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than 20 percent in excess of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls above this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw poultry products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 197, Jan. 3, 1995; 60 FR 10304, Feb. 24, 1995; 69 FR 58802, Oct. 1, 2004]

§§ 381.410–381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion

(Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated 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) The Reference Amounts are calculated 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 product 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, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS 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 product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground poultry), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and 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
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain poultry and poultry sticks, ready-to-serve	55 g

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). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated 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 established by the regulation.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY ^{1,2,3,4,5}

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry).	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a
Bacon; e.g., poultry breakfast strips.	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1.	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco fillings.	55 g	n/a
Linked poultry sausage products, poultry franks, poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	114g
Canned poultry, canned chicken, canned ⁴ turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup; ⁵ e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash, poultry lasagna, poultry-filled pasta.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad.	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
Soups—all varieties	245 g	n/a
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	¼ cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry.		

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY^{1,2,3,4,5}—Continued

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

¹ These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

² Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

³ Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

⁴ 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.

⁵ Pizza sauce is part of the pizza and is not considered to be a sauce topping.

(c) 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., poultry lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) 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, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall 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.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in §381.413(d), such as a “low calorie” version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional 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.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate

sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date) _____

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.412 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., turkey as a luncheon meat);

(vi) 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;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) 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);

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(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin 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.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for 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 mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(1) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(2) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) 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 product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

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

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

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

(C) The study protocol should identify potential biases and describe how potential bi-

ases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) 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.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the

initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of poultry products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written state-

ment by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583-0088.)

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§ 381.413 Nutrient content claims; general principles.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale.