed amount (i.e., mean, median, and mode).

2. Expression of reference amounts

In the 1991 serving size proposal (56 FR 60394 at 60406), FDA described the general principles that it followed in expressing the reference amounts in proposed § 101.12(b). FDA expressed reference amounts for fluids in mL. It expressed reference amounts for other foods, to the extent possible, in g. For a limited number of product categories, FDA expressed the reference amounts in common household measures. For example, when foods within a product category varied considerably in density, and the customarily consumed amounts for different products were more uniform when expressed in volume than in weight, FDA expressed the reference amounts in cups, tbsp., and teaspoons (tsp.). In these limited cases, FDA selected volumes that could easily be expressed in fractions or multiples of common household measures as described in proposed § 101.9(b)(5). Several comments requested changes in some of these principles.

20. One manufacturer stated that all reference amounts should be expressed in g, and another suggested that reference amounts for specific product categories (e.g., soups, sauces, gravies, beans, and mixed dishes) should be in g instead of cups.

FDA agrees that when possible, reference amounts should be expressed in g. As discussed more fully in section III.D.5. of this document, some of the specific product categories originally expressed in volume-based reference amounts have been changed to weight-based reference amounts. However, the agency does not agree that it is appropriate or desirable to do so for all product categories, including some of those specifically mentioned in comments. As explained above, when products within a product category differ widely in density, the use of a fixed g reference amount would result

in a serving size that is too large for some products in the category and too small for others, even though the volume amounts consumed are similar for all products within the category. For example, although the reference amount for "mixed dishes measurable with cup" is 1 cup, the g-weights of different types of products within the category differ widely. e.g., about 160 g for seafood with vegetables without sauce and about 250 g for seafood stew. Also, fluids (e.g., beverages) have been customarily expressed in volume (mL or fl oz) not in weight, and they can easily and accurately be measured in volumetric units. Thus, FDA has used weight-based reference amounts in most cases but has retained volume-based reference amounts for fluids and for a limited number of categories with products that vary greatly in density (e.g., mixed dishes measurable with a cup, product category having aerated products) or for which information on the g-weight of the household measure is scarce, and comments have provided no appropriate weight-based reference amounts that are accurate and nonmisleading for all products within the category (e.g., condiments).

21. A manufacturer stated that reference amounts should, not be adjusted to reflect "nonmetric" household measures. The comment suggested that such adjustments would be confusing and of no assistance to the consumer. A consumer recommended expressing reference amounts in rounded metric units, e.g., 250 mL for juice (8.45 fl oz), not 240 mL (8 fl oz).

FDA disagrees with the comment. The act requires that serving sizes be declared in common household measures, and therefore, those measures must drive the reference amounts. The common household measures are the declaration that appears first on the nutrition label, followed in parentheses by the equivalent metric measure which may or may not be the same as the reference amount. Many consumers complained about odd fractions (e.g., 1.4, 2.3). Therefore, a fractional serving size such as 8.45 fl oz, which was suggested in the comment, is not desirable. Thus, it is important to adjust the reference amounts to be in metric amounts that convert to useful, whole number household measures rather than rounded metric units.

22. A manufacturer requested that FDA express the reference amounts in either U.S. measures or in metric equivalents that reflect the more precise factors of 28.35 g per oz instead of 28 g per oz and 29.57 mL per fl oz instead of 30 mL per fl oz.

FDA notes that the reference amounts are amounts customarily consumed that will guide manufacturers to determine the label serving sizes of their specific products in common household measures. The serving sizes in common household measures will be in units such as pieces, cups, tbsp., and tsp. These household measures are primarily for consumer use, and it is unlikely that they will measure a cup with the 4-digit accuracy suggested in the comment. Accordingly, the reference amount that will be used as a guide for determining the serving size in household measure does not need the 4-digit accuracy of the g and mL equivalency suggested in the comment. Also, both 28.35 g and 28 g will be translated to 1 oz for the label serving size when oz is used as the serving size. Both 29.57 mL and 30 mL will be translated to 1 fl oz for the label serving size. In addition, in the case of fl oz, the 30 mL equivalency of 1 fl oz allows for the exact conversion of 1 cup to 8 fl oz. Therefore, the agency has concluded that for nutrition labeling purposes, 28 g for 1 oz and 30 mL for 1 fl oz are sufficiently accurate and appropriate because they provide the accuracy needed for nutrition labeling purposes without implying unrealistic accuracy, and because whole numbers are easier to use than decimal fractions.

3. Presentation of reference amounts

23. In footnote 2 under Tables 1 and 2 in proposed § 101.12(b) in the 1991 serving size proposal (56 FR 60394 at 60418 and 60419), FDA stated that, unless otherwise noted in the reference amount column, the reference amounts in the tables are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve), and that if the reference amount is not listed separately, the reference amount for the unprepared form (e.g., dry mix, concentrate) of the product is the amount required to make one reference amount of the prepared form.

A trade association requested that FDA delete footnote 2 from Tables 1 and 2 because it "implies that most of the major reference amounts used to determine number of servings will be based on a cooked (consumed) basis." The comment further requested that if FDA did not mean that the number of servings should be based on the cooked basis, the agency should provide a complete explanation in the preamble of this document or in another official, readily accessible reference. The comment contended that it would be difficult to determine the number of servings for the unprepared form of the product.

FDA believes that the comment has misinterpreted the footnote. Many foods are available in the marketplace in several different forms: Ready-to-serve, almost ready-to-serve, dry mixes, batters, or concentrates. For example, pancakes come in three different forms: Dry mix, batter, and the frozen almost ready-to-serve form, which requires only heating before consumption. If FDA were to list reference amounts for all of the different forms of these foods, the tables would be needlessly lengthy. In addition, the list would not include forms of the food requiring further preparation that may be introduced in the future. Because the amounts of food consumed are similar for the ready-to-serve and the unprepared forms on an as consumed basis, as explained in the preamble of the 1991 serving size proposal (56 FR 60394 at 60407), FDA listed all forms of the same food together and provided one reference amount listed on an as consumed basis. Footnote 2 merely explains that the reference amounts in the table are expressed in the quantity of the food that is in the ready-to-eat or the almost ready-to-eat form of the food. Since nutrition labeling is required to be on an "as packaged" basis, the footnote further informs the manufacturer that, for the unprepared form of a product that requires further preparation before consumption (e.g., dry mix, batter, uncooked food), the manufacturer must determine the quantity of the unprepared product that is required to make one reference amount of the prepared product as specified in new § 101.12(b). Using the reference amount for the unprepared product, the manufacturer must then determine what the serving size of the unprepared product "as packaged" should be in common household measure.

For the pancake example, this requires that the manufacturer determine the weight of dry mix or batter required to make one reference amount (110 g) of the prepared pancake according to the label directions for the preparation. If 40 g of a pancake mix is needed to make 110 g of pancakes, 40 g of dry mix is the reference amount of this pancake mix. The serving size for this pancake mix will be about 1/3 cup (40 g). The number of servings per container will then be estimated from the net quantity of contents of the container and the reference amount for the unprepared form of the product. For the pancake example above, if the net quantity of the package is 12 oz, the number of servings per container can be determined by dividing the net quantity in g by the reference amount for the dry

mix (40 g), e.g., (12 oz) x (28.35 g/oz)/40 g = 8.5, i.e., about 9 servings according to the provision for declaring the number of servings per container in new § 101.9(b)(8).

As requested in the comment, FDA has provided a complete explanation of the footnote and how to determine the number of servings per container for unprepared products that require further preparation. Therefore, the agency is retaining Footnote 2 for Tables 1 and 2 in the final regulation to inform manufacturers that the reference amounts in Tables 1 and 2 are the amount of the final product on a ready-to-serve or almost ready-to-serve basis. In addition, for clarity, the agency has added, at the end of footnote 2 to Tables 1 and 2, the following statement: "Prepared means prepared for consumption (e.g., cooked)."

24. A trade association suggested that FDA express the reference amounts in Tables 1 and 2 in proposed § 101.12(b), where possible, in common household measures with the equivalent metric quantity in parenthesis. The comment stated that consumers, FDA, and the food industry will be best served if the reference amounts in the regulation tables are stated as they should appear on the label.

FDA understands the concern expressed by the comment. However, different characteristics (e.g., shape, size, density) of different products preclude the presentation of most reference amounts as they would appear on the product label. For example, the reference amount for bread is 50 g. The serving sizes for most sliced bread will be 1 slice. However, the parenthetical metric measure will differ depending on the thickness of the slice. In addition, if a slice weighs 50 percent or less of the reference amount, the serving size will be the number of slices that most closely approximates the reference amount. Thus, both the household measure and the metric measure may vary for brands that come in different thicknesses as shown in the examples below.

BRAND A: 1 slice (35 g)

BRAND B: 1 slice (28 g)

BRAND C: 2 slices (45 g)

Therefore for most products, FDA cannot express the reference amounts as they should appear on the label.

However, in response to the comment, FDA is adding a label statement column to Tables 1 and 2 in new § 101.12(b). This column provides guidance on how the serving sizes of specific products in each product category will appear on the product labels and should help reduce confusion and promote uniformity in label serving size units. For example, the label statement for

bread and rolls states "----- piece(s) (-----g) for sliced bread and distinct pieces (e.g., rolls); 2 oz. (56 g) for unsliced bread." For sliced bread or rolls, manufacturers will then fill in the number of slices or rolls that most closely approximates the 50 g reference amount and the g-weight equivalent of that number of slices or rolls. For unsliced bread, oz is the household measure most appropriate for the food, and 2 oz most closely approximates the 50 g reference amount for bread. The metric measure equivalent to 2 oz is 56 g because 1 oz in weight is defined as 28 g for nutrition labeling purposes in § 101.9(b)(5)(iv). Therefore, the label statement for unsliced bread states "2 oz (56 g 1-inch slice)."

Where possible, FDA has also provided the exact household measure and the equivalent metric measure for serving sizes in volumetric measures other than oz (e.g., cups, tbsp.), using the g weight of the household measure reported by the USDA. For example, for the product category of "Confectioner's sugar," the reference amount is 30 g which is equivalent to 1/4 cup. Therefore, the label statement column states "1/4 cup (30 g)," which is how the information will appear on the product label.

25. An industry comment urged FDA not to include the reference amount table (proposed § 101.12(b)) in the regulation itself. Instead, the comment asked that FDA generally establish its intention to use such a table, then reference and formalize the table through policy memoranda. The comment stated that if the reference amount table is in the regulation, the petition process for modifying the reference amounts would require a notice and comment rulemaking which would necessitate publication in the **Federal Register** before a change could be made.

The reference amount table appropriately is included in the regulation because these amounts have the force and effect of law. While it is true that any changes in the reference amounts will require a notice and comment rulemaking, FDA concludes that giving the reference amounts legal effect is required to implement section 403(q)(1)(A)(i) of the act. The legislative history of section 2(b)(1)(B) of the 1990 amendments directs FDA to establish meaningful serving size *requirements* (H. Kept 101-538, supra, 18). Such requirements are necessary to ensure that the serving size that appears on the label reflects the amount customarily consumed.

4. Product categories

a. Number of product categories

FDA proposed 131 product categories: 9 for foods specially formulated or processed for consumption by infants or toddlers and 122 for the general food supply. The agency asked for comments on whether these categories adequately cover the food supply (56 FR 60394, 60407).

Many comments addressed whether the 131 product categories are adequate. Some comments expressed their support for the 131 product categories proposed in the 1991 serving size proposal. These comments stated that the proposed product categories are reasonable and recognizable. Several comments suggested that some of the product categories should be combined. The vast majority of the comments, however, stated that the 131 categories were too restrictive and recommended expanding some of the categories.

Because the comments about the number of product categories are closely related to the comments on the reference amount, those comments that requested merging or expanding specific categories will be discussed in the next section of this document on requests for changes in reference amounts for specific product categories. This section includes only those comments that requested recategorization of entire product categories or addition of a product category.

26. A State government comment recommended that FDA regroup all products into six categories and establish one standard measure for each category that is easily understood and multipliable. For example, the comment suggested grouping dry cereal, rice, beans, raisins, nuts, bread, tortilla, crackers, cooked fish, and hard cheese into one category with a standard serving size of 1 oz.

Section 403(q)(1)(A)(i) of the act defines serving size as an amount of food customarily consumed. Therefore, FDA has not grouped products together unless their customarily consumed amounts are similar. Grouping of foods into such broad categories as those suggested by the comment is not possible because the amounts customarily consumed vary widely. For example, 1 oz may be an appropriate reference amount for some foods in the grouping suggested by the comment (e.g., cheese, some ready-to-eat cereals), but it is too small for other foods in that grouping (e.g., bread, fish). Food consumption data show that the amount customarily consumed for fish without sauce is 3 oz cooked, and that for fish

with sauce (e.g., fish with cream sauce), it is 5 oz cooked.

27. A manufacturer requested that FDA add a product category for snack sandwiches, which have recently been introduced into the market, with a reference amount of 70 g.

The 1991 serving size proposal has a product category that includes products such as snack sandwiches. These sandwiches belong to the category of "mixed dishes not measurable with cup." The proposed reference amount for this category, that is retained in the final regulation, is 140 g. Because snack sandwiches are discrete unit products, the label serving size will be one sandwich if it weighs more than 70 g. If the sandwich weighs 70 g or less each, the serving size will be the number of sandwiches that most closely approximates the 140 g reference amount. However, the agency notes that, as discussed in section III.F.1. of this document, new § 101.9(b)(10)(ii) allows manufacturers to voluntarily provide a second column of values per unit on multiserving containers.

Regardless of the size of the individual unit, the 140 g reference amount will be used to evaluate the product's qualification for claims unless the sandwich meets the definition of a meal product or main dish product in new § 101.13(l) and (m). If the sandwich meets the definition of meal product or main dish product, the product's qualification for a claim will be evaluated by the rules described in the nutrient content claim regulation published elsewhere in this issue of the **Federal Register**.

28. A comment from a Federal agency stated that there should be a product category for gelatin salad.

In the 1991 serving size proposal, all gelatin products were included in the "Custards, gelatin, or pudding" category under Desserts. Because some gelatin products are served as salads rather than desserts, FDA agrees with the comment that it would be desirable to have a separate category for gelatin salads. Accordingly, a new category "Gelatin Salad" has been added to Table 2 in new § 101.12(b). Following the general principles and the procedures described in the 1991 serving size proposal (56 FR 60394 at 60402), FDA has determined the reference amount for the category to be 120 g, which is equivalent to 1/2 cup (Ref.41).

29. A manufacturer of "herring salad" and smoked salmon spread stated that their products were not included in the 131 product categories proposed in the 1991 serving size proposal. The manufacturer stated that "herring salad" is a "fanciful name" and is not a fish

salad. "Herring salad" and smoked salmon spread are ground paste of herring or salmon and other ingredients such as celery, pickle relish, mayonnaise, and spices. They are neither used nor marketed for use as sandwich spreads like tuna salad. They are promoted for use as an appetizer to be spread on crackers, in the same manner consumers would use pickled herring. The manufacturer stated that "herring salad" and smoked salmon spread should be added to the "Smoked or pickled fish or shellfish" category.

FDA agrees that the characteristics and the usage of "herring salad" and smoked salmon spread suggested in the comment most closely resemble those products used as appetizers in the "Smoked or pickled fish or shellfish" category. In addition, "herring salad" and smoked salmon are canned fish products. Both of these categories have a reference amount of 55 g. Therefore, it is a matter of choice in which category these products are placed. FDA has concluded that "herring salad" and smoked salmon are types of fish products used in the same manner of those products in the "Smoked or pickled fish or shellfish" category and thus fit better in the "Smoked, or pickled fish or shellfish" category than in the canned fish category. Therefore, FDA has modified the name for the "Smoked or pickled fish or shellfish" category in Table 2 in § 101.12 (b) to include fish or shellfish spread.

30. A consumer comment stated that a category is needed for products such as tempeh. The comment suggested 1 oz as the reference amount for these products.

FDA acknowledges that tempeh should be included in § 101.12(b). However, the agency disagrees with the comment that it should have a separate category with a reference amount of 1 oz. The comment did not provide any data on the amount customarily consumed to support the recommendation of a 1 oz reference amount. Because tempeh is a type of soy product that is used interchangeably with tofu (Ref. 42), the agency concludes that tempeh belongs in the "Bean cake (tofu)" category with a reference amount of 85 g. Accordingly,, FDA has revised the "Bean cake (tofu)" category to include tempeh.

In addition, the agency is aware that there are an increasing number of ethnic foods entering the general food supply. However, available food consumption data do not usually provide information on these ethnic foods. Therefore, FDA requests that manufacturers or other interested persons submit a petition as described in § 101.12(h), if any

additions or amendments to § 101.12(b) are necessary to encompass the ethnic foods sold to the general public.

31. The spice industry requested exemption from nutrition labeling on the basis that spices in general contain insignificant amounts of nutrients on a 1/4 tsp. basis. The comments requested that FDA establish 1/4 tsp. as the reference amount and "acknowledge that when used at that level, the industry is not covered by the mandatory nutrition labeling requirements of the proposals."

Exemptions from mandatory nutrition labeling are discussed, in the final regulation entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" published elsewhere in this issue of the **Federal Register**. The agency agrees with the comment that there is a need for a reference amount for spices and herbs and, accordingly, has added a category for these products. Spices and herbs are used to flavor foods. Cookbooks (Refs. 43 and 44) usually recommend using 1 to 2 tsp. of these products in recipes that make several servings. Therefore, one serving of food contains only a fraction of a tsp. of spices or herbs (e.g., 1/4 tsp. or less). One-fourth tsp. is also the smallest household measure allowed to be declared as a serving size for nutrition labeling purposes. Therefore, FDA has concluded that 1/4 tsp. is the most reasonable reference amount for this product category. For spices and herbs that cannot be measured with a tsp. (e.g., whole clove, whole bayleaf), the agency has determined the reference amount of 0.5 g which represents the average g weight of 1/4 tsp. of spices and herbs. Consequently, FDA has added a new product category under the miscellaneous category for spices and herbs with a reference amount of 1/4 tsp. or 0.5 g if not measurable by a tsp.

32. An industry comment stated that it is confused about which products go into the breads category. Another industry comment requested clarification as to which category canned hot dog chili sauce belongs.

First, the agency notes that as discussed in section III.D.5. of this document, FDA has divided the "Bakery Products: Breads (excluding sweet quick type), biscuits, rolls, * * *" category (the original bread category) into two categories: One for breads and rolls, and the other for the remaining products included in this category in the 1991 serving size proposal. This was done in response to many requests for dividing the original bread category into several subcategories. The breads and rolls category in the final regulation includes

all breads (e.g., white, wheat, rye, multigrain, raisin, and soda bread) and all rolls (e.g., dinner rolls, hamburger rolls; hot dog rolls).

With regard to the hot dog chili sauce, FDA advises that it belongs to the "Major condiments, e.g., catsup * * *" category under "Sauces, Dips, Gravies and Condiments" because it is used, as a substitute for catsup on hot dogs.

To help manufacturers and others to identify the category in which their specific products fit, in the 1991 serving size proposal, FDA provided an extensive list of products for each product category (Ref. 20). The agency has updated this list to incorporate changes made in product categories and in the products included in each product category in response to the comments on the 1991 serving size proposal (Ref. 45). FDA will continue to update the list as necessary. Copies of the list are available from the Division of Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. FDA advises that those who are not sure about which product category their specific products belong should refer to this list or consult with the agency.

33. A manufacturer contended that "not having a provision for new or undefined food products is of concern" to those developing new products.

FDA agrees that new products should be provided for in this regulation. It was for this reason that FDA proposed to establish a petition process in § 101.12(h) by which a reference amount could be amended or added. New § 101.12 (h) describes the information needed in the petition in order for FDA to evaluate the request for a change or addition of a product category or a reference amount of a food in Tables 1 and 2, as well as the information needed to determine a suitable reference amount for the petitioned food, if the agency concludes that the change or addition is appropriate.

From the comments on the 1991 Serving size proposal and through its own observation of products in the marketplace, the agency has identified three additional product classes (dessert shells, pastry shells, and dehydrated vegetables) that were not covered in the 1991 serving size proposal. The agency intends to publish a proposal for reference amounts for these product classes in the near future.

b. Product category names

Because each product category encompasses many different: types and brands of products, it is impossible to fully describe all products within each product category. Therefore, in the 1990

proposal, FDA provided a generic description of each product category. A generic description is also desirable to accommodate the brands and types of products that may be introduced in the future. Some comments on the 1990 proposal stated that because some product categories were not sufficiently descriptive, they experienced difficulty in identifying the product category in which their products fit. Thus, in the 1991 serving size proposal, FDA modified the names of some product categories to be more descriptive and also provided a few recognizable examples where it felt that it was necessary to do so. In addition, the agency provided a separate extensive list of products for each product category (Ref. 20). Several comments on the 1991 serving size proposal again requested clarifications or changes in product category names as described below.

34. An industry comment requested that FDA add "crumcakes and similar products" to the "Coffee cakes * * *" category under Bakery Products.

FDA advises that because crumcakes are similar to coffee cakes in their nutrient content and use in the diet, coffee cakes and crumcakes are included in the same food code in the NFCS. Consequently, crumcakes were included in the coffee cake group in determining the customarily consumed amount of coffee cakes. Therefore, the agency agrees with the comment that it is appropriate to include crumcakes in the name of the coffee cake category. However, the agency finds that it would not be appropriate or desirable to add a term such as "similar products" to the product category name because such a term could be interpreted differently by different companies and may result in an inappropriate classification of a product. For example, because apple crisp has a crumb topping, like crumcakes, it could be misclassified as belonging to the "Coffee cakes * * *" category. However, apple crisp belongs in the "Pies, cobblers * * *" category, not the "Coffee cakes * * *" category because apple crisp resembles products in the "Pies, cobblers * * *" category in nutrient content and in use in the diet as indicated by being listed in the same food group as cobblers in the NFCS. Therefore, FDA has modified the name for the "Coffee cakes * * *" category to read: "Coffee cakes, crumcakes * * *" For clarity, FDA has also modified the name for the "Pies, cobblers * * *" category to read: "Pies, cobblers, fruit crisp * * *"

35. Another comment pointed out that game meats are missing from FDA's product category list.

Game meats belong to the major product category of "Fish, Shellfish, and Meat or Poultry Substitutes," because this category includes all meat or poultry substitutes and is the product category comparable to the meat and poultry categories in the USDA regulation. Because meal and poultry substitutes replace meat and poultry in the diet, FDA used the amount customarily consumed for meat and poultry as a surrogate for the amount customarily consumed for meat and poultry substitute products. Therefore, because game meat is a type of meat and is used interchangeably with other meat, fish, or poultry in the diets similar to those products in the "Fish, Shellfish, and Meat or Poultry Substitutes" category, FDA has included game meat in that category. Accordingly, FDA has modified the name of this major product category, and the names of its two subcategories, to include game meats as shown below:

"Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes:"

"Fish, shellfish, and game meat, canned"
"Smoked or pickled fish, shellfish, or game meat; or fish or shellfish spread"

36. A nut industry comment stated that it is not clear in which category sliced nuts fit, "Nuts, seeds, and mixtures;" or "Nuts and Seeds: Used primarily as ingredients, e.g., coconut, nut, and seed flour, etc."

The agency advises that sliced nuts belong in the "Nuts, seeds, and mixtures" category because they were included in the analysis for the amount customarily consumed for the "Nuts, seeds, and mixtures" category. For clarity, FDA has modified the name for the "Nuts, seeds, and mixtures" category to "Nuts, seeds and mixtures, all types, sliced, chopped, slivered, and whole."

37. A manufacturer requested that FDA not use "popsicle" as part of the product category name because it is a trademark owned by a particular company.

FDA has deleted "popsicle" from the product category name. The new name for the product category is "Frozen flavored and sweetened Ice and pops, frozen fruit juices: all types bulk and novelties (e.g., bars, cups)." As discussed in section III.D.5. of this document, this category has been moved from the category for Sugars and Sweets and placed under the category for Desserts.

38. A pickle trade association stated that the product category name for relish ("Pickles, relish") suggests that the category excludes relishes that contain nonpickle ingredients. The

comment argued that the category should include all relishes and requested that FDA change the category name from "Pickles, relish" to "Pickle relishes."

FDA agrees with the comment that "Pickle relishes" is a more appropriate name for the category that includes all vegetable relishes including relishes containing nonpickle ingredients. The agency notes, however, that fruit relishes (e.g., cranberry relish) are a different type of product end are listed under "Fruits and Fruit Juice" with the reference amount of 70 g.

In addition, for clarity or for a better categorization of products, FDA on its own initiative has modified the names of the following product categories:

(1) Hushpuppies and cornbread have been deleted from the "Coffee cakes * * *" category under Bakery Products and placed in the "Biscuits * * *" category under Bakery Products.

(2) To prevent a misclassification of tortillas as taco shells because they are often used as a wrapper for tacos, the name for the taco shell category has been modified to read: "Taco shells, hard."

(3) To incorporate "frozen flavored and sweetened ice" and to reflect better the products included in the category, the name for the "Ice cream, ice milk, frozen yogurt, sherbet: All types, bulk and novelties * * *" category under Desserts has been changed to "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: All types, bulk and novelties * * *"

(4) To reduce the number of product categories, FDA has deleted water as a separate category. For a better categorization of products, fruit-flavored drinks have been deleted from the "juices, nectars, fruit drinks, or fruit-flavored drinks" category under Fruits and Fruit juices. Water and fruit-flavored drinks have been combined with the category for "Carbonated beverages * * *" under Beverages. The revised name for the "Carbonated beverages * * *" category is "Carbonated and noncarbonated beverages, wine coolers, water."

These changes are intended only to clarify Table 2 and to make it more usable. They do not result in any substantive changes in the reference amounts of the products affected.

As mentioned in the previous section, to help manufacturers identify the product category in which their specific products fit, FDA has updated the list of products for each product category (Ref. 45). The agency will keep updating this list as new products are identified. Copies of the list are available from the

Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

5. Reference amounts for specific product categories

FDA proposed, in § 101.12(b) the reference amounts for 131 product categories that it developed through the use of the general principles and procedures described in the 1991 serving size proposal. These reference amounts were presented in two tables. Table 1 contained the reference amounts for the 9 product categories that are specially formulated or processed for consumption by infants or toddlers. Table 2 contained the reference amounts for the 122 product categories in the general food supply.

FDA received more comments on the proposed reference amounts for specific product categories than on any other serving size issue. Many comments supported the proposed reference amounts. However, the majority of the comments that discussed specific reference amounts opposed one or more specific proposed reference amounts. The agency received requests for changes of the reference amounts for about 80 specific product categories. About half of the requests merely voiced their opinion on the proposed reference amounts for certain product categories (e.g., too large or too small) or provided generic types of bases for wanting the changes. The other half of the requests presented more specific reasons for each product or product category or presented data supporting their requests. FDA will first respond to the requests that provided generic types of bases and then will respond to the requests that provided more specific bases by product category.

a. Generic requests

Because many comments provided similar bases for wanting changes in the reference amounts, responding separately to them would be repetitive and would make the document needlessly lengthy. Therefore, FDA has grouped these bases and is responding to each type of basis for a change.

39. Many comments merely stated that they believed that the proposed reference amounts for specific product categories were too large or too small but they did not present any specific arguments or data supporting their beliefs.

Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily consumed" To determine this amount of food, FDA performed extensive analyses and evaluations of

data from four large national food consumption survey data bases, namely the 1977-1978 NFCS, 1985 CSFII, 1986 CSFII, and the 1987-1988 NFCS conducted by the USDA (56 FR 60394 at 60403). To respond to the recommendations in the IOM report to comments requesting the use of other relevant information in addition to food consumption data, and to promote international harmonization. In addition to the food consumption data, FDA used several other sources of information listed in the proposed §101.12(a)(5) in developing the proposed reference amounts. The agency carefully considered the food consumption data and the other information to determine the reference amounts proposed in the 1991 serving size proposal. Food consumption data and the other information used, along with the detailed description of the procedure and the basis used to determine the proposed reference amounts, were made available to the public (Re f. 2).

The law establishes an objective standard against which serving sizes are to be established. FDA cannot change the proposed reference amounts that were determined after careful and extensive consideration of food consumption data and other relevant information simply because some comments stated that the reference amounts are too large or too small without providing any data to support their assertions. Accordingly, FDA has not adopted recommendations based merely on belief or opinion.

40. A consumer organization and a few fast food companies recommended that FDA change some reference amounts to make them consistent with the average serving sizes of restaurant foods.

First, FDA advises that in determining the customarily consumed amount for each product category, it used both foods consumed at home and away from home (e.g., restaurant foods). Therefore, the serving sizes of restaurant foods were reflected in the reference amounts determined for each product category. In addition, the act mandates the nutrition labeling of retail products, not restaurant foods. Accordingly, new § 101.9(j)(2) exempts restaurant foods from the nutrition labeling regulation unless a claim is made. Therefore, it is more important for the reference amounts to be appropriate and applicable to retail products than to restaurant foods. Reference amounts that are solely based on the serving sizes of restaurant foods may not be appropriate for retail products. Furthermore, most restaurant foods are single-serving products. Based on the

reference amounts in new § 101.12(b) and the definition for single-serving products, the serving sizes for restaurant foods will be one unit. Therefore, FDA has not changed the reference amounts to make them consistent with the average serving sizes of restaurant foods.

41. A manufacturer requested that FDA establish two different reference amounts, one for retail products and one for food-service products, for some product categories (e.g., 1 cup for retail soups and 3/4 cup for food service soups). The comment argued that the proposed reference amounts represent the amount customarily consumed in the home. The serving sizes used for food service products are smaller. Because those products are sold in some retail "club" stores, they will be required to bear nutrition labeling. The comment contended that if these products are required to use the same serving size as for the regular retail products, it would cause problems in providing preparation instructions and yield information directed to the food service operator because the serving size recommended for food service would differ from the serving size shown on the nutrition panel. The comment claimed that such labeling would be very confusing to the food service buyers and operators. The comment requested that food service products be allowed to use serving sizes that correspond to their traditional label instructions as long as the simplified-formal of nutrition information is provided per serving based on the reference amount.

The same food cannot have different reference amounts (or label serving sizes) simply because it is intended to be sold or served for different purposes. Reference amounts of the same food sold at retail stores must be the same to facilitate nutrition comparisons of different brands regardless of where they are purchased. The reference amount for the food service products that are sold at retail stores must be based on the same reference amount as for the regular retail products.

42. Some comments recommended using a range of values rather than a fixed reference amount.

The reference amounts in § 101.12(b) will serve two purposes: (1) They will be used by manufacturers to determine serving sizes for their specific products, and (2) they will be used to determine whether food products meet the definitions for nutrient content end health claims. As explained in the 1991 serving size proposal (56 FR 60394 at 60414), both of these purposes require specific reference amounts, not a range of values. None of the comments

provided any evidence that a range of values would be better than a fixed value to meet the two objectives of the reference amounts. Therefore, FDA has not adopted the recommendations for using a range of values.

43. A comment from a foreign government recommended changing the reference amounts because they differ from the amounts in its own guidelines or differ from the food consumption data developed in its country.

Although the act did not explicitly define the serving size as an amount customarily consumed by the U.S. population, it is implicit that the food consumption data used to determine this amount of food should be based on the food consumption practices by the U.S. population, not food consumption data from surveys conducted in other countries. The nutrition information on products sold in the United States is for the U.S. consumer. Moreover, the legislative history of the 1990 amendment talks about helping Americans to maintain a balanced and healthful diet and to follow the Surgeon General's guidelines (H. Rept. 101-538, supra 9-10). Moreover, one of the main sponsors of the legislation said in thanking the other main sponsor in the House that: "He has insisted that the bill be as effective as possible so that all Americans can be fully and fairly informed about the nutritional characteristics of the food that they eat" (136 Congressional Record H5841 (July 30, 1990)). Therefore, the reference amounts should be appropriate to U.S. consumers. FDA cannot change the reference amounts that reflect the food consumption practices of the U.S. population to make them consistent with the guidelines that are targeted for non-U.S. population groups or to make them agree with the data from food consumption surveys conducted in foreign countries. Accordingly, FDA has not adopted these recommendations

b. Specific requests

In addition, FDA received many comments requesting changes in specific reference amounts. Some comments addressed meat and poultry products which are regulated by USDA. Unless such comments contained specific issues that were directed to FDA or that significantly bear on the labeling of products regulated by FDA (e.g., how to determine reference amounts for the unprepared form of the product), FDA is not responding to those comments pertaining to meat and poultry. FDA has forwarded comments to USDA for consideration. Comments about game meats are included in this document.

Although the names and the order of the product categories in the final regulation have been changed somewhat, for the purpose of discussing the comments on specific reference amounts, the names and the order of the product categories presented in the 1991 serving size proposal are used below for ease of identifying the product category to which the comments were directed.

(1) Infant and toddler foods: other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts

FDA proposed 7 g as the reference amount for this product category.

44. A manufacturer of infant and toddler foods stated that 7 g is appropriate for infants but not for toddlers. Based on the published value for the median amount of ready-to-eat breakfast cereals consumed by toddlers 1 and 2 years of age as reported in the 1977-1978 NFCS, the manufacturer recommended 21 g, or 3/4 oz, as the reference amount for ready-to-eat cereals for toddlers.

FDA derived the proposed 7 g reference amount from the amount consumed by infants. Some of the products in this product category (e.g., teething biscuits, teething cookies) are primarily consumed by infants. However, FDA acknowledges that other products in the product category (e.g., cereals) may be consumed by both infants and toddlers. Therefore, the agency agrees that it is appropriate to have a separate reference amount for toddlers. However, the agency could not adopt the reference amount suggested in the comment because it was based solely on the 1977-1978 NFCS and included only toddlers 1 and 2 years of age. As discussed in section III.D.1. of this document, FDA is not using a reference amount that is solely based on the 1977-1978 NFCS. Also, new §101.9(b)(1) defines toddlers as children 1 through 3 years of age. Therefore, the reference amount for toddlers should reflect the amount customarily consumed by toddlers 1 through 3 years of age. Following the procedures for determining the reference amount described in the 1991 serving size proposal (56 FR 60394 at 60403), FDA has determined the reference amount of cereals for toddlers 1 through 3 years of age to be 20 g (Ref. 41).

(2) Dinner, fruit, vegetable, stew or soup for toddlers, ready-to-serve

FDA proposed 170 g as the reference amount for this product category.

45. A manufacturer of infant and toddler foods stated that 170 g is too

large for fruits and vegetables specially formulated or processed for consumption by toddlers. The comment recommended a separate reference amount of 100 g or 3 to 4 oz for fruits and vegetables based on the published data for the amount of fruits and vegetables consumed by toddlers 1 and 2 years of age reported in the 1977-1978 NFCS.

FDA agrees with the comment that a separate reference amount is needed for fruits and vegetables. Detailed information on the characteristics of fruits and vegetables specially formulated or processed for consumption by toddlers was not available to FDA during the formulation of the 1991 serving proposal. The information provided in the comment showed that fruits and vegetables specially processed for consumption by toddlers differ from fruits and vegetables specially formulated or processed for consumption by infants. Toddlers' products more closely resemble the canned fruits and vegetables in the general food supply than do fruits and vegetables for infants. The toddler products differ from the products in the general food supply primarily in the piece size, which makes them easier for toddlers to pick up with their fingers. Therefore, the agency believes that it is appropriate to use the amount of fruits and vegetables consumed by toddlers reported in the NFCS to derive the reference amount for the fruits and vegetables specially processed for consumption by toddlers.

Consistent with the discussion in section III.D.1. of this document, FDA is not using a reference amount that was suggested in the comment because it was solely based on the 1977-1978 NFCS and included only toddlers 1 and 2 years of age. Following the procedures for determining the reference amount that it described in the 1991 serving proposal (56 FR 60394 at 60403), FDA has determined the reference amount for ready-to-eat fruits and vegetables specially formulated or processed for consumption by toddlers 1 through 3 years of age to be 125 g and 70 g, respectively (Ref., 41). Therefore, FDA has added 2 categories, "Fruits for toddlers, ready-to-serve" with a reference amount of 125 g and "Vegetables for toddlers, ready-to-serve" with a reference amount of 70 g.

(3) Infant and toddlers foods: egg/egg yolk, ready-to-serve

FDA proposed 55 g as the reference amount for this product category.

46. One comment recommended that FDA change the reference amount to 50

g because 50 g corresponds more closely to one-half of the net contents of a jar.

As discussed in the 1991 serving size proposal (56 FR 60394 at 60401), the act requires that the serving size be the amount customarily consumed. Therefore, jar size cannot be used as the basis for determining reference amounts. Furthermore, there is nothing that ties jar size to the amount customarily consumed. One may change, while the other does not. Therefore, FDA has not adopted this recommendation.

(4) Infant and toddler foods: juice, all varieties

FDA proposed 120 mL as the reference amount for juices specially formulated or processed for consumption by infants.

47. A consumer recommended that FDA change the reference amount to 125 mL because 125 mL is a rational metric size.

For the reason explained in section III.D.1. of this document; concerning the presentation of reference amounts in rational metric size, FDA has not adopted this recommendation. Accordingly, FDA has retained the reference amount as proposed.

(5) Bakery products: breads (excluding sweet quick type), biscuits, rolls, croissants, bagels, tortillas, soft bread sticks, soft pretzels (hereinafter referred to as "the original bread category" for simplicity)

FDA proposed 55 g as the reference amount for this product category.

48. Many industry comments requested that FDA divide this category into several subcategories with separate reference amounts for each subcategory. Two bakery trade associations recommended dividing the category into 4 subcategories with the following reference amounts: 45 g for bread, 50 g for rolls, 60 g for biscuits and English muffins, and 70 g for tortillas. The comments submitted published data from the 1977-1978 NFCS to support their position. In addition to these four subcategories, another industry comment suggested separate reference amounts for sliced, and unsliced bread. (e.g., 45 g for sliced bread, and 55 g for unsliced bread). Several additional comments recommended a 45 g reference amount for bread but did not specify what the reference amount should be for other products in the bread category. The major reason stated by the industry in comments was to have a separate, lower reference amount for sliced bread so that the label serving size for sliced bread will be 1 slice, which is consistent with the serving size

in the dietary guidance documents published by Federal agencies. A nutrition professional organization also stated that the 2-slice serving size conflicts with the serving sizes in dietary guidance documents. This comment contended that consumers who hear that dietary guidance documents recommend 6 to 11 servings daily from the bread/cereal group, and then see that a label serving size is 2 slices/may be confused and think that the recommendation means 12 to 22 slices of bread a day. A few other comments suggested a 25 to 30 g reference amount for bread which is equivalent to the g weight of 1 slice of most breads. An international comment suggested changing the reference amount for bread to 45 g but keeping the 55 g reference amount for rolls because rolls are heavier than breads. One comment stated that the amount of bread customarily consumed was overestimated because FDA did not include the bread that was consumed as toast. The comment asserted that many people consume only one piece of bread as toast, and thus the amount customarily consumed would have been lower if FDA had included the bread consumed as toast in the data analysis.

