

name and offering for sale substantially the same menu items may voluntarily register to be subject to the requirements established in this section. Restaurants and similar retail food establishments that voluntarily register will no longer be subject to non-identical State or local nutrition labeling requirements.

(2) *Who may register?* The authorized official of a restaurant or similar retail food establishment as defined in paragraph (a) of this section, which is not otherwise subject to paragraph (b) of this section, may register with FDA.

(3) *What information is required?* Authorized officials for restaurants and similar retail food establishments must provide FDA with the following information on Form FDA 3757:

(i) The contact information (including name, address, phone number, and email address) for the authorized official;

(ii) The contact information (including name, address, phone number, and email address) of each restaurant or similar retail food establishment being registered, as well as the name and contact information for an official on-site, such as the owner or manager, for each specific restaurant or similar retail food establishment;

(iii) All trade names the restaurant or similar retail food establishment uses;

(iv) Preferred mailing address (if different from location address for each establishment) for purposes of receiving correspondence; and

(v) Certification that the information submitted is true and accurate, that the person submitting it is authorized to do so, and that each registered restaurant or similar retail food establishment will be subject to the requirements of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act and this section.

(4) *How to register.* Authorized officials of restaurants and similar retail food establishments who elect to be subject to requirements in section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act can register by visiting <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm>. FDA has created a form (Form 3757) that

contains fields requesting the information in paragraph (d)(3) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(i) Information should be submitted by email by typing complete information into the form (PDF), saving it on the registrant's computer, and sending it by email to menulawregistration@fda.hhs.gov.

(ii) *If email is not available, the registrant* can either fill in the form (PDF) and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301-436-2804 or mail it to FDA, CFSAN Menu and Vending Machine Registration, White Oak Building 22, Rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(5) *When to renew the registration.* To keep the establishment's registration active, the authorized official of the restaurant or similar retail food establishment must register every other year within 60 days prior to the expiration of the establishment's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Signatures.* Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

(f) *Misbranding.* A standard menu item offered for sale in a covered establishment shall be deemed misbranded under sections 201(n), 403(a), 403(f) and/or 403(q) of the Federal Food, Drug, and Cosmetic Act if its label or labeling is not in conformity with paragraph (b) or (c) of this section.

[79 FR 71253, Dec. 1, 2014]

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that the Food and Drug Administration (FDA) considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or

older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These reference amounts are based on data set forth in appropriate national food consumption surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving 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: FOODS FOR INFANTS AND YOUNG CHILDREN 1 THROUGH 3 YEARS OF AGE^{1 2 3}

Product category	Reference amount	Label statement ⁴
Cereals, dry instant	15 g	__ cup (__ g)
Cereals, prepared, ready-to-serve.	110 g	__ cup(s) (__ g)
Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts.	7 g for infants and 20 g for young children (1 through 3 years of age) for ready-to-eat cereals; 7 g for all others.	__ cup(s) (__ g) for ready-to-eat cereals; piece(s) (__ g) for others
Dinners, deserts, fruits, vegetables or soups, dry mix.	15 g	__ tbsp(s) (__ g); __ cup(s) (__ g)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type.	110 g	__ cup(s) (__ g); cup(s) (__ mL)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type.	110 g	__ cup(s) (__ g); cup(s) (__ mL)

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: FOODS FOR INFANTS AND YOUNG CHILDREN 1 THROUGH 3 YEARS OF AGE^{1 2 3}—Continued

Product category	Reference amount	Label statement ⁴
Dinners, stews or soups for young children, ready-to-serve.	170 g	__ cup(s) (__ g); cup(s) (__ mL)
Fruits for young children, ready-to-serve.	125 g	__ cup(s) (__ g)
Vegetables for young children, ready-to-serve.	70 g	__ cup(s) (__ g)
Eggs/egg yolks, ready-to serve	55 g	__ cup(s) (__ g)
Juices all varieties	120 mL	4 fl oz (120 mL)

¹ These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture. We further considered data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006, and 2007–2008 conducted by the Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services.

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 (*e.g.*, 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 the reference amount of the prepared form. Prepared means prepared for consumption (*e.g.*, cooked).

³ Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

⁴ The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (*e.g.*, sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

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

Product category	Reference amount	Label statement ⁴
Bakery Products:		
Bagels, toaster pastries, muffins (excluding English muffins).	110 g	__ piece(s) (__ g)
Biscuits, croissants, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies, scones, crumpets, English muffins.	55 g	__ piece(s) (__ g)
Breads (excluding sweet quick type), rolls.	50 g	__ piece(s) (__ g) for sliced bread and distinct pieces (<i>e.g.</i> , rolls); 2 oz (56 g/ __ inch slice) for unsliced bread
Bread sticks—see crackers.		
Toaster pastries—see bagels, toaster pastries, muffins (excluding English muffins).		
Brownies	40 g	__ piece(s) (__ g) for distinct pieces; fractional slice (__ g) for bulk

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

Product category	Reference amount	Label statement ⁴
Cakes, heavyweight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations) ⁵ .	125 g	__ piece(s) (__ g) for distinct pieces (e.g., sliced or individually packaged products); __ fractional slice (__ g) for large discrete units
Cakes, mediumweight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations; light weight cake with icing; Boston cream pie; cupcake; éclair; cream puff) ⁶ .	80 g	__ piece(s) (__ g) for distinct pieces (e.g., cupcake); __ fractional slice (__ g) for large discrete units
Cakes, lightweight (angel food, chiffon, or sponge cake without icing or filling) ⁷ .	55 g	__ piece(s) (__ g) for distinct pieces (e.g., sliced or individually packaged products); __ fractional slice (__ g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads.	55 g	__ piece(s) (__ g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56 g/ visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies	30 g	__ piece(s) (__ g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones ⁸ .	15 g	__ piece(s) (__ g)
Crackers that are usually used as snacks.	30 g	__ piece(s) (__ g)
Croutons	7 g	__ tbsp(s) (__ g); __ cup(s) (__ g); __ piece(s) (__ g) for large pieces
Eggroll, dumpling, wonton, or potsticker wrappers.	20 g	__ sheet (__ g); wrapper (__ g)
French toast, crepes, pancakes, variety mixes.	110 g prepared for French toast, crepes, and pancakes; 40 g dry mix for variety mixes.	__ piece(s) (__ g); __ cup(s) (__ g) for dry mix
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars.	40 g	__ piece(s) (__ g)
Ice cream cones—see crackers.		

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

Product category	Reference amount	Label statement ⁴
Pies, cobblers, fruit crisps, turnovers, other pastries.	125 g	__ piece(s) (__ g) for distinct pieces; __ fractional slice (__ g) for large discrete units
Pie crust, pie shells, pastry sheets, (e.g., phyllo, puff pastry sheets).	the allowable declaration closest to an 8 square inch surface area.	__ fractional slice(s) (__ g) for large discrete units; __ shells (__ g); __ fractional sheet(s) (__ g) for distinct pieces (e.g., Pastry sheet).
Pizza crust	55 g	__ fractional slice (__ g)
Taco shells, hard	30 g	__ shell(s) (__ g)
Waffles	85 g	__ piece(s) (__ g)
Beverages:		
Carbonated and non-carbonated beverages, wine coolers, water.	360 mL	12 fl oz (360 mL)
Coffee or tea, flavored and sweetened.	360 mL prepared	12 fl oz (360 mL)
Cereals and Other Grain Products:		
Breakfast cereals (hot cereal type), hominy grits.	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal.	__ cup(s) (__ g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains.	15 g	__ cup(s) (__ g)
Breakfast cereals, ready-to-eat, weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g.	40 g	__ cup(s) (__ g)
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	60 g	__ piece(s) (__ g) for large distinct pieces (e.g., biscuit type); __ cup(s) (__ g) for all others
Bran or wheat germ	15 g	__ tbsp(s) (__ g); __ cup(s) (__ g)
Flours or cornmeal	30 g	__ tbsp(s) (__ g); __ cup(s) (__ g)
Grains, e.g., rice, barley, plain.	140 g prepared; 45 g dry	__ cup(s) (__ g)
Pastas, plain	140 g prepared; 55 g dry	__ cup(s) (__ g); __ piece(s) (__ g) for large pieces (e.g., large shells or lasagna noodles) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., spaghetti)
Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles.	25 g	__ cup(s) (__ g)
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g	__ tbsp (__ g)
Stuffing	100 g	__ cup(s) (__ g)
Dairy Products and Substitutes:		
Cheese, cottage	110 g	__ cup (__ g)

