

Dated: August 2, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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Food Labeling; Serving Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document as a reproposal of its proposed regulation entitled "Food Labeling; Serving Sizes" (55 FR 29517, July 19, 1990) in response to the recent enactment of the Nutrition Labeling and Education Act of 1990. The agency also is responding to public comments submitted in response to the July 19, 1990 serving sizes proposal and to the public meeting held on April 4, 1991, on serving sizes (56 FR 8084, February 26, 1991). FDA is proposing to: (1) Define serving and portion 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 131 food product categories; (3) provide criteria for determining label serving size from the reference amounts; (4) require the use of both common household and metric measures to declare serving size; (5) permit the declaration of serving (portion) size in U.S. measures; (6) permit the optional declaration of nutrient content per 100 grams (g), 100 milliliters (mL), 1 ounce (oz), or 1 fluid ounce (fl oz); (7) define a "single-serving container;" and (8) require that the use of claims such as "low sodium" be based on both the serving size declared on the label and the reference amount.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. 301-443-1751.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

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 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. (oz, fl oz) 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 serving size 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 makes several recommendations related to serving sizes.

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (hereinafter referred to as the "1990 amendments") (Pub. L. 101-535). The 1990 amendments add section 403(q) to the Federal Food, Drug, and Cosmetic Act (the act). 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 sizes are similar in many respects to FDA's 1990 proposal, differences do exist, and questions about the exact meaning and the implementation of these provisions have been raised.

On February 26, 1991 (56 FR 8084), FDA announced a public meeting to discuss issues related to how serving and portion size should be determined and presented as part of nutrition labeling. The notice stated that several issues arising from the comments on the serving size proposal and two other recent developments (the 1990 amendments and the IOM report) required further public comment. Therefore, FDA held a public meeting on serving sizes on April 4, 1991, to provide an opportunity to submit oral comments, as well as an opportunity for written comments, on the issues identified in the notice.

The notice of the public meeting outlined five major issues for discussion at the meeting: (1) Whether, in determining serving (portion) sizes (hereinafter referred to as "serving size" for simplicity) based on the amount of food customarily consumed, the agency should limit itself to national food consumption data, or whether there is other information that should be considered; (2) whether in declaring

serving sizes, weight units in addition to household measures should be required, and how the definition of "household measures" should be standardized; (3) whether deviation from the standard serving size should be allowed if standard serving sizes are required by regulations, and if so, how much deviation should be allowed; (4) whether, in addition to nutrient content per serving, the nutrition label should allow (or require) a column that lists nutrient content on a uniform weight (or volume) basis, such as per 100 g and 100 mL or per oz and fluid oz; and (5) how single-serving containers should be defined, and whether compliance with definitions for adjectival descriptors such as "low sodium" on single-serving containers should be based on the standard serving size or the entire content of a single-serving container. In the announcement, the agency solicited written comments on a sixth, essentially legal, issue involving questions of statutory construction: whether FDA should establish standard serving sizes for specific categories of foods or develop criteria for food manufacturers to use in determining their own serving sizes.

II. Rationale for Reproposal of Serving Sizes Regulation

FDA has carefully considered the serving size provisions of the 1990 amendments and the comments that it received in response to the **Federal Register** documents on serving sizes. As a result, the agency has decided to repropose the serving size regulation for two major reasons. First, FDA wishes to take advantage of the explicit legal authority to regulate the serving sizes used on the nutrition label that is provided by the 1990 amendments. Secondly, the agency has decided to make a number of changes in response to the comments received on the **Federal Register** documents and 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 is proposing to adopt regulations that provide standards for defining serving sizes. There are two basic elements to these proposed standards: (1) Reference amounts of food that are customarily consumed per eating occasion (reference amounts) for 131 product categories; and (2) procedures for determining serving sizes for use on product labels from the reference amounts. While the reference amounts are defined primarily in metric units, under the act, the serving size must be expressed in a common household

measure that is appropriate to the particular food.

This reproposal also responds to many requests for changes in other aspects of the 1990 proposal. After careful consideration of all comments, the agency has tentatively concluded that it is desirable to make changes that include:

(1) Revising the definition for single-serving containers to increase the upper limit from "150 percent or less" to "less than 200 percent; and

(2) Revising the basis for evaluating label claims like "low sodium" to include both the declared serving size and the reference amount.

III. Evaluation of IOM Report and Review of Comments

A. FDA's Evaluation of the IOM Report

The agency has carefully reviewed recommendations related to serving size contained in the IOM report. The IOM recommended the continued use of serving size to present nutrition information, the expression of serving sizes in common household measures followed by weight in g in parentheses, and the establishment of a process for manufacturers to petition for deviations from the standard serving size or to create a new subclass of foods with its own serving size. This reproposal adopts these recommendations.

The IOM report also recommended that FDA and USDA jointly establish serving sizes for a limited (few) number of different food categories for ready product comparisons and reference purposes. In response to the IOM report recommendations, FDA established an interagency committee that included representatives of the Food Safety and Inspection Service and the Human Nutrition Information Service of the United States Department of Agriculture (USDA), as well as FDA members. This committee developed general principles and rules used to determine the reference amounts. The committee reviewed data on the amount of food customarily consumed per eating occasion and other information on serving sizes provided by FDA, e.g., serving sizes recommended in dietary guidance materials, serving sizes recommended in comments, serving sizes currently in use, and serving sizes used in Canada. On the basis of these considerations, the committee developed the product categories and the reference amounts listed in § 101.12(b). Interagency cooperation will continue during the development of the final regulation on serving sizes.

In addition, the IOM report recommended that research be

conducted to determine consumers' comprehension of food labeling information and their interpretation of serving sizes declared on the food label. FDA has conducted both consumer focus groups and formal consumer research on the format of nutrition labeling, including consumer use and understanding of serving sizes. FDA will propose a label format regulation that reflects the results in the near future.

The IOM report made a few other recommendations that FDA is not proposing to adopt. The IOM report recommended that the quantities specified by dietary guidance recommendations serve as "the main criteria for selecting the amount of food to be described as a serving." FDA did not adopt this recommendation for several reasons:

1. Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily consumed" (emphasis added). Thus, the act links serving size to the amount consumed and not to an amount recommended by the dietary guidance recommendations or any other system.

2. There is no single set of dietary guidance serving sizes, and, as seen in Table 7-1 of the IOM report (Ref. 1, pp. 206 and 207), the serving size for the same product may differ in accordance with the objectives and goals of the particular guidance.

3. Many serving sizes that do exist in dietary guidance recommendations are for very narrow food categories, e.g., for a specific type of cake, cookie, or cracker, or for a particular fruit or vegetable. Under the act, however, serving sizes have broad application.

4. There are no dietary guidance recommendations for many product categories, particularly processed packaged products for which nutrition labeling is mandatory (e.g., frozen entrees and dinners; snack foods; pickles; sweets; condiments; foods used as ingredients such as dessert toppings/fillings, sauces, and flour; and infant and toddler foods) (Ref. 2). However, in developing the reference amounts, FDA did consider serving sizes recommended in various dietary guidance materials (Refs. 3 through 8), including those identified in the IOM report.

The IOM report recommended establishing serving sizes for a limited number of broad food categories (e.g., fruit juices, breads, cereals, fruits, vegetables, spreads, and salad dressings). FDA does not believe that such broad categories are adequate to implement section 403(q)(1)(A)(i) of the act. This section defines serving size as an amount customarily consumed. The

amount customarily consumed varies widely among foods within the large categories recommended by the IOM. For example, the customarily consumed amount of fruit varies from 1.5 oz for dried fruits to 10 oz for watermelon. Therefore, to implement the act, FDA believes that many more than the limited number of the broad categories recommended by the IOM are necessary. In developing the reference amounts, however, FDA took product comparability into consideration to promote nutritional comparison of similar products.

The IOM report also recommended that the number of servings per container be rounded down to the nearest whole number. FDA did not adopt this recommendation because it would introduce an unacceptably large error, as high as 45 percent (2.9 rounded down to 2), for the number of servings per container declared on the label. Instead, FDA is proposing to round to the nearest whole number which will limit the error to about 20 percent or less (2.4 rounded down to 2).

B. Summary of Comments

FDA has reviewed the written comments received on the serving size proposal, the written comments to the notice of public meeting on serving sizes, and the presentations at the public meeting.

FDA received about 370 comments on the serving size proposal. Approximately 39 percent were from domestic and foreign food industries and trade organizations; about 36 percent were from consumers and consumer organizations; about 17 percent were from health professionals, health and other professional organizations, and academia; and 8 percent were from domestic and foreign governments. Industry generally expressed reservations about some parts of the proposal and discussed technical issues, which were infrequently discussed by the other sectors (e.g., serving sizes for their specific products). Consumers, consumer organizations, and health professionals overwhelmingly expressed the need for FDA to regulate serving sizes and generally supported the provisions in the proposal. Comments from the international sources understandably focused on the international harmonization of food labeling (e.g., recommended the use of 100 g (or mL) as the basis for the nutrition information).

In response to the agency's request for comment on implications of the IOM report only four from industry

addressed issues related to serving sizes. Two comments favored serving sizes based on dietary guidance materials; one supported the use of serving sizes expressed in common household measures; and the other opposed FDA establishing serving sizes and proposed that the agency set criteria.

Thirty-one oral presentations were made at the April 4, 1991 public meeting on serving sizes, including 26 (about 85 percent) by representatives of food industries and trade organizations; three were by professional nutrition organizations; and two were by consumer organizations. A written transcript of the meeting is on file with Dockets Management Branch (address above). FDA also received about 80 written comments in response to the public meeting notice, primarily from the food industry and trade organizations but also from nutrition and consumer organizations, government agencies, and a few consumers. Industry comments generally were against FDA establishing specific serving sizes. These comments interpreted the 1990 amendments as requiring FDA to establish standards for serving sizes. Health professionals and consumers, on the other hand, continued to support FDA establishing specific serving sizes for product categories. Most comments also addressed the issue of the basis for determining serving sizes. Industry and health professionals favored considering additional information (e.g., "longstanding" industry serving sizes and dietary guidance recommendations) to food consumption data. Consumer organizations favored using only food consumption data. Comments from all sectors generally agreed that serving size should be expressed in common household units.

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

IV. The Repropoed Regulation

A. Introduction

In the 1990 proposal, FDA proposed to retain the current requirement that nutrition information in the labeling of food be declared in relation to a serving or, where the food is customarily not consumed directly, in relation to a portion of the food. The 1990

amendments require that nutrition information be presented on a per serving basis. Therefore, § 101.9(b) of this repropoal codifies this requirement.

In the 1990 proposal, FDA identified five options for regulating serving sizes: (1) Permit manufacturers to establish their own serving sizes; (2) permit manufacturers to develop their own serving sizes by applying criteria established by FDA; (3) FDA adopt a single, uniform serving size (e.g., 100 g or 100 mL); (4) FDA develop standard serving sizes with a petition process to provide a mechanism to add or amend the established serving sizes; and (5) permit manufacturers to use dual declaration of nutrition information on the basis of both standard serving sizes developed by FDA and a uniform 100 g or 100 mL. FDA, choosing the fourth option, proposed to establish standard serving sizes with a petition process for adding to or amending them.

Of those commenting on the five options, a large majority agreed with FDA's approach. Virtually all comments from consumers, health professionals, and State government agencies stated that standard serving sizes are essential and generally supported FDA's proposal. Most food industry comments, however, supported the alternative options of maintaining the current system of allowing manufacturers to develop their own serving sizes or allowing manufacturers to develop their own serving sizes using criteria developed by FDA.

The 1990 amendments (section 2(b)(1)(B)) direct FDA to establish standards to define serving sizes. None of the regulatory options in the 1990 proposal except, the fourth option, the one chosen by FDA, fulfills this legal requirement. Therefore the alternative options are not valid under the 1990 amendments.

To implement this requirement of the 1990 amendments, in this repropoal FDA is proposing to establish regulations under which manufacturers will define the serving sizes that are most appropriate for their products by using the reference amounts and procedures for determining label serving sizes adopted by FDA. To comply with the act with respect to serving size, FDA developed the reference amounts to represent the amount customarily consumed of 131 different types of food, covering virtually everything in the food supply that is regulated by FDA. FDA believes that it is appropriate for it to develop these reference amounts that

provide the basis for serving sizes because the amount of food customarily consumed generally reflects the type of food involved and not who manufactured it. Thus, there is no reason why this amount should vary from manufacturer to manufacturer. Under this proposal, however, manufacturers will convert the reference amount into serving sizes in the common household units that are most appropriate and meaningful for their specific products using the conversion provisions of § 101.9(b)(2).

Several comments objected to FDA determining serving sizes. A trade association expressed concern that government-imposed serving sizes raise flexibility problems for the food industry without providing real benefit to consumers. The association stated that where foods in a category vary in richness and flavor, it is better to let the manufacturer select the serving size than to declare an artificially uniform serving size.

The agency does not agree that consumers will not benefit from a system that would ensure uniformity in serving sizes declared by different manufacturers. Consumers have repeatedly stated the need for uniform serving sizes, and that they perceive a benefit to themselves from FDA establishing standard serving sizes. According to consumers, uniform serving sizes will, among other things, allow them to make comparisons among similar products.

One company commented that the serving size upon which the nutrition information is based should be specific or "appropriate" to the product within the package and objected to establishing a uniform serving size for all products within a category.

FDA agrees that a serving size should be appropriate for the individual product. However, it does not agree that each individual product should have its own serving size. The agency believes that by grouping foods that have similar dietary usage into one category, as was done for the 1990 proposal, a reasonable and appropriate serving size for all foods within that category can be established. As stated above, a consistent serving size for similar products enables consumers to compare the nutritional value of foods that are used interchangeably in the diet.

Several food industry comments stated that FDA developed the 1990 proposal with no input from industry. One company suggested negotiated rulemaking on serving sizes to reach a consensus.

Given the conflicting views in the comments on the proposal, FDA decided

that it would be helpful to receive further input before repositing the serving size regulation. In part because of the time constraints imposed by the 1990 amendments, however, negotiated rulemaking was not a practical option. Instead, FDA decided to hold a public meeting on April 4, 1991, to provide an opportunity for all interested parties, including industry, to present their views and supporting data on various serving size issues. Although a general consensus was not achieved on the several issues that were discussed, this meeting provided the agency with valuable additional information that it used in formulating this reproposal. In addition, at the request of the food industry, FDA has met with many individual companies to discuss serving sizes (Refs. 9 through 16).

Moreover, the agency recognizes that, in certain circumstances, negotiated rulemaking may be a useful tool in developing new or amended reference amounts. Therefore, FDA is providing in proposed § 101.12(h)(14) that, as part of a petition to establish or amend a reference amount, the petitioner shall include information about the feasibility of negotiated rulemaking.

Some comments expressed the need for research on consumers' understanding and use of serving size.

FDA agrees that additional consumer research could be useful in developing the final regulation. The agency has conducted both consumer focus groups and formal consumer research on the format of the nutrition label, including consumer use and understanding of serving sizes. As mentioned earlier, FDA will propose a label format regulation that reflects these research results in the near future. The agency also solicits data on consumers understanding and use of serving sizes.

B. Definition of Serving Size

In § 101.9(b)(1) of the 1990 proposal, FDA proposed to define "serving" or "serving size" to mean the amount of food commonly consumed per eating occasion. Section 403(q)(1)(A)(i) of the act defines serving size as an amount of food "*customarily* consumed" (emphasis added). FDA interprets "an amount customarily consumed" to mean "an amount commonly consumed." Webster dictionaries define "customarily" as "usually," and, in turn, define "usual" as "common." The Webster's New Dictionary of Synonyms and Roget's International Thesaurus list "common" as a synonym for "customary." Thus, FDA's interpretation of "an amount customarily consumed" to mean "an amount commonly consumed" is consistent with the meaning of the word

"customarily," as defined in standard authoritative dictionaries and thesauri.