FDA agrees that the 55 g reference amount could result in 2-slice serving sizes for some brands of sliced bread, and that it would be desirable to have serving sizes of sliced bread consistent with that in the dietary guidance documents published by Federal agencies. However, the agency does not agree that it should divide the original bread category into four subcategories with their own individual reference amounts. The data submitted in support of the four subcategories came from a USDA publication from the 1977-1978 NFCS (Ref. 46). These data are inappropriate for use in determining the reference amounts for several reasons.

First, the data represent the mean consumed amount per eating occasion by the total population including infants and children less than 4 years of age. New § 101.9(b)(1) defines the term "serving" or "serving size" for the general food supply as an amount of food customarily consumed by persons 4 years of age or older. Therefore, the reference amounts for the general food supply should reflect the customarily consumed amounts by individuals 4 years of age or older, not by the total population which includes infants and children less than 4 years of age.

Secondly, as discussed in the 1991 serving size proposal (56 FR 60394 at 60400), the mean is often influenced by "outliers" (i.e., extremely small or extremely large amounts). Therefore, the

mean alone is not sufficient to determine the customarily consumed amount. As explained above, FDA has concluded that to determine a reliable estimate of the amount customarily consumed, all three statistical estimates that represent an amount customarily consumed (the mean, the median, and the mode) must be considered.

Thirdly, the data submitted in the comments represent estimates from the 1977-1978 NFCS. The sole use of the 1977-1978 NFCS is not appropriate for the reason stated in section III.D.1. of this document.

FDA, therefore, has reanalyzed the 1977-1978 NFCS and the 1987-1988 NFCS to determine the mean, median, and modal consumed amounts of bread per eating occasion including the bread that was eaten as toast for persons 4 years of age or older. The amounts consumed as toast were adjusted to account for the moisture loss during toasting in order to more closely determine the weight of the bread, i.e., the form sold.

The reanalysis of the food consumption data showed that both the 1977-1978 NFCS and the 1987-1988 NFCS showed somewhat lower customarily consumed amounts for breads and rolls than for other products included in the original bread category (Ref. 47). Therefore, the agency concludes that it is appropriate to divide the original bread category into two categories, one for breads and rolls and one for all other products (e.g., bagel, English muffins, tortillas). Based on the results of the reanalysis, FDA finds that 50 g is the amount customarily consumed of breads and rolls, and 55 g is the amount customarily consumed for all other products. Accordingly, FDA has divided the bread category into 2 categories with separate reference amounts.

FDA notes that the new 50 g reference amount together with the new lower limit for a single-serving unit (more than 50 percent of the reference amount) in § 101.9(b)(2)(i) would make 1 slice as the serving size for most sliced breads on the market. The agency also notes that it has added a provision in new § 101.9(b)(10)(ii) that allows voluntary labeling of a second column of values per unit (per slice in the case of sliced bread) if the serving size of a product in discrete units is more than one unit. Both of these changes should help alleviate any potential for consumer confusion, as discussed in the comments.

As for the other comments, FDA does not agree with having separate reference amounts for sliced and unsliced bread. The same food cannot have different

reference amounts simply because it comes in different forms or shapes. The act directs the agency to establish uniform serving size. Therefore, the same food should have the same reference amount regardless of its form or shape. The agency also disagrees with the comments that recommended reference amounts based on the weight of 1 slice of bread because food consumption data did not support such reference amounts. The agency also does not agree with the international comment that suggested keeping the 55 g reference amount for rolls because rolls are heavier than bread. The agency notes that the act defines the serving size as an amount customarily consumed. Food consumption data of the U.S. population showed that the amount customarily consumed is not higher for rolls than for bread (Ref. 47). Therefore, FDA has not adopted these recommendations.

49. A manufacturer of "lite bread" suggested a separate category for "lite" breads with a reference amount of 40 g. The comment stated that if "lite" breads are grouped with regular breads, the serving size for "lite" breads will be 3 slices, not 2 slices.

FDA advises that § 101.12(e) of the 1991 serving size proposal, which has been combined with new § 101.12(d) (see section III.D.6. of this document), requires that the reference amount for an altered version of a food be the same as for the food for which it is offered as a substitute. Therefore, it is inappropriate to have a lower reference amount for "lite" breads. However, if the product has been modified to be an aerated product as described in new § 101.12(e), manufacturers may determine the density-adjusted reference amount for the "aerated" bread by adjusting for the difference in density of the "aerated" bread relative to the density of the appropriate reference bread. (See section III.D.6. of this document for further discussion).

50. Comments from the tortilla industry unanimously requested a separate category for tortillas because: (1) Tortillas are not used interchangeably with other products in the bread category; (2) the tortilla industry continues to grow and deserves a separate category; and (3) a separate category would "help focus guidelines more specific to tortillas rather than baked goods in general." The comments did not suggest what the reference amount for this separate category should be. A comment from a foreign government contended that tortillas should be included in the "Taco shell" category.

FDA does not agree with the comments. To minimize the number of product categories, FDA proposed to include tortillas in the bread category because the amounts customarily consumed of tortillas and other products in the bread category (e.g., bagel, English muffin) are similar. The comments did not provide data to the contrary. FDA recognizes that tortillas have uses somewhat different from other products in the bread category, and that the tortilla industry is growing. However, balancing the interest in minimizing product categories against the significance of these facts, FDA concludes that it is appropriate to list tortillas with other bakery products that have the same reference amount. Therefore, FDA is not creating a separate category for tortillas.

Also, tortillas cannot be grouped with taco shells because the reference amounts for the two foods differ by two-fold. Although they both are foods that originated in Mexico, tortillas are much higher in moisture content and thus are much heavier than hard taco shells. This difference in the moisture content is reflected in the g weight of the reference amount.

(6) Bakery products: breakfast bars and toaster pastries

FDA proposed 55 g as the reference amount for this product category.

51. Manufacturers of breakfast bars and toaster pastries commented that it is more appropriate to separate these products into two categories with separate reference amounts because they are not consumed in similar amounts or in similar manners. The comments submitted market research data that showed that less than 20 percent of the bars are actually consumed at breakfast, and almost 80 percent are consumed at lunch or as a snack. In contrast, approximately 80 percent of the toaster pastries are eaten at breakfast. The comments suggested 40 g or 41 g as the reference amount for grain-based bars including breakfast bars and granola bars. Another comment suggested a 35 g reference amount for granola bars. The comments agreed on the 55 g reference amount proposed for toaster pastries, but they contended that these products are used interchangeably with the products in the coffee cake category. The comments said that, therefore, they should be included in the coffee cake category.

FDA agrees that grain-based bars should have a separate category with their own reference amount. The agency finds that 40 g is appropriate because it is consistent with the amount of these bars customarily consumed (Ref. 2).

FDA also agrees with including toaster pastries in the Coffee cake category with a reference amount of 55 g. The comments support that doing so reflects how these products are customarily consumed. Therefore, in Table 2 of new § 101.12(b), FDA has deleted the category for breakfast bars and toaster pastries and has added a new category for "Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars" with a reference amount of 40 g, after the category for French toast and pancakes under the major category for Bakery Products. The agency has also revised the name of the coffee cake category to include toaster pastries.

(7) Bakery products: brownies

FDA proposed 40 g as the reference amount for this product category.

52. Two industry comments agreed with the 40 g reference amount. One comment, however, contended that brownies should have the same reference amount as cake because brownies do not differ from cake nutritionally, technologically, or in ingredients. Another comment asserted that an 80 g reference amount for brownies is consistent with consumption data and industry practice. Another comment recommended that FDA change the reference amount for brownies to make it uniform with the reference amount for snacks.

FDA disagrees with all of the comments that requested a change in the reference amount for brownies. Products that are similar nutritionally, technologically, and in ingredients often differ in amounts customarily consumed because they differ in other characteristics that affect the amount consumed (e.g., density). For example, the customarily consumed amount of dense, ready-to-eat breakfast cereals (e.g., sweetened granola cereals) is about twice that of light weight cereals (e.g., flake-type cereals). Therefore, foods do not have the same reference amount simply because they are similar nutritionally, technologically, and in ingredients. They have the same reference amount if consumption data show that they do.

Data from the 1977-1978 NFCS and the 1987-1988 NFCS showed that 40 g, not 80 g, is consistent with consumption data for brownies (Ref. 2). FDA cannot change a reference amount simply to make it consistent with industry practice. The reference amount must reflect the amount customarily consumed. Also, the agency is not adopting the recommendation for a uniform reference amount for brownies and snacks because these foods are not

necessarily used interchangeably, and such a uniform reference amount is not supported by food consumption data (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(8) Bakery products: cake

FDA proposed 4 categories with separate reference amounts based on the density of the cakes: Heavy weight, medium weight, light weight, and very light weight. The heavy weight category included cakes weighing more than or equal to 10 g per cubic inch (e.g., cheese cake, fruit cake, and pineapple-upside down cake). The medium weight category included all cakes weighing more than or equal to 6 g but less than 10 g per cubic inch (e.g., most cakes with icing or filling, carrot cake, pound cake). The light weight category included all cakes weighing more than or equal to 4 g but less than 6 g per cubic inch (e.g., most cakes without icing or filling, very light cakes with icing or filling, éclairs). The very light weight category included all cakes weighing less than 4 g per cubic inch (e.g., angel food, chiffon, or sponge cake without icing or filling).

53. All comments that addressed the reference amounts for cakes opposed the density-based categories. The comments recommended eliminating the density specifications from the product category because: (1) Density has never been used by industry, the Government, or the trade to classify cakes; (2) it is difficult to determine the density because it varies with shelf life, temperature, and atmospheric pressure; (3) the density of a commercially prepared cake and the same cake baked from a mix may be slightly different and may result in the same type of cake falling into two different categories; and (4) there is potential for the manipulation of the densities of cakes that fall near category boundaries to fit in a favorable category.

Most comments recommended that FDA regroup cakes into 3 categories based on cake types: Heavy weight, medium weight, and light weight. The comments essentially requested retaining the proposed heavy and the very light weight categories with some modifications and combining the two proposed middle categories with a reference amount of 80 g. The comments also suggested including only those fruit cakes that contain 35 percent or more of the finished weight as fruit or nuts, as opposed to all fruit cakes, in the heavy weight category. The combined medium weight category would contain all chemically leavened cakes with or without icing or filling and other cakes (e.g., Boston cream pie, éclair) that do

not belong to the heavy or light weight category. A comment submitted a detailed description and results of analysis of data from the 1987-1988 NFCS in support of the 80 g reference amount recommended for the medium weight category.

FDA recognizes that it is difficult to determine the density of cake because it varies with shelf life, temperature, and atmospheric pressure. The agency also recognizes that other problems may arise from using the density-based categories such as that the density of a commercially prepared cake and the same cake baked from a mix may have slightly different densities that could result in the same type of cake falling into two different categories, and that if the product categories based on density may encourage the manipulation of the density of cakes that fall around the borderline of a category to fit in a favorable category. The agency thus agrees with the comments that it is better to group cakes by type and to combine the proposed two middle categories into one medium weight category. The agency has reanalyzed the NFCS to confirm the 80 g reference amount suggested in the comment for the medium weight category (Ref. 41). Accordingly, the product category names for cakes have been renamed by type of cakes as suggested in the comments and the proposed middle two categories have been combined into one medium weight category with a reference amount of 80 g. The revised product category names and reference amounts are as follows:

Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables)—125 g

Cakes, medium weight (chemically 80 g leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; éclair; cream puff)—80 g

Cakes, light weight (angel food/chiffon, or sponge cake without icing or filling)—55 g-

The agency notes that although the cake categories are named by the type of cakes, not by the density, density was used as a guideline to group the cakes into the three categories. The heavy weight category includes cakes that weigh 10 g or more per cubic inch, the medium weight category includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch, and the light weight category includes cakes that weigh less than 4 g per cubic inch. The density information described here

provides guidance for cakes that may enter into the future market and do not fit in the cake types described in the product category names. The agency also notes that angel food, chiffon, and sponge cake without icing or filling that are prepared by traditional recipes and preparation methods are light and usually weigh less than 4 g per cubic inch. Therefore, they are included in the light weight category. However, if angel food, chiffon, or sponge cake contains heavy ingredients (e.g., fruits, chocolate chips, and nuts) that are usually not called for in the traditional recipes of these cakes, or if these cakes are processed in such a way as to increase the density, they will not be qualified to be called light weight cakes.

54. Two comments recommended a three-category system similar to the one discussed above but suggested that the medium weight category include only cakes without icing. The comments contended that the reference amount for the medium weight cakes with icing is not necessary because icing has a separate reference amount.

The system suggested by this comment will work for cakes with icing only. Many cakes have fillings. There is no reference amount for cake fillings. The agency is unable to determine a reference amount for cake fillings because there is no information from food consumption surveys or other sources to determine the customarily consumed amount of the fillings. Accordingly, FDA has not adopted this recommendation.

55. Some comments recommended that FDA include all cheese cakes other than New York style cheese cake in the medium weight category, rather than the heavy weight category. The comments contended that the 125 g reference amount is too large for non-New York-style (aerated) cheese cakes. One comment recommended that if FDA decides not to include cheese cake in the medium weight category, cheese cake should have a separate category with its own reference amount because cheese cakes differ from other cakes in many characteristics that affect the consumption size. The comment recommended 85 g as the reference amount for cheese cakes and submitted data collected by a "mail panel" survey that supported the 85 g reference amount.

FDA acknowledges that some commercially-prepared cheese cakes have air incorporated (aerated cheese cakes) and therefore, weigh much less than the unaerated (New York style) cheese cakes. The agency agrees with the comments that these aerated cheese cakes need a separate approach.

As discussed in section III.D.6. of this document, the agency has provided guidelines for determining the reference amount for products that are modified by incorporating air. If the aerated cheese cakes mentioned in the comment meet the 25 percent minimum reduction in density relative to the density of the appropriate unaerated cheese cake, manufacturers may use the "density-adjusted" reference amount for the aerated cheese cake following the guidelines described in section III.D.6. of this document, provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated cheese cake (see section III.D.6. for further discussion). Therefore, it is not necessary to create a separate category for aerated cheese cake or to establish a separate reference amount for aerated cheese cakes. Accordingly, FDA has retained the proposed 125-g reference amount for cheese cakes.

56. Some comments recommended that FDA include pound cake without icing in the light weight category with angel food, sponge, and chiffon cake without icing. The comments argued that USDA's density data used to convert a piece of pound cake to the g weight (conversion factor) were based on home recipes. The comments contended that commercially-prepared pound cakes are much less dense than the home-prepared versions. Thus, the conversion factor used in the NFCS was too high. Consequently, the amount customarily consumed for pound cake was overestimated. One comment recommended that if FDA decides not to include pound cake in the light weight category, pound cake should have a separate category with its own reference amount because pound cake differs from other cakes in many characteristics that effect the consumption amount. The comment recommended 45 g as the reference amount for pound cakes as a separate category and submitted data collected by a "mail panel" survey in support of the 45 g reference amount.

FDA disagrees with the comments. The cakes included in the light weight category (e.g., angel food, sponge, and chiffon cake) weighs less than 4 g per cubic inch (density). Commercial pound cakes without icing are much higher in density (about 6.1 g per cubic inch) than the cakes included in the light weight category (Ref. 48). The comment did not present density data to prove that commercial pound cakes weigh less than 4 g per cubic inch. All cakes that weigh more than 4 g per cubic inch, with the exception of those included in the heavy weight cake category, are

included in the medium weight cake category.

With regard to the survey data submitted in support of a separate reference amount of 45 g, FDA notes that in this survey, respondents were asked to record the total number of servings (slices) they usually get from a specific size of pound cake but were not asked how many slices each person in the household ate at a particular eating occasion. People often consume multiple slices at a single eating occasion. In addition, the survey included only frozen pound cake manufactured by the company that submitted the comment. The survey did not include the unfrozen, ready-to-eat forms of pound cake or competitors' products. Therefore, the data submitted in the comment do not represent all forms of pound cake in the marketplace. Therefore, the agency questions the representativeness and appropriateness of the data submitted in the comment and finds that they do not support a change in the reference amount.

FDA has thus concluded that the comments did not submit adequate data to justify the inclusion of pound cake without icing in the light weight category or to establish a separate category for pound cake with a reference amount of 45 g. Accordingly, the agency has retained pound cake without icing in the medium weight cake category.

57. One comment suggested a 90 g reference amount for all cakes.

Considering the large variability in the density of cakes, a uniform reference amount, regardless of the value, would result in a serving size too large for some cakes and too small for other cakes. The 90 g reference amount suggested would make the serving size for a light cake (e.g., angel food cake) a huge piece (e.g., about 1/3 of a 10 oz (about 8 inch diameter) angel food cake), whereas the serving size for a heavy fruit cake would be a small, thin slice.

58. One comment suggested separate reference amounts for cupcakes. 55 g for iced cupcakes and 35 g for un-iced cupcakes. The comment, contended that the NFCS data suggest 55 g as the reference amount for frosted cupcakes and that the 55 g reference amount agrees with the reference amount for other products that are used interchangeably with cupcakes (e.g., muffins, Danish, doughnuts, coffee cakes). One comment requested that FDA establish a reference amount for assorted cupcakes.

FDA advises that the smallest reference amount for cake is 55 g for the light weight cake category. The cakes included in the light weight category

(e.g., angel food, sponge, and chiffon cake) weigh less than 4 g per cubic inch.

The comment did not present density data to prove that cupcakes weigh less than 4 g per cubic inch. All cakes that weigh more than 4 g per cubic inch, with the exception of those included in the heavy weight cake category, are included in the medium weight cake category. The labels of cake mixes that belong to the medium weight cake category (e.g., chocolate, yellow, or white cake) frequently provide preparation directions for a 2-layer cake, a sheet cake, and cupcakes. These label directions suggest that cupcakes are the same cake as a 2-layer or a sheet cake included in the medium weight category but differ only in shape, i.e., cupcakes are an individually shaped form of cake. The act directs the agency to establish uniform serving sizes. Therefore, the same food should have the same reference amount regardless of its shape. Thus, the agency included all cupcakes both with and without icing (including assorted cupcakes) in the medium weight category in this final regulation with the reference amount of 80 g. Accordingly, FDA has not established a separate reference amount for cupcakes.

59. One comment requested that FDA change the reference amount for muffins prepared at home, either from scratch or from a mix, to 45 g. The comment contended that a 45 g reference amount more closely approximates the weight of the muffin made with consumer baking pans.

FDA disagrees with the comment. First, food prepared at home from scratch is not subject to nutrition labeling. Secondly, the agency cannot establish a separate reference amount for the same food depending on the equipment used for preparation (e.g., commercial equipment versus equipment used at home). The reference amount for muffins is based on what consumption data show as the amount customarily consumed. Thus, it complies with the statute. Accordingly, FDA has not adopted this recommendation.

60. One comment, suggested that FDA add microwave cakes to the coffee cake category. The comment stated that because of the characteristics of microwave cooking, microwave cakes have an unusually high density (7 to 7.5 g per cubic inch) and are very rich. According to the density classification, microwave cakes belong to the proposed medium weight category with the reference amount, of 110 g. The comment contended that 110 g is too large for the microwave cakes. The comment, therefore, suggested including

microwave cakes in the coffee cake category.

FDA does not agree that microwave cakes should be grouped with the products in the coffee cake category because microwave cakes are not used interchangeably with the products in the coffee cake category. Microwave cakes are a kind of cake that differs from other cakes only in that they are prepared in the microwave oven rather than in the conventional-type oven. Therefore, microwave cakes belong to a cake category. The agency points out that all cakes other than those classified as heavy weight and light weight are included in the medium weight category in the final regulation. The 7 to 7.5 g per cubic inch density for microwave cakes that the comment reported is within the range of the density of cakes in the medium weight cake category (4 g or more per cubic inch but less than 10 g per cubic inch). The agency notes that the reference amount for this new medium weight category is 80 g, not 110 g. Therefore, the agency has provided the relief that the comment sought, although for different reasons.

(9) Bakery products: crackers, all varieties excluding sweet and sandwich type—includes hard bread sticks and ice cream cones

FDA proposed 15 g as the reference amount for this product category.

61. Several comments argued that it is unfair to have two different reference amounts for competing products (i.e., crackers and snacks) that are used interchangeably. The comments requested that FDA establish a uniform reference amount for snacks and "snack crackers." If not, the comments asserted that a false impression will be created that snack crackers are lower in fat than the competing snack products. Some of these comments pointed out that some products that are more appropriately classified as snacks bear the name cracker (e.g., Cracker Crisps). A manufacturer suggested defining snacker crackers as crackers to which oil has been applied after baking (postbaking oil application).

FDA agrees with the comment that many crackers are used interchangeably with products in the snacks category. The agency acknowledges that it is very difficult to draw a line between cracker and snack products. Therefore, FDA has reexamined the products included in the cracker category and has concluded that it is more reasonable to divide it into two categories: Crackers that are usually not used as snacks and crackers that are usually used as snacks, based on their customary usage, how they are positioned in the marketplace, and the

amount of the cracker that is customarily consumed.

The former category includes saltines, soda crackers, and oyster crackers. These crackers are usually used as part of the meal (e.g., with soup) rather than as snacks. Reanalysis of the data from the 1977-1978 NFCS and the 1987-1988 NFCS showed that the proposed 15-g reference amount is reasonable for crackers that are usually not used as snacks. However, the customarily consumed amount of other crackers is closer to 1 oz than to 0.5 oz. Therefore, the agency has concluded that the cracker category should be divided into two categories with separate reference amounts. Accordingly, FDA has revised the cracker category as follows:

Crackers that are usually used as snacks—
30 g

Crackers that are usually not used as
snacks—15 g

The agency could not use the postbaking oil application suggested in the comment to divide the cracker category into “snack crackers” and “nonsnack crackers” because manufacturers can change the practice of the postbaking oil-application, and therefore, a classification system based on this application could easily become irrelevant.

(10) Bakery products: French toast, pancakes

FDA proposed 110 g as the reference amount for this product category.

62. One comment recommended that FDA combine French toast and pancakes with waffles, with a reference amount of 85 g. The comment contended that these products “make similar contributions to the diet and are customarily consumed in the same way.”

FDA agrees that French toast, Pancakes, and waffles are used interchangeably in the diet. However, because French toast and pancakes are denser than waffles, the amount customarily consumed in g is much larger for French toast and pancakes than for waffles. Food consumption data do not support the 85 g reference amount for French toast and pancakes suggested in the comment (Ref. 2). Therefore, these foods cannot be grouped into one category. Accordingly, FDA has retained reference amounts for French toast and pancakes as proposed.

63. One comment recommended that FDA add a new category for dry pancake mix and variety mixes with a reference amount of 55 g. The comment contended that 55 g is equivalent to the amount of mix required to make three 4-inch pancakes, which is equivalent to the reference amount proposed by FDA.

New § 101.12(c) provides that the reference amount of a product that requires cooking or the addition of water or other ingredients be the amount required to prepare one reference amount of the final product as established in new § 101.12(b). Therefore, the reference amount for dry pancake mix will be the amount of the mix required to make one reference amount of the prepared product, so there is not need to establish a reference amount for dry pancake mix. Moreover, this approach is more reasonable than that suggested by the comment because pancake mixes come both in complete and incomplete forms, and the amount to make one reference amount may differ for the different forms.

Because variety mixes are used for many different purposes, the agency agrees with the comment that a reference amount for the dry form would be desirable so that all variety mixes will have a uniform label serving size to facilitate nutrition comparisons of different brands. Otherwise, different brands may choose different uses as the basis to determine the amount of the dry mix to make one reference amount of the prepared food.

According to the product label, a major use of variety mixes is to make pancakes. Using the recipe file for the 1987-1988 NFCS (Ref. 49), the agency has estimated that about 40 g of dry mix is needed to make one reference amount of the prepared pancakes. Therefore, FDA has established the reference amount for the variety mixes to be 40 g of dry mix. Accordingly, the agency has revised the product category to read: “French toast, pancakes, variety mixes.” The reference amount has been revised to read: “110 g prepared for French toast and pancakes; 40 g of dry mix for variety mixes.”

(11) Bakery products: pies, cobblers, turnovers, other pastries

FDA proposed 125 g as the reference amount for this product category.

64. A comment from a trade association for bakery products supported the proposed reference amount. A few other comments opposed the 125-g reference amount. One comment requested that FDA change the reference amount to 4 oz (110 g) based on the size of 1/6 and 1/8 of pies tested. Another comment argued that the proposed reference amount would result in an extremely large serving size for some pies (e.g., 1/3 of an 8-inch frozen cream pie) and a small serving size for other pies (e.g., 1/10 of a 10-inch fruit pie). The comment recommended that FDA establish three separate reference amounts: 1/6 of a pie for 8 inch pies,

1/8 of a pie for 9-inch or larger pies, and 125 g for individual pies and pastries. The comment submitted estimates of amounts consumed per serving for various pies that it manufactures which were derived from a “Mall Intercept Method” survey conducted in 15 cities in the United States. The survey was designed to recruit people who are representative of the demographic and socioeconomic characteristics of the people who buy the test products based on the sales data for frozen pies.

FDA carefully examined all data submitted in the comments. FDA disagrees with the request to change the reference amount to 4 oz. The data submitted in support of the 4-oz reference amount do not represent food consumption data collected under actual conditions of use or an estimate representative of all types and varieties of products included in the product category.

FDA also disagrees with the comment that contended that reference amounts should be expressed in fractions of pies. The agency used fractions as the reference amount for pie crust because in this particular case, fractions are the most meaningful measure, and there is not much concern about the manipulation of the serving size for the pie crust. Because pies come in different diameters and heights, reference amounts based on fractions of pies would result in different reference amounts for different size pies of the same brand as well as for different brands of the same kind of pie. Therefore, there would be no uniform basis to evaluate the qualification for claims on pies. For example, data submitted in the comment showed that the reference amount based on fractions of pies for one brand alone could vary from 64 to 163 g. Furthermore, reference amounts based on fractions of pies may encourage the manipulation of the reference amount to produce a more favorable presentation of the nutrition information or to qualify for a claim by changing the diameter or height.

The agency, however, agrees that the 125-g reference amount would result in an unreasonably large serving size for frozen cream pies. These commercially prepared frozen cream pies differ from homemade cream pies. Commercial cream pies are aerated and thus weigh much less than homemade cream pies. Therefore, FDA believes that these pies need a separate approach that is more reasonable for aerated cream pies.

As discussed in section III.D.6. of this document, the agency has provided guidelines for determining the reference amount for products that are modified by incorporating air. If the aerated

cream pies mentioned in the comment meet the 25 percent minimum reduction in density relative to the density of the appropriate unaerated cream pie, manufacturers may use the "density-adjusted" reference amount for the aerated cream pie following the guidelines described in section III.D.5. of this document, provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated cream pie (see section III.D.6. for further discussion). Therefore, it is not necessary to establish a separate reference amount for aerated cream pies. Accordingly, FDA has retained the proposed 125-g reference amount for cream pies.

(12) Bakery products: taco shell

FDA proposed 30 g as the reference amount for this product category.

65. A comment from a trade association for bakery products supported the proposed reference amount. Another comment recommended that FDA change the reference amount to 15 g which is equivalent to 1 taco shell. The comment contended that one filled taco shell equals the reference amount for the mixed dishes not measurable with cup category (140 g).

FDA disagrees with the latter comment. The agency points out that according to the USDA manual (Ref., 31), one filled taco weighs about 70 to 80 g., Therefore, two filled tacos would approximate one reference amount for filled tacos. Accordingly, FDA has retained the reference amount as proposed.

(13) Bakery products: waffles

FDA proposed 85 g as this reference amount for the product category.

66. Two comments from a trade association for bakery products and a manufacturer supported the proposed reference amount. One comment from another manufacturer opposed the 85-g reference amount. The comment contended that the 85-g reference amount would make the serving size for some of their waffles three waffles instead of two. The comment recommended that FDA revise the reference amount for waffles to state "85 g, and not to exceed 2 waffles or 2 sets of connected waffles, if their total weight is 67 percent of the reference amount or more." The comment submitted data from a "Mall Intercept Method" survey conducted in 15 cities in the United States to support that people customarily consume 2 waffles or 2 sets of connected waffles. The

comment also requested that FDA allow manufacturers to provide nutrition information per waffle or per 1 set of waffles.

FDA advises that it is inappropriate to call 2 pieces of a product that weigh 67 percent of the reference amount one serving when 3 pieces are equal to one reference amount. In addition, FDA notes that the 85-g reference amount was derived using data from large national food consumption surveys that were collected under actual conditions of use and included all types of waffle products, (dry mixes and frozen) and many different brands available in the marketplace. The agency finds that it would be inappropriate to modify the reference amount to make it consistent with questionable data submitted in the comment.

The data submitted in the comment have several problems. First, they are not food consumption data that were collected under actual conditions of use. People were asked to show the number of waffles that the participants and other members of their families normally eat. People did not answer or record the number of waffles that they actually ate during the survey days. In addition, the survey tested only frozen waffles manufactured by the company that submitted the comment. Waffles come in dry mixes and frozen prepared forms. There are many different brands of waffle products in the marketplace. Therefore, it is questionable if the data submitted in the comment are representative of all waffle products in the marketplace.

Accordingly, FDA has retained the reference amount as proposed. The agency notes that new § 101.9{10}(ii) allows voluntary labeling of a second column of values per unit for products in discrete units.

(14) Beverages: all categories

Because FDA proposed a uniform 240-mL (8-fl oz) reference amount for all beverages, comments on all the categories under Beverages are considered together.

67. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. There were no objections to the 8-fl oz reference amount for carbonated beverages, wine coolers, or water. However, two comments from the carbonated beverage industry stated that if FDA abandons the uniform 8-fl oz, reference amount, they want a 6-fl oz reference amount for carbonated beverages. Comments from coffee and tea manufacturers and their

trade associations opposed the 8-fl oz uniform reference amount. These comments contended that the reference amount for coffee and tea should be 180 mL (6 fl oz.). Among other things, these comments argued that: (1) 6 fl oz is the serving size currently used by the industry, in recipe books and other literature, (2) hot beverages are generally not used interchangeably with cold beverages, and (3) standard coffee cups as well as the graduation on coffee makers and pots are designed for 5 1/2- to 6-fl oz serving sizes. The comments contended that changing the serving size for coffee to 8 fl oz would cause unnecessary costs to manufacturers to change the graduation on the coffee making apparatuses. Such cost increases would be passed on to consumers.

First, FDA advises that new § 101.9(j){4} exempts plain coffee and tea from all requirements of the nutrition labeling regulation. Accordingly, the reference amount for plain coffee and tea has been deleted from Table 2 in new § 101.12(b). As for the reference amount for flavored and sweetened coffee and tea, the agency points out that food consumption data support the 8-fl.oz reference amount for these coffees and teas (Ref. 2). The agency notes/that unlike plain coffee, flavored and sweetened coffee are not made in coffee makers, and thus there is no concern about changing the graduations on the coffee making apparatuses which would increase the cost of coffee. Flavored and sweetened tea (e.g., iced tea mixes) is also used interchangeably with other cold beverages. Considering the weight of support for the uniform 8-fl oz reference amount for all beverages and the reasons stated here, the agency has concluded that the uniform 8-fl oz reference amount for all beverages including flavored and sweetened tea is appropriate under section 403(q)(1)(A)(i) of the act. Accordingly, FDA has retained the reference amount as proposed for all beverages under the beverages category except for plain coffee and tea. The uniform reference amount for all beverages facilitates nutrition comparisons among different beverages.

(15) Cereals and other grain products: breakfast cereals (hot cereal type), hominy grits

FDA proposed 1 cup prepared or 40-g plain dry cereal or 55-g flavored, sweetened dry cereal as the reference amounts for this category.

68. Several comments opposed the proposed reference amounts for the dry cereal form. One comment recommended that FDA change the

reference amount to 1-oz dry because this amount is more consistent with current labeling practices by manufacturers. Another comment recommended a 35-g uniform reference amount for all cereals, including hot and ready-to-eat cereals (and a 50-g reference amount for a second category if a second category is necessary). The comment did not submit any supporting data for the recommended reference amounts. A manufacturer of hot cereals recommended that FDA use a uniform reference amount of 40 g for both regular, and flavored and sweetened cereals. To support the uniform 40-g reference amount, the comment submitted estimates of the dry weight of cereals derived from the mean consumed amounts from the 1987-1988 NFCS for the two types of cereals (regular and quick hot cereals and instant hot cereals) and the conversion factors it used to determine the dry weight from the prepared weight.

Under the act, the serving size must reflect an amount customarily consumed, not the current labeling practices by manufacturers. Therefore, the agency cannot change the reference amount derived from the food consumption data, which represents the customarily consumed amount, to make it consistent with the current labeling practices.

With regard to the comment that recommended a uniform reference amount of 40 g for all hot cereals, FDA carefully examined the data submitted in support of the uniform 40-g reference amount. The data showed that the mean intake for the instant cereal was lower than the mean intake for the regular and quick cereal because many instant cereals come in single-serving packages, and the single-serving packages currently on the market generally contain less than the amount of dry cereal required to make one reference amount (1 cup) of the prepared cereal. Therefore, the mean consumed amount of flavored and sweetened cereals was lower than that of regular and of quick hot cereals.

Basing the reference amount on the data in the comment would result in using two different bases for determining the reference amount for hot cereals: (1) Regular and quick hot cereals would reflect the amount customarily consumed from multiserving containers, and (2), flavored, and sweetened hot cereals would reflect the amount customarily consumed from current single-serving containers. As the comment pointed out, the flavored and sweetened hot cereals currently come in single-serving containers only. However, although the

amount of hot dry cereal customarily consumed may remain the same, the single-serving container size may change, or these products may be available in multiserving containers in the future. Therefore, the agency has concluded that the reference amounts for both varieties of hot dry cereal must reflect the multiserving containers.

FDA's independent analysis, using both the 1977-1978 NFCS and the 1987-1988 NFCS showed that the amount customarily consumed for the plain dry hot cereals is 40 g (Ref. 41). The flavored and sweetened hot cereals, however, contain additional ingredients (e.g., sugar, dried fruit) and, therefore, weigh more than plain dry hot cereals on an "as packaged" basis. Based on the difference in weight of plain dry hot cereal and flavored and sweetened cereal, FDA estimated the difference in weight to be, on the average, about 15 g (Ref. 2). Therefore, the reference amount for flavored and sweetened hot cereals must include the 15-g extra weight to account for the additional ingredients. Accordingly, FDA has retained the reference amount as proposed (55 g). The agency points out, however, that according to new § 101.9(b)(2)(i) and (b)(6), the serving sizes of all single-serving packages of hot cereals will be one package.

(16) Cereals and other grain products: breakfast cereals, ready-to-eat, all categories

FDA proposed three reference amounts for ready-to-eat cereals depending on the density or shape of the cereal: 1 cup for cereals weighing less than 3 oz per cup; 1/2 cup for cereals weighing more than or equal to 3 oz per cup; and 50 g for cereals not measurable with a cup (e.g., biscuit type).

69. Most comments objected to the reference amount in a volumetric (cup) measure because of the lack of precision in the measurement of the g weight of the cup measure. The comments preferred weight-based reference amounts. One comment stated that the volumes of small pieces of dry solids can be accidentally altered or even intentionally manipulated to reach different volumetric measurements. Cereals' shapes, sizes, ingredients, and textures, as well as handling practices, settling characteristics, measurement methods, and timing can affect the accuracy of measurements. The comment contended that measured g weights of the servings by two persons trained to follow identical procedures varied not only for servings from the top to the bottom of the boxes but at

identical levels of different boxes. Overall, the g weights of the individual cup measurements differed by more than two-fold (29 to 68 g). The comment contended that because there are large variabilities in the estimates for g-weight-per-cup measure, the specific g weight measure a manufacturer chooses to declare on the label may be arbitrary and, worse, may be manipulated in order to permit nutrient content claims.

As a solution to the problems discussed above, some comments recommended a uniform weight-based reference amount for all ready-to-eat cereals. Others recommended that the cereals be divided into two categories based on density with separate weight-based reference amounts. For a uniform reference amount, a health professional organization recommended 1 oz, and a cereal manufacturer recommended 35 g. Comments that recommended the two-category system differed in both how the two categories should be split and the reference amounts for the two categories. One comment suggested a 35-g reference amount for all cereals and, if a second category is necessary, 55 g for the second category. The comment did not provide details about what products the second category should include. Another comment recommended a 15-g reference amount for plain puffed cereal grains and a 35 to 40 g reference amount for all other cereals. Two other comments recommended a 30-g reference amount for cereals weighing less than 43-g per cup and for cereals that contain at least 8 g of fiber per oz, and a 55-g reference amount for cereals weighing 43 g or more per cup.

The comments provided a good description of the difficulties in accurately determining the g weight equivalents of the cup measures of ready-to-eat cereals. FDA acknowledges the characteristics of ready-to-eat cereals that present particular problems in determining the g-weight equivalents of household measures. The agency agrees with the comments that volume-based reference amounts present compliance problems and may result in manipulation of the serving size. Therefore, FDA has concluded that the reference amounts for ready-to-eat cereals should be in g quantities.

FDA carefully examined the weight-based reference amounts suggested in the comments. FDA does not believe that a uniform reference amount for all ready-to-eat cereals is appropriate. Regardless of the value, a uniform reference amount would result in serving sizes that are too large for some cereals and too small for others. For example, the 35-g reference amount

suggested in the comment would result in serving sizes that range from about 1/4 cup for heavy cereals (e.g., sweetened granola-type cereals) to about 3 cups for light cereals (plain puffed rice or wheat). These serving sizes are not consistent with the amounts of these types of cereals customarily consumed. Food consumption data showed that customarily consumed amounts for the heavy cereals are about 1/2 cup for the light cereals about 1 cup (Ref. 41).

FDA also carefully examined all reference amounts for the two-category system suggested in the comments. One of the comments submitted a detailed description and results of an analysis of data from the 1987-1988 NFCS to support the 43-g per cup dividing line, with 30- and 55-g reference amounts. FDA has done an independent data analysis of ready-to-eat cereals and confirmed the validity and reasonableness of the reference amounts recommended in the comment for most cereals (Ref. 41).

However, the agency does not believe that the 30-g reference amount is reasonable for light cereals that weigh less than 20-g per cup (e.g., plain puffed rice or wheat). The 30-g reference amount would result in a serving size that is about 2 to 2 1/2 times the customarily consumed amounts of these cereals. Therefore, FDA has divided the category for cereals weighing less than 43 g per cup into 2 categories: Cereals weighing less than 20 g per cups which primarily consist of plain puffed cereal grains, and cereals weighing 20 g or more but less than 43 g per cup. Following the principles and Procedures described in the 1991 serving size proposal, FDA has determined the reference amount for light cereals to be 15 g (Ref. 41).

