

FDA Food Label Compliance

As part of the e-monthly newsletter, *Food Label News*, Food Consulting Company answers questions from subscribers. Here are recent questions and answers:

Is there a U.S. labeling regulation that establishes the allowable variance for the analyzed value vs. what is printed on the label? If so, what is the specific regulation?

Yes, FDA regulations published at 21CFR101.9(g) specify two classes of nutrients; the allowable variance is different for each. Regardless of the class, the analyzed value is derived from a composite sample of twelve consumer units, with one unit coming from each of twelve different randomly chosen shipper cases.

Class I nutrients are nutrients added to fabricated foods for the purpose of fortification, such as vitamins, minerals, protein and dietary fiber. For this class, the analyzed value must be at least equal to the label value.

Class II nutrients are naturally-occurring nutrients. For this class, the analyzed value for the "beneficial nutrients" (vitamin, mineral, protein, total carbohydrate, polyunsaturated fat, monounsaturated fat or potassium) must be at least 80% of the label value and the analyzed value for the "nutrients to limit" (calories, sugars, total fat, saturated fat, cholesterol or sodium) must not be greater than 120% of the label value. These allowable variances are commonly referred to as the "80/120 rule."

For our Frozen Italian Dessert, can we refer to this collection of ingredients as "chocolate coating": sugar, palm oil, cocoa powder and soy lecithin?

No. You would need to identify the above ingredients as "chocolate flavored coating" since the standard of identity for sweet chocolate (21CFR163.123) is not met. The key difference in your ingredients and those of standardized chocolate is the use of palm oil instead of cocoa butter.

Though it does not apply to this situation, it is worthy of noting that some chocolate food items that are flavored only with cocoa and not expected to contain the other elements of standardized chocolate (such as chocolate milk and chocolate pudding) can be called "chocolate" as outlined in the FDA Compliance Policy Guide.

The [Compliance Policy Guide](#) states "non-standardized food product that contains cocoa as the chocolate flavoring ingredient may bear the term "chocolate" so long as it can be demonstrated that consumers have long recognized that the food product may be made from cocoa and do not expect it to contain some other chocolate ingredient."

What criteria must be met for a product to be labeled vegetarian? How can we label our product to alert vegetarians who do not eat dairy or egg products?

Neither FDA nor FTC has any labeling regulations for vegetarian statements, other than being "truthful and not misleading." The most conservative course of action is to ensure that the product is free of any animal-derived ingredient or ingredient components and use the term "vegan" when appropriate. This means that the product has no ingredients from animal origin such as milk, eggs, honey or gelatin.

Since there are different types of vegetarians, it is also possible to include a clarifying statement defining the type of vegetarian for which the product is intended to ensure that the statement is clear to the consumer and meets the "truthful and not misleading" requirement for all labels (e.g., this product is suitable for lacto-ovo vegetarians).

What label information is needed to sell products wholesale? Is the same label information necessary for selling to foodservice?

There are five mandatory label components required for both wholesale and foodservice items. These include:

- 1) product identity
- 2) net contents statement
- 3) nutrition facts (exempt on some foodservice items)
- 4) ingredient/allergen statement
- 5) name/address of the manufacturer or distributor

For wholesale items, the outer packaging (i.e., shipping containers used solely for transportation) does not require the mandatory label components, however the inner packaging does.

For foodservice items, nutrition facts may be omitted if the items will be further processed (not sold in the packaging) and do not carry nutrient content or health claims on the label or labeling. However most manufacturers of foodservice items choose to voluntarily include nutrition information because their restaurant customers are now requiring it to comply with restaurant menu labeling regulations.

What label components must be on products that are only sold in farmers markets and on the Internet?

There are no special provisions for products sold at farmers markets or on the Internet. Regardless of the sales channel, all foods sold in the U.S. must be in full compliance with FDA food labeling requirements that are specified in the U.S. Code of Federal Regulations.

Foods sold in farmers markets and on the Internet (like every other retail food) must be labeled with the five requirements for all foods: product identity, net contents, nutrition facts, ingredients/allergens, and company name/address.

However, small businesses may be exempt from nutrition facts labeling, but the other four label components must still be displayed in the manner specified in the U.S. Code of Federal Regulations. See an earlier [Reader Q&A](#) for more on the small business exemption.