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

Product category	Reference amount	Label statement ⁴
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g	__ cup (__ g)
Cheese, grated hard, e.g., Parmesan, Romano.	5 g	__ tbsp (__ g)
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g	__ piece(s) (__ g) for distinct pieces; __ tbsp(s) (__ g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category.		
Cream or cream substitutes, fluid.	15 mL	1 tbsp (15 mL)
Cream or cream substitutes, powder.	2 g	__ tsp (__ g)
Cream, half & half	30 mL	2 tbsp (30 mL)
Eggnog	120 mL	½ cup (120 mL); 4 fl oz (120 mL)
Milk, condensed, undiluted	30 mL	2 tbsp (30 mL)
Milk, evaporated, undiluted.	30 mL	2 tbsp (30 mL)
Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage.	240 mL	1 cup (240 mL); 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes.	240 mL	1 cup (240 mL); 8 fl oz (240 mL)
Sour cream	30 g	__ tbsp (__ g)
Yogurt	170 g	__ cup (__ g)
Desserts:		
Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups).	⅔ cup—includes the volume for coatings and wafers.	⅔ cup (__ g), __ piece(s) (__ g) for individually wrapped or packaged products
Sundae	1 cup	1 cup (__ g)
Custards, gelatin, or pudding.	½ cup prepared; amount to make ½ cup prepared when dry.	__ piece(s) (__ g) for distinct unit (e.g., individually packaged products); ½ cup (__ g) for bulk
Dessert Toppings and Fillings:		
Cake frostings or icings	2 tbsp	__ tbsp(s) (__ g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and non-dairy whipped toppings.	2 tbsp	2 tbsp (__ g); 2 tbsp (30 mL)
Pie fillings	85 g	__ cup(s) (__ g)
Egg and Egg Substitutes:		
Egg mixtures, e.g., egg foo young, scrambled eggs, omelets.	110 g	__ piece(s) (__ g) for discrete pieces; __ cup(s) (__ g)

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

Product category	Reference amount	Label statement ⁴
Eggs (all sizes) ⁸	50 g	1 large, medium, etc. (_ g)
Egg whites, sugared eggs, sugared egg yolks, and egg substitutes (fresh, frozen, dried).	An amount to make 1 large (50 g) egg.	_ cup(s) (_ g); _ cup(s) (_ mL)
Fats and Oils:		
Butter, margarine, oil, shortening.	1 tbsp	1 tbsp (_ g); 1 tbsp (15 mL)
Butter replacement, powder.	2 g	_ tsp(s) (_ g)
Dressings for salads	30 g	_ tbsp (_ g); _ tbsp (_ mL)
Mayonnaise, sandwich spreads, mayonnaise-type dressings.	15 g	_ tbsp (_ g)
Spray types	0.25 g	About _ seconds spray (_ g)
Fish, Shellfish, Game Meats, ⁹ and Meat or Poultry Substitutes:		
Bacon substitutes, canned anchovies, ¹⁰ anchovy pastes, caviar.	15 g	_ piece(s) (_ g) for discrete pieces; _ tbsp(s) (_ g) for others
Dried, e.g., jerky	30 g	_ piece(s) (_ g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g cooked	_ cup(s) (_ g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake.	85 g cooked; 110 g uncooked ¹¹ .	_ piece(s) (_ g) for discrete pieces; _ cup(s) (_ g); _ oz (_ g/visual unit of measure) if not measurable by cup ¹²
Fish, shellfish, or game meat ⁹ , canned ¹⁰ .	85 g	_ piece(s) (_ g) for discrete pieces; _ cup(s) (_ g); 3 oz (85 g/ _ cup) for products that are difficult to measure the g weight of cup measure (e.g., tuna); 3 oz (85 g/ _ pieces) for products that naturally vary in size (e.g., sardines)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages, frankfurters, and seafood.	55 g	_ piece(s) (_ g) for distinct pieces (e.g., slices, links); _ cup(s) (_ g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled fish, ¹⁰ shellfish, or game meat ⁹ ; fish or shellfish spread.	55 g	_ piece(s) (_ g) for distinct pieces (e.g., slices, links) or _ cup(s) (_ g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see Miscellaneous.		
Fruits and Fruit Juices:		
Candied or pickled ¹⁰	30 g	_ piece(s) (_ g)
Dehydrated fruits—see snack category.		
Dried	40 g	_ piece(s) (_ g) for large pieces (e.g., dates, figs, prunes); _ cup(s) (_ g) for small pieces (e.g., raisins)