Accordingly, FDA has revised the product categories, and the reference amounts, for ready-to-eat cereals as follows:

Breakfast cereals, ready-to-eat weighing less than 20 g per cup, (e.g., plain puffed cereal grains)—15 g

Breakfast cereals, ready-to-eat weighing more than 20 g but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g—30 g

Breakfast cereals, ready-to-eat weighing 43 g or more per cup; biscuit types—55 g

70. Other comments on the reference amounts for ready-to-eat cereals included objections to some specific aspects of the methodology used to determine reference amounts. One comment objected to the first step used in determining the product categories (56 FR 60394 at 60403) for cereals. This step divided the cereals into subcategories according to "other characteristics" that are likely to affect

the levels of consumption of foods within the product class, i.e., in this case, the density of the cereals. Other comments objected to relying solely on the 1987-1988 NFCS in determining the reference amount for cereals measurable with a cup. Another comment stated that USDA's density information that FDA used to categorize ready-to-eat cereals differed from the manufacturers' data for at least 11 cereals.

As mentioned above, the amounts customarily consumed for ready-to-eat cereals vary by the density of the cereal. Therefore, the step that divided the cereals into subcategories by density was necessary in order to determine the appropriate amounts customarily consumed for specific types of cereals. As explained in the technical report (Ref. 2), FDA relied solely on the 1987-1988 NFCS because many new cereals have been introduced since the 1977-1978 NFCS, and the 1977-1978 NFCS did not contain food consumption data or density information for the new varieties. Also, density information in the 1977-1978 NFCS was not as useful as that in the 1987-1988 NFCS even for cereals that existed at the time of, or prior to, the 1977-1978 NFCS. Also cereals that differed in density had often been combined into one food code in the 1977-1978 NFCS. In the 1987-1988 NFCS, however, USDA greatly expanded the list of ready-to-eat cereals and their density information. FDA continues to believe that ready-to-eat cereals need to be divided into subcategories, and that it is necessary to rely solely on the 1987-1988 NFCS to estimate the amounts customarily consumed for the cereals currently on the market and to reflect the more recent data on density.

With regard to the discrepancy in measurements of densities of ready-to-eat cereals between USDA and manufacturers' data, the comment did not specify the cereals for which there was a discrepancy, or how large the discrepancies were. USDA's density information is the most current and the best data available to FDA. These density measurements were done without any knowledge about a possible use in nutrition labeling. Therefore, there was no manipulation of the measurements to provide a favorable nutrition profile or to be able to make a claim. In light of the extreme difficulties in measuring the g weights of cup measures and the lack of well-established standard procedures for measuring the g weights of cup measures for ready-to-eat cereals, FDA will use USDA's measurements for compliance purposes to check for proper categorization of ready-to-eat

cereals. USDA's density data can be found in Reference 45.

If a manufacturer does not agree with USDA's density data, the manufacturer can petition FDA for a reevaluation of the density of a particular cereal. The manufacturer should submit density data that includes a detailed description of the methodology used (e.g., materials and equipment used, procedures followed), name and qualification of the operator, records of all individual measurements, the mean and the standard deviation of the measurements, and any other information that may help FDA to evaluate the density of the product in question. Density measurements should be repeated a sufficient number of times to produce a reliable estimate. In determining the density, manufacturers should follow FDA's general Guidelines for Determining the Gram Weight of the Household Measure mentioned in new §101.9(b)(7).

(17) Cereals and other grain products: flours or cornmeal

FDA proposed 30 g as the reference amount for this product category.

71. One comment opposed the 30 g reference amount for bread. The comment contended that their research showed that 55 g (2 oz) of flour is needed to make 2 slices of homemade bread. The comment stated that they used 2 slices as the amount customarily consumed because the 1977-1978 NFCS showed that consumers typically consume 2 slices of bread per eating occasion regardless of the density. Because the primary use of flour is homemade bread, and homemade bread is typically more dense than commercially-made bread, the comment argued that more flour is needed to make 2 slices of homemade bread than 2 slices of commercial bread. The comment did not submit the protocol for the research upon which it relied or data in support of the suggested change in the reference amount.

FDA disagrees with the comment. The agency notes that the comment's assumption that the amount customarily consumed in g is larger for homemade bread than for commercial bread is wrong. Data from the 1977-1978 NFCS and the 1987-1988 NFCS showed that the amount customarily consumed of homemade bread is not greater than 55 g (Ref. 41). The 30-g reference amount is the amount-of flour required to make 55 g of bread. Accordingly, FDA retained the reference amount as proposed.

(18) Cereals and other grain products: grains, e.g., rice, barley, plain

FDA proposed 140 g prepared or 45 g dry as the reference amount for this product category. The agency notes that the product category name in the 1991 serving size proposal (56 FR 60394 at 60418) had a typographical error and included seasoned rice. A correction notice was published on March 6, 1992 (57 FR 8179).

72. Several comments from the rice industry stated that the proposed reference amount was based on the 1977-1978 NFCS data which are outdated. The comments argued that rice consumption patterns have changed since the 1977-1978 NFCS, and that the proposed 140-g reference amount does not reflect the amount of rice customarily consumed today. The comments contended that rice products introduced since the 1977-1978 NFCS (e.g., rice mixes) are customarily consumed in 1/2-cup servings. None of the comments submitted food consumption data to support this claim. One comment pointed out that the 140-g prepared reference amount yields different cup measures for different types of rice, and therefore, the label serving size will differ for different types of rice. The comment contended that rice is easily and conveniently measured with a cup and that a reference amount that is expressed in a volume measure would yield more consistent label serving sizes for different types of rice. The comment recommended 3/4 cup prepared as the reference amount and submitted the g weights per cup measures of different types of rice in support of the 3/4-cup reference amount. A few comments requested that FDA delete the reference amount for the dry form because the customarily consumed amounts are more consistent on a prepared basis among different types and forms of rice.

FDA advises that it used both the 1977-1978 NFCS and the 1987-1988 NFCS to determine the reference amount for plain rice (Ref. 2). In the 1991 serving size proposal, seasoned rice mixes were included in the Mixed dishes measurable with cup category (see further discussion on seasoned rice mixes under the Mixed dishes measurable with cup category).

FDA disagrees that the reference amount for cooked rice should be expressed in cups. Although cup is the household measure most appropriate for expressing the label serving size for rice, its use in defining the reference amount for rice is not desirable for several reasons. First, cooked rice has several unique characteristics that make it

difficult to accurately determine the g weight of the cup measure. For example, cooked rice is not free-flowing, and when cooked, some rice becomes sticky. Secondly, there is no well-established procedure for determining the g weight of the household measure. Therefore, if the reference amount is expressed in cups, the parenthetical metric measure that is used for compliance monitoring would be inaccurate. Thus, the agency has concluded that it is more important to have the reference amount in the most accurate measure possible, i.e., in g. In addition, comments on the 1990 proposal wanted a uniform "standard" serving size (equivalent to the reference amount in the 1991 serving size proposal) for pastas and rice. Changing the reference amount for rice to 3/4 cup would make the reference amounts for these two foods nonuniform. Accordingly, FDA has retained the reference amount of cooked rice as proposed (140 g).

FDA also disagrees that the reference amount for the dry form should be deleted. Because the weight of the cooked rice depends on the amount of water used in the preparation, the amount required to make one reference amount in cooked form can vary widely. The reference amount on a cooked basis also opens a door to a manipulation of the reference amount for dry rice. Therefore, if the reference amount for rice is expressed only on a cooked basis, FDA cannot effectively monitor the compliance. Consequently, the agency rejects this recommendation and has decided to retain the reference amount for the dry form as proposed.

(19) Cereals and other grain products: pastas, without sauce.

FDA proposed 140 g prepared or 55 g dry as the reference amount for the product category.

73. A comment from a trade association for pasta products supported the proposed reference amount. One comment contended that because FDA relied on the 1977-1978 NFCS and the 1987-1988 NFCS, refrigerated filled pastas were not adequately represented. The comment argued that the refrigerated filled pastas (e.g., tortellini, tortellini, and ravioli) were introduced to the market in 1987 and the comment further argued that a study of consumer "habits and attitudes" done by a company showed that people eat smaller portions of meat and cheese filled pastas compared to "cut pasta." Therefore, the comment recommended a 100 g reference amount for filled pasta and claimed that 100 g most closely agrees with the amount customarily consumed of filled pasta. The comment

did not submit the results of the consumer "habits and attitudes" study or data supporting the claim that 100 g represents the amount customarily consumed for filled pasta.

FDA advises that this category includes only plain pastas. Filled pastas contain components from two or more food groups, pasta and filling from another food group (e.g., cheese, meat). Filled pastas are included in the Mixed dishes measurable with cup category (Refs. 2 and 20). Because the refrigerated filled pastas were introduced into the market in 1987, there were more reportings of these products in the 1987-1988 NFCS than in the 1977-1978 NFCS. The 1987-1988 NFCS had a total of 67 individual eating occasions of ravioli and tortellini. The customarily consumed amount was 1 cup or about 200 g without sauce (Ref. 41), not 100 g. Accordingly, FDA has retained filled pasta under the Mixed dishes measurable with cup category, with a reference amount of 1 cup. For clarity, the agency has revised the product category name to read: "Pastas, plain."

74. A few comments stated that the proposed 140 g reference amount is too large for lasagna noodles because lasagna noodles are used only as an ingredient of lasagna. One comment recommended 2 oz prepared as the reference amount for lasagna noodles. The comment contended that 2-oz prepared would be consistent with the amount of lasagna noodles required to make one reference amount of lasagna, but the comment did not explain how it arrived at this amount. Another comment recommended 1-oz dry as the reference amount for lasagna noodles. The comment contended that this amount is reasonable because it is half of the reference amount for the dry form of other pastas in the category.

FDA acknowledges that lasagna noodles have a specific usage, i.e., they are customarily consumed as an ingredient of lasagna. However, other pastas in this category are also used primarily as an ingredient of other foods (e.g., spaghetti noodles in spaghetti, macaroni noodles in macaroni and cheese or macaroni salad). Because neither comment explained or submitted data in support of the recommended reference amount for lasagna noodles, FDA has independently estimated the amount of lasagna noodles that are required to make one reference amount (1 cup) of lasagna. Using the recipe file for the 1987-1988 NFCS (Ref. 49) and the percent yield information reported by USDA (Ref. 18), the agency has estimated that about 3.5-oz prepared or about 1.5-oz dry lasagna noodles are

needed to make 1 cup of lasagna (Ref. 50). These values are considerably larger than the 2 oz prepared and 1 oz dry that were suggested in the comments. The data from the 1977-1978 NFCS and the 1987-1988 NFCS showed that customarily consumed amounts of products in this category vary widely, and the 3.5-oz cooked lasagna is well within one standard deviation of the mean customarily consumed amount (Ref. 41). Considering the large variability in customarily consumed amounts of pastas, the relatively small difference between the amount of lasagna required to make one reference amount of lasagna and the reference amount for the pasta category, and that lasagna is not the only pasta used as an ingredient, the agency has concluded that a separate reference amount specific for lasagna noodles is not warranted. Accordingly, FDA had retained the reference amount as proposed.

(20) Dairy products and substitutes: cheese, grated hard, e.g., Parmesan and Romano

FDA proposed 5 g as the reference amount for this product category.

75. One comment contended that the 5-g reference amount is too small and requested that FDA change it to 1 tbsp. FDA advises that 5 g is equivalent to 1 tbsp. in terms of volume. Accordingly, FDA has retained the reference amount as proposed.

(21) Dairy products and substitutes: eggnog

FDA proposed 120 mL as the reference amount for this product category.

76. One comment requested that FDA change the reference amount to 8 fl oz to make it consistent with the reference amounts for other beverages.

FDA does not believe that a uniform 8-fl oz reference amount is necessary for eggnog. Eggnog differs from other beverages. It usually is not used interchangeably with other beverages. Eggnog is a special type of beverage that is customarily served at special occasions (e.g., holidays and parties) and is customarily consumed in amounts smaller than other beverages, such as soft drinks. Comments on the 1990 proposal supported the 120 mL (4 fl oz) reference amount. Food consumption data did not provide a reasonable basis to increase the reference amount to 8 fl oz. Therefore, FDA has retained the reference amount as proposed.

(22) Dairy products and substitutes: milk, evaporated, undiluted

FDA proposed 15 mL as the reference amount for this product category.

77. Several comments from the dairy industry opposed the proposed reference amount. The comments contended that: (1) Evaporated milk is used interchangeably with condensed milk in recipes, (2) the proposed reference amount reflected the use of evaporated milk in coffee, and (3) evaporated milk is used more often as an ingredient of other foods, and 30 mL is closer than 15 mL to the amount used as an ingredient. The comments requested that FDA change the reference amount to 30 mL. One comment submitted data from a recent survey on the use of evaporated milk involving 2,000 households that showed that about 70 percent of the households surveyed used evaporated milk as an ingredient in recipes as opposed to about 35 percent of the households that used it in coffee. The comment also submitted results from a study done by a manufacturer that showed the amounts of evaporated milk consumed per serving of the recipes most frequently used by consumers.

FDA carefully examined the arguments and data submitted in the comments. The agency agrees that evaporated milk is used primarily as an ingredient of other foods, and that the amount customarily consumed as an ingredient is generally larger than the proposed reference amount. The data submitted in the comment showed that the amount of evaporated milk, as an ingredient, consumed per serving ranged mostly from 20 to 50 mL. The mid-range of these values is 35 mL (about 1 fl oz). Because the major use of evaporated milk is as an ingredient, the agency has concluded that the reference amount for evaporated milk should reflect the amount used as an ingredient. Following the principles in expressing the reference amounts for fluids described in the 1991 serving size proposal (56 FR 60394 at 60406), the agency has determined the reference amount for evaporated milk to be 30 mL. Accordingly, FDA has revised the reference amount to 30 mL.

(23) Dairy products and substitutes: milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa

FDA proposed a uniform 240 mL (8 fl oz) as the reference amount for all beverages.

78. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the

proposed uniform 8-fl oz reference amount for all beverages. A few comments requested that FDA create a separate category for hot cocoa or hot cocoa and cocoa beverages with a reference amount of 6 fl oz. The comments contended that 70 percent of the servings of hot cocoa mix sold are in single-serving envelopes that yield a 6-fl oz serving, and that hot cocoa sold from vending machines also has a 6-fl oz serving.

Cocoa beverages are a type of flavored and sweetened milk beverages. FDA does not believe that it is appropriate to have two different reference amounts for flavored and sweetened milk beverages, one for cocoa beverages and one for other flavored and sweetened milk (e.g., chocolate milk, malted milk). Cocoa beverage mixes are available both in single-serving and multiserving containers. These beverage mixes are consumed both hot or cold and interchangeably with other hot or cold beverages. Food consumption data showed that the amount customarily consumed for cocoa beverages is 8 fl oz (Ref. 41). FDA also notes that the 6-fl oz single-serving envelopes in a multiserving container are single-serving units according to new § 101.9(b)(2)(i). and therefore, the serving size will be one envelope. Considering the weight of the support for the uniform 8-fl oz reference amount for all beverages, food consumption data, and the other reasons stated here, the agency concludes that 8 fl oz is the appropriate reference amount for cocoa beverages under the act. Accordingly, FDA has retained the reference amount as proposed.

(24) Dairy products and substitutes: yogurt

FDA proposed 225 g as the reference amount for this product category.

79. Two comments requested that FDA change the reference amount to 170 g (6 oz). One comment argued that the mean consumed serving from the 1987-1988 NFCS was 6.9 oz. and this value rounded to the nearest container size would be 6 oz. Another comment contended that recent data from a marketing survey on yogurt sales showed that 6 oz rather than 8 oz would be a more appropriate reference amount. The comment stated that on a pound-volume basis, the survey showed that 40 percent of all yogurt was packaged in 6-oz containers or smaller, and approximately 60 percent was packed in 8-oz containers. The comment claimed that when these data were converted to a per serving basis, they showed that 52 percent of yogurt was eaten from 6-oz containers or smaller. The comment did

not submit actual survey data or explain how the 52-percent estimate on a per serving basis was derived.

FDA disagrees with all requests for a change in the reference amount for this category. As for the comment that requested a change based on the mean intake of yogurt from the 1987-1988 NFCS, FDA advises that it is not using the mean alone or a reference amount that is solely based on the 1987-1988 NFCS for the reasons explained in section III.D.1. of this document, unless there is a valid reason for doing so (e.g., trends that are confirmed by another survey that had a high response rate, or information was not available in the 1977-1978 NFCS).

As for the comment that requested a change based on the sales volume of single-serving yogurt containers, FDA notes that sales data are not consumption data and do not necessarily equate to consumption data. For example, some people could have consumed two 4-oz containers of yogurt which makes the consumed amount 8 oz, while the sales data would have counted two 4-oz containers. It is not clear how the comment derived the percent estimates on a serving basis from the sales data. FDA's independent analysis of the sales data from the same source as the comment showed that both on a pound basis and on a serving basis, 8-oz containers were clearly the major container size (Ref. 51). On a pound basis, containers that were 6 oz or smaller accounted for about 21 percent of the total weight, whereas 8-oz containers accounted for about 59 percent. On a serving basis, the respective values were about 27 and 54 percent (Ref. 51). Therefore, the sales data also supported the 8-oz reference amount derived from food consumption data.

Accordingly, FDA has retained the reference amount as proposed.

(25) Desserts: ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones)

FDA proposed 1/2 cup (4 fl oz) as the reference amount for the product category. The reference amount included the volume of coatings and wafers for the novelty type varieties.

80. Several comments recommended that FDA divide this category into two categories, one for bulk products and one for novelties. Some comments agreed with the 1/2-cup (4-fl oz) reference amount for bulk products. A few other comments asserted that the reference amount for bulk products should be larger. One comment suggested 6 oz, and another comment suggested 1 cup. Most comments

recommended a 2.5-fl oz (an average size of 1 novelty) as the reference amount for novelties. The comments contended that novelty type products are consumed by piece, and the serving size should be 1 piece. The comments argued that the proposed reference amount of 4 fl oz would make the serving size 2 bars for some novelties packaged in multiserving containers.

First, FDA notes that food consumption data showed that the customarily consumed amount for novelty-type products was 2.5 oz. When converted to volume, 2.5 oz is equivalent to about 4 fl oz (Ref. 2). Bulk products and novelty-type products are the same type of products in different shapes. Some novelty-type products come without coating or wafers, and thus the bulk-type and the novelty-type differ only in shape. It is inappropriate to have two reference amounts for two forms of the same food that are used interchangeably. If FDA did have two separate reference amounts as suggested in the comments, one for bulk products (e.g., 4 fl oz) and one for novelty-type products (e.g., 2.5 fl oz), nutrition information and the evaluation for the qualification for claims for these two types of products would be based on different amounts. Consequently, although a bulk product might not be able to qualify for a claim, a similar novelty-type product might be able to do so because of the smaller reference amount. This result would be misleading.

Therefore, based on available consumption data, the agency has concluded that a uniform 1/2-cup reference amount is appropriate for both the bulk and the novelty-type products (Ref. 2). The 1/2-cup reference amount is also consistent with the reference amount for other desserts (e.g., custard, pudding, and gelatin desserts), which are often used interchangeably with products in this category as a dessert. The 1/2 cup reference amount is desirable for several other reasons: (1) It is in agreement with most serving sizes in dietary guidance documents, (2) it is consistent with the Canadian serving size guidelines, (3) it is the serving size currently used by many manufacturers, and (4) it was supported by many comments on the 1990 proposal.

The agency notes that new § 101.9(b)(2)(i) allows optional declaration of nutrition information on a single unit basis for products in discrete units that are more than 50 percent but less than 67 percent of the reference amount. Therefore, the serving size for most novelty-type products will be one unit.

For all the above reasons, FDA has retained the reference amount as proposed.

(26) Desserts: custard, gelatin or pudding

FDA proposed 1/2 cup as the reference amount for this product category.

81. Two comments opposed the proposed 1/2-cup reference amount. The comments argued that the powdered mix type of puddings comprised only about 52 percent of the retail food store sales of puddings in 1990. More recently, ready-to-eat puddings have taken the lead in terms of market share and are growing at a faster rate as compared to dry-mix type puddings. The comment stated that the reference amount should reflect the recent sales trend in puddings, or that FDA should establish a separate reference amount of 4 oz for ready-to-eat puddings. The comments contended that ready-to-eat puddings either come in 4 oz single-serving containers or in bulk containers that are multiples of 4 oz. Therefore, the customarily consumed amount of the ready-to-eat puddings is 4 oz. The comments argued that a volumetric measure is appropriate for dry pudding mixes but is inappropriate for ready-to-eat puddings.

FDA recognizes the recent trend in the availability of ready-to-eat puddings. However, the agency is not establishing separate reference amounts for different forms of the same food because the act directs the agency to establish uniform serving sizes. Therefore, it would be inconsistent with the act to have different reference amounts for different forms of the same food that are used interchangeably. The act also relates serving size to the amount of the food customarily consumed, not the form in which the food is sold. The comments did not present any food consumption data to prove that the amount of all forms of puddings customarily consumed is 4 oz, not 1/2 cup. The agency notes that sales data are not consumption data and do not necessarily equate to consumption data.

In addition, the agency points out that direct interpretation of the sales data often result in the wrong conclusion. For example, the comments compared sales data for ready-to-eat puddings and dry-mix type puddings on an as packaged basis. These two types of puddings cannot be compared directly on an as packaged basis because ready-to-eat puddings are in a prepared form whereas dry-mix type puddings are not. Before these two types of products can be compared, they should be on an equal basis in weight, i.e., both types

should be on a prepared basis. FDA's independent analysis of the recent sales data showed that when the two types of products were compared on a prepared basis, dry-mix type puddings are still the major type of puddings in the marketplace, accounting for about 88 percent of the total prepared weight of all types of puddings sold (Ref. 51), as they were when the NFCS's were conducted. The results of this analysis reconfirmed that the 1/2 cup reference amount, which reflects the customarily consumed amount of the dry-mix type puddings, is still valid because the dry-mix type is still the major type of puddings used in the United States.

Finally, the agency notes that according to new § 101.9(b)(2)(i), 4-oz containers of ready-to-eat puddings in the multiserving package are single-serving units, and under that section of the regulations, the serving size for the 4-oz container will be one container, i.e., 4 oz. Accordingly, RDA has retained the reference amount for puddings as proposed (1/2 cup).

(27) Egg and egg substitutes: egg mixture, e.g., egg foo young, scrambled egg, omelet

FDA proposed 110 g as the reference amount for this product category.

82. One comment, contended that the reference amount for this category should be 100 g. The comment argued that it is inappropriate to add the weight of 2 eggs (100 g) and then an arbitrary amount of 10 g for the reference amount of egg mixtures. Another comment stated that the reference amount for an omelet should be related to the number of eggs used per omelet. For example, a "one egg omelet" should have a smaller reference amount than a "two egg omelet."

First, FDA points out that it did not arrive at the proposed reference amount by adding the weight of 2 eggs and then arbitrarily adding 10 g. According to the act, the serving size is an amount customarily consumed. The proposed reference amount represents the customarily consumed amount of the foods belonging to this category determined from food consumption data, following the procedures described in the 1991 serving size proposal (56 FR 60394 at 60403) (Ref. 2). Secondly, the same food cannot have two different reference amounts, one for the egg mixture containing one egg and one for the egg mixture containing two eggs because, under the act, the reference amount is the amount of the food customarily consumed. These mixtures are used interchangeably. Therefore, FDA is establishing the same

reference amount for both. Accordingly, FDA has not adopted these requests.

(28) Fats and oils: butter, margarine, oil, shortening

FDA proposed a uniform 1 tbsp. reference amount for this product category.

83. Comments on this reference amount were split fairly evenly for and against the proposed 1 tbsp. reference amount. Comments from the margarine and oil industry and a few others, including a consumer, supported the 1-tbsp. reference amount. Comments from the dairy industry and others, including a nutrition professional organization, opposed the proposed reference amount. Two comments recommended that FDA change the reference amount to 1 tsp. to be consistent with the serving size in the diabetic exchange list or to be consistent with dietary guidance recommendations which recommend lowering the total fat in the diet.

FDA has examined all arguments for and against the proposed uniform 1-tbsp. reference amount. FDA advises that it cannot change the reference amount to make it consistent with the serving size in the diabetic exchange list because, as explained in the 1991 serving size proposal (56 FR 60394 at 60407) and in section III.B. of this document, the serving size for the diabetic exchange list is designed to meet the needs of a special subgroup of the population having medical problems. It is not intended for the general public. As for the recommendation to change the reference amount to 1 tsp. to be consistent with the dietary guidance recommendations, FDA points out that the serving size on the product label is not the amount recommended for consumption. In section III.D.1. of this document, the agency has explained in detail why the serving sizes in the dietary guidance documents are not appropriate for nutrition labeling purposes. The agency also points out that food consumption data showed that 1 tsp. is not the customarily consumed amount of foods in this category. The amount customarily consumed for most products in this category is 1. tbsp. (Ref. 2). The comments to the 1991 serving size proposal merely reiterated the reasons stated in the comments on the 1990 proposal. No new arguments or data have been presented to persuade the agency to change the proposed uniform 1 tbsp. reference amount. Therefore, FDA finds no basis to change the reference amount, and it has retained the reference amount as proposed.

(29) Fats and oils: dressings for salad

FDA proposed 30 g as the reference amount for this product category.

84. Two comments suggested that FDA change the reference amount to 15 g (equivalent to 1 tbsp.). One comment argued that 30 g is too large and precludes dressings for salads "from claims where they would be considered as good sources of oils that would reduce serum cholesterol."

FDA advises that the serving declared on the product label is by statute an amount customarily consumed. The amount customarily consumed for dressings for salad is 2 tbsp., not 1 tbsp. (Ref. 2). The agency cannot change a reference amount so that certain products can make a claim. Accordingly, FDA has retained the reference amount as proposed.

(30) Fish, shellfish, and meat or poultry substitutes: entrees (cooked) with sauce, e.g., fish with cream sauce, shrimp with lobster sauce

FDA proposed 140 g as the reference amount for this product category.

85. Two comments requested that FDA establish a uniform 85-g reference amount for all fish products with or without sauce. One comment contended that the proposed reference amount of 140 g is too high. The comment did not submit data to support this claim. The other comment contended that it will be difficult to categorize products into two categories, with and without sauce.

FDA advises that the serving declared on the product label is, by statute, an amount customarily consumed. The amount customarily consumed for the products in this category (that is, with sauce) is 140 g, Dot 85 g (Ref. 2). No consumption that would support a different reference amount were presented. The agency notes that it has provided an extensive list of products for each product category to assist manufacturers to locate the product category in which their specific products fit (Ref. 44). Accordingly, FDA retained the reference amount as proposed.

(31) Fish, shellfish, and meat or poultry substitutes: entrees (cooked) without sauce, plain or fried fish and shellfish, fish and shellfish cake

FDA proposed 85 g as the reference amount for this product category. Many comments on the reference amount for this category specifically addressed the reference amount for meat and poultry products FDA has forwarded comments to USDA for consideration in the development of the final regulation for nutrition labeling of meat and

poultry products. The agency is responding to comments that included discussions on the reference amounts of FDA regulated products.

86. Comments from a nutrition professional organization and a nutrition professional supported the proposed 3-oz reference amount. However, FDA received a large number of comments from consumers stating that the 3-oz "serving size" is too small for "meat, poultry, and fish." These consumer comments did not state what the serving size for "meat, poultry, and fish" should be. (Although FDA does not regulate meat and poultry, the comments were responding to a prestructured questionnaire distributed by a consumer organization that discussed the serving sizes of meat, poultry, and fish together. Many other consumer comments that were not recorded on the prestructured questionnaire also stated that the 3-oz serving size is too small for meat and poultry, but they did not mention fish. Thus, the agency is not sure that the comments recorded on the questionnaire apply to the reference amount for fish. Therefore, the agency has presented the food names as they appeared in the questionnaire. Two comments from consumer organizations requested that FDA establish two separate reference amounts for fish and shellfish. They suggested 1.4 or 1.5 oz, for "shrimp" and 4 oz for fish based on the published data for the median consumed amount per eating occasion from the 1977-1978 NFCS. One industry comment requested that FDA create a new category for fish sticks with a reference amount of 70 g. The comment submitted data on the mean, percentiles, and modal consumed amounts from the 1987-1988 NFCS in support of the 70-g reference amount.

FDA has carefully examined all arguments against the 3-oz reference amount and the data submitted in support of the requested changes of the reference amount. FDA believes that comments from consumers indicated a misunderstanding of the meaning and purpose of the serving size on the product label. The serving size on the product label is not the amount recommended as the serving size for any individual. It represents an amount customarily consumed by the U.S. population that manufacturers are to use to present the nutrition information on their products. Therefore, the serving size on the product label may be too small or too large for some individuals. FDA plans to followup the publication of the nutrition labeling regulations with consumer education to assist consumers in using nutrition

information on the label. Consumer education will include information on how nutrition information based on labeled serving size should be adjusted for the individual's own serving size.

As for the request for two separate categories for fish and shellfish, FDA finds that separate categories are inappropriate. As explained in the 1991 serving size proposal (56 FR 60394 at 60403), the agency grouped similar foods to determine reference amounts for product categories, not for specific foods. This grouping allows for product comparisons among similar foods that are likely to be used interchangeably. In determining the reference amount for this product category, fish and shellfish were grouped together because they are used interchangeably as entrees. Two separate reference amounts for fish and shellfish would undermine nutrition comparisons of these products that are used interchangeably in the diet. Although, if determined separately, the amount customarily consumed would be lower for shellfish than for fish (Ref. 41), it is also the case that the 1977-1978 NFCS and the 1987-1988 NFCS showed that about 40 to 50 percent of people consumed 3 oz or more shellfish per eating occasion, the amount of fish consumed per eating occasion by most people (Ref. 47). The two separate reference amounts suggested in the comment (1.5 oz for shellfish and 4 oz for fish) could also give a false message about the nutrient contents of fish and shrimp to the people who consume fish and shellfish in similar amounts. For example, shrimp is known to be high in cholesterol. On the same serving basis, shrimp is about three times as high in cholesterol as most finfish (Ref. 52). However, if shellfish has a serving size that is about one-third of the serving size for finfish as suggested in the comment, there will be little difference in the cholesterol content per serving. This information would be a disservice to the public, particularly to those consumers who have been told by their physician to limit their cholesterol intake. In addition, the agency points out that it is not using a reference amount that is derived solely from the 1977-1978 NFCS for the reasons stated in section III.D.1. of this document.

Therefore, to reduce consumer confusion and to promote uniform serving sizes for nutrition comparisons of products that are used interchangeably, the agency has concluded that fish and shellfish should have the same reference amount.

As for the request for a separate category for fish sticks, FDA advises that a separate category for fish sticks is not justified.

FDA's independent data analysis for fish sticks from the 1977-1978 NFCS and the 1987-1988 NFCS showed that the amount customarily consumed is 85 g, not 70 g (Ref. 41). Also, as discussed in section III.D.1. of this document, unless there is a good reason for relying solely on the 1987-1988 NFCS, FDA has used both the 1977-1988 NFCS and the 1987-1988 NFCS. Data submitted in the comment were based solely on the 1987-1988 NFCS without any explanation.

Having carefully examined all arguments and data submitted in the comments, FDA has concluded that the proposed 85-g reference amount is the amount of fish customarily consumed. Accordingly, the agency has retained the reference amount as proposed.

87. Proposed § 101.12(c) requires that the reference amount of uncooked seafood be the amount required to prepare 85 g of cooked seafood. A seafood trade association stated that they are very concerned that their members will be unable to determine the serving sizes for uncooked seafood needed to produce the reference amount. The comment contended that the amount of uncooked seafood required to make one reference amount is affected by many uncontrollable variables such as methods of cooking (e.g., frying in oil or conventional and microwave cooking) and cooking time. The comment asserted that given these uncertainties, the serving size should be based on an "as packaged" basis for processed foods that require no further preparation other than cooking.

FDA recognizes the variability in cooking methods and time used to prepare seafoods. The agency agrees that this variability makes it difficult to determine the serving size of the uncooked seafood. Therefore, the agency has concluded that it should establish a reference amount for uncooked seafoods except for those fish and shellfish that are allowed to provide nutrition information on a cooked basis in new § 101.9(j)(11) and § 101.45. Using USDA's cooking yield information (Ref. 18), FDA has estimated the reference amount for uncooked fish and shellfish as 110 g (Ref. 53). Accordingly, the description "(cooked)" has been deleted from the product category name and the reference amount has been changed to read: "85 g cooked; 110 g uncooked." A footnote has been added to inform manufacturers that the 119 g uncooked reference amount does not apply to the raw fish and shellfish subject to § 101.45 and packaged single-ingredient fish and shellfish in new § 101.9(j)(11).

(32) Fish, shellfish, and meat or poultry substitutes: fish and shellfish, canned

FDA proposed 85 g as the reference amount for this product category.

88. Two comments opposed the proposed reference amount. One comment from a trade association contended that the category should be divided into subgroups with separate reference amounts: 56 g for canned tuna and bonito and 100 g for canned salmon. The comment contended that these reference amounts are more consistent with the current industry practices and equal to the contents of single-serving containers on the market. A comment from a seafood trade association requested that FDA change the reference amount to 55 g to make it consistent with the reference amount for luncheon meats. The comment submitted data showing that the largest use of tuna is as an ingredient in sandwiches.

FDA advises that it cannot change the reference amount simply to make it consistent with current industry practices or to make it equal to the contents of single-serving containers on the market. The agency's review of the data submitted in the comment showed that the major usage of tuna is as an ingredient in sandwiches. One of the general principles in determining the reference amount in new §101.12(a)(7) states that the reference amount should reflect the major usage of the food. In the United States, more tuna is consumed than other canned fish (Ref. 47), and its major use is as an ingredient in sandwiches. The amount of the sandwich customarily consumed is one sandwich, and about 2 oz tuna (on a drained weight basis) is used to make one sandwich (Ref. 47). Thus, the agency has concluded that the reference amount for canned fish should be changed to 55 g to reflect the use as an ingredient in sandwiches. The 85-g reference amount proposed in the 1991 serving size proposal was based on all uses of tuna and other canned fish, including their use as an entree and for fish salad.

Accordingly, FDA has revised the reference amount to 55 g.

(33) Fish, shellfish, and meat or poultry substitutes: smoked or pickled fish or shellfish

FDA proposed 55 g as the reference amount for this product category.

89. A comment from a seafood trade association stated that smoked/pickled fish are specialty foods consumed as appetizers, not as a "center-of-the-plate item." Therefore, the comment said the reference amount should be closer to the

reference amount for snacks (30 g). The comment did not submit any data to support the 30 g reference amount that it recommended.

FDA advises that food consumption data did not support a 30-g reference amount. The 55-g proposed reference amount reflects the amount customarily consumed for smoked or pickled fish or shellfish (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(34) Fruits and fruit juice; dried

FDA proposed 40 g as the reference amount for this product category.

90. A comment from a Federal agency recommended that FDA change the reference amount to 30 g. The comment contended that the proposed reference amount is too large for some dried fruit (e.g., dried apple rings, dried apricots).

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the amount customarily consumed for the products in this category is 40 g, not 30 g (Ref. 2). The comment did not present any data to support that 30 g better reflects the customarily consumed amounts of products in this category. Accordingly, FDA has retained the reference amount as proposed.

(35) Fruits and fruit juice: fruits used primarily as ingredients, e.g., avocado, cranberries, lemon, lime

FDA proposed 55 g as the reference amount for the product category.

91. One comment from a Federal Government agency opposed the 55 g reference amount. The comment stated that the proposed reference amount is too large, but the comment did not suggest what the reference amount should be. A comment from a trade association for avocados requested that FDA change the reference amount of avocados to 1 oz. The comment contended that USDA's g weight conversions (conversion factors) of small, medium, and large avocados were too high and did not reflect the California avocados which account for over 90 percent of the total U.S. avocado crop. In addition, the percent yield values used to determine the edible portion of avocados in the NFCS were too high. The comment submitted corrected conversion factors from a "National Retail Weight Study" sponsored by a trade association, an extensive list of the updated percent yield values, and results of a reanalysis of the NFCS data using the corrected conversion factors and the updated percent yield values. The data

supported a 1-oz reference amount rather than 2 oz.

FDA carefully examined all of the data submitted in the comment. The results of the "National Retail Weight Study" showed that the conversion factors for small, medium, and large avocados were considerably lower than the values used in the NFCS. The updated percent yield values for 200 avocados of three California avocado varieties were significantly lower than the yield values used in the NFCS. The results of the comment's reanalysis of the 1987-1988 NFCS data using corrected conversion factors, and the updated percent yield values showed that the mean was about 2 oz, the median was about 1 oz, and the primary mode, that which accounted for over 50 percent of the total number of eatings, was 1 oz. The data submitted in the comment clearly showed that the customarily consumed amount is closer to 1 oz than to 2 oz. Because data from the 1987-1988 NFCS showed a decreasing trend in the amount of avocado consumed since the 1977-1978 NFCS, and the trend was confirmed by the CSFII (Ref. 40), the agency is relying on the data from the 1987-1988 NFCS submitted in the comment. Therefore, the agency has concluded that avocados should have a separate category with a reference amount of 30 g. Accordingly, FDA has divided the "Fruits used primarily as ingredients * * *" category into two categories: "Fruits used primarily as ingredients, avocado" with a reference amount of 30 g and "Fruits used primarily as ingredients, others (cranberries, lemon, and lime)" with a reference amount of 55 g as proposed.

(36) Fruits and fruit juice: all other fruits (except those listed as separate categories), fresh, canned or frozen

FDA proposed 140 g as the reference amount for this product category.

92. Several comments from the industry stated that the 140-g reference amount (equivalent to 5 oz) is too large. The comments requested that FDA change the reference amount to the g-equivalent of 1/2 cup.

FDA advises that it cannot use the g-equivalent of the 1/2 cup measure as the reference amount for two reasons: (1) For fruits that can be measured with a cup (e.g., canned or frozen fruits), food consumption data showed that the amount customarily consumed is about 5 oz, not 1/2 cup (Ref. 2), and (2) for the fruits that cannot be measured with a cup (e.g., most fresh fruits), the g-equivalent for the 1/2 cup measure cannot be determined. Food consumption data showed that the amount of fresh fruits is also about 5 oz

(Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(37) Fruits and fruit juice: juice, nectar fruit drinks, or fruit-flavored drinks

FDA proposed 240 mL (8 fl oz) as the reference amount for the product category.