However, to make the definition consistent with the one in the act, in § 101.9(b)(1), FDA is proposing to replace the term "commonly" in the 1990 proposed definition with the term "customarily" and to add a requirement for the expression of serving size in a common household measure. Thus, FDA has revised proposed § 101.9(b)(1) to state: "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 article purports or is represented to be for infants or for 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." (The underlined portion differs from the definition in the 1990 proposal.)

In § 101.9(b)(1) of the 1990 proposal, FDA proposed to define "portion" to mean "an amount of a food customarily used only as an ingredient in the preparation of other foods." This definition is consistent with the description in the act. Therefore, FDA is retaining the definition of "portion" in § 101.9(b)(1) of this reproposal but modifying it slightly to fit the language of the act. The modified definition reads: " * * * The term 'portion' means 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)."

C. Definition of Single-Serving Container

In § 101.9(b)(2) of the 1990 proposal, FDA proposed to define a single-serving container as a container containing 150 percent or less of the standard serving size and to require that the entire content of the package be labeled as one serving. The agency proposed this definition on the basis of an informal survey that it conducted in the Washington, DC area and FDA's Food Labeling and Package Survey (Ref. 17). These surveys suggested that the 150 percent upper limit on single-serving containers would cover almost all packages whose contents are likely to be consumed at a single-eating occasion.

About two-thirds of the comments on the 1990 proposal supported FDA's definition. Several comments recommended a different cutoff level for single-serving containers however. Some comments stated that the upper

limit should be lowered, e.g., to 125 percent, while another comment suggested increasing the upper limit to 200 percent of the standard serving size. A few comments recommended a range such as 75 to 125 or 50 to 150 percent of the standard serving. The IOM report (Ref. 1) also recommended a range of 50 to 150 percent of the commonly consumed unit.

The agency has learned from its own observations in the marketplace and through comments and presentations at the public meeting on serving sizes, that single-serving packages and containers that are larger than 150 percent of the proposed standard serving sizes are not uncommon on the market and may be increasing in number. One company, for example, pointed out that single-serve buffet cans of canned fruits with pop-tops, which contain 200 percent of the proposed standard serving size, are relatively new on the market but are already extremely popular. Presenters at the public hearing also pointed to additional products intended for consumption at a single-eating occasion that exceed 150 percent of the proposed standard serving sizes, e.g., king-size candy bars. The agency is unable to predict the extent to which these types of larger single-serving products may become available but notes that an increasing number of foods are packaged for convenience to individuals in snacking and in eating away from home.

Because many single-serving packages exceed the proposed 150 percent level, the agency believes that it is not appropriate to lower the cutoff level for the definition of a single-serving container. Rather, in light of the evidence of the trend to larger packages, the agency believes that it is more appropriate to increase the upper limit to "less than 200 percent." This higher level, if adopted, will require that more small packages be labeled as a single-serving.

The agency is proposing to set the upper limit at "less than 200 percent" of the reference amount for two reasons. First, products that contain 200 percent of the reference amount are, by definition, 2 servings. Thus, they are not single servings. Second, there is a significant question as to whether these larger size products will usually be consumed at a single-eating occasion by one individual, considering that the customarily consumed amount is one-half or less than the package container. Thus, the agency believes that it would not be accurate to require that packages containing 200 percent or more, be labeled as single-serving containers.

Other concerns about the proposed upper limit of 150 percent of the standard serving size had to do with a possibility that some manufacturers might increase the size of their product to slightly more than this limit to be able to use a smaller standard serving size. This change would mean that the label information would be misleading to consumers who usually consume the entire amount in the container.

FDA is aware that such misrepresentations may occur in relation to any upper cutoff level that the agency may propose. The agency does not believe that there is a ready solution to this problem. The agency believes that the solution that it is proposing is the most fair, because a manufacturer who provides 200 percent or more of the reference amount is providing two servings of the food under the standards that FDA is proposing. That manufacturer is entitled to label its food accordingly.

Some food industries criticized the proposal to label the total content of a single-serving container as one serving because it would result in different nutritional values appearing on the labels of the same food product, depending upon the size of the container in which the product is packaged. The comments stated that consumers would be confused seeing nutrition information that differs on the same food.

In the notice of public meeting, the agency requested views and data on whether differences in the listing of the nutritional content of the same food would be confusing to consumers. No data on this issue were presented at the meeting or in written comments.

FDA continues to believe that nutrition information based on the entire content of the container for small containers that are usually consumed at a single-eating occasion is most meaningful to consumers because it reflects the nutrient content of the quantity of food that is customarily consumed in the circumstances. Moreover, a large number of consumers requested that FDA require that nutrition information on these products be provided for the entire contents of the container.

Some industry comments stated that it was unnecessary to define single-serving containers at all. One industry comment supported defining a single-serving container to be whatever a manufacturer chooses to call a single-serving. However, consumers repeatedly complained about multiple servings declared on some obviously single-serving products such as soft drinks

Therefore, FDA considers it essential to define single-serving containers.

One industry comment addressed the question of how to define single-serving containers using criteria not related to an amount consumed, e.g., whether the package is recloseable.

FDA does not believe such criteria would be practical or meaningful. With the introduction of the recloseable plastic bag and other type of closures, any container can be made recloseable regardless of the package size.

Comments suggested that FDA establish a lower cutoff level, or that it allow a smaller amount, such as 50 to 75 percent of the standard serving size to be labeled as a half serving. These comments were based on concerns about the possibility that serving sizes could be manipulated in a way that would result in the abuse of adjectival descriptors like "low sodium." Many consumers and health professionals who commented on single serving containers expressed concerns about such abuse.

In § 101.12(g), FDA is proposing that both the serving size declared on the label and the reference amount be used in determining whether a food meets the definition for an adjectival descriptor. Use of both the label serving size and the reference amount will prevent a single-serving container from qualifying for the descriptor based on package size alone. Also, elsewhere in this issue of the *Federal Register*, FDA is proposing regulations for adjectival descriptors that the agency believes will also prevent abuses in their use. Therefore, at this time, FDA does not consider it necessary to define a lower limit for single-serving containers. If a lower limit becomes necessary for reasons other than concern about adjectival descriptors, the agency will reconsider this issue.

Based on all of the information presented to the agency, FDA believes that: (1) Single-serving containers should be defined, (2) it is desirable to increase the upper limit, and (3) there is no basis to establish a lower limit at this time. Therefore, in § 101.9(b)(6) of this reproposal, FDA is proposing to require that manufacturers declare that there is a single-serving in a container or package that contains less than 200 percent of the reference amount proposed in § 101.12(b), and that they declare nutrition information based on the total content of the container.

A few industry comments stated that there should be no upper limit on single-serving containers.

The agency would not consider it appropriate to label a very large container, e.g., a half gallon of ice

cream, as a single-serving container. However, to provide flexibility, in § 101.9(b)(6) of this reproposal, the agency is proposing to allow the manufacturer to declare a single-serving on relatively small containers containing 200 percent or more of the reference amount if the entire content of the container can be expected, reasonably, to be consumed at a single-eating occasion. The determination for reasonableness should be based on food consumption data under actual conditions of use. Manufacturers should be prepared to provide the agency with the data that supports the single-serving claim upon request. The agency is aware that this allowance has a potential for misuse. The agency intends to consider regulatory action for misuse of this allowance.

FDA requests comments on the new upper limit for single-serving containers and on whether it is reasonable to allow the manufacturer to determine the single-serving status above that level.

D. Proposed Reference Amounts for Serving Sizes

1. Introduction

In § 101.12(b) of the 1990 proposal, FDA proposed standard serving sizes for 159 product categories that were primarily based on the amount commonly consumed by the relevant population (i.e., persons 4 or more years of age, infants, or toddlers) as reported in the 1977-1978 Nationwide Food Consumption Survey (NFCS) conducted by USDA. The proposed standard serving sizes were generally expressed in U.S. units.

The 1990 amendments require that FDA establish standards to define serving size (section 2(b)(1)(B) of the 1990 amendments). To implement this requirement, FDA is proposing to establish procedures under which manufacturers would derive the appropriate serving size from the reference amounts in § 101.12(b), instead of establishing specific serving sizes.

Before discussing the reference amounts and the other procedures for determining serving size, FDA wishes to respond to comments that it received on the methodology that should be used in determining serving sizes.

1. About two-thirds of the comments on the 1990 proposal, that addressed the methodology question agreed with FDA's approach of using food consumption data. The other comments suggested that other or additional sources be used, such as longstanding industry serving sizes, serving sizes currently in use, the serving sizes in dietary guidance or educational

materials, diabetic food exchange lists, and USDA Handbook number 72, entitled "Nutritive Value of Foods."

Discussion at the public meeting focused largely on this issue. Two consumer organizations supported FDA's use of food consumption data as the basis for establishing serving sizes. One organization stated that the 1990 amendments require the use of only food consumption data in establishing serving sizes. However, most other presenters stated that, in addition to food consumption data, other information such as those listed above, should be used as supplementary sources for determining serving sizes for nutrition labeling purposes.

Section 403(q)(1)(A)(i) of the act has the effect of requiring the use of food consumption data as the primary basis for the serving size determination. FDA believes that without such data, it is impossible to determine the amount of food that is customarily consumed. However, FDA believes that other information related to serving size can be useful, particularly when food consumption data are inadequate. The agency used several additional sources of information in arriving at the reference amounts proposed in § 101.12(b). These additional sources, and when and how they were used, are described in sections IV.D.3.c. and IV.D.3.d. of this document.

With regard to longstanding industry serving sizes, in the February 26, 1991 notice for the public meeting, FDA requested comments and supporting data on the definition of "longstanding" serving size. One comment 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 and serving sizes currently on product labels in arriving at the reference amounts (Ref. 2).

FDA does not consider the diabetic exchange lists to be an appropriate source to use in determining serving size under the act for several reasons. Serving sizes contained in the diabetic exchange lists are tailored so that each food choice within an individual exchange list will provide similar amounts of calories, protein, carbohydrate, and fat (Ref. 5). Therefore, the driving force in determining the serving size for the exchange lists is calorie content and content of energy-producing macronutrients, not an amount of food customarily consumed

as required by the act. Consequently, many different specific serving sizes are given for individual foods that belong to the same category. For example, several serving sizes are given for frozen desserts, ¼ cup for sherbet, ½ cup for frozen yogurt, and ½ cup for ice cream. Also, the serving size for some foods is very small, e.g., one-half English muffin, which does not represent an amount customarily consumed by the general population. In addition, FDA does not believe that serving sizes designed to meet a special dietary need of a subpopulation that has a unique health problem are appropriate to use as serving sizes for the nutrition labeling of products for the general population.

FDA does not consider the serving sizes in any USDA Handbooks, including number 72, to be an appropriate source given the definition of "serving size" in the act. Because these Handbooks are not intended to reflect "amount customarily consumed," the serving sizes in them are not based on food consumption data and are not necessarily representative of an amount customarily consumed. In addition, these handbooks list a limited number of the prepared and packaged foods (e.g., frozen entrees) that are subject to mandatory nutrition labeling.

2. Some industry comments contended that many currently used serving sizes have been used for many years and are familiar to consumers, and therefore that changing them could be confusing.

The act defines serving size as an amount customarily consumed. Thus, the primary basis for serving size must be consumption data, not current labeling practices. Furthermore, a professional nutrition association commented that its members have reported that consumers are generally unaware of the serving sizes that are used by industry. At the public meeting, a consumer organization presented similar data from its own informal survey. Based on this information, the agency does not believe that it would be confusing to consumers to make changes in currently used serving sizes.

3. Industry comments also stated that some of the serving sizes in current use were established cooperatively with FDA.

The agency acknowledges that, in the absence of a formal regulation and upon the request of different segments of the food industry, it has provided advisory opinions on serving size on a food-by-food basis. These advisory opinions have not gone through rulemaking procedures. FDA is now required by law to develop a serving size regulation for all food products based on an amount

that is customarily consumed. Therefore, the proposed reference amounts listed in § 101.12(b), and the label serving sizes derived under the procedures proposed in this document, will supersede all advisory opinions previously given to the industry.

4. Some industry comments objected to the use of only food consumption data in determining serving sizes on the basis that:

(1) Food consumption data have known inaccuracies;

(2) The amount per eating occasion does not reflect the multiple servings or "helpings" that may be consumed at a single-eating occasion;

(3) The data used for the proposal were more than a decade old and eating habits may have changed; and

(4) Food consumption data are not the recommended amounts in terms of diet and health. Some nonindustry comments also supported the use of more recent data such as data from 1987-1988 NFCS.

FDA acknowledges that the 1987-1988 NFCS data may have inaccuracies (e.g., underreporting of intakes) as food consumption surveys usually do.

However, food consumption survey data, such as NFCS, provide objective estimates of amounts of food customarily consumed. The NFCS is nationally representative and represents the most comprehensive data on food consumption practices of the U.S. population that are available to the agency. In using the food consumption data, the agency sought to ensure that the amount reported was reasonable (see section IV.D.3.d. of this document). As for multiple helpings or servings, it is very likely that some people reported amounts that represented multiple helpings or servings because the total reported by such people represents the amount that they customarily consume at a single eating occasion.

Since the 1990 proposal was published, USDA has released the final data tape for the 1987-1988 NFCS. FDA analyzed this new survey data in developing the proposed reference amounts, as discussed in section IV.D.3.a. of this document.

The argument that serving sizes should be recommended amounts in terms of diet and health is not consistent with the requirement of the act. The act defines serving size as "an amount customarily consumed" and not an amount recommended to promote health.

5. Several comments on how to calculate customarily or commonly consumed amounts included suggestions for: (1) the use of the median instead of the mean because mean is more likely influenced by outlier values than the

median, (2) the use of the mode (that is, the most frequently consumed amount), (3) inclusion of the sample size in the criteria, (4) consideration of the demographics of "key" consumers and avoidance of data skewed by nonprimary users, and (5) the use of the lowest common denominator in household measures for a product (e.g., 1 oz for cheese, one slice for bread).

In determining the standard serving sizes proposed on July 19, 1990, FDA used the amount consumed per eating occasion (hereinafter referred to as "consumed serving size (CSS)") by an individual as the basis for serving size. To estimate the amount commonly consumed by a population group, the agency used both the mean and the median CSS for the group, with the mean as the driving force and the median as a guide in rounding the value to a meaningful household measure. For example, if the mean was 2.3 oz and the median was 1.6 oz, the agency rounded the mean down to 2 oz rather than up to 2.5 oz. FDA believes that both the mean and the median CSS are valid values for determining the customarily consumed amount, and that the exclusion of one or the other is not desirable.

Regarding the suggestion for use of the mode, FDA performed additional data analysis for this reproposal to include the mode. The mode was not useful, however, 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. However, the mode did provide additional guidance in determining the reference amount. The agency also took the sample size into consideration in developing the reference amounts, as discussed in sections IV.D.3.d. of this document.

Concerning the suggestion to consider the demographics of "key" consumers and avoidance of data skewed by nonprimary users, the NFCS survey design took into consideration the demographics of all users, and "key" users usually determine the customarily consumed amounts (i.e., mean, median, and modal CSS values). The mean is influenced by outliers, but this influence is lessened as sample size increases. The consideration of sample size, and the median and modal CSS values, which are less influenced by the outliers or skewed data, further improved the determination of the reference amounts in this reproposal.