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

Product category	Reference amount	Label statement ⁴
Fruits for garnish or flavor, e.g., maraschino cherries ¹⁰ .	4 g	1 cherry (_ g); _ piece(s) (_ g)
Fruit relishes, e.g., cranberry sauce, cranberry relish.	70 g	_ cup(s) (_ g)
Fruits used primarily as ingredients, avocado.	50 g	See footnote ¹²
Fruits used primarily as ingredients, others (cranberries, lemon, lime).	50 g	_ piece(s) (_ g) for large fruits; _ cup(s) (_ g) for small fruits measurable by cup ¹²
Watermelon	280 g	See footnote ¹²
All other fruits (except those listed as separate categories), fresh, canned or frozen.	140 g	_ piece(s) (_ g) for large pieces (e.g., strawberries, prunes, apricots, etc.); _ cup(s) (_ g) for small pieces (e.g., blueberries, raspberries, etc.) ¹²
Juices, nectars, fruit drinks	240 mL	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice.	5 mL	1 tsp (5 mL)
Legumes:		
Tofu, ¹⁰ tempeh	85 g	_ piece(s) (_ g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce ..	130 g for beans in sauce or canned in liquid and refried beans prepared; 90 g for others prepared; 35 g dry.	_ cup (_ g)
Miscellaneous:		
Baking powder, baking soda, pectin.	0.6 g	_ tsp (_ g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations.	1 tsp or 4 g if not measurable by teaspoon.	_ piece(s) (_ g) for discrete pieces; 1 tsp (_ g)
Batter mixes, bread crumbs.	30 g	_ tbsp(s) (_ g); _ cup(s) (_ g)
Chewing gum ⁸	3 g	_ piece(s) (_ g)
Cocoa powder, carob powder, unsweetened.	1 tbsp	1 tbsp (_ g)
Cooking wine	30 mL	2 tbsp (30 mL)
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc.	_ tablet(s), _ capsules(s), _ packet(s), _ tsp(s) (_ g), etc.
Meat, poultry, and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes.	Amount to make one reference amount of final dish.	_ tsp(s) (_ g); _ tbsp(s) (_ g)

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

Product category	Reference amount	Label statement ⁴
Milk, milk substitute, and fruit juice concentrates (without alcohol) (e.g., drink mixers, frozen fruit juice concentrate, sweetened cocoa powder).	Amount to make 240 mL drink (without ice).	__ fl oz (__ mL); __ tsp (__ g); __ tbsp (__ g)
Drink mixes (without alcohol): All other types (e.g., flavored syrups and powdered drink mixes).	Amount to make 360 mL drink (without ice).	__ fl oz (__ mL); __ tsp (__ g); __ tbsp (__ g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g	__ tbsp(s) (__ g)
Salt, salt substitutes, seasoning salts (e.g., garlic salt).	1/4 tsp	1/4 tsp (__ g); __ piece(s) (__ g) for discrete pieces (e.g., individually packaged products)
Seasoning oils and seasoning sauces (e.g., coconut concentrate, sesame oil, almond oil, chili oil, coconut oil, walnut oil).	1 tbsp	1 tbsp (__ g)
Seasoning pastes (e.g., garlic paste, ginger paste, curry paste, chili paste, miso paste), fresh or frozen.	1 tsp	1 tsp (__ g)
Spices, herbs (other than dietary supplements).	1/4 tsp or 0.5 g if not measurable by teaspoon.	1/4 tsp (__ g); __ piece(s) (__ g) if not measurable by teaspoons (e.g., bay leaf)
Mixed Dishes: Appetizers, hors d'oeuvres, mini mixed dishes, e.g., mini bagel pizzas, breaded mozzarella sticks, egg rolls, dumplings, potstickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins.	85 g, add 35 g for products with gravy or sauce topping.	__ piece(s) (__ g)
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.	1 cup	1 cup (__ g)
Not measurable with cup, e.g., burritos, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches.	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce ¹³ .	__ piece(s) (__ g) for discrete pieces; __ fractional slice (__ g) for large discrete units
Nuts and Seeds:		