93. Comments from several manufacturers and trade associations (including a juice manufacturer and trade associations for juices) and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. Comments from two other trade associations requested that FDA change the reference amount for juices to 6 fl oz. One comment stated that 6 fl oz is the amount that represents long established industry practice, and that 6 fl oz is a more appropriate reference amount when extended to multiserving containers. The comment submitted no data to support its claims, however. A manufacturer contended that FDA has no authority to manipulate the customarily consumed amount of food in order to standardize the reference amount. The comment argued that FDA's own data from the 1977-1978 NFCS (Ref. 2) indicated that 4 fl oz is the amount customarily consumed, and therefore, FDA must change the reference amount to 4 fl oz. A consumer asserted that 250 mL (8.45 fl oz) is a more appropriate reference amount because most small size juices are sold in 250 mL packs.

The agency notes that data from the 1977-1978 NFCS suggested 6 fl oz (not 4 fl oz as claimed by one comment) to be the customarily consumed amount. The agency notes that the comment that asserted that 4 fl oz is the amount customarily consumed misread the data. Data from the 1977-1978 NFCS had a mean of 6.3 fl oz, the median of 6 fl oz and 3 modes (4 fl oz, 6 fl oz, 8 fl oz.). However, data from the 1987-1988 NFCS suggested that 8 fl oz is the customarily consumed amount for juices. Also, both the 1977-1978 NFCS and the 1987-1988 NFCS showed that 8 fl oz is the customarily consumed amount for fruit juice drinks and fruit-flavored drinks that are used interchangeably with fruit juices. Therefore, the agency has concluded that 8 fl oz is the most reasonable reference amount for all fruit juices and drinks.

As for the consumer comment, the agency advises that food consumption data did not support a 250-mL reference amount. The agency notes that the 250 mL packs of juice are single-serving containers and, therefore, will be labeled as 1 serving.

Considering the weight of support for the uniform 8 fl oz reference amount for all beverages and for the other reasons stated above, the agency has concluded that 8 fl oz is the appropriate reference amount under section 4Q3(q)(1)(A)(i) of the act for all beverages including fruit juices and fruit drinks. The uniform reference amount for all beverages facilitates nutrition comparisons of different beverages. Accordingly, FDA has retained the reference amount as proposed.

(38) Legumes: bean cake (tofu)

FDA proposed 85 g as the reference amount for the product category.

94. A comment from a consumer organization stated that, because the sample size for tofu in the 1977-1978 NFCS was so small (n=12), an accurate estimate of the amount customarily consumed could not be derived from this survey. The comment contended that because tofu is used as a substitute for meat and poultry, the reference amount should be equivalent to the reference amount for meat and poultry.

FDA agrees that the sample size for tofu in the 1977-1978 NFCS was too small to give a reliable estimate of the amount customarily consumed. However, for other reasons explained in section III.D.1. of this document, the agency is not using a reference amount that is based solely on the 1977-1978 NFCS. The 1987-1988 NFCS had a larger sample size for tofu (n=31), and all three statistical values from the 1987-1988 NFCS data that FDA uses in determining the amount customarily consumed (the mean, the median, and the mode) showed that 3 oz is the amount of tofu customarily consumed (Ref. 2). Therefore, the agency has concluded that 3 oz is a reasonable reference amount for tofu. The 3 oz reference amount is the same as the reference amount for fish, shellfish, game meats, and meat or poultry substitutes without sauce regulated by FDA and the reference amount for meat and poultry regulated by USDA. Accordingly, FDA has retained the reference amount as proposed.

(39) Legumes: beans, plain or in sauce

FDA proposed 1/2 cup as the reference amount for the product category.

85. Two comments, from a trade association and a manufacturer, supported the proposed 1/2-cup reference amount. However, the comments requested that FDA change the 1/2 cup reference amount to a g weight. One comment opposed the use of drained weight for plain canned beans. The comment contended that

nutrition information on the canned beans should be based on an as packaged basis, including the liquid.

In light of the difficulty in determining the g weight of the household measure, FDA has concluded in section III.D.2. of this document that volume-based reference amounts should be converted to weight-based reference amounts where a weight-based reference amount is feasible. The agency reexamined foods in this product category and has concluded that the weight-based reference amount can be determined for this category. By taking the average of the g weights per 1/2 cup of cooked plain beans reported by USDA (Ref. 54), the agency has determined that the reference amount for beans that are not canned in liquid or in sauce to be 90 g (Ret. 55).

Regarding the comment that requested nutrition information of canned beans on an as packaged basis, including the liquid, the agency, as discussed in section III.H.2. of this document, has concluded that the nutrition information of canned beans will be based on an as packaged basis including the liquid because a large percentage of people do use the liquid in the canned food. By taking the average of the g weights per 1/2 cup of canned beans including the liquid reported by USDA (Ref. 54), the agency has determined that the reference amount for canned beans, including the liquid, is 130 g (Ref. 55). Also, by taking the average of the g weights per 1/2 cup of beans with sauce (e.g., pork and beans, baked beans) reported by USDA (Ref. 54), the agency has determined that the reference amount for beans in sauce is 130 g (Ref. 55).

Accordingly, FDA has revised the reference amount to read: "130 g for beans in sauce or canned in liquid: 90 g for others."

(40) Miscellaneous category: batter mixes, bread crumbs, meat, poultry, and fish coating mixes, dry

FDA proposed 30 g as the reference amount for this product category.

96. An industry comment, opposed the 30 g reference amount for coating mixes. The comment stated that because of the varying densities of the products and the varying surface areas of the products they coat (e.g., meat and fish), 30 g of coating mix will coat between 3 and 8 oz of meat. The industry suggested including costing mixes with seasoning mixes with a reference amount equal to the amount of the product required to prepare one portion of the end product (e.g., the amount necessary to coat 3 oz of meat or fish).

FDA recognizes that coating mixes vary in density, and that the amount needed to coat the surface areas depends on the type of the mixes and the products they coat. These products are made for use in a specific end dish (e.g., coating mix for fish). Thus, a reference amount that is the amount required to prepare one reference amount of the end product would be more consistent with the amount customarily consumed of coating mixes.

Therefore, the agency has concluded that the reference amount for coating mixes should be changed to the amount to make one reference amount of the final dish as listed in new § 101.12(b). In the case of multiple uses, manufacturers should determine the major use of the coating mix based on food consumption data, marketing survey data on the consumer usage of the product, or in the case of a new product, promoted use, and use that major use to determine the reference amount. The agency agrees that coating mixes should be grouped with seasoning mixes because they are a type of seasoning mixes. Accordingly, FDA has revised the seasoning mixes category to read: "Meat, poultry and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes."

(41) Miscellaneous category: chewing gum

FDA proposed 3 g as the reference amount for the product category.

97. Two comments from the chewing gum industry stated that the reference amount for chewing gum should be one piece because, according to a recent marketing research study, people consume chewing gum piece by piece, not by weight. The comment contended that because chewing gum products vary so widely in the piece size, it is not possible to fix a standard weight that adequately encompasses the serving size. The comment also argued that much of the chewing gum consumed weighs less than 2 g per piece. Another comment argued that a 3 g reference amount is too small because it corresponds to 3/4 stick or 1 7/8 chiclets. The comment requested that FDA change the reference amount to 4 g.

FDA agrees that chewing gums vary widely in the piece size, and that chewing gums are usually consumed by piece. However, the agency cannot use one piece as the reference amount. Some chewing gums come in very small pieces (mini-size chewing gums weighing about 1 g per 10 to 12 pieces), and people usually chew several pieces at a time. Therefore, it is not appropriate

to call one piece of these mini-size chewing gums a serving. The reference amount is needed to determine the serving size of these mini-size chewing gums.

As explained in section III.D.5.a. of this document, for compliance monitoring, the agency also needs a fixed value as the reference amount, not a measure that varies from brand to brand (e.g., piece). The wide variability in the piece size makes the determination of the reference amount difficult. Based on the piece size of the chewing gums commonly available in the Washington, DC metropolitan area, the agency has determined 3 g to be a reasonable reference amount (Ref. 2). The agency acknowledges that there are some chewing gums that weigh less than 2 g per piece. The new lower limit for the single-serving unit in new § 101.9(b)(2)(i), however, will make all chewing gums that weigh more than 1.5 g per piece one serving.

The agency also recognizes that there are many chewing gums that weigh more than 200 percent of the reference amount. Although they weigh more than the upper limit of the single-serving unit, marketing data submitted in the comment show that gums are intended to be single-serving products. Therefore, footnote 9 of Table 2 informs the manufacturer that the serving sizes of all chewing gums that weigh more than 3 g, that can reasonably be consumed at a single-eating occasion, is 1 piece.

As for the comment that recommended the 4-g reference amount, a 4-g reference amount would make the serving sizes of all chewing gums weighing 2 g or less, 2 or more pieces. Chewing gums, with the exception of the mini-size chewing gums, are customarily consumed one piece per eating occasion. In light of the many chewing gums weighing less than 2 g per piece mentioned in the comment, the agency has concluded that a 4 g reference amount is too large. The agency also notes that FDA's measurements showed that commonly available chewing gums weigh about 3 g per stick (Ref. 2).

Accordingly, FDA has retained the 3-g reference amount as proposed.

(42) Miscellaneous category: salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits

FDA proposed 7 g as the reference amount for the product category.

98. One comment opposed the proposed reference amount. The comment recommended that FDA change the reference amount to 5 g (approximately 2 tsp.). The comment contended that a 5-g reference amount

is supported by "consumer-based consumption data" collected by the comment. The comment submitted no data, however, to support this claim.

FDA advises that food consumption data showed that the customarily consumed amount for products in this category is 7 g (Ref. 2). The 7 g reference amount also approximates 1 tbsp., a convenient household measure, and is consistent with the reference amount for croutons that are used as a salad topper. The comment did not submit any data. Thus, there is no basis for the agency to change the reference amount to 5 g. Accordingly, FDA has retained the reference amount for this category as proposed.

(43) Miscellaneous category: salt, salt substitute, seasoning salt (e.g., garlic salt)

FDA proposed 1 g as the reference amount for this product category.

99. One comment agreed with the proposed reference amount because it is in the best interest of the consumers. A comment from a trade association for spice products agreed with the proposed reference amount of 1 g for seasoning salts. However, the comment requested that FDA allow manufacturers to voluntarily declare the sodium content per 1/4 tsp. Another comment objected to the weight-based reference amount. The comment contended that it had developed a low-density salt product that provides a salt taste similar to that of regular salt in a smaller g amount, because the low-density salt is processed to dissolve faster and more completely than the regular salt. Because the low-density salt weighs significantly less than salt, a weight-based reference amount (e.g., 1 g) would result in a serving size of the low-density salt 2 1/2 to 3 times larger than that of salt. Therefore, the comment requested that FDA change the reference amount to a volume-based reference amount (e.g., 1/4 tsp.). The comment did not submit any data to support that regular salt and the low-density salt are consumed equally on a volume basis,

FDA advises that the reference amount for sugar substitutes is "an amount equivalent to one reference amount for sugar in sweetness." Both sugar and salt are used as flavoring agents. People use them to attain the level of sweetness or saltiness that they desire. Therefore, like sugar the reference amount for a salt substitute (e.g., low-density salt) should be the amount necessary to provide a salty taste equivalent to one reference amount of salt. Salt is used both in cooking and at the table. Although regular salt may not completely dissolve when added at

the table, it will dissolve completely when used in cooking. Because, as the name indicates, the low-density salt is lighter than the regular salt, 1/4 tsp. of the low-density salt will contain less salt than 1/4 tsp. of the regular salt. Therefore, when used in cooking, a larger volume of the low-density salt than the regular salt will be required to achieve the same salty taste. Thus, low-density salt and regular salt may not be used on an equal volume basis at least in cooking. Accordingly, the agency rejects the request for a volume-based reference amount.

100. A comment from a consumer organization, stated that the reference amount should be expressed as 1,000 milligrams (mg), instead of 1 g, to be consistent with the sodium content listed in the nutrition information panel. The comment contended that most Americans are unfamiliar with the metric system, so they will not understand; that 1 g is equal to 1,000 mg.

FDA does not agree with the Comment. Whether the reference amount is expressed 1 g or 1,000 mg, the serving size on the product label by statute has to be in a common household measure (e.g., 1/4 tsp.). The nutrition information on the label tells consumers how much sodium is in one serving (1/4 tsp.) of salt. It is not necessary for consumers to know that 1 g equals 1,000 mg to use the nutrition information on the product label. Therefore, the agency has concluded that it is not necessary to change the reference amount to 1,000 mg.

(44) Mixed dishes: measurable with cup, e.g., casserole, hash, macaroni and cheese, pot pie, spaghetti with sauce, stew, etc

FDA proposed 1 cup as the reference amount for the product category.

101. Many comments agreed with the proposed reference amount. One manufacturer agreed with the 1-cup reference amount for mixed dishes that are served as main dishes. However, the comment contended that 1/2 cup is a more appropriate reference amount for mixed dishes that are served as side dishes (e.g., potato dishes, pasta salad, potato salad). The comment contended that, the 1987-1988 NFCS supported, the 1/2-cup reference amount for these products. The comment did not submit data to support this claim.

FDA advises that pasta salad and potato salad have a separate category under Salads with a reference amount of 140 g which is equivalent to about 3/4 cup. Because the comment did not submit data to support the 1/2-cup recommendation, the agency is unable to verify the 1/2-cup reference amount

claimed by the comment for the mixed dishes that belong to this product category. However, the agency notes that both the 1977-1978 NFCS and the 1987-1988 NFCS showed that the customarily consumed amount for products that belong to the "Mixed dishes measurable with cup" category is 1 cup, not 1/2 cup (Ref. 2). The agency recognizes that mixed dishes are used for both a main dish and a side dish. However, FDA rejects the suggestion to establish two different reference amounts for the same type of food for three reasons. First, one of the uses of the reference amount is to determine the appropriateness of nutrient content and health claims made on food products. Such a determination cannot be made for the same food on two or more different bases (i.e., reference amounts), e.g., a smaller reference amount (1/2 cup) to evaluate a claim for a side dish and a larger reference amount (1 cup) to evaluate a similar claim on a similar product labeled as a main dish.

Secondly, there is no assurance that a product labeled as a side dish will not be consumed as a main dish, and vice versa. Thirdly, this suggestion is not in the best interest of the consumers. Two reference amounts for the same type of products will interfere with the goal that there be uniformity among serving sizes declared on similar products by different manufacturers.

In the 1991 serving size proposal (56 FR 60394 at 60402), the agency stated that it would not object to manufacturers providing a second column of nutrition information as a side dish or as a main dish. The agency advises that the second column of information is allowed only if the serving size as a side dish or as a main dish meets the requirement for the second column in new § 101.9(b)(11), i.e., if the serving size for the second column differs from the serving size for the required column by at least two fold. However, the agency wants to make it clear that it will use the appropriate reference amount in new § 101.12(b) to evaluate whether a mixed dish that does not qualify as a meal product or a main dish product as defined in new § 101.13(1) and (m) meets FDA standards for any claim made for the product.

102. Several comments requested that FDA use a weight-based reference amount or include g weight equivalent of 1 cup in the reference amount (e.g., 1 cup (235 g)). One manufacturer suggested a 7.5 oz reference amount. Another manufacturer requested that the same reference amount be used for canned mixed dishes and frozen mixed dishes and suggested a 7.5-oz reference amount.

Although mixed dishes measurable with a cup are consumed in similar quantities by volume (e.g., 1 cup), it is not possible to have one uniform g-weight equivalent reference amount (e.g., 235 g) or weight-based reference amount (e.g., 7.5 oz) because mixed dishes come in many different forms and combinations of ingredients. Therefore, the g-weight-per-cup measure will vary greatly for different dishes. Accordingly FDA has retained the volume-based reference amount.

With regard to the comment that recommended that the same reference amount be used for both canned and frozen mixed dishes, FDA advises that although the reference amounts in new §101.12 (b) are expressed in the prepared ready-to-eat weight, they apply to all forms of the products in the product category: Dry, canned, frozen, refrigerated, and ready-to-eat. Therefore, both canned and frozen (fully-cooked "heat and serve") mixed dishes have the same reference amount. The reference amount for uncooked frozen mixed dishes would be the amount of such a product necessary to prepare one reference amount established in new §101.12(b).

103. A manufacturer requested that FDA use a uniform 6-oz (170 g) reference amount for both mixed dishes measurable with a cup and mixed dishes not measurable with a cup to provide more continuity and consistency in reference amounts for products that qualify as "meal-type" products.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. Both the 1977-1978 NFCS and the 1987-1988 NFCS showed that the amounts customarily consumed for the mixed dishes measurable with a cup and the mixed dishes not measurable with a cup differ considerably (Ref. 2). Therefore, it is not possible to have a uniform reference amount that reflects the amount customarily consumed for the two categories. Accordingly, the agency rejects this request.

104. One comment recommended that FDA delete seasoned flavored rice mixes from this category and include it in the rice category. The comment contended that flavored rice mixes differ from all other products in the mixed dishes category, which all contain two or more components from at least two different food groups. Rice mixes contain only rice and seasoning.

FDA agrees with the comment that many flavored rice mixes are mixtures of rice and seasoning. However, some varieties do contain, two or more components from two or more food

groups. For example, dry spanish rice mix contains rice and tomato. Also, seasoned flavored rice comes both canned and in dry mixes. The canned flavored rice (e.g., canned spanish rice) contains a large amount of tomato.

The agency included seasoned flavored rice mixes in the Mixed dishes measurable with cup category instead of the plain rice category for the following reasons: First, the amount of seasoned flavored rice customarily consumed was generally higher in g than that of plain rice (Ref. 2), and therefore, the 140 g reference amount for the plain rice was not appropriate for seasoned flavored rice.

Secondly, "seasoned flavored rice" includes a diverse variety of rice products. Some are clearly mixed dishes and others are not. Because the customarily consumed amount in volume of seasoned flavored rice (1 cup) was similar to that of other products in the "Mixed dishes measurable with cup" category (1 cup), the agency included all seasoned flavored rice in the "Mixed dishes measurable with cup" category in the proposal.

FDA concludes that seasoned flavored rice fits best in the "Mixed dishes measurable with cup" category because the amount customarily consumed is the same for both of these products. Accordingly, the agency rejects the request.

(45) Mixed dishes: not measurable with cup, e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches

FDA proposed 140 g for pizza and products without sauce and 195 g for products topped, with sauce as the reference amounts for the product category.

105. Some manufacturers contended that unlike other products included in this category that are consumed as a main dish (e.g., burritos, enchiladas, sandwiches, and pizza), pizza rolls and egg rolls are not customarily consumed as the main part of a meal, and thus pizza rolls and egg rolls should not be classified as a mixed dish not measurable with a cup. The comments asserted that these products are designed and promoted as snacks. The comments recommended that FDA either include pizza rolls and egg rolls in the category "Entrees without sauce" or create a separate category for appetizers with a reference amount of 85 g. Another manufacturer agreed with the 5-oz reference amount for pizza as a meal, and they also agreed that the claim evaluation should be based on the 5-oz reference amount. However, the comment requested that FDA establish a

separate reference amount (e.g., 70 g) for presenting the nutrition information when pizza is used as a snack. The comment stated that the manufacturer should have the right to decide if the product is a meal or a snack.

FDA advises that the "Entrees without sauce" category under the major category for Fish, Shellfish, Game Meat, or Meat or Poultry Substitutes includes products whose major ingredients are fish, shellfish, game meat, or meat or poultry substitutes such as plain or fried fish and shellfish, fish and shellfish cake, and meatless hamburger. Pizza rolls and egg rolls do not belong to the "Entrees without sauce" category because the major ingredients of these rolls are not fish, shellfish, game meat, or meat or poultry substitutes. The NFCS included pizza rolls and egg rolls in the same group as pizza which is classified as mixed dishes not measurable with cup in § 101.12(b). Therefore, the agency has concluded that pizza rolls and egg rolls belong to the category of mixed dishes not measurable with cup.

With regard to a separate category for pizza rolls and egg rolls as appetizers, FDA finds no basis to justify a separate category. As explained in the 1991 serving size proposal (56 FR 60394 at 60403), the agency grouped similar foods to determine reference amounts for product categories, not specific foods. This grouping allows for product comparisons among similar foods that are likely to be used interchangeably. The agency included pizza rolls and egg rolls in the category for mixed dishes not measurable with cup because they are frequently used interchangeably with other products in this category as entrees. Although pizza rolls and egg rolls may be promoted as a snack or appetizer, and the amount of these rolls customarily consumed may be smaller than the amount customarily consumed for other products in the mixed dishes not measurable with cup category (e.g., pizza) that are used primarily as an entree, food consumption data show that a large percentage of people consumed 4.5 to 9 oz. (Ref. 47) of pizza rolls or egg rolls per eating occasion, which are amounts that are appropriate for use as an entree, not an appetizer. To promote uniform serving sizes for nutrition comparisons of products that are used interchangeably, FDA has concluded that pizza rolls and egg rolls should have the same reference amount as other products in the mixed dishes not measurable with cup category. Accordingly, FDA rejects this request.

106. A consumer organization contended that the reference amount for pizza should be 7 oz. The comment

stated that the 5-oz reference amount is too small because: (1) The average weight of single-serving pizzas in supermarkets is 6.6 oz, (2) two slices of pizza at a popular pizza restaurant averages 7.3 to 7.4 oz, and (3) a personal pan pizza served at a popular pizza restaurant is 9 oz. The comment also argued that the reference amount for vegetable burgers should be 7 oz because the average weight of hamburgers in fast-food restaurants is 7 oz. The comment contended that the "serving size" should reflect what is commonly consumed at fast food restaurants as well as at home.

FDA advises that all sizes of pizzas mentioned in the comment will be one serving based on the 5-oz reference amount and the single-serving container definition in § 101.9(b)(6). There is no need to change the reference amount which is based on consumption data, not the weight of products on the market (Ref. 2).

As explained in section III.D.5.a. of this document, FDA included the pizza and hamburger consumed at the fast food restaurants in arriving at the 5-oz reference amount. Therefore, there is no need to change the reference amount to reflect the amount, consumed at fast food restaurants.

Accordingly, FDA has retained the reference amount as proposed.

(46) Nuts and seeds: nuts, seeds and mixtures

FDA proposed 40 g as the reference amount for the product category.

107. Many comments were received from the nut industry requesting that FDA change the proposed reference amount to 1 oz or 28 g or 30 g. The comments contended that nuts are used interchangeably with snacks and thus should have the same reference amount as snacks to facilitate nutrition comparisons of different types of snacks. The comments argued that 1 oz is the historical serving size, and airline single-serving packets are less than 1.5 oz. Many of these comments stated that a research study conducted by a consulting firm on the comments' behalf uncovered a series of potential biases built into the protocol for using consumption data for the purposes of determining a reference amount. The comments claimed that many of the g-weight equivalents of cup measures in the NFCS data base used to convert the cup measures of nuts to the g weights were too high. Consequently, the g amounts reported in the NFCS that FDA used to estimate the reference amount for the nut category were overestimated. The comments contended that reanalysis of the NFCS data, using their

own "correct" g-weight equivalents per cup measures, showed that 1 oz is closer to the customarily consumed amount than 1.5 oz. Some comments submitted the g-weight equivalents of cup measures used in the reanalysis and detailed descriptions and data from the reanalysis. Other biases in determining the reference amounts for nuts described in the comments included: (1) FDA's analysis did not include all food codes in the nuts and seeds category, and (2) FDA used mean weights that were between two modal values when one modal value was twice as large as the other.

One comment contended that estimates of nut consumption from the NFCS are not accurate because the amounts consumed were reported in an approximate measure (e.g., cups). To obtain more accurate estimates of the consumption, the comment conducted an independent "in-home usage" survey in 20 cities across the United States, using a diary method in which the respondents recorded the number of nuts that they consumed at each eating occasion. The survey tested four different nuts commonly consumed in the United States and included 568 households. The survey was designed to parallel, as closely as possible, the demographic and socioeconomic characteristics of the nut users in the United States. The comments contended that the results of this survey showed that the amount of nuts customarily consumed is 1 oz, not 1.5 oz. The comment, submitted detailed descriptions of the survey methodology and the methodology for the sample selection and the determination of the number of nuts per oz, and detailed data.

FDA carefully examined all arguments and data submitted in the comments. In the absence of well-established procedures, the agency acknowledges that NFCS data may have inaccuracies, as data from food consumption surveys usually do. The agency also recognizes the difficulties in determining the g-weight equivalents of cup measures of solid foods such as nuts. However, the agency advises that the comments' own reanalysis of the NFCS data using the comments' own estimates of the g-weight equivalents of cup measures did not give any better estimates of the nut consumption. The comments' reanalysis of the NFCS underestimated the nut consumption reported in the NFCS because the technique used to determine the g-weight equivalent of cup measures did not measure a volume of nuts equivalent to 1 cup as defined in new § 101.9(b)(5)(iv), i.e., 240 mL (Ref. 47).

Therefore, FDA cannot use the results of the reanalysis of the 1987-1988 NFCS submitted by the many comments.

However, the agency agrees that the methodology used in the independent "in-home usage" survey (counting the number of nuts) estimated the nut consumption more accurately than the NFCS. The survey also had a much larger sample size (number of individual eating occasions) than the NFCS. The survey's sample size was 8 times as large as that in the 1987-1988 NFCS. The methodology used to determine the number of nuts per oz that was then used to convert the number of nuts consumed to g weight was sound. Data from this survey showed that the amount of nuts customarily consumed is closer to 1 oz than 1.5 oz. Accordingly, FDA has revised the reference amount to 1 oz.

FDA does not agree that FDA's estimate of the customarily consumed amount for nuts was biased because the analysis did not include all food codes in the nuts and seeds category. To facilitate data analysis given severe time constraints, FDA, in some cases, selected foods having a high frequency of consumption to represent the category instead of using all foods appropriate for the category. In response to a similar comment on the 1990 proposal, the agency presented evidence that inclusion or exclusion of infrequently consumed food did not affect the determination of the amount customarily consumed (Ref. 19). In response to the above comment on the 1991 serving size proposal, FDA reanalyzed the data analysis including all food codes for nuts, seeds and mixtures (excluding boiled peanuts which the comment said was inappropriate), and the results showed that the inclusion of all food codes did not make a significant difference (Ref. 41).

With regard to the comment that stated that FDA's estimate of the customarily consumed amount for nuts is inappropriate because it used mean weights that were between two modal values, the agency advises that the comment misinterpreted the way FDA derived the reference amount from the survey data. When the sample sizes were adequate, but the three statistical estimates that represent an amount customarily consumed (mean, median, and mode) did not agree, the agency considered all three values in deciding the reference amount (56 FR 60394 at 60405). Nuts had adequate sample size, but the three values differed. Therefore, the agency considered all three values to determine the reference amount for nuts. When all three values were

considered together, 1.5 oz was determined to be the customarily consumed amount which happened to be closer to the mean value than to either 'of the two modes. The agency did not arbitrarily take the mean weights that were between two modal values.

After a careful examination of all arguments and data submitted in the comments and for the reasons explained above, FDA has concluded that the amount of nuts customarily consumed is 1 oz. Therefore, the agency has revised the reference amount for nuts, to 30 g (equivalent to 1 oz).

(47) Nuts and seeds: nut and seed butter, paste, or cream

FDA proposed 30 g as the reference amount for this product category.

108. A manufacturer pointed out that several new product developments within the peanut butter market, of which FDA was not likely aware during the development of the 1991 serving size proposal, have resulted in a range of product densities among existing products. The comment stated that consumers eat peanut butter according to volume. The comment contended that the weight-based reference amount makes the serving size for whipped butter 3 tbsp., instead of 2 tbsp. Therefore, the proposed weight-based reference amount would severely undermine manufacturers' incentive to produce a peanut butter lower in fat. The comment pointed out that when products within the product category differ widely in density, FDA expressed the reference amount in volume, not in weight. The comment contended that because the densities of different brands of peanut butter differ widely, FDA should express the reference amount for peanut butter in volume, not in weight. The comment, therefore, requested that FDA change the reference amount to a volume-based reference amount (e.g., 2 tbsp.). The comment submitted data showing the differences in the densities of the regular and whipped peanut butter.

FDA acknowledges that it was not aware of the new line of whipped peanut butter during the deliberation of the 1991 serving size proposal. The agency also agrees that it has expressed the reference amount, in volume, not in weight, when the density of the products within the product category vary widely and the amount customarily consumed is more uniform in volume. The agency also acknowledges that commonly used cookbooks show that peanut butter is used by volume (e.g., tbsp. and cups), not by weight (Refs. 43 and 44). Therefore, the agency has concluded that the reference amount for

peanut butter should be changed to a volume-based reference amount to encompass the differing densities of the different brands of peanut butter.

Accordingly, FDA has changed the reference amount for the "Nut and seed butter * * *" category from 30 g to 2 tbsp. (volume equivalent to 30 g). However, manufacturers that make whipped peanut butter must comply with other labeling requirements, for aerated food in new § 101.12(e).

(48) Potatoes and sweet potatoes/yams: French fries, hash browns, skins, or pancake

FDA proposed 70 g as the reference amount for this product category.

109. Two comments stated that French fries come in many different sizes and styles (e.g., shoestrings, thin crinkles, regular crinkles, dinner fries), and that they are prepared in many different ways (e.g., deep fat frying, microwave cooking, skillet frying, conduction oven hearing). The variation in the size and style of the cut and in the preparation method makes it difficult to determine the serving size of frozen French fries because the yield differs for different, sizes, styles, and preparation methods. The comment requested that FDA establish a reference amount of 85 g for the uncooked form of the products. The comment submitted data on the cooking loss for different types of french fries that showed that the weight loss varied from about 15 to 40 percent for different sizes, styles, and quantities cooked.

FDA recognizes that there are many differing sizes, styles, and preparation methods for French fries and agrees that a reference amount for the uncooked frozen product would promote uniformity in the serving sizes of frozen french fries. Based on the average percent cooking yield of 78 percent reported by USDA (Ref. 18), FDA estimated that 89-g frozen French fries would be needed to make the 70 g of prepared French fries that are customarily consumed. The 89-g reference amount approximates 3 oz in a household measure. Therefore, the 85-g reference amount (equivalent to 3 oz) suggested in the comment is reasonable for the uncooked frozen French fries. Accordingly, FDA has revised the reference amount to read: "70 g prepared; 85 g for frozen unprepared French fries."

(49) Potatoes and sweet potatoes/yams: plain, fresh, canned, or frozen

FDA proposed 110 g as the reference amount for this product category.

110. A trade association requested that FDA change the reference amount

to the g weight of 1/2 cup because it is the amount currently used by the industry on canned potato products. The comment also opposed the requirement that the nutrient content be based on the drained weight of the product. The comment contended that nutrition labeling for this product has been traditionally labeled on the contents of the entire container.

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the amount customarily consumed for plain potatoes is 110 g, not the g equivalent of 1/2 cup (90 g drained solids) as recommended in the comment (Ref. 2). Therefore, FDA rejects this request.

Consistent with the agency decision on the nutrition information on an "as packaged" basis for canned beans, potatoes, and vegetables discussed in section III.H.2. of this document, FDA has revised the reference amount for canned potatoes to include the liquid. Using the average yield of 68 percent reported by USDA (Ref. 18), the agency has determined the reference amount for canned potatoes including the liquid, to be 160 g. Accordingly, FDA has revised the reference amount to read: "110 g for fresh or frozen; 160 g for canned in liquid."

(50) Salads: pasta or potato salad

FDA proposed 140 g as the reference amount for the product category.

111. One comment recommended that FDA change the reference amount to a volume-based reference amount. The comment contended that consumers measure these products on a volume basis, and therefore, a volume measure is more consumer friendly than a weight measure. The comment recommended 1/2 cup for the reference amount.

FDA advises that it is not necessary to change the reference amount to a volume-based reference amount to make it consumer friendly. Reference amounts appear only in the Code of Federal Regulations, and consumers usually do not see them. Although the reference amount is in g, the label serving sizes of products in this category will be expressed in cup measures because cup is the common household measure most appropriate for products in this category. Manufacturers should determine the cup measure that most closely approximates 140 g of their product.

112. A few comments claimed that the proposed reference amount is too large. The comments contended that most single-serving containers of these products hold 3.5 oz, and that

manufacturers do not make single-serving containers that hold 5 oz (140 g). One comment claimed that serving scoops measure 3.5 oz. The comments recommended that FDA change the reference amount to 100 g.

The serving size on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the customarily consumed amount of products in this category is 140 g, not 100 g (Ref. 2). Therefore, the agency cannot change the reference amount to make it consistent with the single-serving container size or the serving scoop size. The agency notes that the serving size of a 3.5 oz single-serving container will be the content of the container, not 140 g. However, the 140 g reference amount, not 3.5 oz, will be used to evaluate the qualification of this single-serving container for claims.

(51) Salads: all other salad, e.g., egg, fish, shellfish, bean, fruit, or vegetable salad

FDA proposed 100 g as the reference amount for this product category.

113. One comment requested that FDA expand the salads category to have a separate reference amount for "entree" type salads (e.g., pasta and seafood salad, tuna salad) and to reflect changes in the past decade in the availability and variety of salads in the supermarkets and restaurants. The comment contended that these major changes in salad consumption have occurred since the 1977-1978 NFCS, and therefore, the changes were not reflected in that survey.

FDA advises that it used both the 1977-1978 NFCS and the 1987-1988 NFCS in determining the reference amount for salad proposed in the 1991 serving size proposal. Therefore, by using data from the 1987-1988 NFCS, the changes in the salad consumption practices since the 1977-1978 NFCS were factored into the determination of the reference amounts for salads. The agency also points out that § 101.9(j)(2) find (j)(3) exempt deli foods and restaurant foods (e.g., salad bars). Accordingly, FDA has retained the reference amount as proposed.

(52) Sauces, dips, gravies, and condiments: all categories

FDA grouped these products into five categories with separate reference amounts.

114. One comment stated that some sauces might be more appropriately grouped in different categories. The comment contended that because barbecue sauce and marinade are more similar to catsup than to dips in their usage, they "might" be included in the

major condiments instead of with the hollandaise and tartar sauce. The comment continued that cocktail sauce is used in the same manner as tartar sauce and would more appropriately be grouped with tartar sauce.

Worcestershire sauce might be more appropriately included with major condiments because it is used in a similar manner to steak sauce and soy sauce. The comment did not submit any data to substantiate the suggested regrouping of sauces.

FDA advises that it has classified products in this category according to the similarity in the customarily consumed amounts as reported in the 1977-1978 NFCS and the 1987-1988 NFCS. As explained in section II.D.5.a. of this document, the agency cannot recategorization products merely because someone believes that the products need to be regrouped. Accordingly, FDA rejects this suggestion.

(53) Sauces, dips, gravies, and condiments: barbecue sauce, Hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa), marinade

FDA proposed 2 tbsp. as the reference amount for this product category.

115. Several comments stated that the 2-tbsp. reference amount is too large for marinades. The comments contended that most of the marinade is discarded after use, so the amount consumed is only about 1 tbsp., or less. The comments recommended that FDA include marinade in the "Major condiments" category because the amount of marinade consumed is closer to the reference amount for this category than that of the proposed category.

FDA acknowledges that much of the marinade is discarded after use. There is no good estimate about what percentage of the marinades used is actually consumed, but the amount consumed is certainly less than the amount used. The smaller reference amount for related products is 1 tbsp. Therefore, the agency has concluded that 1 tbsp. is more reasonable for marinades than 2 tbsp. Accordingly, FDA has moved marinades to the "Major condiments" category.

(54) Sauces, dips, gravies, and condiments: major main entrée sauces, e.g., spaghetti sauce

FDA proposed 1/2 cup as the reference amount for this product category.

There was no request for a change in the reference amount for this product category. However, to follow the

document for converting the volume-based reference amount to the weight-based reference amount, the agency has changed the reference amount from 1/2 cup to 125 g (Ref. 55) using the g-weight-per-cup measure for spaghetti and marinara sauce reported by USDA (Ref. 56).

(55) Sauces, dips, gravies, and condiments: minor main entrée sauce (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce) cocktail sauce

FDA proposed 1/4 cup as the reference amount for this product category.

116. One comment stated that the 1/4-cup reference amount seems large, and that a 2-tbsp. reference amount may be more appropriate. The comment also suggested that cocktail sauce is used in the same manner as tartar sauce, so it would be more appropriate to include it in the Barbecue sauce category.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the customarily consumed amount of cocktail sauce is 1/4 cup (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(56) Sauces, dips, gravies, and condiments: major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, etc.

FDA proposed 1 tbsp. as the reference amount for this product category.

117. One comment requested that FDA change the reference amount to 2 tbsp. because it believed that 2 tbsp. is more consistent with the usage of these condiments. The comment submitted no data to support this change in the reference amount.

FDA advises that the 1 tbsp. reference amount was based on the amount customarily consumed of these condiments (Ref. 2). As explained in section III.D.5.a. of this document, the agency cannot change the reference amount because someone believes it is too small. Accordingly, FDA has retained the reference amount as proposed.

(57) Sauces, dips, gravies, and condiments: minor condiments, e.g., horseradish hot sauce, mustard, worcestershire sauce, etc.

FDA proposed 1 tsp. as the reference amount for this product category.

118. One comment argued that 1 tsp. of hot sauce is too large. The comment contended that the average amount consumed is 1/2 tsp. for the regular hot

sauce and 1/4 tsp. for extra hot sauce. The comment did not submit any data to support the suggested reference amounts.

FDA advises that the 1977-1978 NFCS and the 1987-1988 NFCS showed that the amount customarily consumed of hot sauce is about 1 tsp. (Ref. 2). The comment did not submit food consumption data to support that the amounts customarily consumed are 1/2 tsp. for the regular hot sauce and 1/4 tsp. for the extra hot sauce. Accordingly, FDA has retained the reference amount as proposed.

(58) Snacks: all varieties, chips, pretzels, popcorns, extruded snack, fruit-based snacks (e.g., fruit chips), grain-based snack mixes

FDA proposed 30 g as the reference amount for the product category.

119. Many comments from the popcorn industry opposed the weight-based reference amount. The comments stated that popcorn kernels differ in their expansiveness. More expansive hybrid kernels produce a larger volume than less expansive kernels. Therefore, the comments said, the proposed 30-g reference amount would result in different serving sizes in volume (cups) for different brands of popcorns on a popped basis. The comments contended that popcorn typically is consumed by volume rather than weight and requested that FDA establish a separate volume-based reference amount for popcorn. The comments recommended 3 cups popped as the reference amount.