Is enriched flour "natural" in Canada?

No. Per Canadian regulations, "a natural food or ingredient of a food is not expected to contain, or to ever have contained, an added vitamin, mineral nutrient, artificial flavouring agent or food additive." For discussion on this topic including natural requirements in the EU, join us on the [LinkedIn Food Label Community](#).

How much alcohol can be used in an FDA-regulated food product, and how is it regulated?

Ethyl alcohol is generally recognized as safe in foods but only for specific uses including: in the extraction process as a solvent for certain colors (21CFR73) and flavors (21CFR169), in defoaming agents for coatings (21 CFR 176.200), and as an antimicrobial agent on pizza crusts prior to final

baking (21CFR184.1293). FDA considers flavored beverages with traces of alcohol (<0.5% by volume) from flavoring extracts or natural fermentation to be "non-alcoholic."

The Tax and Trade Bureau (TTB) regulates the labeling of alcoholic beverages including distilled spirits, malt beverages, and wine with 7% or more alcohol by volume. Beverages such as diluted wine and cider which have an alcohol content of less than 7% by volume and are not defined in the Federal Alcohol Administration Act, are subject to the labeling requirements of the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act; therefore they must follow FDA labeling rules. See Compliance Policy Guide CPG 510.450.

What should a serving size be for a retail baking flavor? There are so many uses from cookies to smoothies, which would have significantly different serving sizes and nutrition information?

The Code of Federal Regulations (CFR) does not include a specific reference amount customarily consumed (RACC) for baking flavors. FDA's Food Labeling Guide in section L62 includes suggested RACCs for a number of product categories not included in the CFR. Products marketed as flavor substances for baking would most closely resemble flavoring oils with a suggested RACC of 1 tsp (___g).

In this scenario, it would be helpful to consumers to include a second column within the Nutrition Facts that shows nutrition information for other intended uses (such as smoothies). See an example of a dual declaration Nutrition Facts Label at www.foodlabels.com/nutritionfacts-examples-2.htm

If one is making a product consisting of three simple ingredients with no salt, sugar or preservatives added, how extensive does the nutrition statement have to be for the label on such a product?

It depends on the profile of the finished product per serving and whether nutrient content claims are made. If the finished product has no significant nutrients to list (i.e., all label values are zero) **and** no nutrition claims are made, the Nutrition Facts panel can be omitted. Spices and teas for example do not always require that the label includes the Nutrition Facts.

If the profile is such that at least 8 of the mandatory nutrients can be listed as zero, then a simplified format can be used. See Nutrition Facts examples in the simplified format at www.foodlabels.com/nutritionfacts-examples-2.htm

Is the use of "natural-identical flavor" appropriate in USA? I only found guidelines in CFR (Code of Federal Regulations) for "natural flavor" or "artificial flavor." I think natural-identical flavor is mostly used as a standard for Europe.

You are correct. There is not a classification for "natural-identical flavors" in the U.S. The term natural-identical (or nature-identical) is used in Europe for a particular class of flavors that are synthetically produced, but chemically identical to substances found in nature. In the U.S., these synthetically-derived nature-identical flavor ingredients need to be labeled as artificial flavors.

For the FDA definition of natural and artificial flavors, see the U.S. Code of Federal Regulations at 21CFR101.22.

A customer of ours used the 4-4-9 calculation to validate calories on our Nutrition Facts and got a different value than what we show. How do I explain the difference?

The 4-4-9 method is just one of five methods FDA allows for calorie labeling on Nutrition Facts. This method is the least accurate of the five because it uses "average factors" – 4 calories per gram for carbohydrate, 4 calories per gram for protein, and 9 calories per gram for fat. These "average factors" generally overstate calories because specific ingredients often contain fewer calories than the average factor would indicate. For example, dextrose (a carbohydrate) contains 3.4 calories per gram, not 4 calories per gram as the 4-4-9 method would indicate.

The five methods FDA allows for calorie determination are: (1) a 4-4-9 calculation; (2) an adjusted 4-4-9 calculation where insoluble fiber is subtracted from the carbohydrate total before multiplying by 4 (since insoluble fiber does not impact the calorie value of foods); (3) specific Atwater factors; (4) other specific food factors approved by FDA; and (5) bomb calorimetry.