Finally, with respect to the suggested use of the lowest common denominator, in light of the requirement of the act that serving size be the amount customarily consumed, FDA does not believe that

use of the lowest common denominator is legally allowable except when it represents the customarily consumed amount.

6. Another industry comment stated that a weighted average is not appropriate for determining serving size because there are too many varieties of a product/food item.

FDA is well aware of the large variety of food products in the marketplace. One reason why the agency could not establish serving sizes for a limited number of broad categories as recommended by the IOM report is the large variety of food products (see section III.A. of this document). Consequently, the agency performed extensive data analysis to ensure that only foods similar in dietary usage and consumption size were included in a proposed product category. FDA continues to believe that a reasonable reference amount can be established for all product categories by grouping foods that are similar in dietary usage and consumption size.

7. Several oral presentations at the public meeting and written comments that FDA received in response to the meeting notice stated that the amount "customarily consumed" is highly variable and is related to a number of factors such as the age and sex of the individual. Some industry comments stated that the amount of food customarily or typically consumed is also affected by such factors as how a food is packaged and positioned in the marketplace (e.g., as a snack or entree), and that the average consumed amount is difficult to define for many food products because of their many uses and varying consumption at different times of day.

FDA acknowledges that the high variability among individuals in the amounts that are customarily consumed may reduce the value of a reference quantity to any one individual who is not consuming servings of foods that are approximately the size of that reference quantity. Therefore, FDA is also proposing to permit manufacturers to present nutrient values based on a uniform unit (e.g., 100 g or 1 oz), in addition to the declaration of nutrients on the basis of a serving. Such presentations may, in some circumstances, facilitate comparisons of different kinds of the same food. Furthermore, such presentations may also facilitate comparisons of foods belonging to different food groups.

In addition to the variability among individuals, FDA recognizes that the diverse nature of food products also complicates the process for determining

reference amounts. However, national food consumption surveys, including USDA's NFCS, have many factors built into the survey design that make it possible to estimate food consumption patterns representative of the U.S. population. Sample persons in the survey are selected by statistical procedures that ensure representation of all ages, both sexes, and other demographic and socio-economic characteristics of the U.S. population. Dietary intake information is collected throughout the day so as to cover many different uses (e.g., as snacks vs. entrees) and varying consumption at different times of day (e.g., breakfast vs. dinner). Therefore, many concerns raised in the comments are addressed by the design of the NFCS survey.

The agency is willing to consider any data that may give a better estimate of an amount customarily consumed for a specific product category. Although FDA received some data in the comments, these data were unacceptable for various reasons. For example, the estimates were not representative of the food consumption practices of the relevant population group; the data were inappropriate because of flaws in the study design; or there was poor documentation of the methodology. In section K (Petition Process), the agency is proposing general guidelines on how to conduct a survey and to collect data to support a request for change in a proposed reference amount or to establish a reference amount for a subcategory of food or a product category not covered by this proposal.

FDA is well aware of the fact that an amount of food customarily consumed is highly variable among people who differ by age, sex, body build, life style, and other attributes. The agency wishes to make it clear that it is not trying to estimate accurately serving sizes that apply to any particular individual. As pointed out in the 1990 proposal, neither the reference amount nor the serving size declared on the product label are to be interpreted as recommended amounts for consumption. Rather, given the particular product category, the reference amount, which may be modified somewhat as the serving size on the product label because of the size and shape of the product, represents the amount of that type of food that is customarily consumed by persons in a particular population group (e.g., by all persons 4 years of age or older).

8. One of the general principles that FDA followed in arriving at the standard serving sizes in the 1990 proposal was that a serving size should be based on only the edible portion of food, and not

bone, seed, shell, or other inedible components. The National Fisheries Institute commented that serving sizes for fish cannot always be based on edible weight because bones cannot be separated from flesh.

FDA believes that the fish industry should be able to estimate the edible portion of the fish from its own data or other standard statistical data that provide percent refuse information, e.g., USDA Handbook No. 102 entitled "Food Yields Summarized by Different Stages of Preparation" (Ref. 18).

9. Some comments that agreed with the use of food consumption data expressed reservations about some specific aspects of the 1990 proposal. The Association of State and Territorial Officials stated that the basis for serving sizes should be the average amount consumed by an adult. A few health professionals commented that it was unrealistic to calculate average amounts from food consumption data that include all persons 4 years of age and older because of the large differences in the amount of food eaten.

FDA proposed two sets of standard serving sizes in the 1990 proposal, one for infant and toddler foods and one for the general food supply. Infant and toddler foods were presented separately because these foods differ from the general food supply in that they are specially processed for consumption by infants or by very young children. Children 4 years of age and older generally eat from the same food supply as the rest of the family.

FDA acknowledges that there are large differences in the amounts consumed among persons 4 years of age or older. Having several sets of serving sizes for different age subgroups of the general population category would likely produce serving sizes more realistic for each subgroup. However, several columns of nutrition information, one for each age subcategory, would be required on the labels of many products. These additional columns would be unreasonable and impractical. As pointed out earlier, neither the reference amount nor the serving size declared on the product label are amounts recommended for consumption. They represent reasonable quantities of foods for declaring nutritional values. Accordingly, FDA is proposing one set of reference amounts for all persons 4 or more years of age.

10. A baby food manufacturer commented that the amount customarily consumed is not appropriate for foods intended for infants and children because their intakes vary markedly,

and mothers could interpret the serving size as a recommended amount.

FDA believes that this comment misunderstands the purpose of a serving size. 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 this type of misunderstanding 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.

The company suggested using the jar (i.e., the entire content of the jar) as the serving size. The act requires serving size to be the amount customarily consumed and, therefore, jar size cannot be used as the basis for determining the reference amount which, in turn, determines the label serving size, unless the jar size agrees with the customarily consumed amount. The reference amounts for baby foods in § 101.12(b) are the amounts customarily consumed by infants, from which the manufacturers are to determine the label serving size for their products. Because most small jars currently in the marketplace meet the definition for single-serving containers, nutrition information for most baby foods would be provided on a per jar basis. However, an increasing number of multi-serving containers of baby foods are entering the market. The label serving size based on the reference amount enables nutritional comparison of these products.

11. One industry comment on the 1990 proposal stated that, because FDA selected foods having a high frequency of consumption to represent the category instead of using all foods appropriate for the category, the agency results were incorrect. The company further claimed that FDA's misclassification of the pourable salad dressings category led the agency to inappropriately set the serving size for pourable salad dressings at 2 tablespoons rather than 1 tablespoon. The company submitted results of its own analysis which supported 1 tablespoon.

FDA reexamined its original food selection scheme and repeated the data analysis using all foods relevant for the category. The results reaffirmed the appropriateness of the original food selection strategy and the accuracy of the results published in the 1990 proposal (Ref. 19).

12. A government agency commented that some product categories were not sufficiently descriptive, making it difficult to make proper categorization of products. A few industry comments stated that they had difficulty in identifying the product category in which their products belong and requested additional categories. Products cited in the comments were fish sticks and sandwiches.

Fish sticks are included in the category of "Fish, shellfish, and meat or poultry substitutes: entrees (cooked) without sauce" (renamed in this reproposal as "Fish, Shellfish, and Meat or Poultry Substitutes: Entrees without sauce"). In the 1990 proposal, sandwiches were included in the category of "Meal type trays: Lunch or dinner trays, Sandwich." For this reproposal, sandwiches are included in the category of "Mixed dishes: Not measurable with cup * * *."

To help manufacturers and others to identify the category in which their specific products fit, the agency has provided an extensive list of products for each product category (Ref. 20). FDA has also modified the names of some product categories to be more descriptive.

13. A few industry comments stated that there should be two serving sizes for some foods (e.g., rice), one for its use as a side dish and one for its use as an entree.

FDA rejects this suggestion for three reasons. First, one of the uses of the reference amount is to determine the appropriateness of nutrient content and health claims made for food products. Such a determination cannot be made on two or more different bases (i.e., standards), e.g., a smaller reference amount to evaluate a claim for a side dish and a larger reference amount to evaluate a similar claim on a similar product labeled as an entree.

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

The agency would not object, however, to manufacturers providing a second column of nutrition information based on an alternative serving size as a side dish or as an entree. However, the agency wants to make it clear that it will use the reference amount to evaluate whether the product meets FDA standards for any claim made for the product.

14. A consumer organization pointed out that a manufacturer of liquid cream substitutes uses 1 tablespoon as the serving size for nutrition labeling but promotes the product for use with breakfast cereal. Because the amount of the cream substitute consumed with the breakfast cereal is much larger (e.g., 1/2 cup or 8 tablespoons) than when used as a coffee whitener, the nutrition information based on 1 tablespoon is misleading to consumers who use the product with breakfast cereals.

FDA agrees with the comment that nutrition information based on 1 tablespoon, which is the customarily consumed amount of this food, is misleading to consumers who use the product with breakfast cereals as suggested by the manufacturer. This type of promotion can happen to any product. To prevent such misleading labeling, in § 101.9(b)(11) of this reproposal, FDA is proposing 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 in § 101.12(b) is 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 in the promoted use, in addition to the nutrition information per serving derived from the reference amount in § 101.12(b).

15. An industry comment pointed out that portion size varies greatly for all foods used as ingredients.

FDA acknowledges that ingredient usage of a food varies widely depending on the recipe, and food consumption surveys do not usually provide information useful for determining portion size. When survey data were not available, FDA used various alternative approaches to estimate the portion sizes in the 1990 proposal such as the portion size for flour. FDA used similar methods in determining the reference amounts for portion sizes in this reproposal. The technical report on this reproposal (Ref. 2) documents the basis for each portion size proposed.

16. A manufacturer of "cooking sauce" (e.g., soy sauce, teriyaki sauce) suggested using the average amount used in recipes to determine a portion size of cooking sauce.

Some "cooking sauces" (e.g., soy sauce) are used both in the form as purchased and as an ingredient of other foods. As discussed above, ingredient usage varies widely depending on the recipe and there is no easy way to determine the customarily consumed amount of these sauces using recipes. NFCS does provide some estimates of

the consumed serving size of these sauces in the form purchased. Therefore, the NFCS data are the best information available, and FDA used them to determine the reference amount for the "cooking sauces."

2. General Principles Considered in Developing Reference Amounts

The act defines serving size as the amount customarily consumed which is expressed in a common household measure that is appropriate to the food. Although the amount customarily consumed is similar in weight or volume, in many instances, the customarily consumed amounts in household measures differ for different products within the same category because they come in different shapes and sizes. For example, food consumption data show that the amount customarily consumed for vegetables without sauce is about 85 g. A common household measure for this amount of green peas and cut corn would be about 1/2 cup, whereas many other vegetables come in the form that cannot be measured with a cup, e.g., brussels sprouts and broccoli spears. A common household measure appropriate for the latter vegetables would be pieces or oz. Because there is no uniform household measure that can be used for vegetables, the most reasonable approach for this type of food is to establish the reference amount in g and to let the manufacturers determine the label serving size in a common household measure that is most appropriate to their specific products.

FDA, therefore, decided to propose reference amounts that represent the amount customarily consumed of the products within the category, which manufacturers can use as the guide to determine the label serving size in common household measures that are most appropriate for their specific products. To determine the reference amount of food, FDA used the general principles and procedures described in this and following sections. The general principles, which are reflected in proposed § 101.12(a), are:

a. The reference amount represents the amount of food that is customarily consumed per eating occasion by the relevant (target) population group as determined by data from an appropriate national food consumption survey. This principle links the reference amount, and thus the label serving size, to food consumption data as required by the act.

b. An appropriate food consumption survey is one that includes a large sample size representative of the demographic and socio-economic characteristics of the target population

group for which the food is intended and that is based on consumption data under actual conditions of use. Use of such a survey will ensure that the customarily consumed amount determined is a reliable estimate that is representative of all sectors of the U.S. population that consume the food and that reflects the amount that they actually consume.

c. Three target population groups, infants, toddlers, and the general population are relevant for estimating customarily consumed amounts of food. In another technical supporting proposal published in the *Federal Register* of July 19, 1990, entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (55 FR 29476), FDA identified five age groups for nutrition labeling purposes. The five groups are infants, toddlers, pregnant, lactating, and the general population group. The agency is not aware of any foods in the food supply which are specially processed for use by pregnant or lactating women. Therefore, customarily consumed amounts will be estimated only for three age groups: foods intended for the general population, i.e., persons 4 years of age or older; foods specifically formulated or processed for use by infants up to 12 months of age; and foods specially formulated or processed for use by toddlers 1 through 3 years of age.

d. To determine the reference amount, all three statistical estimates that represent an amount customarily consumed, the mean (i.e., average), the median (i.e., 50th percentile value), and the mode (i.e., most frequently consumed amount) of the consumed amount per eating occasion should be considered.

e. In addition to food consumption data, other relevant information on serving sizes of food, such as that listed below in section IV.D.3.c. of this document, should be taken into consideration, particularly when survey data are insufficient to give a reliable estimate of the amount customarily consumed.

f. The reference amount and, in turn, the serving size declared on the product label must be based on the edible portion of the food because the inedible parts, such as bone, seed, shell, or rind, are not consumed and thus do not contribute to the nutritional value of the food.

g. Many foods are consumed both as a serving (i.e., in the form as purchased) and as a portion (i.e., as an ingredient of other foods). For example, butter and margarine are consumed in the form as purchased and as ingredients of foods such as cookies and cakes. Because the amount of such foods used as an

ingredient (i.e., portion size) varies from recipe to recipe, and there usually is no easy way to determine the amount customarily consumed using recipes, the most reasonable approach for estimating the reference amount for these foods is to base it on the amount customarily consumed in the form purchased.

h. The reference amount must reflect the major dietary use of the food when this information is available because the major usage determines the customarily consumed amount. For example, milk may be used as a beverage or as a liquid to add to coffee or cereal. Because the major usage of milk is as a beverage, the reference amount for milk must reflect the amount consumed as a beverage.

i. The reference amount must be uniform for foods that are similar in dietary usage, product characteristics, and customarily consumed amount. For example, chips and other similar snacks (e.g., pretzels and extruded snacks) must have the same reference amount because these foods are consumed in similar manner, are used interchangeably in the diet, and have similar customarily consumed amounts. Uniformity in reference amounts for similar products will enable consumers to make nutritional comparisons of these products.

3. Determination of Reference Amounts for Serving Sizes

This section describes the detailed procedures that FDA used to apply the general principles described above in determining the reference amounts.

a. *Selection of food consumption data base.* FDA needed a food consumption data base that contained individual food intake data representative of the food consumption practices of the three age groups of interest. In determining "standard serving sizes" for the 1990 proposal, FDA chose, from the several national food consumption survey data bases then available, USDA's 1977-1978 NFCS (Refs. 21 through 24). FDA did so because this data base contained: (1) The largest number of persons, 30,777; (2) data on 3-day dietary intakes; and (3) data for all ages. Data from more recent nationwide food consumption surveys (e.g., the NFCS conducted by USDA in 1987-1988 and the third National Health and Nutrition Examination Survey (NHANES III) conducted by the Department of Health and Human Services) were not available. Since the 1990 proposal was published, USDA released the final data tape for the 1987-1988 NFCS (Ref. 25). Dietary intake data from NHANES III are not yet available.

FDA used the 1987-1988 NFCS as a source of food consumption data representative of more recent food consumption practices of the three age groups identified for nutrition labeling purposes. This new survey, however, had an unusually low response rate (Refs. 26 and 27). 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. However, the low response rate limited the use of the new NFCS data base because there is no way to know if respondents and nonrespondents behave in the same way. If the consumption behavior of nonrespondents is different than that of respondents, the results of the 1987-1988 NFCS are not representative of the amount customarily consumed of all users in the relevant population group.