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

Product category	Reference amount	Label statement ⁴
Nuts, seeds and mixtures, all types: Sliced, chopped, slivered, and whole.	30 g	__ piece(s) (__ g) for large pieces (e.g., unshelled nuts); __ tbsp(s) (__ g); __ cup(s) (__ g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams.	2 tbsp	2 tbsp (__ g)
Coconut, nut and seed flours.	15 g	__ tbsp(s) (__ g); __ cup (__ g)
Potatoes and Sweet Potatoes/ Yams:		
French fries, hash browns, skins, or pancakes.	70 g prepared; 85 g for frozen unprepared French fries.	__ piece(s) (__ g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/ __ pieces) for prepared fries; 3 oz (84 g/ __ pieces) for unprepared fries
Mashed, candied, stuffed or with sauce.	140 g	__ piece(s) (__ g) for discrete pieces (e.g., stuffed potato); __ cup(s) (__ g)
Plain, fresh, canned, or frozen.	110 g for fresh or frozen; 125 g for vacuum packed; 160 g for canned in liquid.	__ piece(s) (__ g) for discrete pieces; __ cup(s) (__ g) for sliced or chopped products
Salads:		
Gelatin salad	120 g	__ cup (__ g)
Pasta or potato salad	140 g	__ cup(s) (__ g)
All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads.	100 g	__ cup(s) (__ g)
Sauces, Dips, Gravies, and Condiments:		
Barbecue sauce, hollandaise sauce, tartar sauce, tomato chili sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).	2 tbsp	2 tbsp (__ g); 2 tbsp (30 mL)
Major main entree sauces, e.g., spaghetti sauce.	125 g	__ cup (__ g); __ cup (__ mL)
Minor main entree sauces (e.g., pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	1/4 cup	1/4 cup (__ g); 1/4 cup (60 mL)
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades.	1 tbsp	1 tbsp (__ g); 1 tbsp (15 mL)
Minor condiments, e.g., horseradish, hot sauces, mustards, Worcestershire sauce.	1 tsp	1 tsp (__ g); 1 tsp (5 mL)
Snacks:		

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

Product category	Reference amount	Label statement ⁴
All varieties, chips, pretzels, popcorn, extruded snacks, fruit and vegetable-based snacks (e.g., fruit chips), grain-based snack mixes.	30 g	__ cup (__ g) for small pieces (e.g., popcorn); __ piece(s) (__ g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28g/visual unit of measure) for bulk products (e.g., potato chips)
Soups:		
All varieties	245 g	__ cup (__ g); __ cup (__ mL)
Dry soup mixes, bouillon ..	Amount to make 245 g	__ cup (__ g); __ cup (__ mL)
Sugars and Sweets:		
Baking candies (e.g., chips).	15 g	__ piece(s) (__ g) for large pieces; __ tbsp(s) (__ g) for small pieces; 1/2 oz (14 g/visual unit of measure) for bulk products
After-dinner confectioneries.	10 g	__ piece(s) (__ g)
Hard candies, breath mints ⁸ .	2 g	__ piece(s) (__ g)
Hard candies, roll-type, mini-size in dispenser packages.	5 g	__ piece(s) (__ g)
Hard candies, others; powdered candies, liquid candies.	15 mL for liquid candies; 15 g for all others.	__ piece(s) (__ g) for large pieces; __ tbsp(s) (__ g) for “mini-size” candies measurable by tablespoon; __ straw(s) (__ g) for powdered candies; __ wax bottle(s) (__ mL) for liquid candies; 1/2 oz (14 g/visual unit of measure) for bulk products
All other candies	30 g	__ piece(s) (__ g); 1 oz (30 g/visual unit of measure) for bulk products
Confectioner’s sugar	30 g	__ cup (__ g)
Honey, jams, jellies, fruit butter, molasses, fruit pastes, fruit chutneys.	1 tbsp	1 tbsp (__ g); 1 tbsp (15 mL)
Marshmallows	30 g	__ cup(s) (__ g) for small pieces; __ piece(s) (__ g) for large pieces
Sugar	8 g	__ tsp (__ g); __ piece(s) (__ g) for discrete pieces (e.g., sugar cubes, individually packaged products)
Sugar substitutes	An amount equivalent to one reference amount for sugar in sweetness.	__ tsp(s) (__ g) for solids; __ drop(s) (__ g) for liquid; __ piece(s) (__ g) (e.g., individually packaged products)
Syrups	30 mL for all syrups	2 tbsp (30 mL)
Vegetables:		
Dried vegetables, dried tomatoes, sun-dried tomatoes, dried mushrooms, dried seaweed.	5 g, add 5 g for products packaged in oil.	__ piece(s); 1/3 cup (__ g)
Dried seaweed sheets	3 g	__ piece(s) (__ g); __ cup(s) (__ g)