Food Consulting Company uses a database nutritional analysis with Atwater or other food factors for most of the ingredients and relies on an adjusted 4-4-9 calculation for those ingredients where specific food factors are not available. Over time we have found this to result in a more accurate (and lower) calorie value than the simple 4-4-9 calculation used in most laboratory nutritional analyses.

There are a number of ways to get your questions answered:

- **Subscribe** to *Food Label News* – www.foodlabelnews.com/subscribe
- **Search** the Reader Q&A archive – www.foodlabels.com/q&a.htm
- **Join** the discussion about topics of interest to food labelers on LinkedIn's Food Label Community - www.foodlabels.com/linkedin/community
- **Contact us** for individualized help at www.foodlabels.com

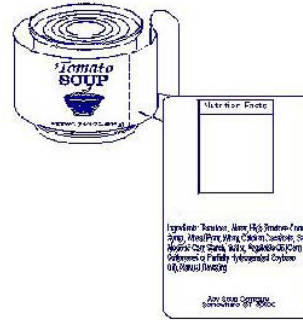
About Food Consulting Company

Food Consulting Company, founded in 1993, delivers nutrition analysis and food label guidance to ensure 100% regulatory compliance. The largest contract provider of food labeling services with well over 1,500 clients worldwide, the company's services are ideal for start-ups, established food manufacturers and distributors, food importers and brokers, and restaurateurs.

Our experienced team of registered dietitians, regulatory specialists and food technologists work side by side with your team, like your virtual food label department. Our goal is to make food label compliance easy.

LABEL LAYOUT INSTRUCTIONS FOR FDA-REGULATED FOODS

FDA regulations require components of every retail food package with positioning and minimum type size as outlined below. The sidebar picture is provided as a sample representation of a Principal Display Panel and an Information Panel. Note that all Information Panel requirements must be placed together without intervening material, starting at the top left of the panel.



Principal Display Panel (PDP) – Front of Package

1. Product Identity

Must include a descriptive name in addition to any fanciful name you use. Descriptive name must be in bold prominent lettering (at least half the largest type size), generally parallel to the base of the container. Fanciful names may be used but are not required.

2. Net Contents Statement

Must include the net contents statement in the lower 30% of the front panel, and generally parallel to the base of the container. Do not crowd with other words or pictures; include space of "N" above and below and "NN" to the right and left. Minimum height of lettering:

- 1/16" when PDP is 5 square inches or less
- 1/8" when PDP is 5-25 square inches
- 3/16" when PDP is 25-100 square inches
- 1/4" when PDP is 100-400 square inches
- 1/2" when PDP is over 400 square inches

Examples of correctly written net contents statements:

- NET WT 12 OZ (340g)
- NET WT 24 OZ (1 LB 8 OZ) 680g
- NET 8 FL OZ (237mL)

Information Panel (IP) – Back or Right Side of Package

3. Nutrition Facts

Graphic requirements are very specific. Regulations for layout and footnotes are based on package dimensions; regulations for the format based on the nutrient profile of the product. Use the print-ready artwork we provide, or consult the [Code of Federal Regulations](#) for graphic specifications.

- Layouts: (a) Vertical, use this display when it fits, (b) Side-by-side, (c) Horizontal, (d) Linear
- Footnotes: (a) Calories per gram, always optional, (b) Full DV Chart, mandatory on packages >40 sq in
- Two Formats: (a) "Full" uses 21CFR101.9c rules, (b) "Simplified" uses 21CFR101.9f rules

4. Ingredient/Allergen Statement

Use lettering at least 1/16" in height (by small "o" unless all upper case letters are used). If an Allergen (Contains) Statement is used, it must be in lettering at least as bold and prominent as the Ingredient Statement and must contain all "big 8" allergens present.

5. Signature Line

Include name, street address, city, state/province, and postal code of the responsible party immediately after the Ingredient/Allergen Statement. (Street address may be omitted if listed in a current city directory or telephone book.) Website and telephone number are optional. Minimum height of lettering is 1/16". County of origin (e.g., Product of Brazil) is required by U.S. Customs for all imported products and typically follows the Signature Line.