Therefore, FDA used both the 1977-1978 and 1987-1988 survey data in developing the reference amounts. When the results from the 1987-1988 NFCS suggested a change in food consumption practices since the 1977-1978 NFCS (e.g., consumption increased or decreased substantially), FDA used other recent USDA data that did not have a response rate problem, namely, the 1985 and 1986 Continuing Surveys of Food Intakes by Individuals (CSFII's) (Refs. 28 and 29) to confirm the trend change. As discussed in the technical report prepared in support of the 1990 proposal (Ref. 17), the CSFII could not be used as the data base for determining customarily consumed amounts of food because it included neither the infant population nor the whole population of persons 4 years of age or older. However, it is an appropriate data base for the limited purpose that FDA used it. If the validity of the trend was supported by the CSFII data, FDA used the 1987-1988 NFCS data. Such a validity check to confirm the trend change observed in the 1987-1988 NFCS was recommended by an expert ad hoc committee that evaluated impact of nonresponse in the 1987-1988 NFCS (Ref. 26).

b. *Determination of the product categories.* This section provides a detailed description of how FDA applied the general principles outlined above to develop the 131 product categories.

i. *Step 1.* FDA started out with the 9 major food groups used by the USDA for the NFCS (Ref. 2). The 9 groups are milk and milk products; meat, poultry, fish, and mixtures containing these products; eggs, mixtures with eggs, and egg substitutes; dry legumes, nuts, and seeds; grain products; fruits; vegetables;

fats, oils, and salad dressings; and sugars, sweets, and beverages.

FDA further divided the foods within each of these major food groups into smaller groups by product class. For example, it divided milk and milk products into such groups as milks, cheeses, and ice creams. The agency then further divided foods within each of these product classes into subgroups according to dietary usage and other characteristics that were likely to affect the levels of consumption of foods within the product class. For example, FDA divided cream and cream substitutes into two subgroups, fluid forms and powdered forms; and pickles into 5 subgroups: dill pickles, sour pickles, sweet pickles, relishes, and olives. The agency grouped the foods in this way to assure that only those foods that were likely to have similar levels of consumption were included in the final food group used to determine the amount customarily consumed. The resultant food groups represented the preliminary product categories.

USDA's major food grouping system classified foods by the major ingredients of the food. Thus, under this system some foods that belong to the same product category, like soups, are not listed together but rather are separated into several major food groups depending on the major ingredients. For example, meat, poultry, or seafood-based soups are included in the meat, poultry, and fish group. Split pea soup is included in the dry legumes, nuts, and seeds group; grain-based soups are included in the grain products group; and vegetable soups are included in the vegetable group. In identifying preliminary product categories, FDA grouped all soups into one category.

ii. *Step 2.* FDA further refined the preliminary product categories by selecting foods available in the marketplace to represent the category. This selection was necessary because the NFCS lists foods on an as consumed basis, and thus, many foods that are not available in the marketplace are on the list. For example, breads are listed both in toasted and untoasted forms. FDA did not use toasted breads for the CSS analysis because this form is not available in the marketplace. In addition, when incomplete information was obtained from survey respondents, foods in the NFCS data base were often described as "not further specified (NFS) as to * * *." When these NFS foods were likely to contain foods that may differ in consumed serving size, FDA excluded them from the CSS analysis. For example, "salad dressing, not further specified" (food code 831-

0010) was not used to estimate the CSS value for pourable dressings (e.g., French dressing, Italian dressing) or for nonpourable dressings (e.g., mayonnaise) because this food code is likely to contain both pourable and nonpourable dressings which may differ in consumed serving size.

iii. *Step 3.* FDA determined the mean, median, and modal CSS per eating occasion for each preliminary product category (see Ref. 2 for more detailed description and data).

iv. *Step 4.* The survey data expressed the amount of food consumed in g. Therefore, FDA converted the g weight of the mean, median, and modal CSS values determined in step 3 to measures that are more meaningful for nutrition labeling purposes, i.e., to household measures such as oz, fl oz, cups, tablespoons, and teaspoons. The agency used the gram-to-household measure, described in USDA's manuals showing the relationship for the common measure and g weight (Refs. 30 and 31), to convert g weights to household measures. This conversion of the g weight to household measures was done to ensure that foods similar in CSS values in household measures are grouped together and that the reference amounts derived from the survey data are meaningful in household measures, which are the label serving size units required by the act. For example, the median CSS value for mixed dishes without sauce appears to be much lower than that for mixed dishes with sauce in g weight (157 g vs. 249 g), giving a false impression that the two products have different CSS values. However, when converted to a cup measure, which is the common household measure for these products, the CSS values for the two products are more uniform (0.9 vs. 1.1 cup). This similarity reflects the fact that while the g weight of 1 cup of mixed dishes without sauce is much lower (about 150 to 200 g) than the g weight of 1 cup of mixed dishes with sauce (about 220 to 250 g), they are consumed in similar amounts in terms of volume. Therefore, expressing CSS values in household measures showed clearly that the same reference amount applies to both mixed dishes with and without sauce.

In converting the g weight to the household measure for the purpose of developing reference amounts, the agency used the following general criteria in determining whether weight or volumetric measures should be used: It used volumetric measures: (1) for beverages (in fl oz) and (2) if all foods in the food group are usually measured on a volume basis by consumers, e.g.,

honey, syrups, preserves, and salad dressings. It used weight measures: (1) if foods in the food group are usually not measured on a volume basis or are in distinct units, e.g., fish, muffins and pizzas; or (2) if some foods in the group are often measured by weight, but others are measured by volume (e.g., for fruits and vegetables, small berries and green peas may be measured by volume (cup), but many whole fruits and vegetables (e.g., broccoli spears) cannot).

v. *Step 5.* FDA collapsed the product categories further to combine product categories that had similar dietary usage or CSS values in household measures to reduce the number of product categories. For example, mayonnaise, sandwich spread, and mayonnaise-type dressings, in the fats and oils category, had similar CSS values, and thus FDA combined them into one product category.

vi. *Step 6.* Because food consumption surveys report amounts of foods as consumed, many foods that are primarily used as ingredients (e.g., flour, pie crust) were not on the NFCS food list. FDA added categories for these and a few other products that were not reported in the NFCS but that were identified through comments and informal checking of the products available in the Washington, DC metropolitan area to the preliminary category list. The resulting list of product categories represented the final product categories.

c. *"Other information" related to serving size.* To respond to recommendations in the IOM report and 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 the following information in developing the proposed reference amounts in § 101.12(b).

i. Serving sizes recommended by dietary guidance recommendations and other authoritative systems or organizations (Refs. 3 through 8).

ii. Serving sizes recommended in comments on the 1990 proposal and in response to the notice of public meeting.

iii. Serving sizes currently used by manufacturers (e.g., product labels) and grocers (e.g., major supermarket chains).

iv. Serving sizes used by other countries (e.g., Canada).

d. *Procedure for determining reference amounts.* To determine the reference amounts that are proposed, FDA examined both the survey data (CSS values) obtained by the procedures described in section IV.D.3.b. of this

document and the other information listed above. Using the general guidelines described below, the agency determined the proposed reference amount for each product category. The CSS values and the detailed description of how the proposed reference amount was determined for each product category are contained in FDA's technical report (Ref. 2).

i. Because the act requires that food consumption data be used as the primary data source for the serving size determination, in determining the reference amounts for specific product categories, FDA first considered food consumption data and whether it provided an appropriate basis from which to derive reference amounts. In deciding whether the data provided an appropriate basis, FDA considered the adequacy of the sample size and the consistency of the data.

ii. FDA believes that a sample size (number of eating occasions) of 140 or larger is large enough to provide reasonable assurance for a reliable estimate for the customarily consumed amount. This sample size is the same as the minimum sample size used by USDA to present the 5th and the 95th percentile values for the NFCS data (Ref. 32). Although FDA did not use the 5th and the 95th percentile values in developing the reference amounts, it did use the mode. Many product categories had multiple modes, which, to be reliable, must be based on a larger sample size than that which would be necessary to ensure the reliability of the mean or the median values. Therefore, to ensure that the modal values were reliable, FDA used 140 as the cutoff for the adequate sample size, which is the largest minimum sample size required for presenting the NFCS data (Ref. 32).

FDA believes that a sample size of 40 through 139 (intermediate range) may not be large enough to provide reasonable assurance of a reliable estimate of the customarily consumed amount considering the multiple modes observed for many product categories. The lower cutoff level for the intermediate range (40) is the same as the minimum sample size used by USDA to present the 25th and the 75th percentile values for the NFCS data (Ref. 32).

FDA believes that a sample size of less than 40 is inadequate to provide reasonable assurance of a reliable estimate of the customarily consumed amount.

iii. *Steps followed in selecting survey data* As mentioned earlier, FDA used both the 1977-1978 NFCS and the 1987-1988 NFCS as the source of food consumption data because the 1987-1988

NFCS could not be used alone given the low response rate problem in this survey. The agency used the following guidelines in selecting the survey data for determining the reference amount for each product category:

(A) If the 1987-1988 NFCS data did not substantially differ from the 1977-1978 NFCS data, and the sample sizes for both surveys were equally adequate, data from both surveys were used. The use of data from both surveys increased the data points, i.e., provided two sets of the mean, median, and modal CSS values, rather than one set from a single survey. Therefore, the reliability of the reference amount determined was strengthened.

(B) If the 1987-1988 NFCS data suggested a change in consumption practices since the 1977-1978 NFCS (i.e., CSS values increased or decreased), and the validity of the change was supported by the CSFII data, the new survey data were used because the trend change observed in the 1987-1988 NFCS is likely to be a real change in consumption practices. For example, CSS values from the 1987-1988 NFCS for the popsicles and snow cones category showed a slight but consistent increase in the consumption of these foods. This trend increase was supported by the 1985 and 1988 CSFII's (Ref. 2). Therefore, FDA used the 1987-1988 NFCS data to determine the reference amount for this category.

(C) If the new survey data suggested a change in consumption practices, but the change was not or could not be supported by the CSFII data, the agency made its best judgment based on the available evidence, and it documented the basis for its judgment (Ref. 2). For example, both the median and modal CSS values from the 1977-1978 NFCS (N=98) suggested 2 tablespoons to be a reasonable reference amount for the condensed milk category. The data from the 1987-1988 NFCS suggested a much smaller reference amount, about ½ tablespoon. However, the sample size for the new survey was grossly inadequate (N=11), and thus, this smaller value could not be used. The CSFII had only one observation, and therefore, could not provide any information to support or deny the smaller CSS values observed in the 1987-1988 NFCS. There was no consistency in the serving size recommended in comments, serving size currently in use by the manufacturers and grocers, and the Canadian serving size. The applicable serving sizes from these sources ranged from ¼ cup to ½ cup. Although the sample size fell in the intermediate range, the 1977-1978 NFCS consistently suggested 2 tablespoons to

be a reasonable reference amount for the category. Condensed milk is usually used as an ingredient of other foods. Two recipes on the product label showed 2 to 2.5 tablespoons of condensed milk is needed to make 1 serving (Ref. 2). FDA, therefore, chose 2 tablespoons as the reference amount.

(D) If appropriate data were not available in the 1977-1978 NFCS, FDA used the 1987-1988 NFCS data.

iv. If the sample sizes were adequate and CSS values were consistent (i.e., any two of the three types of CSS values (i.e., mean, median, and mode) agreed), the consistent CSS values were used. For example, if the median and mode were 2 oz and the mean was 3 oz, and sample sizes were adequate (i.e., 140 or larger), FDA chose 2 oz as the reference amount for the category. If the sample sizes were adequate, but CSS values did not agree, all three types of CSS values were considered in deciding the proposed amount. For example, if the mean, median, and mode were 2.5 oz, 2 oz, and 1.5 oz, respectively, and the sample sizes were adequate (i.e., 140 or larger), FDA took all 3 values together and chose 2 oz as the reference amount for the category.

v. If the sample sizes were in the intermediate range (i.e., 40 through 139), but CSS values were consistent, the consistent values were used. However, if the survey data were inconsistent, FDA used its best judgment in determining the reference amount and documented the basis for its judgment (Ref. 2). For example, the sample size for the food group that represented the product category "Cake, very light weight, less than 4 g per cubic inch" fell in the intermediate range, but mean, median, and modal CSS values consistently suggested a reference amount of 2 oz. Therefore, FDA chose 2 oz as the reference amount for the category. The sample size for the food group "sundae" fell in the intermediate range and the CSS values ranged from about 1 cup to 1¼ cup. FDA believes that 1 cup is more convenient household measure than 1¼ cup and therefore, is proposing 1 cup as the reference amount for the category.

vi. If the sample sizes were inadequate (i.e., less than 40), FDA used the survey data cautiously. Other relevant information such as those listed in section IV.D.3.c. of this document, was given more weight. FDA documented the basis for its selection of the reference amount on a case-by-case basis (Ref. 2). For example, the food group powdered butter replacement had an inadequate sample size (N=10). The only other relevant information

available was the serving size currently in use by manufacturers, which ranged from ½ teaspoon to 1 teaspoon. Although the sample size fell in the inadequate range, the median and modal CSS values consistently suggested 1 teaspoon to be a reasonable reference amount which is within the range of the serving size currently in use by the manufacturers. FDA, therefore, chose 1 teaspoon as the reference amount for the category.

vii. If multiple food groups represented a product category and CSS values varied among food groups, the food groups having the largest sample sizes were used as the driving force in determining the reference amount for the product category. For example, the product category "cookies, sweet crackers, or sandwich type crackers" includes three food groups: cookies, sweet crackers, and sandwich type crackers. CSS values for these three groups ranged from 0.5 oz to about 2 oz. However, the cookie group had the largest sample size which was about 10 to 50 times as large as the sample sizes for the other two food groups. The CSS values for the cookie group consistently suggested 1 oz. as the reference amount for the category. Therefore, using the cookie group as the driving force, FDA determined the reference amount for the category to be 1 oz.

viii. FDA tried to select a reference amount that approximates a household measure, e.g., the weight of whole units for products in discrete units; ¼ cup increments for products measurable in cups; in whole tablespoons for quantities less than ¼ cup but greater than or equal to 1 tablespoon; in whole teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon. These efforts were made to establish reference amounts that are meaningful when expressed in common household measures on the product label.

ix. When survey data were insufficient or not available, FDA followed the following general principles and documented the specific actions that it took (Ref. 2):

(A) If there was no compelling reason to change the standard serving size proposed on July 19, 1990, that is, if no objections had been raised on the proposed serving size, or comments generally supported the proposed serving size, the proposed serving size is being repropounded as the reference amount.

(B) FDA considered any available relevant information. For example, no appropriate information was available to determine the reference amount for cooking wine. A major chain grocer used

1 oz. (which is about equal to 1 fl. oz.) as the serving size for cooking wine in its information booklet. Based on this information, 1 fl. oz. appears to be a reasonable amount for this food for nutrition labeling purposes, and therefore, FDA chose 1 fl. oz. as the reference amount for the cooking wine category.

(C) If there were no consumption data, no other relevant information, and no appropriate alternative, FDA is proposing the reference amount that it believes is the most reasonable for nutrition labeling purposes and has documented the basis for such belief (Ref. 2). For example, there was no information from food consumption surveys or from any other relevant sources, such as those listed in section IV.D.3.c., that could be used in determining the reference amount for the product category, "Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations." Customarily consumed amounts for these products are likely to vary considerably depending on how they are used by consumers. FDA believes that 1 teaspoon of these products is sufficient to decorate one reference amount of cookies (i.e., 3 medium-size cookies). Therefore, the agency is proposing 1 teaspoon or 4 g (g equivalent to 1 teaspoon sugar) if the decoration cannot be measured by teaspoon as the reference amount for the category.

x. Several other factors were also taken into consideration in arriving at the reference amounts proposed in § 101.12(b). These factors when used were documented for case-by-case (Ref. 2).