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

Product category	Reference amount	Label statement ⁴
Vegetables primarily used for garnish or flavor (e.g., pimento, ¹⁰ parsley, fresh or dried).	4 g	— piece(s) (_ g); — tbsp(s) (_ g) for chopped products
Fresh or canned chili peppers, jalapeno peppers, other hot peppers, green onion.	30 g	— piece(s) (_ g) ¹² ; — tbsp(s) (_ g); — cup(s) (_ g) for sliced or chopped products
All other vegetables without sauce: Fresh, canned, or frozen.	85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash.	— piece(s) (_ g) for large pieces (e.g., Brussels sprouts); — cup(s) (_ g) for small pieces (e.g., cut corn, green peas); 3 oz (84 g/visual unit of measure) if not measurable by cup
All other vegetables with sauce: Fresh, canned, or frozen.	110 g	— piece(s) (_ g) for large pieces (e.g., Brussels sprouts); — cup(s) (_ g) for small pieces (e.g., cut corn, green peas); 4 oz (112 g/visual unit of measure) if not measurable by cup
Vegetable juice	240 mL	8 fl oz (240 mL)
Olives ¹⁰	15 g	— piece(s) (_ g); — tbsp(s) (_ g) for sliced products
Pickles and pickled vegetables, all types ¹⁰ .	30 g	1 oz (28 g/visual unit of measure)
Pickle relishes	15 g	— tbsp (_ g)
Sprouts, all types: Fresh or canned.	1/4 cup	1/4 cup (_ g)
Vegetable pastes, e.g., tomato paste.	30 g	— tbsp (_ g)
Vegetable sauces or purees, e.g., tomato sauce, tomato puree.	60 g	— cup (_ g); — cup (_ mL)

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 U.S. Department of Agriculture and updated with data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006 and 2007–2008 conducted by the Centers for Diseases Control and Prevention, in the Department of Health and Human Services.

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 (e.g., 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 the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

³ Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

⁴ The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

⁵ Includes cakes that weigh 10 g or more per cubic inch. The serving size for fruitcake is 1 ½ ounces.

⁶ Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

⁷ Includes cakes that weigh less than 4 g per cubic inch.

⁸ Label serving size for ice cream cones, eggs, and breath mints of all sizes will be 1 unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be 1 unit.

⁹ Animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

¹⁰ If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (*e.g.*, canned chopped clam in juice).

¹¹ The reference amount for the uncooked form does not apply to raw fish in § 101.45 or to single-ingredient products that consist of fish or game meat as provided for in § 101.9(j)(11).

¹² For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR part 101) Code of Federal Regulations.

¹³ Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) If a product requires further preparation, *e.g.*, cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a reference amount for the product in the prepared form, but not the unprepared form, then the reference amount for the unprepared product must be the amount of the unprepared product required to make the reference amount for the prepared product as established in paragraph (b) of this section.

(d) The reference amount for an imitation or substitute food or altered food, such as a “low calorie” version, shall be the same as for the food for which it is offered as a substitute.