One comment contended that when products within the product category differ widely in density, FDA expressed the reference amount in volume, not in weight. As an example, the comment argued that FDA proposed the reference amount for ready-to-eat breakfast cereals in cups, instead of g. The comment contended that because the densities of different brands of popcorns differ widely, FDA should also express the reference amount for popcorn in volume, not in weight. Some comments claimed that consumers will be confused, when they see different volume serving sizes on different brands that represent the same serving-size because they weigh the same. The comments, did not submit any food consumption data to support their contention that more expansive popcorns and less expansive popcorns are consumed in equal volume on a popped basis, or data to substantiate the claim that the different volume serving sizes on different brands of popcorn would be confusing to consumers.

FDA recognizes that popcorns differ in their expansiveness, and that the

weight-based reference amount would result in different volume serving sizes for different brands of popcorn because the expansiveness of popcorn kernels depends on the variety of corn and its moisture content (Ref. 57). However, the agency advises that it cannot have a volume-based reference amount (cups) for popcorn because the g weight of the cup measure of popcorn cannot be determined accurately. Expansiveness of unpopped corn depends on the popping method (Ref. 57). Many factors such as handling and shipping practices, measurement methods, and timing of measurement can affect the accuracy of the g weight of the cup measure of popped corn. As discussed in sections III.D.5. and III.F.1. of this document, there is no well-established standard procedures for determining the g-weight equivalents of the household measures. This inaccuracy in volume-based reference amount makes compliance monitoring impossible. The agency notes that in light of the difficulty in accurately measuring the g-weight equivalents of the household measures, it has decided to convert volume-based reference amounts to the weight-based reference amount where feasible (see section III.D.2. of this document). As a result, the reference amount for ready-to-eat breakfast cereals in the final regulation is in g, not in cups.

Because none of the comments submitted food consumption data to support their contention that more expansive and less expansive popcorns are consumed in equal volume, the agency is not sure that popcorns having different expansion ratios are consumed in equal volume. Furthermore, the agency points out that popcorns come in many different varieties: Plain, flavored, and carameled with or without nuts. The uniform 3 cup reference amount suggested in the comments may not be applicable to all popcorns. Food consumption data showed that the customarily consumed amount of carameled popcorn is 1 cup (Ref. 41).

As for the comments that claimed that consumers will be confused to see serving sizes that differ in the number of cups on different brands of popcorn, the comments did not submit any data to substantiate this claim. Therefore, the agency is not sure of its validity.

However, the agency recognizes that many consumers may consume popcorn by volume rather than weight. For the benefit of consumers who consume popcorn on a volume basis and would like to know the nutrient contents of different brands of popcorn on an equal volume basis, the agency would not object to manufacturers providing

voluntary labeling of a second column of values on a per cup popped basis (see § 101.9(b)(10)(iii)). This voluntary second column per cup applies only to popcorn and not to other snacks.

For the reasons explained above, the agency has concluded that the weight-based reference amount for popcorn should be retained. Accordingly, FDA has retained the 30-g reference amount as proposed in new § 101.12 (b), Table 2.120. Some comments stated that it is not clear whether the reference amount for popcorn refers to the weight of the kernels before popping or to the weight of the finished product because popcorn is sold both in popped and unpopped form. The comments contended that the reference amount for popcorn should be on a popped basis.

As explained in the preamble (56 FR 60394 at 60407) and in footnote 2 to Tables 1 and 2 in the 1991 serving size proposal, the reference amounts in § 101.12 (b) are for the ready-to-serve or almost ready-to-serve (e.g., heat and serve, brown and serve) form of the product. Therefore, the 30 g reference amount is for the popped popcorn. New § 101.12(c) provides that the reference amount of a product that requires cooking or the addition of water or other ingredients is the amount required to prepare one reference amount of the final product as established in new § 101.12(b). Therefore, the reference amount for the unpopped popcorn would be the amount of unpopped corn that is required to make 30 g popped corn,

121. One comment recommended that FDA change the reference amount for all "bulk snacks measurable by a cup" other than popcorn to 1 cup. The comment claimed that NFCS data showed that the mean consumption of snacks is "38.1 g" which reasonably supports the 1 cup reference amount that it recommended.

As stated above, the serving size on the product label is, by statute, an amount customarily consumed. Food consumption data show that the customarily consumed amount for snacks is 30 g (Ref. 2). The g-weight-per-cup measure reported by USDA (Ref. 31) showed that the g weight of 1 cup of snacks, other than popcorn, that are measurable by a cup vary widely. For example, one cup of cheese balls weighs 35 g, whereas one cup of corn nuts weighs 91 g. Therefore, the 1 cup reference amount suggested in the comment does not reflect the amount customarily consumed of snacks, and FDA rejects this recommendation.

122. A manufacturer of "dried fruit snacks" (pressed dried fruit) stated that each individual piece of the dried fruit

snack comes in 0.5 to 1 oz pieces. The 30-g reference amount would make the serving size of many of these products two pieces. The comment requested that FDA change the reference amount to the "dried fruit snacks" to 0.5 or 0.75 oz. The comment did not submit any food consumption data to support the suggested reference amounts.

The serving size on the product label is, by statute, an amount customarily consumed. Because the 1977-1978 NFCS did not have dried fruit snacks listed, the agency used the 1987-1988 NFCS to determine the amount customarily consumed for all types of pressed dried fruit. The analysis showed that the customarily consumed amount for pressed dried fruit is about 1 oz. not 0.5 or 0.75 oz (Ref. 41). Therefore, FDA rejects the request.

(59) Soups: all varieties

FDA proposed 1 cup as the reference amount for the product categories.

123. A manufacturer requested that FDA define the reference amount for soups in g. The manufacturer contended that a volume-based reference amount will cause an enormous additional laboratory and administrative burden for the manufacturer.

In light of the difficulty in determining the g weight of the household measure, FDA has concluded in section III.D.2. of this document that the volume-based reference amount should be converted to the weight-based reference amount where the weight-based reference amount is feasible.

Because the g-weight-per-cup information is available, and products in this category are relatively uniform in density, the agency has concluded that a weight-based reference amount can be determined for this category. Using the g-weight-per-cup measure reported by USDA (Ref. 58), the agency has determined the average weight per cup for soups to be 245 g (Ref. 55). Accordingly, FDA has revised the reference amount to 245 g.

(60) Sugars and sweets: baking candies (e.g., chips) and hard candies

FDA proposed 15 g as the reference amount for the product category.

124. Several comments from the hard candy industry opposed the uniform 15 g reference amount for all hard candies. The comments stated that the entire package of breath mints or the entire roll of roll candies would be one serving with a 15 g reference amount. The comments contended that some hard candies (e.g., breath mints, hard roll candies) are consumed in much smaller quantities than other hard candies and

should have separate smaller reference amounts.

The comments differed with respect to specific recommendations for the reference amounts. Comments from the breath mint industry stated that breath mints are consumed for the purpose of "freshening" one's breath, not as a candy. Most of these comments recommended one piece as the reference amount for breath mints because breath mints are customarily consumed one piece at a time. One comment stated that a recent consumer survey showed that 60 percent of those surveyed customarily consumed one piece of the breath mint per eating occasion. The comment did not submit any data to support the statement. Another comment recommended that the reference amount should be one piece for hard roll candies and three pieces for "bite-size" hard candies, including breath mints. The comment submitted data from a marketing research survey to support the recommended reference amounts. This survey showed the number of candies that people put in their mouth at a time,

One comment argued that although breath mints and hard candies are often consumed one piece at a time, several pieces are consumed together during what should be considered one eating occasion. Therefore, the reference amount for these candies should not be one piece. The comment did not submit any supporting data.

One comment recommended that FDA divide hard candies into three categories by the piece size and establish a separate reference amount for each size category. Another comment from a manufacturer of hard candies recommended a 4-g reference amount for hard candies that weigh 4 g or less based on the candy consumption data that it collected through an independent "home use test" mail survey. The comment also suggested placing these candies under the Miscellaneous category with baking decorations. The manufacturer submitted detailed descriptions of the survey methodology and demographic and socioeconomic distributions of the survey respondents, the methodology used to determine a piece, weight, and detailed piece weight and consumption data. The survey tested four different "mini candies and mints" that weigh 2.4 g or less per piece. The survey included 1,333 households, covering all 9 U.S. census divisions, that have used the "test candies" or similar candies. The survey was designed to parallel, as closely as possible, the demographic and socioeconomic characteristics of the U.S. population ages 4 and older.

A comment from a Federal agency suggested a 10-g reference amount because it believed that the 15-g reference amount was too large. No data were submitted to support: the suggested 10-g reference amount. A comment from a foreign government recommended that FDA change the reference amount to 30 g. The comment stated that, in the case of baking chocolate, 30 g closely approximates 1-oz squares of baking chocolate and is equivalent to the weight of chocolate chips in 3 to 5 cookies.

FDA recognizes that the hard candy category encompasses a wide variety of hard candies which may differ in amounts customarily consumed. Because the NFCS grouped all hard candies in one food code, the agency was unable to establish separate reference amounts for different types of hard candies. The NFCS showed that the amount customarily consumed for all hard candies was 1/2 oz. Consequently, the agency proposed a 15-g reference amount for the hard candy category.

FDA carefully examined all arguments and data submitted in the comment. With regard to the comments that requested a 1-piece reference amount for breath mints, the comments did not submit any food consumption data to support that 1 piece is the customarily consumed amount. Therefore, FDA has not adopted this request.

With regard, to the comment that requested a 1-piece reference amount for hard roll candies and a 3-piece reference amount for "bite-size" hard candies, the data from the marketing research survey that, were submitted in support: of these reference amounts do not represent the customarily consumed amount. The survey asked how many pieces of the test candies people put in their mouth at a time. The survey, however did not ask how many candies the people wound up eating per eating occasion. To determine the amount consumed per eating occasion, information on the number of candies people put in their mouth at a time and the number of times this process was repeated. Consequently, the data submitted are inappropriate. Therefore, FDA rejects this request.

With regard to the comment that requested dividing hard candies into three categories by the size of the candy and establishing a separate reference amount for each size, the comment did not submit food consumption data to show that the customarily consumed amounts of hard candies by size. In addition, dividing hard candies into three categories by the size of candy can

encourage manipulation of the candy size to fit in a more favorable category. Therefore, FDA rejects this request.

FDA examined carefully the data from the "home use test" mail survey. The data were collected under the actual conditions of use and represented the consumption by the U.S. population 4 years of age or older. The survey had a sample size over 10 times that of the 1977-1978 NFCS and over 40 times that of the 1987-1988 NFCS for the hard candy consumption. The results of this survey supported that the customarily consumed amount is 2 g, for breath mints and 5 g for roll-type hard candies. The survey also showed that the customarily consumed amount of mini-size candies in dispenser-type packages is less than 5-g. Although the survey only tested the comment's own brand, this study is the only food consumption data available to the agency for specific types of hard candies that were collected under actual conditions of use, and the manufacturer is a major producer of the types of candies tested.

Therefore, the agency has concluded that breath mints, roll-type candies, and mini-size candies in dispenser-type packages should have separate reference amounts. Accordingly, FDA has divided hard candies, based on the type of candy, into three categories each with their own reference amount as shown below.

Hard candies, breath mints—2 g
Hard candies, roll-type and mini-size in dispenser-type packages—5 g
Hard candies, others—15 g

With regard to the comment from the Federal agency, the comment did not submit any food consumption data to support the 10-g reference amount. With regard to the comment from the foreign government, the agency also notes that because the reference amount for cookies is 30 g, the reference amount for baking candies (e.g., chocolate chips), which are only part of the cookie, cannot be 30 g. Therefore, FDA rejects these requests.

(61) Sugars and sweets: all other candies

FDA proposed 40 g as the reference amount for this product category.

125. A few comments recommended a 1-oz reference amount. The comment contended that a uniform 1-oz reference amount would allow for fast and accurate nutrition comparisons of different candies.

Food consumption data showed that 40 g (not 1oz) is the amount customarily consumed of candies. (Ref. 2). The agency notes that regardless of what the reference amount is, most candies come in discrete units, and

therefore, the serving size for most candies will be in the number of pieces according to new § 101.9(b)(2)(i). Because the piece size varies for different candies, the serving sizes for candies will differ. Therefore, a uniform 1-oz reference amount is not going to facilitate nutrition comparisons of different candies any better than the 40-g reference amount. Accordingly, based on these factors and the fact that the comment did not present any data to show that the amount customarily consumed is any different than the amount that the agency proposed, FDA has retained the reference amount as proposed.

126. One comment from a manufacturer requested that FDA create a separate category for specialty fine chocolates/pralines with a reference amount of one piece. The comment contended that these specialty fine chocolates/pralines are unique and deserve a separate category because: (1) The proposed reference amount would make the serving size of these candies three to four pieces, yet these candies are individually wrapped and intended and promoted to be consumed one piece at a time, (2) purchasers of these candies do not "customarily consume" three to four pieces at a time, and (3) unlike other candies that come in several sizes, the manufacturer's chocolates/pralines come only in one size. A comment from another manufacturer stated that the 40-g reference amount is too large for "after dinner mints," and that FDA should establish a separate reference amount for "after dinner mints." Two comments from a foreign country stated that the proposed reference amount is too large for fine bonbons. The comments did not suggest what the reference amount for bonbons should be or submit any data to support their claim.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. None of the comments submitted food consumption data that show that the customarily consumed amounts of these candies differ from the proposed reference amount. Therefore, FDA has rejected this request.

(62) Sugars and sweets: confectioner's sugar

FDA proposed 1/4 cup as the reference amount for this product category. The agency notes that the reference amount in the 1991 serving size proposal (56 FR 60394 at 60419) had a typographical error and stated that the reference amount is 2 tbsp. A correction notice was published on March 6, 1992 (57 FR 8179).

No objections have been raised on the proposed reference amount. As discussed in section III.D.2. of this document, the agency has decided to change the volume-based reference amount to the weight-based reference amount where feasible. Accordingly, FDA has changed the 1/4-cup reference amount to the g-weight equivalent to 1/4 cup, i.e., 30 g, using the g-weight-per-cup measure in the USDA Agriculture Handbook (Ref. 57).

(63) Sugars and sweets: honey, jams, jellies, fruit butter, molasses

FDA proposed 1 tbsp. as the reference amount for this product category.

127. A comment from a trade association for jelly and preserves supported the proposed reference amount. Comments from a trade association and a consumer organization requested that FDA change the reference amount to 2 tsp. for honey. One comment contended that the reference amount for honey should be the same as the reference amount for sugar because these products are used interchangeably. In addition, the comment asserted that data from the 1977-1978 NFCS supported the 2-tsp. reference amount for honey because the median consumption was 2 tsp., and the mode was 1 tsp.

FDA acknowledges that honey is used interchangeably with sugar in some foods (e.g., tea). However, honey has many uses. It is also used interchangeably with jam and jelly on toasts and in sandwiches, as shown by the manufacturers' suggested uses on the label. The agency notes that the 1977-1978 NFCS and the 1987-1988 NFCS together reveal that the customarily consumed amount of honey is 1 tbsp., not 2 tsp. (Ref. 2). As explained in section III.D.1. of this document, the agency is not using a reference amount that is based solely on the 1977-1978 NFCS. The agency also notes that the 1977-1978 NFCS showed the mean consumed amount was 3.3 tsp. with two modes (not one as claimed in the comment), one at 1 tsp. and one at 3 tsp. (equivalent to 1 tbsp.). The comments thus have not shown that a separate 2 tsp. reference amount for honey is appropriate. Accordingly, FDA has retained the reference amount as proposed.

128. A manufacturer requested adding "Nutella" to this category. "Nutella," imported from Europe, is a chocolatey spread made from sugar, milk powder, cocoa, pulverized toasted hazelnuts, cocoa butter, and vegetable oil. The company promotes it for use with fruit, crackers, breads, or desserts and asserted that it is used like jams and

jellies and, therefore, should be included in this category with a reference amount of 1 tbsp. The company submitted a home use survey conducted by an independent research group to support its assertion.

Because this product is not a commonly consumed food in the United States, it was not listed in the USDA NFCS, which FDA relied on as the source for information on food consumption practices of the U.S. population. As a result, "Nutella" was not included in the "List of products for each product category" that FDA referenced in the 1991 serving size proposal (Ref. 20). According to the description provided in the comment, the product resembles chocolate syrups used as a dessert topping, except that "Nutella's" consistency is thicker than chocolate syrup. The survey data submitted by the manufacturer showed that the major use of "Nutella" is as a dessert topping with ice cream as opposed to a substitute for jam and jelly with bread. Twenty-seven percent of the 157 respondents surveyed stated that their favorite way of using "Nutella" is with ice cream, whereas only 8 percent named bread. FDA concludes, based on the product characteristics and the usage data provided in the comment, that "Nutella" belongs to the "Other dessert toppings * * *" category under Dessert Toppings and Fillings, not the "Honey, jams, jellies, * * *" category under Sugars and Sweets with a reference amount of 2 tbsp. FDA has revised the product category name for dessert toppings to include the dessert spread. The modified name reads: "Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow * * *" If the company believes that FDA misclassified its product, it can petition FDA to reclassify the product category, but the petition must be accompanied with information specified in § 101.12(h), including food consumption data (the amount customarily consumed) under actual conditions of use.

(64) Sugars and sweets: popsicles, snow cones

FDA proposed 85 g as the reference amount for this product category.

129. Two comments recommended moving popsicles to the frozen dessert category because they are frozen desserts, and they are used interchangeably with products in that category (e.g., ice cream, frozen yogurt, sherbet). The comments differed, however, in the recommended reference amount. One comment recommended a 1/4-cup or 2.5-fl oz reference amount for popsicles because the nutrition

information for these products has been traditionally declared on a volume basis. The other comment recommended a 1/2-cup reference amount, the same as for other frozen desserts in the "Ice cream, ice milk ***" category (the ice cream category).

First, FDA notes that the product category name has been changed to read: "Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)" (referred to as frozen pops for simplicity) (see section III.D.4.b. of this document).

With regard to the placement of these products, in the 1991 serving size proposal, the agency listed the frozen pops under Sugars and Sweets following the categorization system for the NFCS. The agency agrees with the comments that frozen pops are used as a substitute for other frozen desserts, as shown by how they are positioned in the marketplace, and by how they are grouped in common food composition books (Refs. 37 and 59). Therefore, the agency has concluded that frozen pops should be moved to the Desserts category.

With regard to the request for changing to a volume-based reference amount because the nutrition information on these products has been traditionally declared on a volume basis, the agency advises that according to the act, the serving size should be in a common household measure that is appropriate to the product (section 403(q)(1)(A)(i) of the act). Products in the frozen pops category, with the exception of frozen ice, come in discrete units (e.g., bars), and therefore, the serving size will be the number of pieces, not the volume (e.g., fl oz or 1/2 cup) that is customarily consumed. Consequently, under the act, the nutrition information on frozen pops (excluding frozen ice) will be provided on a piece, and not a per fl oz or per cup, basis. Therefore, the comments' arguments do not justify changing the weight-based reference amount to a volume-based reference amount. Unlike the products in the ice cream category, which are difficult to express in weight because they tend to be highly aerated and differ in density, frozen pops are usually not aerated, are high in moisture, and are relatively uniform in density. Thus, the reference amount can be expressed in g. For compliance monitoring purposes, the weight-based reference amount is more effective than the volume-based reference amount. Therefore, the agency has decided to retain the weight-based reference amount for frozen pops.

With regard to the request to change the reference amount to 4 fl oz to make it the same as the reference amount for other frozen desserts, the agency advises that the customarily consumed amount in volume is not the same for the frozen pops and the products in the ice cream category. The 3-oz customarily consumed amount for frozen pops is equivalent to about 2.6 to 2.8 fl oz because of their high density. Consequently, the agency cannot change the reference amount of frozen pops to 4 fl oz to make it the same in volume as the reference amount for the ice cream category.

Accordingly, FDA has retained the reference amount as proposed.

(65) Sugars and sweets: sugar

FDA proposed 8 g as the reference amount for this product category.

130. Two industry comments requested that FDA change the reference amount to 1 tsp. One comment contended that the available food consumption data do not provide a good estimate of the amount of sugar customarily consumed. The comment stated that the concept of an eating occasion is not suited to a serving size determination for sugar because of the multiple uses of sugar that result in its being consumed in several foods at one eating occasion and in multiple servings of food with added sugar (e.g., coffee) as part of that eating occasion. For example, sugar may be added to coffee, cereal, and grapefruit at breakfast. The amount of sugar consumed per eating occasion in this case would be the total amount of sugar added to all three foods. In addition, many people consume multiple servings of coffee per eating occasion, and the sugar consumed in the multiple servings must be summed to arrive at the amount consumed per eating occasion. The comment also pointed out that the 1977-1978 NFCS and the 1987-1988 NFCS assumed a 2-tsp. serving size when the quantity consumed was not provided by the respondent. The comment contended that this assumption contributed to the conclusion that 2 tsp. is the amount customarily consumed. The comment submitted results of its analysis of data from the 1987-1988 NFCS to show the impact that the use of the default serving size and the consumption of multiple servings had on the determination of the customarily consumed amount of sugar. The comment urged FDA to utilize other relevant information in determining the reference amount, such as the 1-tsp. serving size currently used by the industry and in single-serving packets

currently available in grocery stores and restaurants. The comment also contended that: (1) The 1 tsp. serving size has been used by industry for over 12 years, (2) the 1 tsp. serving size is well understood and accepted by consumers, and (3) 1 tsp. is the most convenient and practical measure of sugar.

FDA carefully examined all arguments and data submitted in the comment in support of the 1-tsp. reference amount. FDA acknowledges that because the determination of the serving sizes of foods was not one of the major objectives of the NFCS, data were not collected in a manner to accurately determine all serving sizes, and the NFCS does not accurately reflect the amount of sugar customarily consumed per eating occasion. The agency acknowledges that the amount customarily consumed per eating occasion derived from the NFCS may have been overestimated because the amount of sugar consumed per eating occasion may have included the sugar used in several foods rather than in separate eating occasions. The agency also acknowledges that a major home use of sugar in the United States is to sweeten coffee and tea. The data submitted in the comment showed that a large percentage of people consumed multiple servings of coffee (i.e., 2 or more times the reference amount). The amount of sugar consumed in these multiple servings of coffee would be more than what is used in one reference amount of coffee. Consequently, the amount of sugar customarily consumed in coffee would have been overestimated each time more than 1 cup was consumed.

For the reasons explained above, the agency has concluded that the 2-tsp. customarily consumed amount, derived from the NFCS, is an overestimate of the true customarily consumed amount for sugar. The true customarily consumed amount for sugar is less than 2 tsp. Therefore, the agency has concluded that NFCS data are insufficient to determine the amount customarily consumed for sugar.

As stated in § 101.12(a)(5), when food consumption survey data are insufficient, the agency considered other sources of information including serving sizes recommended in comments and serving sizes used by manufacturers. Because: (1) The next smallest reference amount less than 2 tsp. that corresponds to a common household measure is 1 tsp., (2) 1 tsp. serving size has been used for over 12 years and thus consumers are likely to be familiar with the 1 tsp. serving size, (3) several comments both on the 1990

and the 1991 serving size proposals supported 1 tsp. serving size, and (4) food consumption data did not provide a reasonable basis to change the current industry practice, the agency has concluded that 1 tsp. is the most reasonable reference amount for sugar. Accordingly, FDA has revised the reference amount to 4 g (equivalent to 1 tsp.).

(66) Sugars and sweets: syrups

FDA proposed 60 mL as the reference amount for this product category.

131. An industry comment requested that FDA change the reference amount for light and dark corn syrups to 30 mL. The comment contended that these syrups are used for different purposes than the syrups used on pancakes and waffles. The comment submitted data from a "strategic study" showing that these syrups are used as cooking ingredients rather than poured on pancakes or waffles.

FDA has examined the data submitted in the comment. The agency agrees that the data submitted in the comment show that light and dark corn syrups are used as cooking ingredients rather than poured on pancakes or waffles. Because these syrups are consumed as an ingredient of other foods, NFCS did not have food consumption information for these syrups per se. Using the recipe file for the 1987-1988 NFCS (Ref. 49), the agency has estimated the average amount of these syrups consumed in one reference amount of the final dishes that contain these syrups is about 30 mL. Therefore, the agency has concluded that 30 mL (equivalent to 30 g) is a more reasonable reference amount for light and dark corn syrups than 60 mL (Ref. 50). Accordingly, FDA has revised the reference amount to read: "30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others."

(67) Vegetables primarily used for garnish or flavor, e.g., pimento, chili pepper, green onion, parsley: fresh or canned

FDA proposed 30 g as the reference amount for this product category.

132. One comment contended that pimiento/pimento is a specialty canned food item and is an ingredient that is used only in small quantities to enhance the flavor and color of various dishes. The comment argued that because pimento is never used by itself as a vegetable, the 30-g reference amount is too large for pimentos. A nutrition professional organization stated that the proposed reference amount reflects use as a vegetable, not a garnish or flavor.

FDA has reexamined the reference amount for this category. In the interest of minimizing product categories, in the 1991 serving size proposal, the agency included pimento, chili pepper, green onion, and parsley in one group. Because pimento is used primarily as an ingredient of other foods, and the analysis to determine the amount of pimento customarily consumed is time consuming, the agency did not determine the customarily consumed amount for pimento per se due to time constraints. In response to the comment, FDA has determined the amounts of pimento and parsley customarily consumed. The results of the data analysis supported a smaller reference amount (4 g) for pimento and parsley than for chili pepper or green onion (Ref. 41). Therefore, the agency has concluded that this product category should be divided into two categories: Vegetables primarily used for garnish or flavor, e.g., pimento, parsley with a reference amount of 4 g, and chili pepper, green onion with a reference amount of 30 g. FDA has revised § 101.12(b) accordingly.

(68) Vegetables: all other vegetables without sauce: fresh, canned, or frozen

FDA proposed 85 g as the reference amount for this product category.

133. Comments from two trade associations supported the reference amount. One comment opposed the use of the nutrition information on a drained weight basis. The comment presented data showing that a large percentage of consumers consume the liquid in canned vegetables.

As discussed in section III.H.2. of this document, the agency has decided that nutrition information on canned vegetables should be on an "as packaged" basis including the liquid. The 85-g proposed reference amount represents the amount customarily consumed for the solids only, and therefore, it is still applicable to fresh and frozen vegetables without sauce. To reflect the decision in section III.H.2. of this document, the reference amount for canned vegetables has to be reestimated to include the liquid. Using the information on the percent yield of the drained solids for canned vegetables reported by USDA (Ref. 18), the agency has determined that the amount customarily consumed for canned vegetables including the liquid is as follows: 95 g for vacuum packed vegetables and 130 g for vegetables canned in liquid (Ref. 55).

In the 1991 serving size proposal, pumpkin and winter squash were included in the vegetables with sauce category because although pumpkin and

winter squash do not contain sauce, the customarily consumed amount was closer to the 110 g than the 85-g reference amount. In the final regulation, the agency has grouped pumpkin and winter squash with vegetables canned in liquid under the category of vegetables without sauce because the customarily consumed amounts of these vegetables are similar. In addition, FDA has moved cream-style corn and canned or stewed tomatoes from footnote 5 of Table 2 in the 1991 serving size proposal to the reference amount column in the final regulation because the reference amount for these two vegetables is the same as that for the vegetables canned in liquid, and therefore, the footnote is no longer necessary. The revised reference amount reads: "85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash."

134. One comment recommended that vegetables with pasta and vegetables with rice be included in the vegetable category, not in the Mixed dishes category. The comment contended that the dietary guidance documents recommend 1/2 cup for vegetables, rice, and pasta, so there may be consumer confusion if 1/2 cup is not used for these foods when combined.

Vegetables with pasta and vegetables with rice are neither rice nor pasta nor vegetables. They are clearly mixed dishes because they contain two foods from two different food groups (the grain product group and the vegetable group). The comment did not submit any data to show that, for these products, a serving size other than 1/2 cup would cause consumer confusion.

Accordingly, FDA has rejected this comment.

(69) Vegetables: all other-vegetables with sauce: fresh, canned, or frozen

FDA proposed 110 g as the reference amount for this product category.

135. A comment from a consumer recommended that FDA change the reference amount to 100 g because 100 g is a more rational metric size than 110 g.

FDA advises that for reasons explained in section III.D.1. of this document, it is not changing the reference amount to make it more rational in metric quantity. Accordingly, FDA has retained the reference amount as proposed.

(70) Vegetables: vegetable juice

FDA proposed a uniform 240-mL (8 fl oz) reference amount for this product category.

136. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed, uniform 8-fl oz reference amount for all beverages. One comment from a manufacturer requested that FDA establish a separate category for vegetable juice with a reference amount of 6 fl. Oz.

Considering the weight of support for the uniform 8-fl oz reference amount for all beverages and the benefit of the uniform reference amount that facilitates nutrition comparisons of different beverages, the agency has decided to retain the uniform 8-fl oz reference amount for all beverages, including vegetable juice. Vegetable juice is frequently used interchangeably with fruit juice and other beverages. Food consumption data also did not show that the customarily consumed amount for vegetable juice differs from that of fruit juice or of many other beverages (Ref. 2). The comment did not submit data that would support a different result. Accordingly, FDA has retained the reference amount as proposed.

(71) Vegetables: olives

FDA proposed 15 g as the reference amount for this product category.

137. One comment requested that FDA change the reference amount to 30 g. The comment contended that 30 g is the serving size that is currently used on packaging, and because pickles and olives have similar consumer usage patterns, the reference amount for olives should be the same as the reference amount for pickles.

FDA disagrees with the comment. The agency advises that the serving size on the product label is, by statute, an amount customarily consumed. Both the 1977-1978 NFCS and the 1987-1988 NFCS showed that the customarily consumed amount of olives is closer to 0.5 oz, not 1 oz. The comment did not present any data to show that 0.5 oz is not the customarily consumed amount. Accordingly, FDA has retained the reference amount as proposed.

6. Reference amounts for imitation or substitute food, altered food, and foods for special dietary use

To prevent the manipulation of serving sizes for nutrient content claims, FDA proposed in § 101.12(d) that the reference amount for an imitation or substitute food be the same as that of the food for which it is offered as a substitute. In addition, the agency proposed in §101.12(e) that the reference amount for an altered version of a food such as a "low calorie"

version, be the same as for the food for which it is offered as a substitute.

FDA received about a dozen comments on this proposal from manufacturers, trade associations, and professional organizations. About one third of the comments supported the proposal. The rest of the comments opposed it.

138. Comments opposing the proposal stated that one way that industry is reducing the fat and calorie content of foods is through a new technology that incorporates air into the product (referred to as "aerated, food" for simplicity). Many aerated foods weigh significantly less than their regular counterparts. Comments stated that there is no concern when the reference amount is established in volume, but that there is "a concern when a weight" based reference amount is used. For example, using a reference amount of 85 g for waffles, 3 aerated waffles would be compared to 2 regular waffles of the same size and shape. Therefore, the calorie and fat content of the aerated food would not be lower than that of the regular food when compared on an equal weight basis. Manufacturers would thus be unable to use a nutrient content claim for the aerated foods.

These comments argued that the proposal would diminish manufacturers' incentive to develop "nutritionally improved" foods and prevent consumers from benefiting from low fat, low calorie alternatives. The comments suggested that when the reference amount is determined by weight, FDA should allow the manufacturers to use "the volume measure (e.g., common household volumetric or dimensional measure or number of discrete units) equivalent to the volume measure of the manufacturer's regular product pursuant to the reference amount," e.g., 2 waffles for both the aerated and the regular food.

FDA has given careful consideration to all arguments and suggestions presented in these comments. Although the comments claimed that the amount customarily consumed for the regular and the aerated food is the same in volume, not in weight, no food consumption data were presented with the comments or are available from other sources to verify the claim. It is possible that people eat three aerated waffles, instead of two, to attain satiety. Therefore, FDA is not certain that the amount customarily consumed for the aerated foods and their regular counterpart is the same in volume.

At the same time, in light of the current dietary guidelines for reducing fat and calorie intakes (Refs. 60 through

62), FDA acknowledges that it is desirable to have a wide selection of low fat and low calorie foods available to consumers. Some consumers may benefit from having such aerated foods if they consume an equivalent volume of aerated food as they would have the regular food, e.g., two instead of three aerated waffles. However, FDA does not believe that the solution suggested in the comments is appropriate or desirable considering the wide variability in the unit size and shape of the regular products in discrete units. This variability would make it difficult to determine a reference point, i.e., volume equivalent to the reference amount of the regular counterpart.

FDA finds that the most reasonable solution to this problem is to allow the manufacturers to determine the reference amount in g for the aerated food by adjusting for the difference in density of the aerated food relative to the density of the regular counterpart (density-adjusted reference amount). For example, if the density of the aerated food is 30 percent lower than the density of the regular counterpart, the reference amount for the aerated food would be 30 percent less than the reference amount of the regular counterpart. For example, the reference amount for regular waffles is 85 g, so the reference amount for aerated waffles, which are 30 percent lower in density, would be 60 g. A manufacturer may use the density-adjusted reference amount to determine the label serving size and the qualification of the aerated, food for nutrient content and health claims, provided that, upon request, the manufacturer will show FDA the detailed protocol and records of data described below. FDA will consider regulatory action under sections 402(b) and 403 of the act on any misuse of this allowance.

Such density-adjusted reference amounts may not be done for cakes. Although the product categories for cakes in the final regulation are identified by types of cakes, not by density, the three cake categories in Table 2 in, new § 101.12(b) were determined according to the density of various cakes. FDA took the differences in the densities of different types of cakes having different degrees of air incorporation into consideration in determining the reference amounts for cakes. Therefore, further adjustment of the reference amounts for aeration is not permissible for cakes.

For the aerated food to qualify to use the density-adjusted reference amount, the product must be sufficiently lower in density than the regular counterpart. The agency finds that a 25-percent

reduction in density is a reasonable cutoff level for this purpose. The 25-percent minimum reduction is consistent with the minimum percent reduction requirement to qualify for a "less" or "reduced" claim in the regulation entitled "Food Labeling; Nutrient's Content Claims, General Principles, Petitions, Definition of Terms" (hereinafter referred to as the nutrient content claims regulation), published elsewhere in this issue of the **Federal Register**. In estimating the difference in density, manufacturers must use an appropriate reference food as described in new § 101.13(j)(ii)(A) of the nutrient content claims regulation, published elsewhere in this issue of the **Federal Register**, for the regular counterpart.

In expressing the weight-based reference amounts for the regular foods in new § 101.12(b), FDA rounded the values to the nearest 5-g increment to avoid the appearance of an overly exact g-weight. Under § 101.12(e), this procedure must also be followed in determining the reference amount for the aerated food. Manufacturers must use the rounded density-adjusted reference amount to determine the serving size and whether the aerated food qualifies for a claim. The table below shows an example of the calculated density-adjusted reference amount and the corresponding rounded reference amount to be used for aerated waffles that have been reduced in density by 25 to 35 percent. As the table shows, aerated waffles with density reductions of 27 to 32 percent must use 60 g, not 58 to 62 g, as the reference amount.

Reference Amount for the Regular Waffle: 85 g

Percent reduction in density	Calculated Density-adjusted reference amount	Reference amount for "aerated" food
(%)	(g)	(g)
25	64	65
26	63	65
27	62	60
28	61	60
29	60	60
30	60	60
31	59	60
32	58	60
33	57	55
34	56	55
35	55	55

To use a density-adjusted reference amount, manufacturers must have the following available for inspection by protocol and records of all raw data and calculations used to determine densities of both the regular and the aerated products; (2) records of the sample size,

the mean, and the standard deviation for the density measurements of the regular and the aerated products; and (3) records of all data, calculations, and procedures used to arrive at the "density-adjusted" reference amount for the aerated product. The protocol must contain identification and descriptions of all materials used (e.g., equipment) to determine the density. In determining the differences in the densities of the regular and the aerated products, manufacturers must also observe the following: (1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (e.g., waffles), manufacturers must use a device or method that ensures that the volumes of the regular and aerated products are the same. One way to ensure the same volume is to use the same equipment to make the regular and the aerated products; (2) sample selections for the density measurements must be done in accordance with the provisions in § 101.9(g); (3) density measurements of the regular and the aerated products must be conducted by the same trained operator using the same methodology (e.g., the same equipment, procedures, and techniques) under the same conditions; and (4) density measurements must be replicated a sufficient number of times to ensure that the average of the measurements is representative of the true differences in the densities of the regular and the aerated products.

Manufacturers must use a descriptive term such as "whipped" or "aerated" as part of the product name (e.g., whipped peanut butter, aerated waffle) so that consumers are properly informed that extra air has been incorporated into the product. The use of this term is necessary, under section 201(n) and 403(a) of the act, to disclose a material fact.

To incorporate the labeling requirements for aerated foods, FDA has combined § 101.12(d) and (e), redesignated as § 101.12 (d), and added the requirements for aerated products in § 101.12(e).

139. A manufacturer of medical foods stated that several aspects of the serving size regulation (e.g., expressing the serving size in the common household measure) are not accurate enough for medical foods.

FDA advises that the serving size regulations do not apply to medical foods because section 403(q)(5)(A)(iv) of the act exempts medical foods from all requirements of nutrition labeling. The agency intends to develop regulations for proper labeling and uses of medical

foods in a future **Federal Register** document.

7. Reference amounts for products consisting of 2 or more foods having individual reference amounts

FDA proposed in § 101.12(f) that the reference amount for products packaged and presented to be consumed together (e.g., peanut butter and jelly combination, cracker and cheese pack, pancakes and syrup pack) be the sum of the reference amounts for the individual foods in the package.

140. FDA received only a few comments on this aspect of the proposal. Comments from nutrition professional organizations agreed with the proposal. A consumer organization disagreed with the proposal and stated that the proposal is reasonable only for foods that are not packaged in single-serve containers such as peanut butter and jelly. The comment contended that for foods in single-serve containers (e.g., cheese-and-cracker snack trays, yogurt and granola, pancakes and sausage, waffles and fruit sauce, spaghetti and tomato sauce, macaroni and cheese, or rice with vegetables), the reference amount should be based on the weight of the entire package.

First of all, FDA wishes to clarify that the proposal applies to the products that contain two or more foods having individual reference amounts that are not listed in proposed § 101.12(b). Although this fact was mentioned in the preamble (56 FR 60394 at 60407), FDA did not state it in the codified language in proposed § 101.12(f). To clarify its intent, FDA has revised § 101.12(f) to read:

The reference amount for products that represent two or more foods packaged and presented to be consumed together * * * shall be the sum of the reference amounts for individual foods in the package if the reference amount for the product is not listed in paragraph (b) of this section.

Some of the examples mentioned in the comment (spaghetti and tomato sauce, macaroni and cheese, rice with vegetables) are mixed dishes measurable with a cup that have reference amounts in new § 101.12(b). As explained previously, FDA does not believe that it

is consistent with the act to have different reference amounts for the same product in different package sizes, one for single-serving packages and one for multiserving packages. The reference amount for the same product must be the same regardless of the package size.