(A) Proposed reference amounts for related products (e.g., consideration of proposed reference amounts for other fruit categories in determining the reference amount for a fruit category).

(B) Whether the amount is comparable to the reference amounts for products that are used interchangeably and are similar in product characteristics (e.g., potato salad and pasta salad).

(C) For products containing two or more foods, whether the amount approximates the sum of the proposed reference amounts of the component foods. For example, the proposed reference amount for a pie should approximate the sum of the reference amount for pie crust and the pie filling.

e. *Expressing the Reference Amounts.* FDA followed the following principles in expressing the proposed reference amounts that were developed using the general principles and procedures described above.

i. Reference amounts are expressed in metric units (g, mL).

ii. Reference amounts for fluids are expressed in mL. Reference amounts for other foods are expressed in g as much as possible. However, when foods within a product category vary considerably in density, and the CSS values for different products are more uniform when expressed in volume than in grams, reference amounts are expressed in household volumetric measures such as cups, tablespoons, and teaspoons instead of g. For example, the median CSS values for three subcategories of ready-to-eat breakfast cereals weighing less than 3 oz. per cup ranged from 25 g to 56 g, but the CSS values in terms of cups were 1 cup for all three categories (Ref. 2). Therefore, the agency is listing the reference amount for breakfast cereals weighing less than 3 oz. per cup in terms of volume, i.e., 1 cup.

iii. When FDA found that the reference amount was best expressed in mL, it followed the following principles:

(A) For volumes of greater than 30 mL, the volume is expressed as a multiple of 30 mL. FDA has done so to assure that when the reference amounts are converted to the label serving sizes in common household measures, they will be in ¼ cup increments as required in § 101.9(b)(5) and in a whole number of fl. oz., if manufacturers voluntarily provide the equivalent fl oz. measure.

(B) For volumes of less than 30 mL, the volume is expressed in mL equivalent to a whole number of teaspoons or one tablespoon. For example, FDA found 1 teaspoon as a reasonable reference amount for lime and lemon juice and therefore, the reference amount is expressed as 5 mL, the mL equivalent to 1 teaspoon.

iv. In expressing reference amounts in g, FDA used the following principles:

(A) For quantities of greater than 10 g, weights are expressed in the nearest 5 g increment to avoid the appearance of an overly exact g weight. For example, FDA expressed reference amounts that it determined to be 2 and 3.5 oz. as 55 g and 100 g, respectively, instead of 56 g and 98 g. FDA believes that the use of an exact g weight is not desirable because it implies an accuracy that the food consumption data and other relevant information sources used to develop the reference amount do not really provide.

(B) For quantities of less than 10 g, exact g weights are used because rounding to the nearest 5 g increment would introduce too much error to the customarily consumed amount.

4. Presentation of Reference Amounts

The reference amounts developed through use of the general principles and procedures described above are proposed in § 101.12(b). Paragraph (b) contains two tables. Table 1 lists proposed reference amounts for foods represented or intended for use by infants and toddlers, and Table 2 lists proposed reference amounts for foods intended for use by persons 4 years of age and older. For both tables, the agency based the calculations on the appropriate CSS values reported for the particular group. Because there are only a few products on the market specifically intended for toddlers, the agency grouped these foods with baby foods. However, in analysis of consumption of toddler foods, the agency used the amounts customarily consumed by children 1 through 3 years.

Unless the reference amount is specifically stated for the unprepared form (e.g., dry form) of the product, the reference amounts proposed in Tables 1 and 2 represent the amount of the ready-to-serve, or almost ready-to-serve (i.e., "heat and serve," "brown and serve"), form of the product. Heat and serve products include products which are fully cooked and require only heating before consumption, e.g., a fully cooked frozen entree. For a few categories of dry products, such as dry pastas, dry ice products, and dry regular coffee and tea, that have relatively uniform composition, the reference amount is proposed for both dry and prepared forms of the food. The proposed reference amount for the dry form is based on the amount needed to prepare the reference amount for the prepared form (Ref. 2). To convert the amount as consumed to the amount in dry form, FDA used the percent yield reported in "Food Yield Summarized by Different Stages of Preparation" published by USDA (Ref. 18) and other pertinent information (e.g., manufacturer's directions). However, in general, dry mixes and concentrated products such as cake mixes, dry beverage mixes, and frozen concentrated fruit juices are not listed.

Other unprepared forms of products (e.g., fresh pastas, fresh or frozen doughs, and batters), imitation or substitute food, altered food (e.g., "low sodium"), foods for special dietary use, and most products containing two or more foods having individual reference amounts, are also not listed in § 101.12(b). The next three sections of this preamble discuss reference amounts for these types of products.

In determining the reference amounts for two product categories, FDA

deviated from the principles and rules described above.

1. The carbonated beverage category, primarily represented by soft drinks, had a large sample size, and the mean, median, and modal CSS values were consistently 12 fl oz, reflecting the preponderance of soft drink consumption in 12 fl oz containers. However, the modal analysis showed two additional smaller peaks at both 8 and 16 fl oz. FDA is proposing 8 fl oz (240 mL) as the reference amount for the carbonated beverage category based on the following reasons:

FDA is proposing 8 fl oz as the reference amounts for all other beverages including fruit and vegetable juices based on their CSS values and the principles and procedures described in sections IV.D.2. and IV.D.3. of this document. Although food consumption data consistently supported 12 fl oz as the reference amount for the carbonated beverage category, the 12 fl oz value may have been unduly influenced by the wide use of 12 fl oz single-serving containers as indicated by the sales data. Industry data showed that 12 fl oz was the largest single-serving container size sold and represented about 32 percent (45 percent in terms of dollar volume) of the total quantity of all soft drinks sold in the U.S. during the same time period as when the 1987-1988 NFCS was conducted (Ref. 33).

Consumer complaints related to soft drinks focused on the 6 fl oz serving size currently used on these products that results in multiple serving declarations on 12 fl oz cans which are obviously consumed as a single-serving. This concern is addressed by proposed § 101.9(b)(6) which requires that a container containing less than 200 percent of the reference amount be declared as one serving. In addition, several comments, including the IOM report, suggested a uniform serving size for all beverages.

Considering the reference amounts of 8 fl oz for all other beverages, consumer concerns, and several recommendations for a uniform serving size for all beverages, FDA believes that a uniform 8 fl oz reference amount for all beverages would be more reasonable for nutrition labeling purposes. Such a reference amount would help consumers make nutritional comparisons across all beverage categories. Therefore, the agency is proposing 8 fl oz (240 mL) as the reference amount for carbonated beverages.

2. The other reference amount that deviated from the general principles and procedures described in sections IV.D.2. and IV.D.3. of this document is the

category of "butter, margarine, oil, and shortening." Of the products included in this category, butter and margarine had the largest sample sizes, but the mean, median, and modal CSS values for these products did not agree. When all three types of CSS values (excluding whipped type) were considered together, 2 teaspoons could be proposed as the reference amount for this category. Two teaspoons would also be consistent with the Canadian serving size which is 1 to 2 teaspoons. However, although sample sizes were much smaller, data on whipped butter, oils, and shortening consistently supported 1 tablespoon as a more reasonable reference amount. Although butter and margarine are also used as spread, all four types of fats and oils are used interchangeably in food preparation. Therefore, a uniform serving size for all four types of fats and oils would be reasonable and would allow nutritional comparisons of different types of fats and oils.

Most products in this category bearing nutrition labeling have been using 1 tablespoon as the serving size. Accordingly, regulatory decisions to date have been based on a 1 tablespoon serving size (Refs. 34 and 35). Serving size suggestions in comments were split between 1 teaspoon by the butter industry and 1 tablespoon by a trade association representing the shortening, edible oil, and margarine industries. Considering the regulatory history, industry practices, and the recommendation by the fats and oils industry, the agency is proposing 1 tablespoon as the reference amount for the category.

FDA solicits comments on the proposed reference amounts, including the two discussed above, and on any product or product categories that should be added to the reference amount list in § 101.12(b). Comments recommending additions to the list should submit information listed in § 101.12(h) to assist the agency to determine the appropriate reference amounts.

5. Reference Amounts for Products Requiring Further Preparation

Products that require further preparation include dry mixes, concentrates, and fresh or frozen pasta doughs, and batters. Dry mixes and concentrates vary greatly in their ingredients and degree of concentration. An increasing number of other unprepared forms of products, such as fresh or frozen pastas, doughs, and batters, are being introduced into the retail market. Percent yields of these products may vary among products

within the product category, and appropriate yield information is not available. It is, thus, not possible or practical to determine reference amounts for these types of products.

In § 101.12(c) of the 1990 proposal, the agency proposed that the serving or portion of a product that requires cooking or the addition of water or other ingredients be the amount required to prepare one serving of the final product as established by regulation. In § 101.12(c), FDA is reproposing this provision modified to reflect the changes made in this reproposal. Thus, the agency is proposing that the reference amount for a product that requires cooking or the addition of water or other ingredients is that amount required to prepare one reference amount of the final product as established by regulation. For example, FDA proposed the reference amount for pancakes to be 110 g as prepared. For dry pancake mixes, the reference amount would be the amount of the dry mix that is needed to make 110 g of pancake as prepared. If 40 g of pancake mix is needed to make 110 g of prepared pancake, the reference amount for this pancake mix will be 40 g.

6. Reference Amounts for Imitation or Substitute Food, Altered Food, and Foods for Special Dietary Use

Section 101.12 (d) and (e) of the 1990 proposal provided that the serving size of an imitation or substitute food, and an altered version of a food, such as "low calorie" version, must be the same as that of the food for which the imitation or altered food substitutes.

As discussed in section III.A. of the 1990 proposal, and echoed in comments on that proposal, some manufacturers appear to have manipulated the serving sizes of their products so that the per serving content would allow claims such as "low calorie" or "low sodium." To address these concerns, and similar concerns regarding imitation or substitute foods (as defined in § 101.3(e)), in § 101.12 (d) and (e), FDA is reproposing the same provisions for these types of foods, with slight modification to be consistent with this reproposal. Thus, these proposed sections provide that the reference amount for an imitation or substitute food, and for an altered version of the food, must be the same reference amount as that of the regular counterpart food.

Certain foods for special dietary or medical use are exempt from § 101.9 (55 FR 29487) and therefore, they do not have counterparts listed in § 101.12(b). Dietary supplements are subject to proposed § 101.36 *Nutrition labeling of*

dietary supplements of vitamins and minerals in FDA's proposal on Mandatory Nutrition Labeling published elsewhere in this issue of the *Federal Register*. Infant formulas and other foods represented for use as the sole item of the diet, and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions, are subject to special labeling requirements, which are set out elsewhere in title 21, chapter I of the Code of Federal Regulations.

A company requested special exemption on serving sizes of products sold only as part of a weight-control program that prescribes a complete meal plan with serving sizes and which are available only to persons enrolled in their program. The agency has studied this request and has tentatively concluded that the serving size requirements that apply to foods intended for weight control or weight reduction that are available in the marketplace should also apply to the products sold only as part of a weight-control program. Reference amounts for these products should be the same as the reference amounts for their regular counterparts. Dual columns of nutrition information, based on both the reference amount and the serving size prescribed by the program, could, however, be useful and educational to the enrollees. Therefore, FDA would not object to such labeling.

7. Reference Amounts for Products Consisting of 2 or More Foods Having Individual Proposed Reference Amounts

There are three types of products currently in the marketplace that consist of two or more distinct foods, each of which has a proposed reference amount. One type usually consists of two distinct foods placed in the same container that are intended to be consumed together. Examples of such products are peanut butter and jelly, cracker and cheese snack packages, and frozen pancakes and syrup. They are sold in single-serving and multi-serving containers. The 1990 proposal did not address this type of product. In § 101.12(f) of this reproposal, FDA is proposing that the reference amount for this type of product is the sum of the reference amounts for the individual foods, as listed in § 101.12(b). For example, the reference amount for peanut butter and jelly would be the weight in g equivalent to the sum of the proposed reference amounts for peanut butter (30 g and for jelly (1 tablespoon).

The second type is meal-type products (e.g., breakfast, lunch, or dinner trays). Meal-type products are usually sold in single-serving containers. In the 1990

proposal, FDA proposed standard serving sizes for these products under the category of "Meal type trays." However, in this reproposal, the agency is not proposing to establish reference amounts for these products. Because of the wide variety and varying sizes of these products, it would be difficult to determine the amount customarily consumed. Instead, in a proposed regulation entitled "Food Labeling: Nutrient Content Claim, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the *Federal Register*, FDA is proposing a definition for such products and a compliance system that do not require a reference amount for evaluating nutrient content and health claims. Under proposed § 101.9(b)(3), label serving size for meal-type products is the entire content of the package.

Entrees such as spaghetti, macaroni and cheese, burrito, pizza, and sandwich, which are marketed in single-serving and multi-serving containers, are not considered to be meal-type products. The USDA NFCS's used to derive reference amounts proposed in § 101.12(b) contained information on the amount of food consumed per eating occasion for entrees. Following the general principles and procedures described in sections IV.D.2. and IV.D.3. of this document, FDA is proposing two reference amounts for entrees, one for products that can be measured in a cup and one for products that cannot be measured in a cup. Under this proposal, the serving size of entrees that can be measured in a cup, such as spaghetti and macaroni and cheese, will be based on the reference amount for the category of "Mixed Dishes: Measurable with cup." The serving size of entrees that cannot be measured in a cup, such as burrito, pizza, and sandwich, will be based on the reference amount for the category of "Mixed Dishes: Not measurable with cup."

Some frozen entrees are packaged in separate pouches and contain more than one distinct food per package (e.g., rice or pasta with sauce or toppings). The component foods 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, and the serving size of these products will be based on the reference amount for the category of "Mixed Dishes: Measurable with cup."

The third type is products that contain two or more foods that are not

necessarily intended to be consumed together. An example of this type of product is one having multi-compartments, with each compartment containing a different food such as cheese sauce in one compartment and salsa in the other compartment. Another example of this type of product is a variety pack of single-serving products, e.g., a package containing several varieties of single-serving dry instant hot cereals. These products represent different products in individual containers that are placed together and sold as a single product for convenience, for example, to suit the preference of different family members. Because the food in each individual container within the product package represents a unique product, under proposed § 101.9(b)(4), nutrition information for this type of product is to be provided for each product using its own reference amount. A major manufacturer of a variety pack of dry instant hot cereals is currently providing nutrition information on the variety pack in this manner.

E. Procedures for Converting the Reference Amount to Serving Size

In § 101.9(b)(2) of this repropounded regulation, FDA is proposing procedures that manufacturers must follow in converting the reference amounts listed in § 101.12(b) to the serving sizes in common household measures appropriate for their specific products. These procedures will ensure that the conversions are made in a way that will provide consistency in the serving sizes declared for different brands within a product category.

Many comments, including one from a supermarket chain with many years of consumer experience, stated that consumers want to be able to make nutritional comparisons among the same types of products. Consistency in serving size among products within a food category is necessary for making such comparisons.

Many industry comments opposed the fixed standard serving sizes in the 1990 proposal on the basis that standardized serving sizes do not take into consideration the varied shapes and characteristics of different products within a product category. The procedures in proposed § 101.9(b)(2) permit the manufacturer to take these factors into consideration in converting the reference amount to serving size in common household measures.