(e) If a food is modified by incorporating air (aerated), and thereby the density of the food is lowered by 25 percent or more in weight than that of an appropriate reference regular food as described in § 101.13(j)(1)(ii)(A), and the reference amount of the regular food is in grams, the manufacturer may determine the reference amount of the aerated food by adjusting for the difference in density of the aerated food relative to the density of the appropriate reference food provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated food. The reference amount for the aerated food shall be rounded to the nearest 5-g increment. Such products shall bear a descriptive term indicating that extra air has been incorporated (*e.g.*, whipped, aerated). The

density-adjusted reference amounts described in paragraph (b) of this section may not be used for cakes except for cheese cake. The differences in the densities of different types of cakes having different degrees of air incorporation have already been taken into consideration in determining the reference amounts for cakes in § 101.12(b). In determining the difference in density of the aerated and the regular food, the manufacturer shall adhere to the following:

(1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (*e.g.*, waffles), manufacturers shall use a device or method that ensures that the volumes of the regular and the aerated products are the same.

(2) Sample selections for the density measurements shall be done in accordance with the provisions in § 101.9(g).

(3) Density measurements of the regular and the aerated products shall be conducted by the same trained operator using the same methodology (*e.g.*, the same equipment, procedures, and techniques) under the same conditions.

(4) Density measurements shall be replicated a sufficient number of times to ensure that the average of the measurements is representative of the true differences in the densities of the regular and the “aerated” products.

(f) For products that have no reference amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and

that consist of two or more foods packaged and presented to be consumed together (e.g., peanut butter and jelly, cracker and cheese pack, pancakes and syrup, cake and frosting), the reference amount for the combined product shall be determined using the following rules:

(1) The reference amount for the combined product must be the reference amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient (e.g., peanut butter, pancakes, cake) plus proportioned amounts of all minor ingredients.

(2) If the reference amounts are in compatible units, the weights or volumes must be summed (e.g., the reference amount for equal volumes of peanut butter and jelly for which peanut butter is represented as the main ingredient would be 4 tablespoons (tbsp) (2 tbsp peanut butter plus 2 tbsp jelly)). If the reference amounts are in incompatible units, all amounts must be converted to weights and summed, e.g., the reference amount for pancakes and syrup would be 110 g (the reference amount for pancakes) plus the weight of the proportioned amount of syrup.

(g) The reference amounts set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as “low calorie,” and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in paragraph (b) of this section followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, “Very low sodium, 35 mg or less per 240 mL (8 fl oz)”).

(h) The Commissioner of Food and Drugs, either on his or her own initiative or in response to a petition submitted pursuant to part 10 of this chapter, may issue a proposal to establish or amend a reference amount in para-

graph (b) of this section. 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. Reference amounts for other foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons, are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density, such as frozen desserts.

(i) In expressing the reference amounts in milliliters, the following rules shall be followed:

(A) For volumes greater than 30 milliliters (mL), the volume shall be expressed in multiples of 30 mL.

(B) For volumes less than 30 mL, the volume shall be expressed in milliliters equivalent to a whole number of teaspoons or 1 tbsp, i.e., 5, 10, or 15 mL.

(ii) In expressing the reference amounts in grams, the following general rules shall be followed:

(A) For quantities greater than 10 g, the quantity shall be expressed in the nearest 5-g increment.

(B) For quantities less than 10 g, exact gram weights shall be used.

(11) A petition to create a new subcategory of food with its own reference amount shall include the following additional information:

(i) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size; and the mean, standard deviation, median, and modal consumed amount per eating occasion for the petitioned product and for other products in the category, excluding the petitioned product. All data must be derived from the same survey data.

(ii) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the petitioned product from the rest of the products in the category.

(12) A claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter, and

(13) In conducting research to collect or process food consumption data in support of the petition, the following general guidelines should be followed.

(i) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(ii) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(iii) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(iv) The methodology used to collect or process data should be fully documented and should include: study design, sampling procedures, materials used (e.g., questionnaire, and 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.

(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 (5 U.S.C. 561).

[58 FR 44051, Aug. 18, 1993; 58 FR 60109, Nov. 15, 1993, as amended at 59 FR 371, Jan. 4, 1994; 59 FR 24039, May 10, 1994; 62 FR 40598, July 29, 1997; 62 FR 49848, Sept. 23, 1997; 63 FR 14818, Mar. 27, 1998; 64 FR 12890, Mar. 16, 1999; 66 FR 56035, Nov. 6, 2001; 81 FR 34041, May 27, 2016]

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or