In addition, the agency points out that the package of yogurt and granola is one food. It simply is another variety of flavored yogurt. Like frozen entrees in pouches, yogurt and granola are

packaged in separate containers for technical reasons (e.g., better preservation of the texture), but they are combined before consumption and eaten as one food. The reference amount for yogurt and granola is 225 g, the same as for other yogurts.

141. An industry comment stated that the reference amount is not necessary for "meal-type" products because claims on these products will be evaluated on a per 100 g basis.

The agency disagrees with the comment. Reference amounts are also used to determine the label serving sizes of specific products for presenting nutrition information. Many "meal-type" products (reclassified and redefined as "meal product" and "main dish product" in the final nutrient content claims regulation published elsewhere in this issue of the **Federal Register**) (e.g., lasagna, pizza) are available both in single-serving and multiserving containers. Reference amounts provide a basis on which to determine the label serving sizes of these products in multiserving containers and whether these products are qualified to be called single-serving.

142. A consumer organization requested that FDA establish reference amounts for "frozen meals" (e.g., breakfast, lunch, or dinner trays) based on the average weight of the products in the marketplace or on the "industry-wide average."

The agency notes that the "frozen meals" mentioned in the comment currently come only in containers clearly intended for a single serving, and therefore, the nutrition information for these products will be based on the entire content of the package. The agency also notes that the reference amount is not needed to evaluate whether these products are qualified for claims because the qualification for claims on these products will be based on 100 g of the product and not on the reference amount as discussed in the final nutrient content claims regulation published elsewhere in this issue of the **Federal Register**. If a reference amount is needed for "frozen meals," new § 101.12 (f) can be used to determine the reference amount for specific frozen meals. Breakfast, lunch, or dinner trays contain two or more distinct products which have reference amounts in new § 101.12 (b). According to new § 101.12 (f), the reference amounts of these products are the sum of the reference amounts of the individual foods in the tray. For example, the reference amount of a dinner tray containing fish, trench fries, and mixed vegetables will be the sum of the reference amounts of fish (85 g), French

fries (70 g if cooked), and mixed vegetables (85 g), i.e., 240 g. Therefore, there is no need to establish separate reference amounts for these "frozen meals."

8. Miscellaneous issues related to reference amounts

143. Some industry comments stated that restaurants should be permitted to declare nutrition information according to their own specifications for serving size.

Restaurant foods are not required to bear nutrition labeling. However, when nutrient content or health claims are made for restaurant foods, the restaurateur must provide nutrition information in compliance with the nutrient content or health claims regulations published elsewhere in this issue of the **Federal Register**. Meals, entrees, or other menu items served in restaurants are analogous to single-serving products. Therefore, in most cases, the restaurateur must have a reasonable basis for believing, based on the amount served, that the food qualifies for the claim. However, if nutrient content claims are made relative to a competitor's product, it is important that like amounts be compared.

144. A trade association recommended that FDA allow manufacturers to deviate from the reference amounts if such deviation is supported by food consumption data.

The act requires that FDA establish standards providing that uniform serving sizes information will be furnished on the food label (H. Rept. 101-538, supra, 7). The reference amounts are part of the standards. Manufacturers cannot deviate from the reference amount simply because they believe that such deviation is supported by food consumption data. If the uniformity expected by Congress is to be maintained, the information on the need for revised or separate reference amounts must be evaluated by FDA through the petition process that it has established in new § 101.12(h) before changes in or deviations from the reference amount can occur.

E. Procedures for Converting the Reference Amount to Serving Size

For the purpose of converting the reference amounts for multiserving products into label serving sizes, FDA grouped these products into three categories according to the shape and characteristics of products and the way products are usually served. The three categories were: (1) Products in discrete individual units (e.g., muffin, sliced bread, apple), (2) products in large

discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), and (3) nondiscrete bulk products (e.g., breakfast cereals, flour, sugar). The agency proposed separate procedures for each category to ensure that the serving size declared on the label is most appropriate for the specific type of product.

FDA received about 20 comments on issues related to these procedures. About one-third of the comments agreed with the proposed procedures. The remaining two-thirds suggested other ways of determining label serving sizes for specific products or requested modification or clarification of certain specific aspects of the procedures. FDA will first respond to the "general" types of comments and then discuss the comments on procedures for each specific category.

145. A foreign manufacturer stated that the reference amounts should be used only to ascertain that the serving size chosen by the manufacturer is reasonable, and that they should not be used to determine the label serving size. The comment argued that products packed in foreign countries are packaged according to "whole number" metric amounts and do not translate easily into U.S. household units. The comment requested that FDA show a certain amount of flexibility. A domestic comment stated that several of the reference amounts are "atypical in retail practice" in the United States even though they may represent consumers' consumption practice. The comment, therefore, suggested that FDA permit industry to use the reference amount as a guideline and require them to justify, with marketing data, those serving sizes that substantially deviate from the reference amount. A few consumer comments, on the other hand, requested that FDA not allow the manufacturers to deviate from the "standard serving size."

The 1990 amendments direct FDA to establish standards, not guidelines, to define serving sizes. As alluded to above, the House report on the 1990 amendments, in explaining section 2(b)(1)(B) states: "It is critical to the successful implementation of this legislation that the FDA develop meaningful serving size requirements * * ." (H. Rept. 101-538, supra, 18). Accordingly, FDA established the standards described above to define how to determine the label serving size that is most appropriate for a specific product. FDA believes that the standards provide enough flexibility to both domestic and foreign manufacturers to permit them to determine the serving sizes most

appropriate for their products from the reference amounts in new § 101.12(b).

FDA does not agree with the comment that products packaged in foreign countries according to "whole number" metric amounts cannot easily be translated into common U.S. household measures. Some domestic products are also packaged according to "whole number" metric amounts (e.g., 1-or 2-liter (L) bottles of soft drinks). FDA allows the number of servings per container to be expressed in an approximate number. Therefore, it should not be difficult to translate the products packaged according to "whole number" metric amounts into common U.S. household measures. For example, the serving size and the number of servings for a 1-L container of soft drink can easily be translated to the common U.S. household measure by dividing the 1-L (1,000 mL) net quantity of the product by the 240-mL reference amount for soft drinks and expressing an approximate number of servings, e.g., serving size: 1 cup (240 mL); number of servings per container: about 4.

FDA notes that the act links serving size to food consumption practices, not to the "typical retail practice" or marketing data. Therefore, FDA cannot use information (e.g., "typical retail practice" or marketing data) other than food consumption data as the primary basis for reference amounts when appropriate food consumption data are available. The agency has considered serving sizes used by the industry (i.e., retail practice) in developing the reference amounts in this final rule. When appropriate food consumption data were not available, the agency gave more weight to other information listed in new § 101.12(a)(5), including serving sizes currently used by the industry, in arriving at the reference amount.

146. An industry comment asked that FDA clarify how to determine the label serving size if there are more than one use of a product.

The reference amounts in new § 101.12(b) reflect the major usage of the products in each product category. If there is more than one use for a product, manufacturers should use the major usage of the product to determine the label serving size. For example, the label serving size for a cake mix which has directions for a 2-layer cake and cupcakes should be based on the 2-layer cake. Manufacturers should determine the major usage of the product based on food consumption data, marketing survey data on the consumer usage of the product, or, in the case of a new product, promoted use.

147. An industry comment requested that FDA clarify how to determine the

label serving size if the label serving size determined according to the procedures in proposed § 101.9(b)(2) and the incremental rules in proposed § 101.9(b)(5) falls exactly halfway between two sizes, e.g., exactly 2.5 tbsp.

FDA notes that the common standard procedure for rounding is to round up values 0.5 or larger. FDA is not aware of any reason not to follow this procedure. Therefore, for clarity, FDA has added a new § 101.9(b)(5)(v), on rounding rules as follows:

When a serving size, determined from the reference amount in § 101.12(b) and the procedures described in this section, falls exactly half way between two serving sizes, e.g., 2.5 tbsp, manufacturers shall round the serving size up to the next incremental size.

148. Several comments suggested different serving sizes for celery or for other of the 20 most frequently consumed raw fruits and vegetables identified in § 101.44.

FDA advises that serving sizes for the 20 most frequently consumed raw fruits and vegetables, including celery, are provided in Appendix A to the regulation entitled "Food Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Definition of Substantial Compliance" (56 FR 60880 as amended at 57 FR 8174, March 6, 1992). Retailers who wish to use different serving sizes for these fruits and vegetables may do so subject to the provisions of § 101.45. FDA urges such retailers, and retailers who wish to provide the nutrition information of raw fruits and vegetables not included in § 101.44, to use the reference amount specified in new § 101.12(b) for the fruit or vegetable category appropriate for the specific fruits or vegetables and to follow the procedures described in this section to determine the label serving size.

1. Products in discrete individual units

FDA proposed in § 101.9(b)(2)(i) that "for products in discrete units (e.g., muffin, sliced bread, apple), the serving size shall be the number of units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent, of the reference amount, the serving size shall be one unit. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion."

149. Several industry comments opposed the lower limit of the single-serving unit because single units of

many products in discrete units weigh less than 67 percent of the reference amount. One comment requested changing the lower limit from 67 percent to 50 percent because food consumption data (e.g., 1977-1978 NFCS) show that a significant proportion of "eatings" (e.g., up to 25th percentile) were about one-half or less of the average quantity consumed. Therefore, the comment contended, a unit that weighs 50 percent of the reference amount should be able to declare one serving per unit. Another comment requested changing the lower limit, from 67 percent to 50 percent and allowing single-serving declaration on a single unit that weighs less than 50 percent of the reference amount if a single unit can reasonably be consumed at a single-eating occasion. The latter comment stated that this approach is analogous to the optional declaration as a single serving of a single unit that weighs 200 percent or more of the reference amount if the whole unit can reasonably be consumed at a single eating occasion. Some comments recommended that FDA let the manufacturers determine whether a unit that weighs less than 67 percent is a single serving.

FDA carefully examined all requested changes for the lower limit of a single-serving unit. The agency has examined the amount of food consumed per eating occasion for several products that come in discrete units and find that a significant number of people consume between 50 and 67 percent of the reference amount per eating occasion (Ref. 63). Considering that: (1) Many single units fall between 50 and 67 percent of the reference amount, (2) a significant number of people consume between 50 and 67 percent of the reference amount per eating occasion, and (3) serving sizes in dietary guidance documents are often based on a single unit, FDA believes that it is reasonable to let manufacturers have the flexibility to determine whether a unit that weighs more than 50 percent but less than 67 percent is a single serving. However, a unit that weighs 50 percent of the reference amount is, by definition, one-half of a serving, not one serving. Therefore, products that weigh 50 percent or less cannot be called one serving. Accordingly, FDA has revised § 101.9(b)(2)(i) to allow optional declaration of a serving based on a single unit of a product if the unit weighs more than 50 percent but less than 67 percent of the reference amount.

150. Several industry comments requested that FDA permit the use of an oz measure for the serving size for products that naturally vary in piece

size (e.g., shrimp, pickles) instead of the number of discrete units. A seafood trade association stated that great difficulty and financial burden would be placed on the industry if serving sizes of seafoods have to be expressed in the number of discrete units. The comment pointed out that seafoods such as shrimp, scallops, oysters, clams, lobster, and fillet of fish vary naturally and substantially in size. For example, processed breaded shrimp products are made in as many as 12 to 15 sizes because of the natural variation in shrimp size. The comment stated that if a manufacturer packed these products in three different sized packages, up to 45 different labels would be necessary to accurately designate serving sizes based on discrete units, and the cost of printing different labels would be prohibitive.

A pickle trade association also stated that the size and shape of cucumbers naturally vary widely because of numerous factors, including the variety, weather conditions, and maturation when harvested. Therefore, according to the comment, pickles, even in the same grade established by the USDA, vary considerably in size and weight. The comment contended that the serving size cannot be declared by the number of pickles because of the inherent variability in pickle sizes. If the serving size of pickles were required to be declared in the number or fraction of pickles, the comment continued, pickle manufacturers would have to have a different label for each pickle size. The comment contended that such a result would represent an unnecessary burden and cost. Therefore, the comment recommended that the serving size for pickles should be declared in terms of oz.

FDA recognizes the wide variability in the unit size of seafoods and agricultural commodities such as pickles where the size is determined by nature, not the manufacturer. The costs incurred in ensuring that the number of discrete units in the serving size declaration for these naturally-variable products is appropriate would be unreasonable because of the numerous labels for each product size, and the costs would likely be passed on to the consumer. The agency, therefore, believes that the most reasonable solution to this problem is to express the serving size in an oz measure most closely approximating the reference amount, followed by the g equivalent weight and the approximate number of pieces for small pieces (e.g., shrimp) or the dimension for a large piece (e.g., fillet of fish) in parenthesis. For example, serving sizes may be declared

as 3 oz (84 g/about 5 shrimp) for cooked shrimp, 3 oz (84 g/about one fillet) for cooked fish fillet, 1 oz (28 g/about 1 pickle) for small pickles, and 1 oz (28 g/about 1/2 pickle) for large pickles. This approach will satisfy the act by providing the declaration in household measures in terms of oz. It also provides a uniform g weight within and across brands. This approach also facilitates nutrition comparisons among brands. Because many consumers stated that they do not understand oz measure, the approximate number of pieces or the dimension allows consumers to visualize the serving size in more easily identifiable units. Therefore, FDA has revised § 101.9(b)(25)(i) to exempt products that vary naturally in the unit size such as pickles, shellfish, whole fish, and fillet of fish. In addition, the agency has added a statement that serving sizes for these products shall be expressed in the amount in oz that most closely approximates the reference amount for the product category, and a second statement that refers manufacturers to § 101.9(b)(5) for instructions on how to express the serving size in oz. The agency notes that this exemption does not apply to processed products, such as fish sticks and fish squares, where manufacturers can control the piece size.

FDA recognizes that unit sizes of products in individual discrete units (e.g., fish sticks, muffins, sliced products) for which the size of the product is controlled by the manufacturer, not by nature, also vary somewhat from unit to unit within the package as well as from batch to batch for the same container size. This variation is also true for products in large discrete units (e.g., cake, pizza). Therefore, the g weight of a unit or a fraction will vary from unit to unit as well as from batch to batch. It is thus impossible to label accurately the g weight that is equivalent to the household measure in each package. FDA concludes that the most reasonable solution for this problem is to state the average g-weight equivalent of the unit or the fraction that represents the serving size. To determine the average g-weight equivalent of the household measure, manufacturers must follow the sampling procedures in § 101.9(g)(2) for nutrient analysis. The g-weight equivalent of a unit or a fraction for each package can be determined by dividing the net weight of the package in g by the number of units or fractions in the package or by actually weighing the units or the fractions. In determining the average g-weight equivalent, the measurements should be replicated a

sufficient number of times to ensure that the average of the measurements is truly representative of the g-weight equivalent of the serving size in household measure. FDA urges manufacturers to maintain records of all data and calculations used to determine the average g-weight equivalent to substantiate the parenthetical metric quantity declared on the label.

151. A comment from a maraschino cherry trade association stated that according to the 1991 serving size proposal, the serving size for maraschino cherries would be 1 cherry. However, maraschino cherries naturally vary in size ranging from 4 g for a small cherry to 7 g for a large cherry depending of the locality of growth and the crop year. The comment contended that because of this natural variation in the size of cherries, the maraschino cherry packers would have to keep changing the labels to have the accurate serving size information. In addition, the comment stated that the number of servings per container vary because of the variation in the cherry size. The comment requested that FDA allow the maraschino cherry packers to use a range of values (e.g., 4 to 7 g) for the parenthetical metric measure for the serving size and exempt the maraschino cherries from the declaration for the number of servings per container,

As for pickles, FDA recognizes the wide variability in the unit size of agricultural commodities where the size is determined by nature, not the manufacturer. As stated above, the costs incurred in insuring that the number of discrete units in the serving size declaration would be unreasonable because of the numerous labels necessary for each product size. Unlike pickles, however, cherries cannot have a serving size expressed in oz because the reference amount for cherries (4 g) is too small to express in oz. Therefore, the agency finds that the most reasonable solution to this problem is to declare the serving size as one cherry and the parenthetical metric measure as the g-weight equivalent of one medium cherry (e.g., 1 cherry (5 g)). The number of servings per container would then be declared as the usual number of servings per size of container (e.g., usually 20 servings), and the nutrition information would thus be provided for one medium cherry. The agency recognizes that different size containers hold different numbers of cherries. Therefore, this approach will require the manufacturer to have one set of labels for each size of container. Accordingly, new § 101.9(b)(2)(i) has been further revised to include the special serving

size requirement for maraschino cherries.

152. Several industry and professional comments stated that the serving size for products in discrete units (e.g., sliced, bread, frozen novelties) should be one unit

FDA disagrees with the comments. Products in discrete units vary widely in unit size. For example, the unit size for sliced bread varies from about 0.3 oz to 1.2- oz and from 0.4 oz to 6 oz for muffins. If one unit were defined as the serving size, there would be no uniformity in the serving sizes for products in discrete units. Furthermore, single units of some of these products are too small, to be reasonably considered a serving.

The act defines serving size as an amount customarily consumed. Reference amounts established by this regulation represent FDA's best estimate of the amounts customarily consumed for the 139 product categories. To provide flexibility and to ensure that the serving size in common household measures is meaningful for specific types of products, FDA has provided procedures in new § 101.9(b)(2) to convert the reference amounts to the label serving size. Therefore, unless one unit represents the serving size for the product, as determined from the reference amount in new § 101.12(b) using the procedures in new § 101.9(b)(2), one unit cannot be used on the labels as the serving size.

153. Some comments requested that FDA clarify serving sizes of packages within packages.

FDA advises that packages within a package (i.e., individually wrapped products in a multi-serving container) are considered to be products in discrete units. Each individually wrapped package (e.g., fun size candy bars, roll candies, tiny box of raisins) is one unit. The serving size of these products is the number of individual units whose total net content most closely approximates the reference amount. FDA has revised § 101.9(b)(2)(i) to clarify this point by adding individually packaged products within a multiserving package to the list of examples of products in discrete units.

154. A manufacturer suggested that FDA change the single-serving unit criteria from "67 percent or more, but less than 200 percent" of the reference amount to "2/3 or more, but less than twice" the reference amount. The comment asserted that this modification would avoid a difference of opinion as to whether 66.67 percent should be rounded to 67 or should be considered less than 67 percent for a single-serving determination.

As discussed earlier, the common standard procedure for rounding is to round up values 0.5 or larger. Thus, 66.67 percent is considered to be 67 percent. Therefore, defining the lower cutoff point as 67 percent is as clear as defining it as 2/3, and defining the upper limit as less than 200 percent is as clear as defining it as less than twice. Since the proposed language and the suggested change are equally clear, the agency has concluded that it is not necessary to modify the proposed regulatory language. Accordingly, FDA has retained the language for the single-serving unit criteria as proposed.

155. A consumer organization requested that FDA clarify whether, for products in discrete units, manufacturers must list the nutrition information on the basis of units that constitute the label, serving size (e.g., 2 slices) or for the underlying reference amount, (e.g., 2 1/2 slices). The comment contended that FDA should require nutrition information for products in discrete units to be listed based on the former approach.

FDA agrees that clarification is needed. Accordingly, the agency is revising § 101.9(b)(2)(i) to state that, except for products that naturally vary in size, the serving size of discrete-unit products is the number of whole units that most closely approximates the reference amount for the product category. This revision makes it clear that the serving size is to be expressed in whole number of units which was the original intent in the proposal.

156. A manufacturer requested that FDA clearly state in the preamble to the final regulation that a slice of cheese, whether or not wrapped individually, like sliced bread, constitutes a discrete unit for purposes of determining serving size. The manufacturer stated that this fact was evident, but ambiguous, in light of specific examples of discrete units cited in the 1991 serving size proposal.

Because it is impossible to provide the entire list of the products that are sold in discrete units, FDA provided a few examples of products that are sold in discrete units in § 101.9(b)(2)(i) of the 1991 serving size proposal. They included muffins, sliced bread, and apples. The specific examples given in the 1991 serving size proposal were to provide some idea of what is meant by products in discrete units. The agency included "sliced bread" as an example to convey the message that a slice of sliced products is a discrete unit product. A slice of sliced cheese is thus a discrete unit product. For clarity, FDA has modified the "sliced bread" example to read "sliced products such as sliced bread."

2. Products in large discrete units that are usually divided for consumption.

FDA proposed in § 101.9(b)(2)(ii) that for products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving size is the fractional slice of the food (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category.

157. A manufacturer recommended that the fractional slice should be "geometrically friendly" to consumers. The comment stated that some fractional slices may not be easy for the consumers to cut or visualize. For example, a cake cannot be easily cut into seven even slices. The comment provided two separate lists of "geometrically friendly" fractions in support of their position, one "for products that are not cut in two directions" (e.g., round cakes), and one for "products that must be cut in two directions" (e.g., sheet cakes). A few other comments also expressed a concern about odd fractional serving sizes.

FDA recognizes that the proposal could result in an odd fractional slice such as 1/7 of a cake or pie. The agency agrees with the comment that the serving size for products in large discrete units should be expressed in fractions friendly to consumers. Although manufacturers may have a means to cut these products in odd fractions, consumers generally would have difficulty in cutting them into certain odd fractions such as 1/7.

To rectify this problem, the agency carefully examined all possible fractional slices including those suggested in the comment. FDA could not directly adopt the two sets of fractional schemes suggested in the comment because the agency cannot require that some products be cut in one direction and others in two directions. Contrary to the assumption in the comment, some large, round cakes are often cut in two directions. The fractional, list provided by the manufacturer was also inconsistent in that it suggested that a square cake could not be divided into five pieces but listed 1/20, which, is a multiple of 5, as "geometrically friendly" for a square or rectangular product.

For the reasons outlined above, FDA cannot directly adopt the list of fractions suggested by the comment. However, the agency agrees with the concept of friendly fractions and is responding to the spirit of the comment by adopting a two-part scheme for identifying them. The scheme involves

establishing a base set of fractions and describing a process for generating a continuing set of smaller divisions of the base set. For the base set, FDA has selected integer increases of fractions up to and including 6 (1/2, 1/3, 1/4, 1/5, and 1/6). The agency has not included 1/7, which both FDA and the comment recognize would be difficult to cut and which the comment did not include in either of its suggested lists. This base set is consistent with the comment's list of fractions for round products but not for square and rectangular products, which excluded 1/5 as geometrically unfriendly. The agency acknowledges that dividing a product into five pieces is more difficult than other fractions in the base set. However, the difference between a serving size of 1/4 and 1/6 of a product is substantial and therefore could result in a serving size that is too large or too small. The comment also included 1/5 as a friendly fraction for round products. Thus, the agency has included a 1/5 fraction to provide a more reasonable serving size for products that contain between 450 and 550 percent of the reference amount.

The process for generating a continuous set of friendly fractions is based on creating further divisions of the base set. FDA and the comment both agree that it is easy to divide objects into two or three pieces. Therefore, the process selected for generating additional fractions involves dividing any of the base set or any newly created fractions by 2 or 3. Thus under this scheme, the set of friendly fractions includes 1/2, 1/3, 1/4, 1/5, 1/6, 1/8, 1/9, 1/10, 1/12, 1/16, 1/18, 1/20, 1/24, 1/32, 1/36, etc. The only fraction included in the comment list and not included here is 1/28 because it involves a division by 7 and that was not acceptable to the comment or FDA. Therefore, the agency excluded 1/28 from the friendly fractions.

To incorporate the friendly fractions in the regulations, FDA has revised § 101.9(b)(2)(ii) to read: "For products in large discrete units that are usually divided for consumption * * * the serving size shall be the fractional slice of the food * * * that most closely approximates the reference amount for the product category. In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3."

F. Declaration of Serving Size on the Product Label

1. Label statement of serving size

FDA proposed in § 101.9(b)(7) that a label statement regarding a serving shall

be the serving size expressed in common household measures followed by the equivalent metric quantity in parenthesis. In addition, FDA proposed that serving sizes may be declared in oz and fl oz (U.S. measure), in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving size, e.g., 1 cup (28 g)(1 oz).

158. Over 100 comments addressed this issue. The majority supported the use of common household measures as the primary unit for the serving size. About one-third of the comments agreed that the equivalent metric quantity should be required, and that manufacturers should be allowed to voluntarily list the equivalent U.S. measure. Comments disagreeing with the proposal varied widely as to how serving sizes should be stated.

Several comments stated that the U.S. measure should be mandatory in addition to or instead of the metric measure. Others objected to voluntary declaration of the U.S. measure in addition to the common household measure, arguing that it was unnecessary, would crowd the label, and would be confusing to consumers. However, none of the comments presented any supporting data or evidence.

Several comments opposed the use of the metric measure arguing that U.S. consumers are not familiar with metric measurements, that a g is not commonly used in food preparation, and that declaration of the exact metric weight might mislead consumers by implying an accuracy that is often unachievable for food products. Some suggested making the metric measure optional. Other comments favored allowing only one of the three measures; some of these expressed no preference and others specifically supported one of the three. However, many comments from professional organizations and consumers supported listing the metric measure parenthetically. These comments noted that the world is progressively moving toward the metric system, and it is important for Americans to become familiar and feel comfortable with metric measurements. They stated that using metric measurements to declare serving sizes would educate consumers about the metric system.

The 1990 amendments require that serving size be expressed in a common household measure that is appropriate to the specific food. The Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100-418) declares that the metric system is the preferred measurement system for U.S. trade end commerce.

Federal agencies are required to use the metric system in procurement, grants, and other business-related activities to the extent economically feasible by the end of fiscal year 1992. As discussed in the 1991 serving size proposal, FDA needs a precise quantity statement (e.g., metric measure), in addition to the common household measure, for compliance purposes because of the variability in the quantity of different brands in common household units. After carefully considering the statutory requirement, the Omnibus Trade and Competitiveness Act of 1988, the need for a compliance measure, and the arguments presented in the comments, FDA concludes that the most straightforward way to comply with the law, to fulfill the agency's regulatory needs, and to make the label most useful to consumers is to require the serving size to be declared in common household units followed by the equivalent metric quantity in parenthesis as proposed in the 1991 serving size proposal.

Given the conflicting views in comments on the use of the U.S. measure, the agency has decided to make the listing of the equivalent U.S. measure after the metric measure voluntary. Because of consumers' familiarity with U.S. measures, this declaration is likely to help consumers understand the serving size. However, because its use is voluntary, there is no reason to believe that it will create a crowding problem. Manufacturers will only include this information if they have ample label space. Accordingly, FDA is retaining in new § 101.9(b)(7) the requirement that the label serving size be expressed in common household measures, followed by the metric quantity in parentheses.

159. An industry comment stated that the parenthetical listing of the equivalent metric weight of the serving size is unnecessary on those single-serving containers for which the metric weight of the net quantity of contents is provided on the principal display panel. The comment requested that single-serving containers be exempted from this requirement. The comment contended that the parenthetical metric statement unnecessarily uses valuable label space for small single-serving containers.

FDA agrees that the parenthetical listing of the equivalent metric quantity is not necessary on the single-serving containers when the metric quantity of the net quantity of contents is provided on the principal display panel. However, for some products the metric quantity for the serving size and the metric quantity for the net quantity of

contents may differ. For example, the serving size for products packed or canned in liquid that is not customarily consumed (e.g., canned fish, pickles) must be expressed on a drained weight basis. In this case, the metric quantity on the principal display panel, which includes both the solids and the liquid, may differ from the parenthetical metric quantity for the serving size, which is based on the drained solids only. Thus, FDA has concluded that it is reasonable to exempt single-serving containers from the requirement for listing the parenthetical metric measure but only if the metric quantity for the net quantity of contents is the same as the metric quantity for the serving size. Accordingly, FDA has revised § 101.9(b)(7) to reflect this conclusion.

160. An industry comment stated that because individual products that belong to the same category, and thus have the same reference amount, vary in size and shape, the parenthetical metric measure equivalent to the serving size in household measure can vary from brand to brand. For example, g equivalents of 1/4 cup of nuts may vary from 30 g to 40 g. Thus, different metric equivalent can be declared by different brands for the same product. One brand may declare 30 g as the metric equivalent and present the nutrition information based on the 30 g serving, and another brand may declare 40 g as the metric equivalent and present the nutrition information based on the 40 g serving. The comment stated that this result is confusing and invites manipulation of the metric equivalent of the household measure. The comment recommended that FDA standardize the metric quantity of the reference amount for bulk products and have manufacturers declare an approximate household measure that is closest to that reference amount (e.g., about 1/4 cup (30 g)). Several other industry comments stated that there is no standard procedure for determining g equivalents of household measure, and that it is difficult to measure the g weight of a household measure accurately.

FDA recognizes that the parenthetical metric equivalents of the household measure of the same food may differ for different brands due to the differences in the products' size and shape. However, the agency notes that the 1990 amendments provided FDA with the authority to establish the standards to define serving sizes, not specific label serving sizes. Standardizing the parenthetical metric quantity on the reference amount is like using the reference amount (standard) as the label serving size. Therefore, FDA rejects this request.

However, the agency recognizes that the procedure for determining metric equivalents of household measures needs to be standardized, and that there is no well established standard procedure used by industry or any other organization for doing so. To promote uniformity in label serving sizes in household measures of the same food declared by different manufacturers, the agency is providing Guidelines for Determining the Gram Weight of the Household Measure. The guidelines can be obtained from Division of Nutrition (HFF-260) Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW Washington, DC 20204.

161. An industry comment requested that FDA allow voluntary labeling of the number of pieces in addition to the serving size in oz for products such as chips and nuts.

FDA agrees that oz is an appropriate household measure for chips. The agency points out that new § 101.9(b)(5)(iii) requires an appropriate visual unit of measure when oz is used as the serving size. Therefore, manufacturers must provide a visual unit of measure, such as the number of chips or a fraction of the package (e.g., 1/4 package), that is equivalent to the oz amount declared.

FDA does not agree that oz is the common household measure most appropriate for nuts. The agency believes that cups is the appropriate household measure for most nuts because most nuts are small in size and can be measured with a cup. When cups are used to express the serving size for nuts, the parenthetical statement for the number of nuts is not required. However, the agency does not object to a manufacturer voluntarily providing an additional visual measure such as the number of nuts, which may help consumers better visualize the serving size. For some exceptionally large nuts that are hard to measure with a cup (e.g., (unshelled walnuts), the agency believes the number of nuts would be the most appropriate household measure.

162. A trade association expressed concern that the use of several parentheses (e.g., 1slice (28 g) (1 oz)) would make the serving size statement more difficult to understand. The comment recommended that FDA allow the flexibility to use commas and slashes.

FDA disagrees with the comment. Allowing such flexibility would result in nonuniformity in the declaration of label serving sizes by different manufacturers. For example, the serving size for sliced breads could be expressed

in five different ways: 1 slice (28 g) (1 oz.) by brand A; 1 slice (28 g, 1 oz) by brand B; 1 slice (28 g/1 oz) by brand C; 1 slice, 28 g, 1 oz by brand D; and 1 slice/28 g/1 oz by Brand E. The use of these various formats for this declaration would be confusing.

After examining all possible combinations of the formats, FDA finds that the most desirable format is to require the presentation of all serving size information other than the mandatory common household measure, in one set of parenthesis with the different serving size statements separated by slashes, i.e., 1 slice (28 g/1 oz). This format requires less space than most of the other formats and separates the household measure from the rest of the information. Therefore, FDA has modified § 101.9(b)(7) to require that all serving size information, other than the mandatory common household measure, be presented in one set of parenthesis with the different serving size information separated by slashes.

163. An industry comment stated that the label statement example given in proposed § 101.9(b)(7) is confusing because there is no indication of the product for which the example applies.

FDA has revised § 101.9(b)(7) to correct this oversight by adding a phrase indicating what product was used for the example.

164. Several comments recommended that FDA allow voluntary listing of nutrient contents per unit for products that come in discrete units (e.g., 1 slice of bread, 1 doughnut, 1 ice cream bar), when the declared serving size of a multiserving package is more than one unit. These comments stated that: (1) Per-unit nutrition information would aid nutrition professionals in providing dietary guidance to their clients, and (2) although two or more units are determined to be the label serving size according to the FDA regulation, these foods are clearly meant to be consumed one unit at a time. The comments said that per-unit nutrition information will thus help consumers to better understand the nutrient content of the food as consumed.

Because many products in discrete units come in small units and people customarily consume more than one unit per eating occasion, reference amounts of these products are in multiunits (e.g., 2 small doughnuts) However, FDA recognizes that some individuals may consume only one unit at a time. In addition, the serving sizes contained in some dietary guidance or nutrition education documents (e.g., diabetic exchange list) are often expressed in terms of a single unit. In

an attempt to make the nutrition information on these products more useful to those consumers who consume only one unit at a time and to nutrition professionals who provide dietary guidance to their clients, the agency has revised § 101.9(b)(10) to allow voluntary labeling of a second column of nutrition information on a per unit basis. Finally, for individuals who consume multiple units that differ from the label serving size, the per-unit labeling would facilitate calculating the nutrient content for any multiple of a single unit.

However, products in discrete units vary greatly in size. Also, "mini" or "bite" size versions (e.g., "mini" cookies) are gaining popularity in the marketplace. FDA believes that per unit nutrition information on some of these products would be misleading. For example, a "bite" size version of a product could be labeled as containing zero fat or calories because of FDA's round-off rules for nutrient declaration, when in fact, enough units to constitute a serving contain significant amounts of fat and calories. The agency, therefore, considers that per unit labeling of "mini" or "bite" size products is misleading. FDA will consider regulatory action under section 403(a) of the act for any misuse of this allowance.

165. An industry comment recommended that the serving size declaration should conform to the rules for the net quantity of contents in §101.105.

Most rules in § 101.105 do not apply to the serving size regulation. The applicable portion of the net quantity rule has been incorporated in the Guidelines for Determining the Gram Weight of the Household Measure mentioned in new § 101.9(b)(7).

2. Definition of household measures

FDA proposed in § 101.9(b)(5) to define "common household measure" or "common household unit" to mean cup, tbsp., tsp., piece, slice, fraction (e.g., 1/4 pizza), oz, or other common household equipment used to package food products (e.g., jar, tray).

166. One comment recommended that units other than those listed in proposed § 101.9(b)(5) be allowed to be used for a common household measure, e.g., 1 cake for single-serving cakes, 1 bar for frozen novelties, and 1 sandwich for sandwiches.

FDA advises that new § 101.9(b)(5)(ii) allows the use of 1 cake, 1 bar, 1 sandwich, and similar units for label serving sizes. These units are examples of "piece" measurements for specific products. FDA listed them as a generic term "piece" because it is not possible to name all common household

measures appropriate for specific products in discrete units.

167. Because all beverages can be measured with a cup, the proposed definition for the household measure did not include fl oz. Some comments stated that it would be helpful to have fl oz measures for liquids. Although many consumer comments stated that they do not understand oz measures, they stated that fl oz is known and understood. The comments suggested that parts of the public want fl oz as a measure for expressing serving sizes.

FDA notes that fl oz is a common measure used to express the serving sizes of beverages. Therefore, on the basis of the comments, the agency concludes that it is appropriate to include fl oz in the definition of common household measures. Accordingly, FDA has revised § 101.9(b)(5) to include fl oz as a household measure. In addition, § 101.9(b)(5)(i) has been modified to allow beverages to express the primary household measure in fl oz.

3. Rules for declaring household measures

168. FDA proposed in § 101.9(b)(5)(i) through (b)(5)(iv) a set of rules that manufacturers should follow in expressing serving sizes in household measures. Most comments agreed with the proposed rules. One comment, however, stated that some foods would be more precisely measured in 1/3 cup increments rather than 1/4 cup increments and requested that this option be added to the final rule.

FDA proposed to require that cup measurements be declared in 1/4 cup increments to assure as much uniformity as possible in label serving sizes within a product category. Without such a rule, one manufacturer may choose to use 1/3 cup as the serving and another manufacturer may choose to use 1/4 cup for similar quantities of products. To prevent such inconsistencies in serving sizes, the agency proposed to require that cup measures be expressed in 1/4 cup increments. FDA has reexamined this aspect of the proposal. The agency agrees with the comment that some foods can be measured more precisely in 1/3 cup increments. In addition, FDA recognizes that contrary to the agency's intention, 1/4 cup increments may result in a larger discrepancy in label serving sizes of different brands or contribute to the manipulation of serving sizes when the label serving size is on the borderline between two sizes. One manufacturer may declare 1/4 cup and another manufacturer may declare 1/2 cup for similar quantities of a

product. Therefore, FDA has concluded that adding 1/3 cup increments to the final rule is desirable. Accordingly, FDA has revised § 101.9(b)(5)(i) to read: "Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. * * * Cups shall be expressed in 1/4 or 1/3 cup increments, ***."

169. Because common household measures such as cups, tbsp., and pieces may not be appropriate for some foods, FDA proposed in § 101.9(b)(5)(iii) the use of oz as the common household unit for such foods. When oz is used as the common household measure for serving size, FDA proposed that the oz statement should be accompanied by an appropriate visual unit of measure such as a dimension of a piece (e.g., "about 1 inch slice" for unsliced bread). An industry comment objected to the proposed requirement for an appropriate visual unit of measure. The comment stated that oz is a unit of measure that is understood by the public, and that the parenthetical dimensional measurement will only confuse the consumers. The comment did not submit any data to support its claim.

FDA disagrees that oz is a unit of measure well understood by the public. Consumer comments on the 1990 proposal overwhelmingly opposed the oz measure for serving sizes. They stated that they did not understand the oz measurement very well, and that they did not have a scale to measure food. They preferred common household measures such as cups, tbsp., and pieces. Several consumer comments on the 1991 serving size proposal again stated that they did not understand oz measurement. Therefore, FDA rejects the industry comment. Based on the comments, the agency concludes that when the oz measurement is used as the primary unit for serving size, an appropriate visual unit of measure is needed to help consumers visualize the serving size. Accordingly, FDA has retained the requirement for an appropriate visual unit of measure. However, FDA has revised § 101.9(b)(5)(iii) to permit the use of a fraction as a visual unit if it is the appropriate unit.

170. FDA stated in § 101.9(b)(5)(iii) that when oz is used as the common household measure for serving size, the oz measurements must be expressed in 0.5-oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

A manufacturer recommended that oz measures should be rounded to the nearest 0.1-oz increment. The

manufacturer stated that since an appropriate visual unit of measure is required, there is no need to round the oz measure to the nearest 0.5 oz. The comment contended that when consumers complained about fractional numbers, it is because they have no means of visualizing what quantity the weight represents. Therefore, as long as they have a visual description, consumers would not object to fractions. The comment further stated that under the proposal, products weighing from 22 to 35 g would all be listed as "about 1 oz." In addition, a product with an exact serving size of 64 g would declare "about 2.5 oz" whereas a product with an exact serving size of 63 g would declare "about 2 oz." The manufacturer stated that it would be a disservice to metric education in this country if people thought that a 1 g difference was a 1/2 oz difference. Because listing g quantities will be mandatory, the manufacturer felt that more exact oz measures need to be used, e.g., in increments of 0.1 oz.