For the purpose of developing procedures for converting the reference amount to label serving sizes, FDA grouped all multi-serving products into three categories according to the shape and characteristics of products and the

way products are usually served. The agency is proposing separate procedures for each category to ensure that the serving size declared on the label is most appropriate for the specific type of product. Single-serving containers have already been discussed in section IV.C. of this document, and thus, they are not included in this discussion. Procedures for nutrition labeling of products containing multi-serving assorted varieties (e.g., assorted candies) and multi-component gift boxes are addressed in the supplementary proposal for Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision in proposed § 101.9(e)(1) (published elsewhere in this issue of the *Federal Register*) and are not covered by proposed § 101.9(b).

1. Products in Discrete Individual Units

Comments from all sectors stated that nutrition information on products in discrete individual units (e.g., muffin, egg, sliced bread, and most fruits) should be labeled per unit because that is how these foods are customarily eaten and that is the measure that consumers most prefer for nutrition information on these products. Other products that belong in this category include sliced or individually shaped mini pizzas and individually wrapped or packaged products in multi-serving containers. Section 403(r)(1)(A)(i) of the act requires that serving size be declared in common household measure that is appropriate to the food. FDA agrees with the comments that the measure most appropriate for products in discrete units would be the unit itself (i.e., piece).

However, these products come in many different sizes. For example, the size of most sliced breads ranges from 0.5 oz to 1.3 oz per slice, and the size of muffins ranges from 0.4 oz to 6 oz each. If nutrition information for these products is expressed on a single unit basis, there would be no uniformity in serving sizes declared on these products, and consumers would have to compare the nutritional value of a 0.4 oz muffin with that of a 6 oz muffin.

To assure uniformity in the serving size used for different sizes of similar products, FDA is proposing in § 101.9(b)(2)(i) that serving sizes for products that come in discrete units be the number of units that most closely approximates the reference amount in § 101.12(b) applicable to the product. For example, the label serving size for sliced bread weighing 1 oz per slice will be 2 slices because the weight of 2 slices (56

g) most closely approximates the reference amount for breads (55 g).

Under this proposed provision, only products in units that weigh at least 67 percent of the reference amount can use 1 unit as their serving size. If two units of a product each weigh 67 percent of the reference amount, their total weight is 34 percent more than the reference amount. However, one of these units weighs 33 percent less than the reference amount. Thus, one unit more closely approximates the reference amount than 2 units. However, for a product whose units weigh 66 percent of the reference amount per unit, 2 units weigh 32 percent more than the reference amount, while 1 unit weighs 34 percent less than the reference amount. Therefore, the label serving size for a product whose units weigh 66 percent of the reference amount, per unit is 2 units.

To further promote uniformity in the serving sizes declared for these products, FDA is also proposing in § 101.9(b)(2)(i) that all products in discrete individual units that weigh less than 200 percent of the reference amount must declare 1 serving per unit. This upper limit is the same as the upper limit for a single-serving container which is discussed in section IV.C. of this document.

Most of the products in discrete individual units weigh less than 200 percent per unit. As discussed in section IV.C. of this document, the agency is proposing to set the upper limit at "less than 200 percent" of the reference amount for two reasons. First, a unit that weighs 200 percent of the reference amount is by definition 2 servings. Thus it is not a single-serving product. Secondly, there is a significant question as to whether these larger units will be consumed at a single-eating occasion by one individual, considering that the customarily consumed amount is one-half or less than the unit. Thus, the agency believes that it would not be accurate to require that units that weigh 200 percent or more be labeled as one serving.

However, some exceptionally large pieces weigh more than 200 percent of the reference amount. For example, a large muffin may weigh more than 4 oz, which is more than 200 percent of the reference amount for muffins, and many people may eat the whole muffin at a single-eating occasion. Therefore, FDA is proposing to allow the manufacturer to declare one unit as a serving for products that weigh 200 percent or more of the reference amount if the whole unit reasonably can be consumed at a single-eating occasion. As discussed above, the agency is aware that this allowance

creates a potential for misuse by a manufacturer who claims that an unreasonably large unit is a single-serving in order to show a high content of a nutrient such as fiber and calcium. The agency will consider regulatory action on a case-by-case basis for misuse of this allowance.

The determination of the reasonableness of a single-serving should be based on food consumption data under actual conditions of use. Manufacturers should be prepared to provide the agency with the data that supports the single-serving claim upon request. FDA requests comments on the upper limit for single-serving declaration for products in discrete units, and whether it is reasonable to allow the manufacturer to determine the single-serving status above that level.

2. Products in Large Discrete Units That Are Usually Divided for Consumption

Foods in large discrete units such as cake, pie, pizza, melon, and cabbage are usually divided into slices or pieces for consumption. For example, a 2-layer cake may be divided into 12 pieces, or a 9-inch pie may be divided into 8 slices for consumption. FDA believes that the household measure most meaningful for these products is a fraction of the whole unit. In § 101.9(b)(2)(ii), FDA is proposing that the serving size for these products be expressed as the fraction of the whole food, such as $\frac{1}{12}$ cake, $\frac{1}{8}$ pie, $\frac{1}{4}$ pizza, and $\frac{1}{4}$ melon, that most closely approximates the reference amount in § 101.12(b). For example, the proposed reference amount for pizza is 140 g. A $\frac{1}{4}$ slice of a pizza weighing 21 oz weighs 147 g and a $\frac{1}{2}$ slice of this pizza weighs 118 g. The $\frac{1}{4}$ slice is closer to the reference amount than the $\frac{1}{2}$ slice. Therefore, the serving size for this pizza would be $\frac{1}{4}$ pizza.

3. Nondiscrete Bulk Products

In § 101.9(b)(2)(iii), FDA is proposing that the serving size for all products that are not in individual or large discrete units and are packaged in multi-serving containers (e.g., flour, sugar, breakfast cereals with the exception of large biscuit types) be the amount in common household measure most closely approximating the reference amount for the product category. For example, the proposed referenced amount for mayonnaise is 15 g. One tablespoon mayonnaise weighs about 14 g and therefore, the label serving size for mayonnaise will be 1 tablespoon.

F. Declaration of Serving Size on the Product Label

1. Label Statement of Serving Size

FDA proposed in § 101.9(b)(3) of the 1990 proposal to require the declaration of serving size in U.S. units (oz or fl oz), followed by the equivalent metric quantity in parenthesis (with weight expressed in g and volume in mL). In addition, the agency proposed that manufacturers could voluntarily declare, in parenthesis, household measures such as cups, tablespoons, slices and pieces. Section 403(q)(1)(A)(i) of the act requires that serving sizes be expressed in common household measures. FDA stated in the announcement of the public meeting on serving sizes that in light of the variability that is likely in household measures, the agency continues to believe that a parenthetical listing of weight equivalent to the household measure is necessary for compliance reasons. The agency also pointed out that the declaration of metric quantity would promote international harmonization of food labeling, and that consumers would not have to deal with these measures since the label serving sizes would be declared in common household measures.

Most comments that addressed this issue opposed the use of metric units for serving sizes on the basis that few U.S. consumers understand the metric system, and therefore such information would not be useful to consumers. A number of comments opposed using metric units and supported the continued use of U.S. units.

The presentations and discussion at the public meeting on serving sizes also generally did not favor the use of metric units for serving sizes. However, a health professional at the public meeting stated that metric units would be very useful to immigrants, who make up a substantial portion of the population in some parts of the country, because they come from countries where metric units are used. Some presenters at the meeting stated that if household measures are used, some sort of parenthetical weight measure is needed because of the variability in common household measures, e.g., in the size of a bagel.

The IOM report recommended the use of metric units in parenthesis after the household measure. A Canadian government comment also supported the use of metric units in serving sizes. Comments from other foreign sources urged requiring the use of the metric system and stated that to do otherwise would decrease international harmonization and raise non-tariff trade

barriers. A few U.S. comments also supported the use of metric units.

FDA acknowledges that many consumers are unlikely to use the metric information. However, the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100-418) declared that the metric system is the preferred measurement system for U.S. trade and 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 stated earlier, the agency believes that it needs an additional precise weight statement for compliance purposes because of the variability in weight of different brands in common household units. To comply with the requirements of the Omnibus Trade and Compliance Act and for compliance purposes, the agency is proposing in § 101.9(b)(7) to require that manufacturers provide the equivalent metric quantity, in parentheses, after the common household measure, e.g., 1 cup (28 g). The agency is also proposing to allow manufacturers voluntarily to list the equivalent U.S. measure in parentheses after the metric measure. The agency believes that metric measures on food labels will contribute to educating children, as well as older consumers, about the metric system.

A Canadian government comment supported using metric units rounded to a convenient size when converting from a common household measure to a metric measure (e.g., rounding from an actual weight of 172 g for a slice of pizza to 170 g). If this proposal is adopted, however, metric weight will be used by the agency for compliance purposes, such as in evaluating adjectival descriptors used on the label. Therefore, the metric measure needs to reflect accurately the common household measure, and the agency is not proposing to permit the rounding of the metric measures.

2. Definition of Household Measures

Section 403(q)(1)(A)(i) of the act requires that the serving size be 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. Numerous comments also expressed preference for household measures, which were described in terms of familiar units including oz, cup, tablespoon, teaspoon, slice, and piece.

In § 101.9(b)(4) of the 1990 proposal, FDA proposed definitions for several household measures, including teaspoon, tablespoon, cup, fl oz, and oz.

In § 101.9(b)(5) of this reproposal, FDA is proposing the terms "common household measure" and "common household unit" to mean cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), oz, and other common household equipment used to package food products, such as jar and tray. As in the 1990 proposal, the agency is proposing in § 101.9(b)(5)(iv) 1 teaspoon to mean 5 mL; 1 tablespoon to mean 15 mL; a cup to mean 240 mL; 1 fl oz to mean 30 mL; and 1 oz in weight to mean 28 g.

One comment stated that 1 oz in weight should be defined as 28.35 g to be consistent with the agency policy for declaring the net weight of the package. FDA does not believe that such accuracy is needed for nutrition labeling purposes, or that the small difference (0.35 g) in the g equivalency to 1 oz between the serving size and the net weight statement would present confusion or a regulatory problem. For simplicity, the agency believes that, for nutrition labeling purposes, 28 g is a more desirable g equivalency to 1 oz than 28.35 g. Therefore, the agency is reproposing that 1 oz be defined as 28 g.

3. Rules for Declaring Household Measures

FDA is proposing in § 101.9(b)(5) of this reproposal, several rules for expressing serving size in common household measures. These rules are intended to assure as much uniformity as possible in label serving sizes within a product category. Without such rules, the same quantity of serving size could be expressed in cups by one manufacturer and in tablespoons by another. Also, one manufacturer may choose to use ⅓ cup as the serving and another manufacturer may choose to use ¼ cup for similar quantities of products. To prevent such inconsistencies in serving sizes, the agency is proposing the following rules for expressing serving sizes in common household measures.

a. Whenever possible, cups, tablespoons, or teaspoons must be used. Numerous comments on the 1990 proposal and at the public meeting requested preferential use of these common household measures in expressing serving sizes on food products. For uniformity in expressing these measures, cups should be expressed in ¼ cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 1

tablespoon, teaspoons in whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon, and in ¼ teaspoon increments for quantities less than one teaspoon.

b. If cups, tablespoons, or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction of the whole piece or package, as appropriate, are to be used. These units are the common household measures that are most appropriate for products not measurable by a cup, tablespoon, or teaspoon.

c. If (a) and (b) are not applicable, oz are to be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 2 oz (56 g) (about 1 inch slice) for unsliced bread. Such an approach will provide the most readily understandable description for consumers. Ounce 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). Such increments are necessary to limit the use of fractional numbers such as 2.3 oz. Consumers repeatedly complained about use of fractional numbers. However, use of fractional numbers is necessary to reduce the error in the equivalent oz measure provided. The agency believes that rounding to the nearest half-ounce increments is reasonable and it will also prevent use of unusually accurate fractional numbers (e.g., 2.1 oz) in serving size.

To promote consistency in the use of units, if a manufacturer elects to use abbreviations for units, the following abbreviations should be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, oz for ounce, and fl oz for fluid ounce.

G. Listing Nutrient Contents Based on 100 Grams, 100 Milliliters, 1 Ounce, or 1 Fluid Ounce

The agency also proposed in § 101.9(b)(6) of the 1990 proposal to allow another separate, additional column of figures to be declared on the nutrition label based on 100 g or 100 mL of the food as packaged or purchased.

Most comments from consumers and health professionals did not directly address this issue, but a few comments from both groups expressed opposition to the additional column of nutrition information, primarily because they felt that the additional information would not be useful to consumers. Several industry comments suggested using a uniform unit of weight/volume (e.g., 1 oz and 1 fl oz or 100 g and 100 mL) for all products, either with or in lieu of serving sizes. The international comments favored the use of metric units and the use of 100 g or 100 mL rather than

requiring serving sizes, citing the fact that 100 g or 100 mL is required in nutrition labeling in many other countries and the need for international harmonization. Some comments said that manufacturers should have the choice of using 100 g or 100 mL in agreement with the nutrition labeling guidelines of Codex Alimentarius (Ref. 36).

The notice of a public meeting on serving sizes raised the issue of presenting nutrition information in a second column based on a uniform weight or volume basis such as 100 g or 100 mL. Written comments and discussion of this issue at the public meeting essentially reiterated the same positions as those in the comments on the 1990 proposal. Consumer and nutrition professional organizations did not support the use of metric units or of an additional column of numbers because they felt that the information was unlikely to be useful to consumers and would present too much information on the label. Representatives from the food industry and trade organizations generally also did not support requiring a second column, citing the space limitations on many food labels. A representative of the pizza industry, however, stated that a uniform weight would be useful on products such as pizza because of the lack of uniformity and the many size and weight variations in these types of foods.

On this issue, it is obviously impossible for the agency to be responsive to all positions. After carefully considering the statutory requirement, and in light of the comments from several sectors opposing metric usage, FDA is reproposing in § 101.9(b)(10) to allow manufacturers to list voluntarily a second column of values. Such values may be based on either 100 g or 100 mL or on 1 fl oz or 1 oz in weight. An important consideration in FDA's tentative decision to provide for such information in a unit (oz) is that the measure is familiar to most Americans to facilitate understanding of the information presented in the nutrition label. Allowing manufacturers to use values based on the metric measures, 100 g or 100 mL, is also consistent with the Omnibus Trade and Competitiveness Act of 1988. Values based on the metric unit also will contribute to international harmonization. Although at the present time many manufacturers may not elect to list nutrition information based on metric measures, and not many consumers in the near future may be likely to use the information, these conditions are likely to change as the

U.S. adopts the metric system. Therefore, the agency believes that it is important to provide manufacturers with this option. The agency also believes that the additional column could become an important educational tool for consumers as they become more familiar with the metric system.

The presentation of nutrition information on a uniform weight or volume basis would allow consumers to make nutritional comparisons not only across different brands of the same food but also across all classes of food products. These types of comparisons could be very useful to persons who wish to make healthful food substitutions in their diet.

H. Declaration of Number of Servings per Container

FDA proposed in § 101.9(b)(5) of the 1990 proposal that the number of servings per package or container should be declared in the nearest 0.5 serving (e.g., 2.5 servings, not 2.3 servings; 7 servings not 7.2 servings), with rounding indicated by use of the term "about" (e.g., about 7 servings).

Many consumer comments complained that they did not like to see a fractional number of servings on the product label. The IOM report recommended that the number of servings per container be rounded down to the nearest whole number. Because this recommendation introduces an unacceptably large error to the number of servings declared on the product label, FDA decided not to adopt the IOM recommendation (see section III.A. of this document for FDA's evaluation of the IOM report).

FDA, therefore, is proposing in § 101.9(b)(8) that the number of servings per package or container be declared to the nearest whole or approximate whole number. Manufacturers would be allowed to either declare the approximate serving size in household measure that results in a whole number of serving per package (e.g., serving size: approximately ½ cup; number of servings per container: 10) or to declare the exact serving size in household measures and the approximate number of servings per container (e.g., serving size: ½ cup; number of servings per container: approximately 10).

Several comments stated that regulation of the number of servings per package must be flexible to accommodate products, such as cheese, in random weight packages. Cheese industry representatives stated that for some types of foods, such as cheeses from large wheels cut in random weights, manufacturers would have a problem in declaring number of servings

per package. The agency had not previously considered this special problem that relates to random-weight packages. As a means for dealing with it, FDA is proposing in § 101.9(b)(8) a special exception for random weight packages that would allow manufacturers to declare the number of servings per container as "varied" provided the nutrition information is based on the reference amount expressed in oz. The agency is soliciting comments on whether this exception is a reasonable provision for these types of packages, and, if not, what provision should be made for random weight packages.

I. Use of Serving Size to Evaluate Nutrient Content and Health Claims

FDA proposed in § 101.12(f) of the 1990 proposal that for any container with more than one serving, the proposed standard serving size would be used to determine the appropriateness of a nutrient content claim (descriptor) such as "low sodium." For single-serving containers containing 100 percent or less of the standard serving, evaluation of the label claim would be based on the standard serving size. However, for single-serving containers containing more than 100 percent, but 150 or less percent of the standard serving, the claim would be evaluated on the basis of the entire content of the package.

A majority of comments on FDA's proposal supported the proposed basis for evaluation of descriptors. However, many food industry and trade organization comments objected to the proposed evaluation criteria. These comments generally argued that the established serving size, not the package content, should be used to evaluate descriptor claims on all sizes of packages.

Manufacturers pointed out that under the rule proposed in 1990, the same food product that could be labeled as "low sodium" (or a similar adjectival descriptor) on the basis of a standard serving size might not qualify for "low sodium" labeling when packaged in a single-serving container containing between 100 percent and 150 percent of the standard serving size. For example, an 8 fl oz container of skim milk containing 126 milligrams (mg) of sodium would meet the definition of "low sodium," but a 10 fl oz single-serving container of the same milk that contains 158 mg of sodium would not.

In the notice of public meeting, FDA raised the question of whether these differences in the use of descriptors on food products would be confusing and asked for data to support any views

presented. No data on this issue were presented at the meeting. FDA also suggested two alternative solutions to the concerns expressed about use of label descriptors on single-serving containers: (1) To label single-serving containers that do not contain the standard serving with the nutritional content in both the total container and in the standard serving and to permit descriptor use based on the standard serving; or (2) to provide a weight factor on the label that consumers could use to determine the nutritional values based on a standard serving size (e.g., multiply by ¾ for a single-serving that contains 150 percent of the established serving size). Comments generally offered little support, or opposed, such additional information on the nutrition label. The general sense of the comments was that most consumers would not understand or use this additional information, and that it would contribute to label overload and confusion.

A manufacturer suggested, as resolution for the issue, that FDA establish reference serving sizes, and that both the reference serving size and the serving size declared on the product label be required to be used to evaluate the compliance with FDA criteria for the descriptors. The agency believes that this suggestion represents a reasonable approach to regulating the use of nutrient content and health claims not only on single-serving containers but also all other products when the serving size declared on the label differs from the reference amount (e.g., products in discrete units). Therefore, FDA is proposing in § 101.12(g) that if the serving size declared on the product label differs from the reference amount, the amount of the nutrient or substance in both the reference amount listed in § 101.12(b) and the serving size declared on the product label must meet the FDA criteria for nutrient content and health claims, as set forth in regulations relating to such claims, for the food to qualify for the claim.

The agency recognizes that the proposed approach could result in differences in claims made on the same product depending on the package or unit size. For example, a product which contains the same or less than the reference amount may bear a claim such as "low sodium," whereas a single-serving container of the same product that contains one and a half times the reference amount may not. As mentioned earlier, many industry comments opposed such differences. The agency considered using the reference amount to evaluate whether a label claim meets the criteria for the

claim. Industry generally supported this option. This option will allow the same product to bear the same claim regardless of the package or unit size. However, it also presents major problems.

If the label serving size of the product differs from the reference amount, and the product does not meet the criteria for the claim per serving, it would require an additional statement on the label such as "this package content does not meet the FDA standard for the claim," to inform consumers properly. Such an additional statement would make the label more complicated. Considering other additional label information required by the act, e.g., disclaimers, many products, particularly small single-serving containers, would not have enough space for all of the additional information. Also, such an additional statement is likely to be ineffective if it is present all the time. Furthermore, a product that contains an undesirably large amount of a nutrient from the public health standpoint could bear a claim for which it is qualified only on the basis of the reference amount. For example, based on the reference amount, a product could qualify for use of a "low sodium" claim, which is defined by FDA as 140 mg or less per serving. The same product in a large single-serving container could contain more than 140 mg of sodium and would not qualify but would still be able to bear the "low sodium" claim. This result would be misleading and undesirable from the public health standpoint. Therefore, FDA decided not to adopt this option. The agency solicits comments on this option and on the approach it has chosen to evaluate nutrient content and health claims on food labels.

J. Other Related Issues

1. Nutrition Information on an as Packaged Versus an as Consumed Basis

In § 101.9(b)(6) of the 1990 proposal, FDA proposed that nutrient and food component quantities be declared on the basis of the food as packaged or purchased. Some comments stated that the declaration should be based on the food as consumed.

Many products come in a form (e.g., dry mixes and concentrates) that requires further preparation or an addition of other ingredients before consumption. In many cases, the nutrient content of these products as consumed differs from the nutrient content as packaged. The agency recognizes that consumers will benefit from the nutrition information on an as consumed (prepared) basis since this

information reflects the nutrient content of the product actually consumed. Manufacturers usually provide directions for preparation on the package. These directions could be used as a compliance tool for regulating products on an as consumed basis if there is only one direction for preparation and that is the only preparation method that consumers use. Some manufacturers, however, provide multiple directions for preparation (e.g., using different types of fats such as butter and margarine) and different directions often yield different nutrient contents following the preparation. There is no obvious basis for selecting a particular direction for regulatory purpose such as for use in providing nutrition information and for evaluating label claims. 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. Consequently, FDA cannot effectively regulate products on an as consumed basis. Therefore, FDA is maintaining the "as packaged or purchased" requirement redesignated as § 101.9(b)(9), with the exception of raw fish covered under § 101.42 and canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables. The serving size for raw fish is discussed in a separate rulemaking concerning voluntary nutrition labeling of raw fruit, vegetables, and fish that is published elsewhere in this issue of the **Federal Register**. For purposes of the voluntary nutrition labeling program, the agency has defined "raw fish" as fish in the natural state that have received minimal or no processing (56 FR 30468 at 30470). This definition includes "whole or filleted fish that are fresh (unpacked or packaged by the retailer), fresh frozen (unpacked or packaged by the retailer), or alive in the retail store (e.g., lobster, crab); shrimp that have been shelled and deveined; and lobster, crab, and shrimp that have been thermally processed or shelled, but not otherwise processed or prepared. (56 FR 30468 at 30470). Other forms of fish, such as packaged frozen fillets, are not included in the proposed exemption in § 101.9(b)(9).

Some foods such as canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables, are usually packed in water, brine, or oil, but the liquid is usually discarded before consumption. Therefore, the nutrient content of these foods as consumed may differ from the nutrient content as packaged. FDA believes that the label serving size most

meaningful for these products would be the serving size based on the drained solids. Proposed § 101.9(b)(9) exempts these foods from the requirement for nutrition information on an as packaged basis. Nutrition information for these products will be based on the drained solids. Reference amounts for these products are based on the drained solids as customarily consumed, as noted in the footnote to table 2.

For the benefit of the consumers who follow the package directions in preparing these products, the agency encourages manufacturers voluntarily to provide nutrient content of their products on an as consumed basis using the package directions for preparation and in the case of multiple directions, using the direction that most likely represents the major usage of the product.

Section 101.9(d)(2) of the proposed nutrition labeling regulation (55 FR 29487) provides for the use of an additional column of figures to declare nutrition information on the basis of food as consumed, e.g., cereal with milk or cake mix prepared according to instructions.

2. Flexibility in Serving Size Declared on the Product Label

Some industry comments on the 1990 proposal expressed the need for greater flexibility in serving sizes because of differences, for example, in package sizes and differences in size between pieces within packages. In the notice of public meeting, the agency raised the issue of whether deviation from the standard serving size should be allowed and, if allowed, how much.

A consumer representative at the public meeting stated that FDA should allow some deviation in serving size within a product category, but that it should be minimal and should result in a size close to the amount customarily consumed to protect consumers from both economic deception and misrepresentation of nutrition and health claims. Another consumer representative stated that there is no reason to allow deviation, except for foods like pizza and pies. An industry representative stated that a manufacturer must be permitted deviation from a uniform serving size when a feature of a food distinguishes it, so that a different serving size that more accurately reflects the amount that is customarily consumed may be used, e.g., a prewrapped slice of cheese would be the amount that is customarily consumed. However, the agency has not received any data on what might be a feasible deviation for various food

categories if such deviations were allowed.

The agency agrees that it should provide some flexibility for the serving size declared on the product label to account for differences in package sizes and differences in size between pieces within packages. However, under the act, the serving size declared on the product label must at least approximate the amount customarily consumed, i.e., the reference amount established for the product category. The agency believes that the procedures for converting the reference amount to serving size for use on the product label proposed in § 101.9(b)(2) of this reproposal provide sufficient flexibility to account for the varied characteristics of different products while assuring a relative uniformity of serving sizes used for different brands within a product category.

3. Range Versus Fixed Reference Amount

The Minister of Health and Welfare of Canada submitted as comments Canada's guidelines to the food industry on serving sizes. The Canadian guidelines allow declaration of serving sizes within established ranges, e.g., 40 to 100 g for a muffin and 200 to 250 mL for milk.

FDA is proposing to establish specific reference amounts for 131 product categories, not ranges of values. As mentioned earlier, the reference amounts, if adopted, will serve two purposes: (1) They will be used by manufacturers in determining serving size for their specific products, and (2) they will be used in determining whether food products meet the definitions for nutrient content and health claims. Both of these purposes require a specific reference amount, not a range of values. Therefore, FDA is not proposing to adopt the Canadian approach of using a range.

In addition, it is difficult to determine an appropriate range value for each product category to cover all of the different shapes and varied characteristics of products within each category. FDA also does not know whether any set range would be appropriate for products that will enter the market in the future. FDA believes that the procedures in proposed § 101.9(b)(2) for converting the reference amounts to serving sizes provide the flexibility necessary to deal with diverse shapes and characteristics of specific products. Therefore, FDA has tentatively concluded that ranges are not needed. Furthermore, the procedures that FDA is proposing can be applied to

any products that enter the market as well as to those currently in the market.

K. The Petition Process

In § 101.12(g) of the 1990 proposal, FDA proposed to establish a petition process for manufacturers to use to add to or amend a standard serving size. Provision for a petition process was supported by the IOM report and by comments on the 1990 proposal, as well as by comments to the notice of the public meeting on serving sizes. In § 101.12(h), FDA is proposing an updated petition process for manufacturers to use to add to or amend a reference amount listed in § 101.12(b) or to establish a new subcategory if a reference amount for a product category does not apply to a particular product. Section 101.12(h) describes information needed by FDA to evaluate a 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 to be needed.

As discussed earlier, a few manufacturers submitted supporting data with their request for changes in standard serving sizes in the 1990 proposal. However, these data could not be used in developing the reference amounts in this reproposal because of problems in the methodology used to collect or to process data (see the introduction to section IV.D. of this document). To help guide manufacturers in conducting research to collect or process food consumption data to determine the suggested reference amount in support of a petition, FDA is providing the following general guidelines:

1. Sampled population should be representative of the demographic and socio-economic characteristics of the relevant population group (i.e., infants, toddlers, or people 4 or more years of age) for which the food is intended.
2. Sample size (i.e., number of eaters) should be large enough to give a reliable estimate of the amount of food that is customarily consumed.
3. The study protocol should identify potential biases and describe how these potential biases are controlled for, or, if they cannot be controlled for, how they will affect interpretation of results. For example, a survey that asks the participants to measure the amount of food that they usually consume or serve per eating occasion is likely to be biased by downsizing a food having a negative nutritional connotation (e.g., high fat, high calorie foods) and upsizing for foods with positive connotations.
4. 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.

V. Other Affected Rules

In the 1990 proposal, the agency proposed to revise 21 CFR 101.8(a) to provide 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 used for nutrition information. FDA proposed this revision to prevent consumer confusion over serving size. For completeness, FDA is once again including § 101.8(a) as part of this reproposal on serving size regulations.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. The proposed requirements pertaining to serving sizes to be used on food labels qualify for a categorical exclusion under 21 CFR 25.24(a)(11), and the proposed requirements pertaining to petitions that seek to establish or amend a reference amount qualify for exclusion under 21 CFR 25.24(a)(8).

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the \$100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the *Federal Register*. The agency requests comments on the RIA.

VIII. Effective Date

In the 1990 proposal, FDA proposed to make the serving size regulation effective 1 year after the publication of a final rule. FDA requested comment on this deviation from the agency's normal practice of making food labeling

regulations effective on the uniform compliance date that follows publication of the final rule. The agency is proposing that any final rule that may be issued based upon this proposal become effective 6 months following its publication in the **Federal Register**.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost \$1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101-538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of

section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

IX. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

X. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 101.12(h) relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

XI. References

The following information has been placed on file 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.

1. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling: Issues and Directions for the 1990s," National Academy Press, Washington, DC, 1990.
2. Park, Youngmee K., memo to file, October 30, 1991.
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List of Subjects in 21 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, it is proposed that 21 CFR part 101 be 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 may 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.

* * * * *

3. Section 101.9 is amended by revising paragraph (b) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) All nutrient and food component quantities shall be declared in relation to a serving or, where the food is customarily not consumed directly, to a portion, 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 12 months of age or by children 1 through 3 years of age. The term "portion" means 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., ¼ cup flour or ¼ cup tomato sauce).

(2) Except as provided in paragraphs (b)(3) and (b)(4) of this section, serving (portion) 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 following procedures:

(i) For products in discrete units (e.g., muffin, sliced bread, apple), 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, 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.

(ii) For products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving (portion) size shall be the fractional slice of the food (e.g., ½ 2 cake, ⅓ pie, ¼ pizza, ¼ melon, ⅓ cabbage) that most closely approximates the reference amount for the product category.

(iii) For nondiscrete bulk products (e.g., breakfast cereal, flour, sugar), serving (portion) size shall be the amount in household measure that most closely approximates the reference amount for the product category.

(3) Serving size for meal-type products as defined in proposed § 101.13(1) of this chapter shall be the entire content (edible portion only) of the package.

(4) A variety pack such as a package containing several varieties of single-serving packages 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.

(5) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving (portion) size in household measures, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼ cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ 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 ¼ 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., 2 oz (56 g) (about 1 inch slice) for unsliced bread. 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.

(6) A product that is packaged or sold individually and that contains less than 200 percent of the applicable reference amount shall be considered to be a single-serving, and the entire content of the product shall be labeled as one serving. Small 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 (portion) shall be the serving (portion) 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). In addition, serving (portion) size may be declared in oz and fl oz, in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving (portion) size, e.g., 1 cup (28 g) (1 oz). 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.