FDA advises that the proposed § 101.9(b)(5)(iii) applies to the oz measure when it is used as the primary serving size. It does not apply to the parenthetical oz measure equivalent to the metric measure that is provided voluntarily by the manufacturer (see § 101.9(b)(7)). The nonuniformity in the oz measure described in the comment (i.e., about 2 oz for 63 g and about 2.5 oz for 64 g) would not occur when oz is used as the primary serving size because in determining the reference amounts, FDA made sure that the values would be in 0.5-oz increments.

However, in expressing the reference amounts in g, FDA rounded the g quantity to the nearest 5 g for quantities. Therefore, some reference amounts will not convert to exactly 0.5-oz increments. For example, 30 g reference amount would be translated to about 1.1 oz. To prevent the use of odd decimals and unusually accurate fractional numbers for the primary serving size, the agency proposed to require in § 101.9(b)(5)(iii) that oz measures be expressed in 0.5-oz increments. When oz is used as the primary serving size, the main purpose is to be a reference for consumers. Comments from consumers have strongly objected to odd decimals and fractions (55 FR 29517 at 29524, July 19, 1990) (56 FR 60394 at 60411, November 27, 1991). Therefore, the agency concludes that the primary serving should be expressed in 0.5-oz increments to be meaningful to consumers. Accordingly, FDA has retained the 0.5-oz incremental rule in

§ 101.9(b)(5)(iii) when oz is used as the primary serving size.

In the 1991 serving size proposal, FDA did not specifically address how to express voluntary parenthetical labeling of the oz measure that is equivalent to the primary household measure. The oz measure in this case can be any decimal quantity (e.g., 1.4 oz, 2.2 oz, 5.1 oz). These oz measures are not the primary serving size required. They represent the equivalent oz quantity that corresponds to the metric quantity declared. For example, the primary measure would be the household measure followed in parentheses by the g equivalent weight. At the manufacturer's discretion, the equivalent oz quantity could also be included. The primary measure is presented in household units or common fractions of household units (1/4 cup) that are familiar and meaningful to consumers. For secondary measures, it is important that the equivalent oz quantity be an accurate reflection of the primary household measure, and it is less important to round to even divisions since the primary measure is "consumer friendly." Therefore, FDA concludes that it is desirable to have a more accurate oz quantity and has modified § 101.9(b)(7) to provide that the oz quantity equivalent to the metric quantity should be expressed in 0.1 oz increments.

For the same reason, it is important that the g-weight equivalent be an accurate reflection of the primary household measure. In the 1991 serving size proposal, the agency did not provide specific guidelines for expressing the parenthetical g-weight equivalent of the household measure. Because the product categories in new § 101.12 (b) have been expanded to include spices and herbs that have very small serving sizes (usually less than 1 g), the agency has concluded that it is particularly important to provide guidelines for expressing the g-weight equivalent of the household measure, so that the parenthetical g-weight equivalent would accurately reflect the primary household measure. The agency is providing the following guidelines for expressing the parenthetical g-weight equivalent: For a parenthetical g-weight of 5 g or more, the values should be expressed in the nearest whole number of g. For a parenthetical g-weight of 2 g or more but less than 5 g, the values should be expressed in 0.5-g increments. This incremental rule is consistent with the incremental rule in § 101.9(b)(8) for the number of servings per container for products that contain 2 or more servings but less than 5

servings per container. For a parenthetical g-weight of less than 2 g, the values should be expressed in 0.1-g increments. Accordingly, FDA has revised § 101.9(b)(7) to read:

A label statement regarding a serving shall be the serving size expressed in common household measure * * * followed by the equivalent metric quantity in parenthesis * * * The g quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g. The g quantity between 2 and 5 g should be rounded to the nearest 0.5 g and the g quantity less than 2 g should be expressed in 0.1 g increments. In addition, serving size may be declared in oz and fl oz * * *.

171. A consumer organization recommended that FDA require manufacturers to round up the label serving size when the reference amount is 0.5 oz. For example, 0.5 oz should be rounded up to 1 oz, 1.5 oz up to 2 oz, and so forth.

FDA disagrees with the comment. Such rounding would introduce large errors in the label, serving size, and the label serving sizes would not reflect the amount customarily consumed. For example, rounding 0.5 oz to 1 oz would introduce 100 percent error and rounding 1.5 oz to 2 oz would introduce 33 percent error. Accordingly, FDA has not adopted this recommendation.

172. A manufacturer recommended that the serving size for a single-serving container should be the net weight of the container, and that it should not be rounded to the nearest 0.5 oz. The comment pointed out that if this were not the case, the serving size of a single-serving container having a net weight of 7.2 oz will state 7 oz. The comment said that such a discrepancy would be confusing.

FDA points out that new § 101.9(b)(5) allows manufacturers to use oz as the serving size only if cups, tbsp., tsp., or units such as piece, slice, tray, jar, and fraction cannot be used. The household unit most appropriate for a single-serving container is the description of the container itself (e.g., tray, package, carton, or box), not oz. Therefore, the serving sizes of single-serving containers must be stated in tray, package, carton, or a similar unit. appropriate for the specific container. Accordingly, the rounding rule in new § 101.9(b)(5)(iii) does not apply to the single-serving containers.

173. Some consumers requested that FDA standardize abbreviations used on the label.

FDA advises that new § 101.9(b)(7) standardizes abbreviations for units (e.g., g, mL) if a manufacturer elects to use abbreviations.

4. Labeling of "meal-type" products

FDA proposed in § 101.9(b)(3) that the serving size for "meal-type" products, as defined in § 101.13(1) of the nutrient content claims proposal, be the entire content of the package.

174. Several comments requested that the entire content of "meal-type" products that come in multiserving containers (e.g., lasagna, pizza) not be required to be labeled as one serving.

FDA agrees with the comment.

Accordingly, the agency is revising § 109.9(b)(3) to exclude multiserving containers. The agency also notes that it has revised § 101.13(1) of the nutrient content claims regulation, published elsewhere in this issue of the **Federal Register**, by dividing these products into two categories, meal products and main dish products, and adopting new definitions for these products. For clarification, FDA advises that the serving size for a multiserving product that has a reference amount in new § 101.12(b) must be determined according to provisions in § 101.9(b), even if these products are classified as a "meal product" or a "main dish product" in new § 101.13(l) and (m). FDA also notes that for products that do not meet the definition of "meal product" or a "main dish product," claims will be evaluated according to the reference amount in new § 101.12 (b) applicable to the product.

To reflect the reclassification and new definitions of "meal product" and "main dish product" in new § 101.13(l) and (m), and for clarity, FDA has revised § 101.9(b)(3) to read: "Serving size for meal products and main dish products as defined in § 101.13(l) and (m) of this chapter that come in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in § 101.12(b) if the product is listed in § 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in § 101.12(b) shall be based on the reference amount according to § 101.12(f)."

175. One comment requested that FDA require dual declaration, per serving and per 100 g, on "meal-type" products to facilitate nutrition comparisons of these products on an equal basis and to ensure "a level playing field."

FDA disagrees with the comment. The agency recognizes, that because many of these products are used interchangeably

in the diet, consumers may want to compare nutritional values of these products. "Meal-type" products (reclassified and redefined as "meal product" and "main dish product" in new § 101.13(1) and (m)) encompass a wide variety of products which vary in product characteristics. Therefore, these products differ greatly in amounts customarily consumed. The agency believes that nutrition information per serving derived from the reference amount applicable to each type of these products facilitates nutrition comparisons of these products on an equal basis in terms of the amount used in the diet. In addition, the 1990 amendments do not provide the authority to require nutrition information per 100 g or 100 mL basis. Accordingly, FDA has not adopted the recommended modification. (However, the agency notes that under new § 101.13(l) and (m) the eligibility of such products to bear nutrient claims will be determined on a per 100 g basis.)

176. Several industry comments suggested that frozen entrees packaged in separate pouches that contain more than one distinct food per package (e.g., rice or pasta with sauce or toppings) should be classified as "meal-type" products rather than mixed dishes.

For the purpose of determining the label serving size, the agency considers these "pouch-type" frozen entrees to be "mixed dishes" rather than "meal-type" products. The components of these frozen entrees are packaged separately for technical reasons, such as differences in required cooking times for the different components and better preservation of the texture and flavor during storage. However, the components from all pouches in a package are consumed as one product like other products in the mixed dishes categories. The only difference between the "pouch-type" products and other mixed dishes is that different components of the "pouch-type" products are packaged in separate pouches within the container, while all components of the other type of mixed dishes are packaged in one container. There is no difference in the characteristics, usage, or the manner of consumption between these two types of products.

However, if a "pouch-type" product meets the definition of "meal product" or "main dish product" in new § 101.13(1) and (m) of the final regulation on nutrient content claims, it will be classified as such for the evaluation of whether the product qualifies to bear a nutrient content claim. If a "pouch-type" product does not meet the definition of "meal

product" or "main dish product," its qualification for claims will be based on the reference amount of the specific product.

5. Labeling of variety packs

FDA proposed to require in § 101.9(b)(4) that a variety pack, such as a package containing several varieties of single-serving packages or a product having two or more compartments with each compartment containing a different food, provide nutrition information for each variety or food per serving size that is derived from the reference amount applicable to each variety or food.

177. One comment requested that FDA revise the proposed rule on the labeling of variety packs to state that nutrition labeling should be based on the individual serving actually in each inner container rather than serving size derived from the reference amount.

FDA advises that as long as each inner package meets the requirements for the single-serving unit as defined in § 101.9(b)(2)(i), the content of each inner package is one serving. Thus, the nutrition information would be based on the content in each inner package. Many variety packs contain different products that differ in reference amounts. Therefore, to determine whether each inner package qualifies for the single-serving unit, manufacturers must use the reference amount applicable to each product.

Accordingly, FDA has not adopted the comment's request. However, for clarity, FDA has revised § 101.9(b)(4) to read: "A variety pack such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section * * * shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section."

6. Labeling of foods for special dietary use

In the preamble to the 1991 serving size proposal (56 FR 60394 at 60408), FDA tentatively concluded that the serving size requirements that applied to foods intended for weight control or weight reduction, available in the marketplace, should also apply to the products sold only to enrollees of a weight control program. The agency also stated that it would not object if products available only as part of a weight-control program provided dual columns of nutrition information based on the reference amount and the serving size prescribed by the program.

178. A consumer organization supported the proposal but recommended that FDA require both the nutrition information and the product's qualification for claims to be based on the reference amount. Industry comments objected to the proposed requirement. A manufacturer of weight-control products requested that FDA allow manufacturers of portion controlled or other products that are part of a weight-control or weight-maintenance plan to base serving sizes on amounts specified under such plans and not necessarily on serving sizes derived from reference amounts in new 101.12(b). Comments from the providers of weight-control programs requested that FDA allow them to determine serving sizes that are consistent with the meal plans for products that are available only through the weight-control program. The comments asserted that if portion controlled products are required to use the same serving size as for the regular counterpart, it could lead to overconsumption of these foods and defeat the purpose of the program. The comments claimed that the dual labeling proposed by FDA could be confusing. A nutrition professional organization also stated that dual columns of nutrition information on these products may be confusing.

FDA has given careful consideration to all arguments presented in the comments on this issue. To ensure that the labeling is not misleading, the serving sizes for all foods available in the marketplace to the general public, including those intended for weight-control or weight-reductions, must be based on the reference amount in new § 101.12(b). However, the agency also finds that for weight-control products that are available only as part of a weight-control program, the use of a serving size that differs from the serving size for the meal plan may be confusing to the enrollees and may undermine the purpose of the program. Therefore, the agency concludes that, for products that are available only through the weight-control program and are not available at a general retail store, it is in the best interest of the enrollees of the weight-control program to have labeling that is consistent with the meal plan of the program in order to avoid any potential confusion about the serving size. FDA has revised § 101.9(b)(2) to exempt products that are both intended for weight-control and available only through weight-control or weight-maintenance programs. To avoid any confusion with the general retail products, manufacturers are required to

label their products as "for sale only through the ---program" (fill in the blank: with the name of the appropriate weigh control program, e.g., Smith's Weight Control), on the principal display panel. If these products are also available at the retail market, the serving size derived from the reference amount must be used. FDA advises that qualification of these products for nutrient content or health claims will be based on the reference amount, not the serving size determined by the provider of the weight-control program.

In addition, FDA advises that the label statements regarding the usefulness of these products in reducing or maintaining body weight are subject to the provisions in new § 105.66 of the nutrient content claims regulation published elsewhere in this issue of the Federal Register.

G. Declaration of Number of Servings Per Container

FDA proposed in § 101.9(b)(8) that a manufacturer, in declaring the number of servings per container, may use either of the two options listed in that section, choosing the one most meaningful for a specific product. The options proposed were: (1) Declare serving size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately 1/2 cup; number of servings per container: 10) or (2) declare the serving size in the exact household measure and the approximate number of servings per container (e.g., serving size: 1/2 cup; number of servings per container: approximately 10). In either case, FDA proposed to require that whole numbers of servings be used with the exception of random weight products. For random weight products, FDA proposed to use "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz.

179. Most comments supported the proposed requirements for the declaration of the number of servings per container. However, several comments objected to rounding the number of servings to the nearest whole number. The comments argued that rounding to the nearest whole number does not accurately account for the actual number of servings in a container and in many cases would significantly distort a container's contents, especially for packages containing between 1.5 to 4.5 servings. Some of the comments acknowledged that many consumers do not like fractional numbers of servings on the label but argued that this dislike

results primarily from the use of odd decimal fractions (e.g., 2.7 servings) and from fractional numbers of servings on packages typically consumed in their entirety (e.g., 1.5 servings on a 12 fl oz can of soda). The comments stated that rounding to the nearest 0.5 servings would be understood by virtually all consumers. A few comments suggested that at the very best, FDA should permit rounding to the nearest half-serving for packages containing 4.5 servings or fewer.

FDA acknowledges that consumer objections to the fractional number of servings maybe the result of the use of odd fractional numbers of servings and of their use on products typically consumed in their entirety. The agency agrees that, for packages containing 4.5 servings or less, the number of servings in 0.5-increments would reflect more closely the number of servings in the container. For larger containers, the 0.5 serving difference between the next lower or next higher whole number is a smaller relative percentage of the total number of servings in the package and, therefore, reflects an unrealistic and meaningless precision (e.g., 8.5 servings or 28.5 servings) because the number of servings are approximations. For this reason, FDA has revised § 101.9(b)(8) to allow fractional servings on packages containing between 2 and 5 servings. This procedure would reduce the errors in the number of servings per container to a maximum of about 12 percent (2.24 servings rounded to 2 servings) or less.

179a. Several comments addressed the two options proposed in § 101.9 (b) (8) for declaring the number of servings per container. A comment from a trade association stated that the two options would provide manufacturers flexibility in deciding the number of servings per container appropriate to their food products and providing the consumer with the most useful serving size information. Other comments from industry, consumers, and consumer organizations expressed concern about providing an option. They stated that allowing the two options would result in different serving sizes (and thus different nutrition information) for different brands of the same food, making nutrition comparisons of different brands difficult. One consumer organization contended that it is more important for consumers, especially those on medically-prescribed diets, to know the exact serving size that is the basis for the nutrition information than the exact number of servings. These latter comments recommended that FDA require manufacturers to list the exact serving size and an approximate number of servings per container.

Although the two options would provide flexibility to manufacturers, FDA recognizes that it would result in nonuniformity in serving sizes of different brands of the same food. The agency also agrees with the latter comments that it is more important to have the exact serving size than the exact number of servings. Many comments on the 1991 serving size proposal stated that the serving size regulation should facilitate nutrition comparisons of different brands. Therefore, FDA has revised § 101.9(b)(8) to require the exact serving size and the approximate number of servings.

180. Most comments approved of permitting the "varied" declaration for the number of servings on random weight products. However, one comment from a consumer organization expressed concern. The comment argued that the "varied" declaration is unnecessary because random weight products, such as cheese, are usually priced per pound, and the retailer or manufacturer must weigh a package of cheese to determine the price. The comment contended that once the weight has been measured, the servings per container can be easily calculated.

FDA agrees that random weight products are usually priced by weight, and that the retailer or manufacturer must weigh the product first to price it. However, because these products vary widely in weight, it would be difficult for retailers and manufacturers to have labels printed with the number of servings per container unless they have automated label machines that print the number of servings as they print the weight. Therefore, it would be unreasonable to require all retailers and manufacturers to include the number of servings on random weight products. Accordingly, FDA is retaining the "varied" declaration for the number of servings on random weight products. However, the agency encourages the retailers and manufacturers to label the number of servings per container if they have automated machines or some means to provide the information.

181. A few comments suggested that FDA permit an optional declaration of "typical number of servings" with the term "varied" on random weight packages. The comments contended that an approximate number of servings per container could help consumers determine the approximate number of servings contained in the package.

FDA agrees with the comment. Accordingly, FDA has revised § 101.9(b)(8) to allow voluntary labeling of the "typical number of servings" when "varied" is used to declare the number of servings per container, e.g.,

"varied (usually 5 servings)" or "varied (usually 4 to 6 servings)." The agency encourages manufacturers to provide the typical number of servings whenever feasible.

182. Several comments from the pickle industry stated that the size and shape of the vegetables used to make pickles vary widely as a result of numerous factors, including the variety, weather conditions, and maturation when harvested. The comment contended that pickles are random weight products and should be allowed to use "varied" for the number of servings per container.

FDA disagrees with the comments. Products that contain individual units in the container that vary in size, such as pickles, are not random weight products because the net quantity of the container size remains constant. Random weight products are those products that are sold in units whose net quantity of contents is random, e.g., cheese. In the case of random weight cheese, the number of servings is difficult to estimate because the net quantity of content vary widely from package to package of the same product. Because the container size of pickles (and thus the net quantity of contents) is constant, pickle manufacturers, unlike cheese manufacturers, can have a label printed for each size of the container. Therefore, FDA is not allowing a "varied" declaration on pickles.

However, because the serving size for pickles will be based on the drained solids, the net quantity of the drained solids in the same size container may vary somewhat because of the variation in the size and shape of pickles. Consequently, the number of servings per container may vary somewhat for different containers of the same size. Therefore, FDA has revised § 101.9(b)(8) to allow declaration of the typical number of servings per container (e.g., usually 5 servings) for canned products that naturally vary in unit size, and the serving size is required to be expressed on the drained solids basis (e.g., pickles).

183. A few comments from the produce industry requested that FDA clarify in the serving size regulation that raw fruits and vegetables are exempt from declaring the number of servings per container.

FDA advises that raw fruit, vegetables, and fish are exempt from mandatory nutrition labeling requirements under new § 101.9(j)(10) (see document entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision" published elsewhere in this issue of the **Federal**

Register). These foods are subject to the guidelines of the voluntary nutrition labeling program in § 101.45. Section 101.45(b)(3) states that the number of servings per container need not be included in nutrition labeling of raw fruit, vegetables, and fish. Accordingly, there is no need to cover this exemption in new § 101.9(b).

184. A manufacturer requested that FDA confirm in a preamble statement to the final rule that the product of the number of servings multiplied by the parenthetical metric equivalent of the serving size is not expected to precisely equal the net quantity of the product declared on the principal display panel.

FDA concurs with the comment's statement. It is true for two reasons: (1) An oz is defined differently for the net quantity of content regulation than for the serving size regulation, and (2) the number of servings are usually an approximate number. One oz is defined as 28.3452 g for the determination of the net quantity of contents (Ref. 39) and 28 g for the purpose of labeling serving size.

H. Other Related Issues

1. "As packaged" versus "as consumed" as the basis for the nutrition information

In § 101.9(b)(9) of the 1991 serving size proposal, FDA proposed that the declaration of nutrient content information shall be on the basis of food as packaged or purchased with the exception, of those products that were specifically excluded. Additionally, FDA encouraged manufacturers to voluntarily provide the nutrient content of their products on an as consumed basis using package directions for preparation (56 FR 60394 at 60413).

185. Several comments supported the proposed rule. A health professional organization strongly opposed nutrition labeling on an as prepared (i.e., as consumed) basis because nutrition information should reflect the content of food in the package that consumers are selecting and purchasing. A consumer comment stated that all nutrition information should be based on food as packaged. Anything beyond that becomes the consumer's responsibility.

Many other comments objected to the proposal for basing the nutrition information of the products that require further preparation before consumption (e.g., dry mixes) on an as packaged basis. The comments requested that FDA require that nutrition information on these products be provided on an as consumed basis. The comments contended that because these products cannot be eaten in the form packaged and often require adding additional

ingredients, nutrition information on an as packaged basis is not meaningful to consumers. Some comments argued that nutrition information on an as packaged basis does not allow consumers to make informed comparisons between similar products in different forms (prepared and dry) and provides no incentive for manufacturers to develop preparation directions in support of current dietary recommendations. A manufacturer argued that the nutrition information on an as packaged basis for products that require the addition of other ingredients often underestimates the nutritional contribution of the product in the total daily diet because it does not include the nutrient contribution of other ingredients added in the preparation for consumption. The comment contended that in these cases, as packaged information violates the 1990 amendments that require the nutrition information to be conveyed in a manner which enables the public to understand its relative significance in the context of a total daily diet.

Some comments from the popcorn industry objected to nutrition labeling on an as packaged basis because: (1) Popcorn is inedible as packaged, and (2) some of the fat that is added to microwave popcorn to facilitate popping sticks to the bag after popping and is therefore not consumed. Nutrition labeling on an "as packaged" basis would, therefore, overstate the fat content as consumed.

Several comments also asserted that the qualification of a product for nutrient content claims should be based on the product "as prepared." Comments stated that nutrient content claims based on the product as packaged could be misleading on those products that, when prepared according to package directions, would not meet the criteria for the claim on an "as prepared" basis.

Other comments suggested that products that require the addition of ingredients, such as dry cake mixes, should list nutrition information on both an "as packaged" and an "as prepared" basis. The comments contended that if they did not, labels that list the fat and sodium contents as "o" (zero) would lead consumers to believe that these products are fat free or sodium free when eaten, even though fat and salt must be added according to the preparation directions.

FDA does not agree with the comments that suggested that FDA should require nutrition information on an "as prepared" basis. The agency has found that it cannot regulate products as effectively on an "as prepared" basis. For example, many products that

require further preparation before consumption require the addition of ingredients. The nutrient content of a particular ingredient may vary from brand to brand (e.g., different brands of butter may vary in sodium content; different brands of fats and oils may vary in saturated fatty acid content). In addition, manufacturers often provide multiple directions for preparation (e.g., using different, types of fats, several directions for preparing different foods such as pancakes, waffles, and biscuits). There may be no obvious or rational basis for the agency to determine which set of directions should be used to check the accuracy of the nutrition information. Furthermore, a product may be used by consumers in many different ways, and the agency has no control over how a product is used after purchase.

However, FDA recognizes that it would be helpful to make comparisons of foods in their prepared state (e.g., prepared package salad dressing and bottled salad dressing). Therefore, for the benefit of the consumers who follow the package directions in preparing these products, the agency continues to encourage manufacturers to voluntarily provide nutrient information on their products on an as prepared basis, using the package directions in preparing the food, and in the case of multiple directions, using the directions that represent the major usage of the product. The agency agrees that such voluntary information may provide an incentive for manufacturers to develop methods of preparation that support dietary recommendations.

The agency disagrees with the comment that "as packaged" nutrition information violates the 1990 amendments because the "as packaged" information underestimates the nutritional contribution of the product to the total daily diet. Section 403(q)(1) of the act states that nutrition information is to be provided on a food intended for human consumption and is offered "for sale ***" (emphasis added). Thus, the manufacturer has the responsibility to provide nutrition information on the product as offered for sale. Once the product is purchased and other ingredients are added, the packaged product becomes a different product. Therefore, the contribution of a product to a total daily diet must be evaluated in terms of the nutrient content of the product in the package as sold.

With regard to the comments about the nutrition labeling of unpopped popcorn, the agency notes that popcorn is no different than other foods that require further preparation before

consumption (e.g., cake mixes, pancake mixes) and that are required to provide nutrition information on an as packaged basis. Therefore, no special provision is needed for unpopped popcorn. The agency notes, however, that §101.9(b)(10)(iii) permits a second column on nutrition information on popcorn products in multiserving containers on a per cup popped basis.

As for the fat in microwave popcorn, the agency notes that the amount of fat that is retained with the popcorn may vary depending on the popping conditions and equipment used.

Therefore, the agency cannot monitor compliance on an as consumed basis.

In regard to comments that nutrient content claims should be based on the product "as prepared," FDA notes that it did not address this issue in either the 1991 serving size proposal or the proposal entitled "Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (56 FR 60421, November 27, 1991). The agency does not believe that the 1990 amendments contemplated regulation of claims on products as prepared by the consumer. Section 403(r) of the act focuses on claims for nutrients in the food that is offered for sale. Moreover, regulation on an "as prepared" basis would raise significant compliance problems. However, the agency does agree that a nutrient content claim could be misleading if directions for use of the packaged product specify the addition of ingredients that would result in the finished edible product no longer meeting the criteria for the claim. If FDA finds that a problem exists in the marketplace after implementation of these final rules, the agency will consider further rulemaking under section 403(a) of the act.

Likewise, FDA did not propose to require that a product that requires the addition of ingredients declare nutrition information on both an as purchased and an as prepared basis, and, as discussed previously, the agency does not believe that it is appropriate to do so.

186. Some comments stated that for products where water must be added before the product can be consumed (e.g., dry soup or noodle mixes), the nutrition information should be based on the rehydrated product.

FDA advises that water contains some minerals. In its final rule on the declaration of sodium content in nutrition labeling, the agency reviewed and discussed data on the sodium content of the U.S. water supplies (49 FR 15510 at 15524). The data showed that sodium ranged from less than 3 mg to approximately 52 mg per 6 fl oz.

However, to prevent the introduction of error in the analysis of a product for compliance purposes, the agency is denying this request.

187. A health professional organization recommended that for products where choice in the preparation method can markedly alter its nutritional content nutrition information on the product as prepared should be provided through educational point of purchase materials or in places on the package other than the nutrition label.

FDA has no objections to the placement of nutrition information other than that required in the nutrition label on other places on the label or in labeling (such as point of purchase materials). However, the agency has no authority to require such information. Accordingly, no action is being taken on this comment.

2. Nutrition information on a drained solids basis

Food consumption data showed that the liquid in foods such as canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables is not customarily consumed. Therefore, FDA proposed in § 101.9(b)(9) to require that the declaration of nutrient and food component content of such foods be based on the drained solids.

188. Comments from a food manufacturer and a trade association opposed the proposal for basing nutrition information on a drained solids basis for beans, potatoes, and vegetables canned in liquid. The comments contended that upon cooking starch and other nutrients are released into the packing medium. The comments argued that because the entire contents of the container is frequently consumed, information on a drained weight basis would be misleading. One comment submitted data from a marketing survey showing that a large percentage of people use the liquid.

FDA agrees with the comment that the marketing survey showed that a large percentage of people use the liquid and that the liquid also contains nutrients (Ref. 64). Accordingly, the agency has deleted canned beans, potatoes, and vegetables from the list of foods in new § 101.9(b)(9) that are exempted from the requirement for nutrition information on an "as packaged" basis and has modified footnote 6 for Table 2 in new § 101.12(b) to reflect this change. Canned beans, potatoes, and vegetables will, therefore, be required to provide nutrition information on an "as packaged" basis.

189. An industry comment stated that the liquid that is present in "Alaska" canned salmon is the natural juice that has cooked out of the fish during thermal processing, and no additional liquid is added to "Alaska" canned salmon. The comment, therefore, asserted that nutrition information for canned salmon should be on an "as packaged" basis.

FDA agrees with the comment that nutrition information on canned salmon to which liquid has not been added for canning should be based on an as packaged basis. Accordingly, the agency has revised the footnote to Table 2 in new § 101.12 (b) so that canned salmon that is not in a liquid packing medium is required to be labeled on an "as packaged" basis. Canned salmon that is in a liquid packing medium is subject to being labeled on a drained weight basis. The revised footnote reads: "If packed or canned in liquid ***."

3. Miscellaneous issues

190. A manufacturer requested that FDA install a toll-free telephone number regarding questions on the reference amounts.

FDA advises that budgetary constraints do not allow for the installation of a toll-free telephone number to assist manufacturers in any aspect of the implementation of these final rules. However, agency personnel will respond to the maximum extent possible to all written or telephone requests for assistance. In addition, the agency intends to prepare materials to assist manufacturers in implementing these regulations as well as the educational materials to assist consumers in understanding and using the new nutrition labels.

I. Listing of a Second Column of Values

1. Listing nutrient contents based on 100 g, 100 mL, 1 oz, or 1 fl oz

FDA proposed in § 101.9(b)(10) that another column of figures may be used to declare the nutrient and food component information on the basis of 100 g or 100 mL or of 1 oz or 1 fl oz of the food as packaged or purchased.

191. Most comments on this issue supported voluntary labeling of a second column of values on a uniform basis. These comments reasoned that the second column of values provides nutrition information on a uniform basis, which aids consumers in making nutrition comparisons of different products. Some comments that supported voluntary labeling of a second column of values stated that FDA should not provide two choices for the basis of the second column.

Comments that addressed the choice for the basis of the second column preferred 100 g or 100 mL over 1 oz or 1 fl oz. These comments stated that nutrition information per 100 g (or mL): (1) May be useful for persons on a special diet for medical reasons. (2) may assist consumers in understanding the metric system, or (3) is the only presentation of nutrition information internationally understood. One international comment stated that nutrition information per 100 g should be mandatory, and the information per serving should be voluntary. Another international comment stated that nutrition information per 100 g or 100 mL should be allowed on European products. A domestic comment stated that the second column of values per 100 g or 100 mL should be mandatory.

Comments objecting to the use of a second column stated that: (1) The second column of values would be confusing to consumers or is too much information, thus contributing to label clutter, (2) consumers may not understand why this information is on the label or understand how this quantity differs from a typical serving size. (3) consumers may have little need to compare 100 g of mustard with 100 g of a 12 oz frozen dinner, or (4) it is not necessary to add a second column on a per 100 g or 100 mL basis for the reason of international harmonization because every country has its own unique label requirements. Comments argued that because of these vastly different requirements, it is virtually impossible to use U.S. labels internationally.

FDA has given careful consideration to all arguments for and against the second column of values presented in the comments. To facilitate comparison of the nutritional composition of different products, the agency agrees that it would be desirable to have a uniform basis for the second column. However, for consistency with USDA's regulation, the agency has decided to retain the two choices for the basis of the second column as proposed.

FDA disagrees with the comment that stated that the second column of values per 100 g or 100 mL should be mandatory. The 1990 amendments do not mandate such a requirement. Further, nutrition information per 100 g or 100 mL is not meaningful for many foods that are customarily consumed in small quantities (e.g., croutons crackers, cream and cream substitutes, sugar, butter, margarine, oil, and condiments) and dry mixes (e.g., dry beverage mixes). Therefore, the agency has not adopted this recommendation.

FDA is not persuaded that the declaration of nutrition information in a second column on a per 100 g or 100 mL basis should be prohibited. The provision is voluntary; therefore, manufacturers who do not wish to present the second column of values are not required to provide it. However, the presence of the information could help to facilitate comparisons between types of foods. While one comment stated that there is little need to compare 100 g of foods which would not be used interchangeably (e.g., mustard and frozen dinner), FDA notes that facilitation of nutrition comparisons is intended for different products which are used interchangeably in the diet.

Considering the weight of the comments supporting the second column of values on a uniform basis, FDA believes that voluntary labeling of a second column of values is desirable. This information will enable those who desire the information to benefit from it. Additionally, in response to comments that said a second column would be confusing, FDA intends to follow publication of these final rules with consumer education activities about the new food labeling requirements. This education initiative will assist consumers in understanding the utility of a second column of values based on 100 g, 100 mL, 1 oz, or 1 ft oz and should minimize consumer confusion.

Therefore, FDA has retained § 101.9(b)(10) as proposed and redesignated as § 101.9(b)(10)(i).

2. Mandatory listing of nutrient contents for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based

FDA proposed in § 101.9(b)(11) that if a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer must provide a second column of nutrition information based on the amount customarily consumed for the promoted use in addition to the nutrition information per serving derived from the reference amount in § 101.12(b).

192. Two comments from consumer and nutrition professional organizations supported the proposal. One of the comments recommended that FDA also require dual columns of values on foods that are consumed in two quantities that differ by two-fold or greater, as long as the alternative use occurs at least 25 percent of the time. To illustrate the point, the comment cited the use of

liquid cream substitutes in coffee versus on cereal or fruit. On the other hand, a comment from a trade association argued that this approach is not required under the act and could severely hamper traditional marketing techniques and reduce the flow of helpful information to consumers. They further stated that such a requirement is simply unworkable, particularly for nondiscrete bulk products packaged in multiserving containers (e.g., flour, sugar, multipurpose baking mixes). Many manufacturers make recipes available to the consumer through labeling (e.g., recipe booklets) and advertising. Many of these recipes are for the use of modified substitutes in regular recipes, such as lower fat alternatives. Manufacturers may also promote multiple uses of their products, some of which may suggest the use of the quantity of the product by twofold or greater than the reference amount. In such circumstances, the manufacturer could not possibly label the amount customarily consumed for every promoted use. Under such a rule, manufacturers will be less likely to promote several types of legitimate uses for their products. The comment stated that FDA should not discourage the dissemination of information that consumers find useful and informative.

FDA disagrees that in addition to requiring dual columns for promoted uses, FDA should also require dual columns for alternative uses that occur at least 25 percent of the time. Many foods are used for more than one purpose, and it is not always possible for manufacturers to determine which uses constitute 25 percent or more of the total usage of the food and to continually monitor trends in usage with this kind of precision. Consequently, FDA is not requiring dual columns based on percentage of use of the food.

However, FDA does find that this situation must be addressed. Section 403(q) of the act defines a serving size to be an amount customarily consumed. In some cases, such as the example given in proposed § 101.9(b)(11) of cream substitutes, the reference amount for the product category in § 101.12(b) clearly does not, represent the customarily consumed amount for the product's promoted use on breakfast cereal. Thus, a separate customarily consumed amount is needed for the promoted use according to the definition of the serving size under the act. In addition, the agency notes that under 403 (a) of the act, the nutrition information based on the reference amount (1 tbsp.) for the liquid cream substitute example is misleading for its

promoted use with breakfast cereals (1/2 cup). Therefore, FDA believes that it has legal authority under section 403(a) and (q) of the act to require dual columns of values based on the customarily consumed amount for each use.

Finally, FDA agrees with the comment that stated that it is unreasonable to require multiple columns of values for some nondiscrete bulk products that are used primarily as ingredients, (e.g., flour, sweeteners, shortenings, oils), traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes (e.g., mixes with multiple recipes) because the products are promoted generically and are listed in hundreds of recipes and requiring hundreds of columns would be impractical and impossible.

Accordingly, in regard to dual columns, in new § 101.9(b)(11). FDA has retained the requirement for dual labeling for products that are promoted for a use that differs by twofold or greater from the use upon which the reference amount is based. However, the agency has added a statement that specifically exempts certain foods from this requirement for dual labeling: nondiscrete bulk products used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils) or traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes.

193. A trade association objected to the use of advertising to determine whether a second column of nutrition information is required under § 101.9(b)(11).

The agency advises that it views advertising as evidence of how the manufacturer intends the product to be used. If, as discussed in the preceding comment, this use is significantly different than the use on which the reference amount is based, the provisions of new § 101.9(b)(11) are triggered. Accordingly, FDA is not making the suggested change.

J. Use of Serving Size to Evaluate Nutrient Content and Health Claims

FDA proposed in § 101.12(g) to require that the reference amount be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. However, the agency noted that label serving sizes often differ from the reference amounts. Thus, products that meet the criteria for a claim on a reference amount basis may not qualify on a serving size basis. For example, a soft-drink that contains 30 mg of sodium per reference amount (240

mL) meets the criteria for a "very low sodium" claim (less than or equal to 35 mg per 8 fl oz (240 mL)). A 12-fl oz single-serving container of this soft drink, however, contains 50 mg of sodium and, therefore, would not qualify for the "very low sodium" claim. For these products, FDA proposed that both the reference amount and the label serving size be used to determine whether the product meets FDA criteria for a claim. The agency also discussed another option based solely on the reference amount plus a disclaimer and solicited comments on both options.

194. Many comments supported the proposal to base claims on both the reference amount and the label serving size. However, numerous comments from the food industry, nutrition professionals, Government, and consumers contended that claim evaluations for all products should be based solely on the reference amount. The comments argued that claims should reflect the true characteristics of the product, and that a product that qualifies for a claim should be able to bear the claim on all container sizes. According to these comments, using both the reference amount and the label serving size as criteria will result in a product that would be able to bear a claim for one container size but would not be able to bear the same claim for another. The comment stated that such inconsistency in the use of claims for the same product in different-sized containers would be confusing to consumers and should not be permitted. Some of these comments suggested that FDA's concern about the misleading claims could be alleviated by requiring a statement of the basis for the claim along with the claim on a product that meets the criteria only on the basis of the reference amount, e.g., "very low sodium, 35 mg or less per 8 fl oz."

As discussed in the 1991 serving size proposal (56 FR 60394 at 60412), there are advantages and disadvantages to both options. After careful consideration of the comments received and of the advantages and disadvantages of both options, FDA concludes that the most reasonable solution for this issue is to base claim evaluations on the reference amount and to require a disclaimer with the claim. FDA agrees with the comments that claims should reflect the true characteristics of a product, and those characteristics do not change if the product is packaged in a different size container. Thus, it is appropriate to use the standard established by FDA, the reference amount, as the basis for evaluating claims. However, FDA also recognizes that products packaged in

containers that differ from the reference amount may contain an amount of the nutrient significantly different from the amount on which the claim is based (e.g., 50 mg of sodium in a 12-fl oz container that can claim "very low sodium" since it contains only 35 mg sodium per 8 fl oz). In order to not be misleading, FDA agrees with the comments suggesting that a disclaimer that includes a statement of the basis for the claim is appropriate on such products. The agency recognizes that consumers may not readily understand the significance of the disclaimer (i.e., that it is alerting them to the fact that the product does not meet the criteria for the claim on the basis of the label serving size). The agency intends to inform consumers about the meaning of various claims on product labels through nutrition education activities that will follow the publication of the final regulations for food labeling. Accordingly, FDA has revised § 101.12(g) to base the qualification for a claim on the reference amount and to require a disclaimer if the label serving size of a product differs from the reference amount, and the product does not qualify for the claim on the basis of the label serving size.