(8) In declaring the number of servings per container, a manufacturer may use either of the two options listed below, choosing the one most meaningful for a specific product. In either case, whole numbers must be used with the exception of random weight products. 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.

(i) Declare serving (portion) size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately ½ cup; number of servings per container: 10) or

(ii) Declare serving (portion) size in exact household measure and approximate the number of servings per container (e.g., serving size: ½ cup; number of servings per container: approximately 10).

(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 and foods that are packed or canned in water, brine, or oil but the liquid is not customarily consumed such as canned fish, maraschino cherries, pickled fruits, olives, and canned or 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 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 on the basis of 100 g or 100 mL or of 1 oz or 1 fl oz of the food as packaged or purchased, in the same format as required by paragraph (c) of this section.

(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).

* * * * *

4. Section 101.12 is added to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that 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 must include 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 (portion) 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 sizes 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 size 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}

Product category	Reference amount
Cereal, dry instant.....	15 g
Cereal, prepared, ready to serve.....	110 g
Other cereal and grain products, dry ready-to-eat, e.g. ready-to-eat cereals, cookies, teething biscuits, and toasts.	7 g
Dinner, dessert, fruit, vegetable or soup, dry mix.	15 g
Dinner, dessert, fruit, vegetable or soup, ready-to-serve, junior type.	110 g
Dinner, dessert, fruit, vegetable or soup, ready-to-serve, strained type.	60 g
Dinner, fruit, vegetable, stew or soup for toddlers, ready-to-serve.	170 g
Egg/egg yolk, ready-to-serve.....	55 g
Juice, all varieties.....	120 mL

¹ These values represent the amount 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 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.

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).

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3}

Product category	Reference amount
Bakery Products:	
Breads (excluding sweet quick type), biscuits, rolls, croissants, bagels, tortillas, soft bread sticks, soft pretzels.	55 g.
Breakfast bars and toaster pastries.	55 g.
Brownies.....	40 g.
Cake, heavy weight, more than or equal to 10 g per cubic inch.	125 g.
Cake, medium weight, more than or equal to 6 g but less than 10 g per cubic inch.	110 g.
Cake, light weight, more than or equal to 4 g but less than 6 g per cubic inch, and eclairs.	75 g.
Cake, very light weight, less than 4 g per cubic inch.	55 g.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3}—Continued

Product category	Reference amount
Coffee cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, hushpuppies, cornbread.	55 g.
Cookies, sweet crackers, and sandwich type crackers.	30 g.
Crackers, all varieties excluding sweet and sandwich type—includes hard bread sticks and ice cream cones ¹ .	15 g.
Croutons.....	7 g.
French toast, pancakes.	110 g.
Pies, cobblers, turnovers, other pastries.	125 g.
Pie crust.....	1/4 of 8 inch crust. 1/2 of 9 inch crust.
Pizza crust.....	55 g.
Taco shell.....	30 g.
Waffles.....	85 g.
Beverages:	
Carbonated beverages (excluding water), wine cooler.	240 mL.
Noncarbonated beverages—see fruits and fruit juices category	
Coffee or tea, regular or flavored without sugar or cream/cream substitute.	240 mL prepared or 2 tbsp ground coffee or 2 tsp dry instant coffee or 2 g dry instant or leaf tea.
Coffee or tea, flavored and sweetened.	Amount to make 240 mL prepared.
Water, all types.....	240 mL.
Cereals and Other Grain Products:	
Breakfast cereals (hot cereal type), hominy grits.	1 cup prepared or 40 g plain dry cereal or 55 g flavored, sweetened cereal
Breakfast cereals, ready-to-eat (weighing less than 3 oz per cup).	1 cup.
Breakfast cereals, ready-to-eat (weighing more than or equal to 3 oz per cup).	1/2 cup.
Breakfast cereals, ready-to-eat, not measurable with cup, e.g., biscuit type.	50 g.
Bran or wheat germ.....	15 g.
Flours or cornmeal.....	30 g.
Grains, e.g., rice, barley, plain or seasoned.	140 g prepared or 45 g dry.
Pastas, without sauce....	140 g prepared or 55 g dry.
Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles.	25 g.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3}—Continued

Product category	Reference amount
Starch, e.g., cornstarch, potato starch, tapioca, etc..	10 g.
Stuffing.....	100 g.
Dairy Products and Substitutes:	
Cheese, cottage.....	110 g.
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g.
Cheese, grated hard, e.g., Parmesan, Romano.	5 g.
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g.
Cheese sauce—see sauce category	
Cream or cream substitute, fluid.	15 mL.
Cream or cream substitute, powder.	2 g.
Cream, half & half.....	30 mL.
Eggnog.....	120 mL.
Milk, condensed, undiluted.	30 mL.
Milk, evaporated, undiluted.	15 mL.
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL.
Shakes or shake substitutes, e.g., dairy shake mix, fruit frost mix.	240 mL.
Sour cream.....	25 g.
Yogurt.....	225 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 waters for the novelty type varieties
Sundaes.....	1 cup.
Custard, gelatin or pudding.	1/2 cup.
Dessert Toppings and Fillings:	
Cake frosting or icing.....	35 g.
Other dessert toppings, e.g., fruits, syrups, marshmallow cream, nuts, dairy and non-dairy whipped toppings.	2 tbsp.
Pie fillings.....	85 g.
Egg and Egg Substitutes:	
Egg mixture, e.g., egg foo yung, scrambled egg, omelet.	110 g.
Eggs (all sizes) ⁴	50 g.
Egg substitutes.....	An amount to make 1 large (50 g) egg
Fats and Oils:	
Butter, margarine, oil, shortening.	1 tbsp.
Butter replacement, powder.	2 g.
Dressings for salad.....	30 g.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3}
Continued

Product category	Reference amount
Mayonnaise, sandwich spread, mayonnaise-type dressing.	15 g.
Spray type.....	0.25 g
Fish, Shellfish, and Meat or Poultry Substitutes:	
Bacon substitute, canned anchovy, ⁵ anchovy paste, caviar.	15 g.
Dried, e.g., jerky.....	30 g.
Entrees (cooked) with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g.
Entrees (cooked) without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake.	85 g.
Fish and shellfish, canned ⁵ .	85 g.
Substitute for luncheon meat, sandwich spread, Canadian bacon, sausage and frankfurter.	55 g.
Smoked or pickled fish ⁵ or shellfish.	55 g.
Substitutes for bacon bits—see miscellaneous category	
Fruits and Fruit Juice:	
Candied or pickled ⁵	30 g.
Dehydrated fruits—see snacks category	
Dried.....	40 g.
Fruit for garnish or flavor, e.g., maraschino cherries ⁵ .	4 g.
Fruit relishes, e.g., cranberry sauce, cranberry relish.	70 g.
Fruits used primarily as ingredients e.g., avocado, cranberries, lemon, lime.	55 g.
Watermelon.....	280 g.
All other fruits (except those listed as separate categories), fresh, canned or frozen	140 g.
Juice, nectar, fruit drinks, or fruit-flavored drinks.	240 mL
Juice used as ingredients, e.g., lemon juice, lime juice.	5 mL
Legumes:	
Bean cake (tofu) ⁵	85 g.
Beans, plain ⁵ or in sauce.	½ cup.
Miscellaneous category:	
Baking powder, baking soda, pectin.	1 g.
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations.	1 tsp or 4 g if not measurable by teaspoon.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3}
Continued

Product category	Reference amount
Batter mixes, bread crumbs, meat, poultry, and fish coating mixes, dry.	30 g
Cooking wine.....	30 mL.
Drink Mixers (without alcohol).	Amount to make 240 mL drink (without ice).
Gum.....	3 g.
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g.
Salt, salt substitute, seasoning salt (e.g., garlic salt).	1 g.
Seasoning mixes dry, e.g., chili seasoning mix, pasta salad seasoning mix.	Amount to make one reference amount of the final dish.
Mixed Dishes:	
Measurable with cup, e.g., casserole, hash, macaroni and cheese, pot pie, spaghetti with sauce, stew, etc.	1 cup.
Not measurable with cup, e.g., burrito, egg roll, enchilada, pizza, pizza roll, 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. ⁶
Nuts and Seeds:	
Nuts, seeds and mixtures.	40 g
Nut and seed butter, paste, or cream.	30 g.
Used primarily as ingredient, e.g., coconut, nut and seed flour, etc.	15 g.
Potatoes and Sweet Potatoes/Yams:	
French fries, hash browns, skins, or pancake.	70 g.
Mashed, candied, stuffed, or with sauce.	140 g.
Plain, fresh, canned, ⁵ or frozen.	110 g.
Salads:	
Pasta or potato salad....	140 g.
All other salad, e.g., egg, fish, shellfish, bean, fruit, or vegetable salad.	100 g.
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.	2 tbsp.
Major main entree sauce e.g., spaghetti sauce.	½ cup.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1 2 3}
Continued

Product category	Reference amount
Minor main entree sauce (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	¼ cup
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, etc..	1 tbsp
Minor condiments, e.g., horseradish, hot sauce, mustard, worcestershire sauce, etc..	1 tsp.
Snacks:	
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips), grain-based snack mixes.	30 g
Soups:	
All varieties.....	1 cup.
Sugars and Sweets:	
Baking candies (e.g., chips) and hard candies.	15 g.
All other candies.....	40 g.
Confectioner's sugar.....	2 tbsp.
Honey, jams, jellies, fruit butter, molasses.	1 tbsp.
Marshmallows.....	30 g.
Popsicles, snow cones..	85 g.
Sugar.....	8 g.
Sugar substitute.....	An amount equivalent to one reference amount for sugar in sweetness.
Syrups.....	60 mL.
Vegetables:	
Vegetables primarily used for garnish or flavor, e.g., pimento, chili pepper, green onion, parsley: fresh or canned ⁵ .	30 g.
All other vegetables without sauce: fresh, canned, ⁵ or frozen.	85 g.
All other vegetables with sauce: fresh, canned, or frozen.	110 g
Vegetable juice.....	240 mL.
Olives ⁵	15 g.
Pickles, all types ⁵	30 g.
Pickles, relish.....	15 g.
Vegetable pastes, e.g., tomato paste.	30 g.
Vegetable sauce or puree, e.g., tomato sauce, tomato puree.	60 g.

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, fresh and frozen pasta) is the amount required to make one reference amount of the prepared form.

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 Label serving size for ice cream cones and eggs of all sizes will be one unit.

⁵ Because this product is packed or canned in liquid, and the liquid is not customarily consumed, the reference amount is for the drained solids except for canned cream-style corn and canned or stewed tomatoes. Both the solids and liquid of canned cream-style corn and canned or stewed tomatoes are customarily consumed and therefore, the reference amount for these vegetables will be 130 g (i.e., g weight equivalent to ½ cup).

⁶ 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 shall be the same as that of the food for which it is offered as a substitute.

(e) The reference amount for an altered version of a food, such as a "low calorie" version, shall be the same as for the food for which it is offered as a substitute.

(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.

(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 health claims. If the serving size declared on the product label differs from the reference amount, both the reference amount and the serving size declared on the product label shall be used to determine whether the product meets the FDA criteria for a claim.

(h) The Commissioner of Food and Drugs, either on his or her own initiative or on behalf of any interested person who has submitted a petition 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 (portion) 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 ready-to-eat breakfast cereals and 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, median, and modal consumed amount per eating occasion for the petitioned product and for all 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 socio-economic 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 affect 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: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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21 CFR Parts 5, 101, and 105

[Docket No. 91N-0384]

RIN 0905-AD08

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing: (1) To amend its food labeling regulations to define nutrient content claims and to provide for their use on food labels; (2) to provide definitions for specific nutrient content claims that include the terms "low," "free," "reduced," "light" or "lite," "source," and "high;" (3) to provide for comparative claims using the terms "less," "fewer," and "more;" (4) to set forth specific requirements for sodium and calorie claims; (5) to establish procedures for the submission and review of petitions regarding nutrient content claims; (6) to revise 21 CFR 105.66, which covers special dietary foods with usefulness in reducing or maintaining caloric intake or body weight; (7) to establish criteria for the appropriate use of the term "fresh;" and (8) to address the use of the term "natural". FDA is addressing claims for cholesterol, fat, and fatty acid content in a separate proposal published elsewhere in this issue of the *Federal Register*. This action is part of the food labeling initiative of the Secretary of the Department of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based on this proposal become effective 6 months following its publication in accordance with the provisions of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

FDA has a long history of interest in prescribing label statements concerning the dietary properties of food. As early as 1940 [5 FR 1199, March 28, 1940], FDA held a hearing to discuss what label statements might be used to inform purchasers of the value that a particular food purports to have. Initially, these label statements were concerned with foods that purported or were represented to be for special dietary use by humans. While these statements focused to a large extent, but not exclusively, on vitamins and minerals, the early rulemaking also dealt with control of body weight and the value of food for use in dietary management of disease through controlling the intake of various nutrients.

By 1953 (18 FR 7249, November 14, 1953), FDA had begun to focus on specific nutrients such as sodium. The 1953 notice, for example, announced a hearing on label statements relating to certain foods used as a means of regulating the intake of sodium for the purposes of dietary management with respect to disease. On July 1, 1954 [19 FR 3999], FDA issued a final regulation recognizing that sodium restricted diets were widely used for dietary management of edema associated with some types of heart, liver, and kidney diseases; and that food purporting to be, or represented for, special dietary use in regulating the intake of sodium in dietary management should bear information concerning its sodium content.

In 1973 (38 FR 20708, August 2, 1973), FDA issued a final regulation, which was temporarily stayed and later revised, in part, as § 105.3 (21 CFR 105.3), stating that the term "special dietary use" applied to a food supplying a special dietary need that exists by reason of a physical, physiological, or other condition including convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. In 1978, FDA adopted regulations that defined the terms "low" and "reduced" for describing calorie content and set conditions for other label statements on special dietary foods used to reduce or

maintain weight or in diabetic diets (43 FR 43278, September 22, 1978).

In the 1980s, FDA changed the focus of nutrient claims from providing guidance for the dietary management of certain diseases to providing information that is useful to the general population. In 1984, the agency adopted regulations (49 FR 15510, April 18, 1984) that defined how the terms "very low," "low," "free," or "reduced" may be used to describe the sodium content of food. In addition, in 1986, the agency proposed to define terms to describe the cholesterol content of foods (51 FR 42584, November 25, 1986).

This change in focus towards defining descriptors is in large part the result of recent scientific developments and recommendations that have emphasized the role of diet in the maintenance of health. For example, the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS) have jointly developed a set of recommendations known as "Dietary Guidelines for Americans" (Ref. 1). These recommendations, which were published in 1980 and revised in 1985 and 1990, are based on the view that the judicious selection of foods containing low or high levels of certain nutrients as part of an overall diet is prudent on the part of all consumers, not just those with special dietary needs.

In addition, two scientific consensus reports, "The Surgeon General's Report on Nutrition and Health" (1986) (Ref. 2) and the National Academy of Sciences' report "Diet and Health: Implications for Reducing Chronic Disease Risk" (1989) (Ref. 3), concluded that changes in current dietary patterns, namely reducing consumption of fat, saturated fatty acids, cholesterol, and sodium and increasing consumption of complex carbohydrates and fiber, could lead to reduced incidence of certain chronic diseases.

In the *Federal Register* of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative of DHHS to take a new look at food labeling as a tool for promoting sound nutrition for the nation's consumers. FDA asked for public comment on five areas of food labeling, including the use of descriptors such as "low" or "free" to characterize foods.

FDA received over 2,000 written comments in response to this notice, plus over 5,000 responses to a questionnaire that had been distributed by a consumer organization. Over 500 comments addressed issues related to specific descriptors. Four hundred and