In presenting the disclaimer, manufacturers must state the reference amount as it appears in new § 101.12 (b). The reference amount in metric measure should be followed, in parenthesis, by the equivalent household measure appropriate for the food. Many consumers have complained that they do not understand metric measures. The parenthetical household measure should help consumers to visualize the quantity on which the claim is based. For example, a 12-fl oz soft drink that meets the criteria for "very low sodium" per reference amount, but not per 12 fl oz, would state "very low sodium, 35 mg or less per 240 mL (8 fl oz)." A slice of bread that meets the criteria for "high in fiber" per reference amount, but not per slice, would state "high in fiber, 20 percent or more of the Recommended Daily Intake per 50 g (about 1 1/2 slices)."

Revised § 101.12(g) reads:

The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b) followed, in parenthesis, by the amount in

common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl oz)."

195. A few comments recommended that the determination as to whether a food qualifies to bear a nutrient content or health claim—should be based only on the label serving size.

FDA disagrees with the comment. Basing claim evaluations only on the label serving size could encourage manipulation of serving sizes to qualify for claims. Therefore, FDA is not adopting this recommendation.

196. Other comments recommended using 1 oz as the basis for the claim evaluation. The comments contended that 1 oz is a simple criterion and provides a "level playing field" for all products making claims.

FDA believes that 1 oz is inappropriate to use for declaring nutrient content or for evaluating claims because it has no relation to the amount of food customarily consumed or a food's contribution to the total daily diet as required by the 1990 amendments and thus will result in misleading or meaningless claims. For example, on a 1 oz basis, foods that may qualify for a "high" claim on a per serving basis (e.g., "high calcium" on yogurt) may not be able to bear the claim, whereas foods that may not qualify for a "low" claim on a per serving basis (e.g., "low calorie" cake) may be able to bear the claim. Therefore, FDA is not adopting this recommendation.

K. Petition Process

FDA proposed in § 101.12(h) a set of requirements for filing a petition to establish or amend a reference amount.

Several comments from nutrition professional organizations and the industry supported the petition process. A major trade association stated that the system is necessary because of the changing consumption patterns of Americans and the everchanging nature of food products. The association further stated that it agrees with the type and amount of information proposed by FDA to be included in the petition. A few comments opposed or expressed a reservation on certain specific aspects of the petition process as described below.

197. FDA proposed in § 101.12(h)(11)(i) to provide that a petition to create a new subcategory of food with its own reference amount must include data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size

and the mean, median, and modal amounts consumed per eating occasion for the petitioned product and for the products in the parent category, excluding the petitioned product.

An industry comment objected to the requirement in proposed § 101.12(h)(11)(i) for data on other products in the category. The comment stated that this information is not necessary, and that the data requirement is so burdensome that a petition for a new subcategory is almost impossible.

FDA disagrees with the comment that the data requirement for other products in the parent category is not necessary. The consumption data for other products in the category are needed to compare with the consumption data for the petitioned product to ensure that the customarily consumed amounts of the two product groups differ enough to warrant a separate reference amount for the petitioned product. The consumption data for other products in the parent category serve as the reference standard against which the consumption data for the petitioned product can be compared. Without a reference standard, it can not be known whether the difference in the customarily consumed amount of the petitioned product and the reference amount for the parent category is real or the result of the methodological or procedural differences in the surveys used. Use of the data on the other products is analogous to using a control or a reference standard in a laboratory experiment to validate the value of a test article.

FDA also disagrees that the data requirement is so burdensome that a petition for a new subcategory is almost impossible. Available national food consumption data bases provide information needed to meet the data requirement in new § 101.12(h)(11)(i). Some comments on the 1991 serving size proposal presented evidence that a relatively inexpensive survey can be conducted to collect food consumption data under actual conditions of use when information is not available from databases.

However, to avoid an overly stringent data requirement, paragraph (h)(11)(i) has been modified to reduce the amount of information that must be submitted. While the proposed provision required information “* * * for the petitioned product and for all products in the category, excluding the petitioned product * * *,” the modified provision seeks only data “* * * for the petitioned product and for other products in the category, excluding the petitioned product * * *.” Also, to correct an oversight, the agency has added

standard deviation to the data requirement to read “* * * Data must include sample size; and the mean, standard deviation, median, and modal consumed amount * * *.”

198. FDA proposed in § 101.12(h)(14) that as part of the petition submission, a statement must be included concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act of 1990 (Pub. L. 101-648). A consumer organization opposed the negotiated rulemaking in establishing a reference amount through a petition. The comment contended that the process is resource-intensive and will favor those organizations and companies that have the time and money to devote to such negotiations.

FDA believes that in certain circumstances, negotiated rulemaking may be a useful tool in developing new or amended reference amounts. The feasibility of convening an appropriate group of interested parties would be discussed by the petitioner; however, the decision on whether to convene a discussion session would be at FDA's discretion with full awareness of agency resources. FDA is convinced that it is frequently useful to provide a forum for open discussion of particularly contentious issues. All interested parties, including consumer organizations, would be invited to participate in any such negotiated rulemaking. Therefore, FDA has retained § 101.12(h)(14) as proposed.

199. One industry comment requested that a procedural method be established to modify, add, or expand a category or reference amount. Because of the length of time necessary for issuing and finalizing a proposal as a result of a petition, the comment stated that the proposed petition method is not optimal. The comment recommended that USDA and FDA investigate alternatives to the proposed petition process.

FDA believes that the petition process referred to in § 101.12(h) is the appropriate process to establish or amend a reference amount. Such a process is necessary because the reference amounts adopted by the agency have the force and effect of laws. However, new § 101.12(h) merely incorporates the citizen petition process in § 10.30. This petition process will ensure full participation of all interested parties. FDA recognizes that issuing and finalizing a proposal does take time. Therefore, the agency will do its best to expedite the petition for establishing or

amending a reference amount so that the petitioner can properly label and market its product at the earliest date possible.

200. A trade association contended that manufacturers of the products with reference amounts in § 101.12(b) are at a competitive advantage over those manufacturers whose products are not included in § 101.12(b) because they do not have the burden or expense of petitioning for a reference amount. The comment argued that the petition process is unfair, and that it is the government's responsibility to provide a rational basis for determining serving sizes on all products. The comment further contended that in the absence of a meaningful reference amount for a product, a “small” business should be permitted to determine an appropriate reference amount or to delay nutrition labeling until FDA has completed its task.

FDA disagrees with the comment. To comply with the act, the agency has established reference amounts for virtually all foods in the current food supply that are regulated by FDA. The agency notes that the list of reference amounts in new § 101.12(b) is extensive and applicable to all products that belong to the generic description of the product category. Therefore, manufacturers should be able to find reference amounts for practically all products currently in the food supply.

The agency is aware that products are continuously being introduced into the market. Because the product category description is generic, manufacturers should also be able to find the reference amounts in § 101.12(b) that are applicable to most of these new products. However, some new products may not fit in the product categories in § 101.12(b). Therefore, the agency has installed a petition process to establish or amend reference amounts to encompass new products that do not fit in any of the product categories in § 101.12(b) and any products in the current food supply that were not brought to FDA's attention in this rulemaking process. Although FDA recognizes that there is both time and money involved in the petition process, this process is necessary to keep the reference amounts in § 101.12(b) current.

The agency agrees that it has the authority to establish the reference amount. However, it is not FDA's responsibility to know every new food product that is introduced in the market. The agency points out that it is the manufacturer's responsibility to inform FDA if any products have not been covered by § 101.12(b) and to provide appropriate information to

establish or amend the reference amounts in § 101.12(b).

Lastly, the agency points out that "small" businesses as defined in § 101.9(j)(1) are exempt from nutrition labeling and thus, there is no need for concern about the petition process.

V. Other Affected Rules

The agency proposed to revise 21 CFR 101.8(a) to state that where nutrition information is required, and firms elect to place statements on product labels concerning the number of servings in a package in other locations in addition to the location where nutrition information is placed, such statements must be in the same terms as that used for nutrition information. FDA proposed this revision to prevent consumer confusion over serving size.

FDA received no comments on this provision. However, to correct a typographical error in the 1991 serving size proposal, the agency has modified § 101.8(a) to read: " * * * Such statement shall not be misleading in any particular * * * "

V. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the **Federal Register** of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

In its November 1991 nutrition labeling proposed rules, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**. Several comments on the nutrition labeling proposed rules suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal

capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste.

Based on its consideration of comments received, the agency has decided to allow additional time for companies to use up their old labels. Thus, the nutrition labeling final rules will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the \$100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (58 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA-305), Food and Drug

Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857 and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. Paperwork Reduction Act

In the **Federal Register** of February 14, 1992 (57 FR 5398), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60394) that provided, in part, for petitions regarding serving sizes. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

Based on its consideration of the written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling, FDA modified the serving size petition requirements from those that were proposed. Those modifications were discussed in detail earlier in this final rule. Accordingly, FDA has also revised its estimated annual collection of information burden.

This final rule contains collection of information requirements that are subject to review by OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). Therefore, in accordance with 5 CFR 1320, the title, description, and respondent descriptions of the collection of information requirements are shown below with an estimate of the annual collection of information burden. Included in the estimate is the amount of time for reviewing instructions, searching existing data sources, gathering necessary information, and completion and submission of petitions.

Title: 21 CFR 101.12--Food Labeling: Serving Sizes.

Description: This final rule provides the procedures and format for the submission of petitions to the agency. Section 101.12(h) describes the information needed by FDA to evaluate the need for the change or addition requested in the petition and to

determine the appropriate reference amount for the petitioned food if the change or addition is judged as needed. The information included in these

Petitions will be reviewed by the agency, and a decision will be made in accordance with the criteria specified in this final rule.

Description of Respondents: Persons and small businesses, including small businesses.

Estimated Annual Reporting and Recordkeeping Burden:

Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Annual Burden Hours
101.12(h).....	10	1	10	60	600
Total.....					600

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301,402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331,342, 343, 348, 371).

2. Section 101.8 is amended by revising paragraph (a) to read as follows:

§101.8 Labeling of food with number of servings.

(a) The label of any package of a food that bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example cups, tablespoons) when such differing term is common to cookery and describes a constant quantity. Such statement shall not be misleading in any particular. Where nutrition labeling information is required in accordance with the provisions of § 101.9, however, the statement of the net quantity of each serving shall be consistent with the requirements for serving size expression set forth in that section (e.g., 10 1-cup (240 milliliters) servings). A statement of the number of units in a package is not in itself a statement of the number of servings.

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3. Section 101.9 is amended by revising paragraph (b) to read as follows:

§101.9 Nutrition labeling of food.

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(b) Except as provided in § 101.9(h)(3), all nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(1) The term "serving" or "serving size" means 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 121 months of

age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(3), (b)(4) and (b)(6) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion" (reference amounts) that appear in § 101.12(b) using the procedures described below. For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, "for sale only through the ——— program" (fill in the blank with the name of the appropriate weight control program, e.g., Smith's Weight Control), on the principal display panel. However, the reference amounts in § 101.12(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrient content claims or health claims.

(i) For products in discrete units (e.g., muffins, sliced products such as sliced bread, apples, or individually packaged products within a multiserving package), except for products that naturally vary in size such as maraschino cherries, pickles, shellfish, whole fish, and fillet of fish, serving size shall be the number of whole units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, the serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the reference amount, the manufacturer may declare one unit as one serving. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion. Serving size for maraschino cherries shall be expressed as 1 cherry with the parenthetical metric measure equal to the average weight of a medium size cherry. Serving size for other products that naturally vary in size shall be expressed in the amount in oz that most closely approximates the reference amount for the product category. Manufacturers shall adhere to the requirements in paragraph (b)(5) of this section for expressing the serving size in oz.

(ii) For products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving size shall be the fractional slice of the food (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category. In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3.

(iii) For nondiscrete bulk products (e.g., breakfast cereal, flour, sugar, dry mixes, concentrates), serving size shall be the amount in household measure that most closely approximates the reference amount for the product category.

(3) The serving size for meal products and main dish products as defined in § 101.13(l) and (m) of this chapter that come in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in § 101.12(b) if the product is listed in § 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in § 101.12(b) shall be based on the reference amount according to § 101.12(f).

(4) A variety pack such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section, and a product having two or more compartments with each compartment containing a different food, shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section.

(5) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., 1/4 pizza), ounce (oz), fluid ounce (fl oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving size in household measures, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fl oz. Cups shall be expressed in 1/4 or 1/3 cup increments, tablespoons in whole

number of tablespoons for quantities less than 1/4 cup but greater than or equal to 1 tablespoon, and teaspoons in whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon and in 1/4 teaspoon increments for quantities less than 1 teaspoon.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If paragraphs (b)(5)(i) and (b)(5)(ii) of this section are not applicable, oz may be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 1 oz (28 g/about 1/2 pickle). Ounce measurements shall be expressed in 0.5 oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

(iv) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL); a tablespoon means 15 mL; a cup means 240 mL; 1 fluid ounce (fl oz) means 30 mL; and 1 oz in weight means 28 g.

(v) When a serving size, determined from the reference amount in § 101.12(b) and the procedures described in this section, falls exactly halfway between two serving sizes, e.g., 2.5 tbsp, manufacturers shall round the serving size up to the next incremental size.

(6) A product that is packaged and sold individually and that contains less than 200 percent of the applicable reference amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving except for products that have reference amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the reference amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(7) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(6) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in mL and all other foods in g) except for single-serving containers. For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a

drained weight basis according to § 101.9(b)(9). The g quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g. The g quantity between 2 and 5 g should be rounded to the nearest 0.5 g and the g quantity less than 2 g should be expressed in 0.1-g increments. In addition, serving size may be declared in oz and fl oz, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size. e.g., 1 slice (28 g/1 oz) for sliced bread. The oz quantity equivalent to the metric quantity should be expressed in 0.1 oz increments. If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, oz for ounce, and fl oz for fluid ounce. To promote uniformity in label serving sizes in household measures declared by different manufacturers, FDA has provided Guidelines for Determining the Gram Weight of the Household Measure. The guidelines can be obtained from Division of Nutrition (HFF-260). Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(8) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section. The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term "about" (e.g., about 2 servings, about 3.5 servings). When the serving size is required to be expressed on a drained solids basis and the number of servings vary because of a natural variation in unit size (e.g., maraschino cherries, pickles), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings). For random weight products, a manufacturer may declare "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz. The manufacturer may provide the typical number of servings in parenthesis following the "varied" statement.

(9) The declaration of nutrient and food component content shall be on the basis of food as packaged or purchased with the exception of raw fish covered under § 101.42 (see § 101.44), packaged

single-ingredient products that consist of fish or game meat as provided for in paragraph (j)(11) of this section, and of foods that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed (e.g., canned fish, maraschino cherries, pickled fruits, and pickled vegetables). Declaration, of nutrient and food component content of raw fish shall follow the provisions in § 101.45. Declaration of nutrient and food component content of foods that are packed in liquid but the liquid packing medium is not customarily consumed, shall be based on the drained solids.

(10) Another column of figures may be used to declare the nutrient and food component information,

(i) Per 100 g or 100 mL or per 1 oz or 1 fl oz of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multiserving container is more than one unit.

(iii) Per cup popped for popcorn in a multiserving container.

(11) If a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in § 101.12(b) was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer shall provide a second column of nutrition information based on the amount customarily consumed in the promoted use, in addition to the nutrition information per serving derived from the reference amount in § 101.12(b), except that nondiscrete bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or traditionally used for multipurposes (e.g., eggs, butter,

margarine), and multipurpose baking mixes are exempt from this requirement.

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4. Section 101.12 is added to subpart A to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that the Food and Drug Administration (FDA) considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the 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. These reference amounts are based on data set forth in appropriate national food consumption surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating

occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving size used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the reference amount and, in turn, the serving declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The reference amount is based on the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal).

(8) The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased.

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

(b) The following reference amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1
REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS^{1 2 3 4}

Product Category	Reference amount	Label statement ⁵
Cereals, dry instant.....	??.....	1/3 cup (13 g)
Cereals, prepared, ready-to-serve.....	??g.....	-----cup(s) (----- g)
Other cereal and grain products, or ready to eat e.g., ready to eat cereals, cookies, teething biscuits, and toasts.	7g for infants and 20g for toddlers for ready-to-eat cereals; 7g for all others.	(-----cup(s) (-----g) for ready-to-eat cereals; --- piece(s) (----- g) for others
Dinners, desserts, fruits, vegetables, or soups, dry mix	15 g.....	-----tbsp(s) (----- g) or -----cup(s) (----- g)
Dinners, desserts, fruits, vegetables, or soups, ready-to-serve, junior type.	110 g.....	-----cup(s) (-----g)
Dinners, desserts, fruits, vegetables, or soups, ready-to-serve strained type.	60 g.....	-----cup(s) (-----g)
Dinners, stews or soups for toddlers, ready-to-serve....	170 g.....	-----cup(s) (-----g)
Fruits for toddlers, ready-to-serve.....	125 g.....	-----cup(s) (-----g)
Vegetables for toddlers, ready-to-serve.....	70g.....	-----cup(s) (-----g)
Eggs/egg yolks, ready-to-serve.....	55 g.....	-----cup(s) (-----g)
Juices, all varieties.....	120 mL.....	4 fl oz (120 mL)

¹ These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 Nationwide Food Consumption Surveys conducted by the U. S. Department of Agriculture.
² Unless otherwise noted in the Reference amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry cereal) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).
³ Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).
⁴ Copies of the list of products for each product category are available from the Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C st. SW., Washington, DC 20204.
⁵ The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

TABLE 2
REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3 4}

Product Category	Reference amount	Label statement ⁵
Bakery Products.....
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies.	55 g.....	----- piece(s) (-----g)
Breads (excluding sweet quick type), rolls.....	50 g.....	----- piece(s) (-----g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/ ----inch slice for unsliced bread
Bread sticks—see crackers.....
Toaster pastries—see coffee cakes.....
Brownies.....	40 g.....	----piece(s) (-----g) for distinct pieces; fractional slice (----g) for bulk
Cakes, heavy weight (cheese cake, pineapple upside-down cake, fruit, nut, and vegetable cakes with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; éclair; cream puff)?.	80 g.....	----piece(s) (-----g) for distinct pieces (e.g., sliced or individually packaged products); -----fractional slice (-----g) for large discrete units.
Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling) ⁸	55 g.....	----- piece(s) (-----g) for distinct pieces (e.g., sliced or individually packaged products); -----fractional slice (-----g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, toaster pastries.	55 g.....	-----piece(s) (-----g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56g/visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies.....	30 g.....	----piece(s) (-----g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones.....	15 g.....	-----piece(s) (-----g)
Crackers that are usually used as snacks.....	30 g.....	----piece(s) (-----g)
Croutons.....	7 g.....	-----tbsp(s) (-----g) or -----cup(s) (---- g); ----piece(s) (-----g) for large pieces
French toast, pancakes, variety mixes.....	110 g prepared for french toast and pancakes; 10 g dry mix for variety mixes.	-----piece(s) (-----g); -----cup(s) (-----g); for dry mix
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars	40 g.....	----piece(s) (-----g)

Ice cream cones—see crackers.....
Pies, cobblers, fruit crisps, turnovers, other pastries.....	125 g.....	-----piece(s) (---g) for distinct pieces; ---fractional slice (---g) for large discrete units
Pie crusts.....	1/6 of 8 inch crust; 1/8 of 9 inch crust.....	1/6 of 8 inch crust (---g); 1/8 of 9 inch (---g)
Pizza crust.....	55 g.....	---fractional slice (---g)
Taco shells, hard.....	30 g.....	---shell(s) (---g)
Waffles.....	85 g.....	---piece(s) (---g)
Beverages
Carbonated and noncarbonated beverages, wine coolers, water.....	240 mL.....	8 fl oz (240 mL)
Coffee or tea, flavored and sweetened.....	240mL prepared.....	8 fl oz (240 mL)
Cereals and Other Grain Products
Breakfast cereals (hot cereal type), hominy grits.....	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal	---cup(s) (---g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains.	15 g.....	---cup(s) (---g)
Breakfast cereals, ready-to-eat weighing 20 g or more, but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g.	30 g.....	---cup(s) (---g)
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	55 g.....	---piece(s) (---g) for large distinct pieces (e.g., biscuit type); ---cup(s) (---g) for all others
Bran or wheat germ.....	15 g.....	---tbsp(s) (---g) or ---cup(s) (---g)
Flours or cornmeal.....	30 g.....	---tbsp(s) (---g) or ---cup(s) (---g)
Grains, e.g., rice, barley, plain.....	140 g prepared; 45 g dry.....	---cup(s) (---g)
Pastas, plain.....	140 g prepared; 45 g dry.....	---cup(s) (---g); ---piece(s) (---g) for large pieces (e.g., large shell) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., lasagna or spaghetti noodles)
Pastas, dry ready-to-eat, e.g., fried canned chow mein noodles	25 g.....	---cup(s) (---g)
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g.....	1 tbsp(8 g) for cornstarch; 1 tbsp (10 g) for tapioca; 1 tbsp (---g) for others
Stuffing.....	100 g.....	---cup(s) (---g)
Dairy Products and Substitutes
Cheese, cottage.....	110 g.....	1/2 cup (105 g) for small curd; 1/2 cup (113 g) for large curd, low fat, or with fruit added; 1/2 cup (---g) for others
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g.....	1/3 cup(48 g) for dry curd cottage cheese; 1/4 cup (62 g) for ricotta cheese
Cheese, grated hard, e.g., Parmesan, Romano	5 g.....	1 tbsp(s) (5 g)
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g.....	---piece(s) (---g) for distinct pieces; ---tbsp(s) (---g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category.....
Cream or cream substitutes, fluid.....	15 mL.....	1 tbsp (15 mL)
Cream or cream substitutes, powder.....	2 g.....	1 tsp (2 g)
Cream, half & half.....	30 mL.....	2 tbsp (30 mL)
Eggnog.....	120 mL.....	1/2 cup (120 mL) or 4 fl oz (120 mL)
Milk, condensed, undiluted.....	30 mL.....	2 tbsp (30 mL)
Milk, evaporated, undiluted.....	30 mL.....	2 tbsp (30 mL)
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL.....	1 cup (240 mL) or 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes	240 mL.....	1 cup (240 mL) or 8 fl oz (240 mL)
Sour cream.....	30 g.....	2 tbsp (30 g)
Yogurt.....	225 g.....	1 cup (---g)
Desserts
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones).	1/2 cup—includes the volume for coatings and wafers for the novelty type varieties.	---piece(s) (---g) for individually wrapped or packaged products; 1/2 cup (---g) for others
Frozen flavored and sweetened Ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups).	85 g.....	---piece(s) (---g) for individually wrapped or packaged products; 1/2 cup (---g) for others
Sundae.....	1 cup.....	1 cup (---g)
Custards, gelatin or pudding.....	1/2 cup.....	---piece(s) (---g) for distinct unit (e.g., individually packaged products); 1/2 cup (---g) for bulk
Dessert Toppings and Fillings
Cake frostings or icings.....	35 g.....	---tbsp(s) (---g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and nondairy whipped toppings.	2 tbsp.....	2 tbsp (---g)
Pie fillings.....	85 g.....	---cup(s) (---g)
Egg and Egg substitutes
Egg mixtures, e.g., egg foo young, scrambled eggs, omelets	110 g.....	---piece(s) (---g) for discrete pieces; ---cup(s) (---g)

TABLE 2 ----Continued
 REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3 4}

Product Category	Reference amount	Label statement ⁵
Eggs (all sizes)(9).....	50 g.....	1 large, medium, etc. (---- g)
Egg substitutes.....	An amount to make 1 large (50 g) egg.....	---- cup(s) (---- g)
Fats and Oils
Butter, margarine, oil, shortening.....	1 tbsp.....	1 tbsp (14 g) for butter, margarine, or oil; 1 tbsp (9 g) for whipped butter or margarine; 1 tbsp (13 g) for shortening
Butter replacement, powder.....	2 g.....	---- tsp(s) (---- g)
Dressings for salads.....	30 g.....	2 tbsp (---- g)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g.....	1 tbsp (14 g) for mayonnaise; 1 tbsp (15 g) for imitation mayonnaise, mayonnaise-type dressings or sandwich spread
Spray types.....	0.25 g.....	About ---- seconds spray (---- g)
<i>Fish, Shellfish, Game Meats¹⁰, and Meat or Poultry Substitutes</i>
Bacon substitutes, canned anchovies, ¹¹ anchovy pastes, caviar	15 g.....	---- piece(s) (---- g) for discrete pieces; ---- tbsp(s) (---- g) for others
Dried, e.g., jerky.....	30 g.....	---- piece(s) (---- g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g cooked.....	---- cup(s) (---- g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake	85 g cooked; 110 g uncooked ¹²	---- piece(s) (---- g) for discrete pieces; ---- cup(s) (---- g); ---- oz (---- g/visual unit of measure) if not measurable by cup ¹³
Fish, shellfish, or game meat ¹⁰ , canned ¹	55 g.....	---- piece(s) (---- g) for discrete pieces; ---- cup(s) (---- g)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters	55 g.....	---- piece(s) (---- g) for distinct pieces (e.g., slices, links); ---- cup(s) (---- g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled ¹¹ fish, shellfish, or game meat ¹⁰ ; fish or shellfish spread	55 g.....	---- piece(s) (---- g) for distinct pieces (e.g., slices, links); ---- cup(s) (---- g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see miscellaneous category
Fruits and Fruit Juices
Candied or pickled ¹¹	30 g.....	---- piece(s) (---- g)
Dehydrated fruits—see snacks category.....
Dried.....	40 g.....	---- piece(s) (---- g) for large pieces (e.g., dates, figs, prunes); ---- cup(s) (---- g) for small pieces (e.g., raisins)
Fruits for garnish or flavor, e.g., maraschino cherries ¹¹	4 g.....	1 cherry (---- g)
Fruit relishes, e.g., cranberry sauce, cranberry relish	70 g.....	---- cup(s) (---- g)
Fruits used primarily as ingredients, avocado	30 g.....	See footnote 13
Fruits used primarily as ingredients, others (cranberries, lemon, lime)	55 g.....	---- piece(s) (---- g) for large fruits; ---- cup(s) (---- g) for small fruits measurable by cup ¹³
Watermelon.....	280 g.....	See footnote 13
All other fruits (except those listed as separate categories), fresh, canned, or frozen	140 g.....	---- piece(s) (---- g) for large fruits; ---- cup(s) (---- g) for small fruits measurable by cup ¹³
Juices, nectars, fruit drinks.....	240 mL.....	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice	5 mL.....	1 tsp (5 mL)
Legumes
Bean cake (tofu) ¹¹ , tempeh.....	85 g.....	---- piece(s) (---- g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce.....	130 g for beans in sauce or canned in liquid; 90 g for others	½ cup (---- g)
<i>Miscellaneous category</i>
Baking powder, baking soda, pectin.....	1 g.....	¼ tsp (---- g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations	¼ tsp or 4 g if not measurable by teaspoon	---- piece(s) (---- g) for discrete pieces; ¼ tsp (---- g)
Batter mixes, bread crumbs.....	30 g.....	----tbsp(s) (---- g) or ---- cup(s) (---- g)
Cooking wine.....	30 mL.....	2 tbsp (30 mL)
Drink mixers (without alcohol).....	Amount to make 240 mL drink (w/out ice)	----fl oz (---- mL)
Chewing gum(9).....	3 g.....	---- piece(s) (---- g)
Meat, poultry and fish coating mixes; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes.	Amount to make one reference amount of final dish	----tsp(s) (---- g) or ----tbsp(s) (---- g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g.....	----tbsp(s) (---- g)

Salt, salt substitutes, seasoning salts (e.g., garlic salt).....	1 g.....	----	tsp(s) (---- g); ----piece(s) (---- g) for discrete pieces (e.g., individually packaged products)
Spices, herbs (other than dietary supplements).....	¼ tsp or 0.5 g if not measurable by teaspoon	----	¼ tsp (---- g); ---- piece(s) (---- g) if not measurable by teaspoons (e.g., bay leaf)
<i>Mixed Dishes</i>	----
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc..	1 cup.....	----	1 cup (---- g)
Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches.	140 g. add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce ¹⁴ .	----	---- piece(s) (---- g) for discrete pieces; ----fractional slice (---- go for large discrete units
<i>Nuts and Seeds</i>	----	----
Nuts, seeds, and mixtures, all types: sliced, chopped, slivered, and whole.	30 g.....	----	---- piece(s) (---- g) for large pieces (e.g., unshelled nuts); ---- tbsp(s) (---- g) or ---- cup(s) (---- g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams.....	2 tbsp.....	----	2 tbsp (---- g)
Coconut, nut and seed flours.....	15 g.....	----	---- tbsp(s) (---- g)
<i>Potatoes and Sweet Potatoes/Yams</i>	----	----
French fries, hash browns, skins, or pancakes	70 g prepared; 85 g for frozen unprepared french fries	----	---- piece(s) (---- g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/
Mashed, candied, stuffed, or with sauce.....	140 g.....	----	---- pieces) for prepared fries; 3 oz (84 g/ ---- pieces) for unprepared fries
<i>Salads</i>	----	---- piece(s) (---- g) for discrete pieces;
Gelatin Salad.....	120 g.....	----	---- cup(s) (---- g) for sliced or chopped products
Pasta or potato salad.....	140 g.....	----	½ cup (120 g)
All other salads, e.g., egg, Fish, shellfish, bean, fruit, or vegetable salads.	100 g.....	----	---- cup(s) (---- g)
<i>Sauces, Dips, Gravies and Condiments</i>	----	----
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).	2 tbsp.....	----	2 tbsp (---- g)
Major main entrée sauces, e.g., spaghetti sauce.....	125 g.....	----	½ cup (---- g)
Minor main entrée sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	¼ cup.....	----	¼ cup (---- g)
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades.	1 tbsp.....	----	1 tbsp (---- g)
Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce.	1 tsp.....	----	1 tsp (---- g)
<i>Snacks</i>	----	----
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips,) grain-based snack mixes.	30 g.....	----	---- cup(s) (---- g) for small pieces (e.g., popcorn) ---- piece(s) (---- g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28 g/visual unit of measure) for bulk products (e.g., potato chips)
<i>Soups</i>	----	----
All varieties.....	245 g.....	----	1 cup (---- g)
<i>Sugars and Sweets</i>	----	----
Baking candies (e.g., chips).....	15 g.....	----	---- piece(s) (---- g) for large pieces; ---- tbsp(s) for small pieces; ½ oz (14 g/visual unit of measure) for bulk products(e.g., potato chips)
Hard candies, breath mints.....	2 g.....	----	---- piece(s) (---- g)
Hard candies, roll-type, mini-size in dispenser packages.....	5 g.....	----	---- piece(s) (---- g)
Hard candies, others.....	15 g.....	----	---- piece(s) (---- g) for large pieces; ---- tbsp(s)
All other candies.....	40 g.....	----	(---- g) for "mini-size" candies measurable by tablespoon; ½ oz (14 g/visual unit of measure) for bulk products
Confectioner's sugar.....	30 g.....	----	---- piece(s) (---- g); 1 ½ oz (42 g/visual unit of measure) for bulk products
Honey, jams, jellies, fruit butter, molasses.....	1 tbsp.....	----	¼ cup (30 g)
Marshmallows.....	30 g.....	----	¼ cup (---- g)
Sugar.....	4 g.....	----	---- cup(s) (---- g) for small pieces or ---- piece(s) (---- g) for large pieces
		----	1 tsp (---- g); ---- piece(s) (---- g) for discrete pieces (e.g., sugar cubes, individually packaged product)

TABLE 2— Continued
 REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3 4}

Product Category	Reference amount	Label statement ⁵
Sugar substitutes.....	An amount equivalent to one reference amount for sugar in sweetness	-----tsp(s) (----- g) for solids; ----- drop(s) (----- g) for liquid; ----- piece(s) (----- g) (e.g., individually packaged products)
Syrups.....	30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others.	2 tbsp (30 mL) for syrups used primarily as an ingredient; ¼ cup (60 mL) for all others
<i>Vegetables</i>
Chili pepper, green onion.....	30 g.....	-----piece(s) (----- g) ¹³ ; -----tbsp(s) (----- g) or ----- cup(s) (----- g) for sliced or chopped products
Vegetables primarily used for garnish or flavor, e.g., pimento, parsley	15 g.....	-----piece(s) (----- g); ----- tbsp(s) (----- g) or ----- cup(s) (----- g) for sliced or chopped products
All other vegetables without sauce: fresh, canned, or frozen	85 g for fresh or frozen; 95 g for vacuum canned; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash	----- piece(s) (----- g) for large pieces (e.g., brussel sprouts); ----- cup(s) (----- g) for small pieces (e.g., cut corn, green peas); 4 oz (112g/ visual unit of measure) if not measurable by cup ¹³
All toher vegetables with sauce: fresh, canned, or frozen	110 g.....	----- piece(s) (----- g) for large pieces (e.g., brussel sprouts); ----- cup(s) (----- g) for small pieces (e.g., cut corn, green peas); 4 oz (112g/ visual unit of measure) if not measurable by cup
Vegetable juice.....	240 mL.....	8 fl oz (240 mL)
Olives ¹¹	15 g.....	-----piece(s) (----- g); -----tbsp(s) (----- g) for sliced products
Pickles, all types ¹¹	30 g.....	1 oz (28g/ visual unit of measure)
Pickle relishes.....	15 g.....	1 tbsp (15 g)
Vegetable pastes, e.g., tomato paste.....	30 g.....	2 tbsp (33 g) for tomato paste; 2 tbsp (----- g) for all others
Vegetable sauces or purees, e.g., tomato sauce, tomato puree	60 g.....	¼ cup (61 g) for tomato sauce; ¼ cup (63g) for tomato puree; ¼ cup (----- g) for all others

¹ These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the USDA.

² Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked)

³ Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

⁴ Copies of the list of products for each product category are available from the Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

⁵ The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

(6) Includes cakes that weigh 10 g or more per cubic inch.

⁷ Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

⁸ Includes cakes that weigh less than 4 g per cubic inch.

(9) Label serving size for ice cream cones and eggs of all sizes will be one unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-serving occasion will be one unit.

¹⁰ Animal products not covered under the Federal Meat Inspection Act or the Poultry Products, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

¹¹ If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (e.g., canned chopped clam in juice).

¹² The reference amount for the uncooked form does not apply to raw fish in § 101.45 or to single-ingredient products that consist of fish or game meat as provided for in § 101.9(b)(j)(11).

¹³ For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices A and B to the regulation entitled "Food Labeling: Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Definition of Substantial Compliance; Correction" (56 FR 60880 as amended 57 FR 8174, March 6, 1992).

¹⁴ Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) The reference amount of a product that requires cooking or the addition of water or other ingredients shall be the amount required to prepare one reference amount of the final product as established in paragraph (b) of this section.

(d) The reference amount for an imitation or substitute food or altered food such, as a "low calorie" version, shall be the same as for the food for which it is offered as a substitute.

(e) If a food is modified by incorporating air (aerated), and thereby the density of the food is lowered by 25 percent or more in weight than that of an appropriate reference regular food as described in § 101.13(j)(1)(ii)(A), and the reference amount of the regular food is in g, the manufacturer may determine the reference amount of the aerated food by adjusting for the difference in density of the aerated food relative to the density of the appropriate reference food provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated food. The reference amount for the aerated food shall be rounded to the nearest 5 g increment. Such products shall bear a descriptive term indicating that extra air has been incorporated (e.g., whipped, aerated). The density-adjusted reference amounts described above may not be used for cakes except for cheese cake. The differences in the densities of different types of cakes having different degrees of air incorporation have already been taken into consideration in determining the reference amounts for cakes in § 101.12(b). In determining the difference in density of the aerated and the regular food, the manufacturer shall adhere to the following:

(1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (e.g., waffles), manufacturers shall use a device or method that ensures that the volumes of the regular and the aerated products are the same.

(2) Sample selections for the density measurements shall be done in accordance with the provisions in § 101.9(e).

(3) Density measurements of the regular and the aerated products shall be conducted by the same trained operator using the same methodology (e.g., the same equipment, procedures, and techniques) under the same conditions.

(4) Density measurements shall be replicated a sufficient number of times to ensure that the average of the measurements is representative of the

true differences in the densities of the regular and the "aerated" products.

(f) The reference amount for products that represent two or more foods packaged and presented to be consumed together (e.g., peanut butter and jelly, cracker and cheese pack, pancakes and syrup) shall be the sum of the reference amounts for individual foods in the package if the reference amount for the product is not listed in paragraph (b) of this section.

(g) The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b) followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl oz)").

(h) The Commissioner of Food and Drugs, either on his or her own initiative or in response to a petition submitted pursuant to part 10 of this chapter, may issue a proposal to establish or amend a reference amount in § 101.12(b). A petition to establish or amend a reference amount shall include:

- (1) Objective of the petition;
- (2) A description of the product;
- (3) A complete sample product label including nutrition label, using the format established by regulation;
- (4) A description of the form (e.g., dry mix, frozen dough) in which the product will be marketed;
- (5) The intended dietary uses of the product with the major use identified (e.g., milk as a beverage and chips as a snack);
- (6) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;
- (7) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);
- (8) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(9) The suggested reference amount (the amount of edible portion of food as consumed, excluding bone, seed, shell, or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested reference amount. In determining the reference amount, general principles and factors in paragraph (a) of this section should be followed.

(10) The suggested reference amount shall be expressed in metric units. Reference amounts for fluids shall be expressed in milliliters (mL). Reference amounts for other foods shall be expressed in grams (g) except when common household units such as cups, tablespoons, and teaspoons, are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as frozen desserts.

(i) In expressing the reference amounts in mL, the following rules shall be followed:

(A) For volumes greater than 30 mL, the volume shall be expressed in multiples of 30 mL.

(B) For volumes less than 30 mL, the volume shall be expressed in mL equivalent to a whole number of teaspoons or one tablespoon, i.e., 5, 10, or 15 mL.

(ii) In expressing the reference amounts in g, the following general rules shall be followed:

(A) For quantities greater than 10 g, the quantity shall be expressed in nearest 5 g increment.

(B) For quantities less than 10 g, exact g weights shall be used.

(11) A petition to create a new subcategory of food with its own reference amount shall include the following additional information:

(i) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size; and the mean, standard deviation, median, and modal consumed amount per eating occasion for the petitioned product and for other products in the category, excluding the petitioned product. All data must be derived from the same survey data.

(ii) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the

petitioned product from the rest of the products in the category.

(12) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under §25.31 of this chapter; and

(13) In conducting research to collect or process food consumption data in support of the petition, the following general guidelines should be followed.

(i) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(ii) Sample size (i.e., number of eaters) should be large enough to give reliable

estimates for customarily consumed amounts.

(iii) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they effect interpretation of results.

(iv) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(14) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act (Pub. L. 101-648).

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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