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Institute of Medicine (US) Committee on Examination of Front-of-Package Nutrition Rating Systems and Symbols; Wartella EA, Lichtenstein AH, Boon CS, editors. Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report. Washington (DC): National Academies Press (US); 2010.

Appendix B FDA Regulatory Requirements for Nutrient Content Claims¹

<i>FREE</i>	
Calories	<ul style="list-style-type: none"> • Less than 5 calories per RACC and per labeled serving.
Total fat	<ul style="list-style-type: none"> • Less than 0.5 g per RACC and per labeled serving (or, for meals and main dishes, less than 0.5 g per labeled serving). • Contains no ingredient that is fat or understood to contain fat, except as noted below.* • “__% Fat Free” may be used if food meets the requirements for “low fat” and the % declared is in same type size as “fat free.” • 100% Fat Free: Food must be “fat free” and contain less than 0.5 g fat per 100 g.
Saturated fat	<ul style="list-style-type: none"> • Less than 0.5 g saturated fat and less than 0.5 g <i>trans</i> fatty acids per RACC and per labeled serving (or, for meals and main dishes, less than 0.5 g saturated fat and less than 0.5 g <i>trans</i> fatty acids per labeled serving). • Contains no ingredient that is understood to contain saturated fat except as noted below.*

	<ul style="list-style-type: none"> • Must declare the amount of cholesterol if 2 mg or more per RACC, and the amount of total fat if 0.5 g or more per RACC (or, for meals and main dishes, the amount of cholesterol, if 2 mg or more per labeled serving and the amount of total fat if 0.5 g or more per labeling serving).
Cholesterol	<ul style="list-style-type: none"> • Less than 2 mg per RACC and per labeled serving (or, for meals and main dishes, less than 2 mg per labeled serving). • Contains no ingredient that contains cholesterol except as noted below.* • Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or, for meals and main dishes, 2 g or less saturated fat per labeled serving size. • Must declare the amount of total fat per serving next to claim when fat exceeds 13 g per RACC and per labeled serving (or per 50 g if RACC is small), or when fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.
Sodium	<ul style="list-style-type: none"> • Less than 5 mg per RACC and per labeled serving (or, for meals and main dishes, less than 5 mg per labeled serving). • Contains no ingredient that is sodium chloride or generally understood to contain sodium except as noted below.* • “Salt Free” must meet criterion for “sodium free.” • “No Salt Added” and “Unsalted” are allowed if no salt is added during processing. Must declare “This is not a sodium-free food” on information panel if food is not “sodium free.”

Sugars	<ul style="list-style-type: none"> • “Sugar Free”: Less than 0.5 g sugars per RACC and per labeled serving (or, for meals and main dishes, less than 0.5 g per labeled serving). • Contains no ingredient that is a sugar or generally understood to contain sugars except as noted below.* • Disclose calorie profile (e.g., “low calorie” or “not a low calorie food”). • “No added sugars” and “Without added sugars” are allowed if no sugar or sugar containing ingredient such as jam, jelly, or concentrated fruit juice is added during processing. Must state if food is not “low” or “reduced calorie.”
<i>LOW</i>	
Calories	<ul style="list-style-type: none"> • 40 calories or less per RACC (and per 50 g if RACC is small). • Meals and main dishes: 120 calories or less per 100 g.
Total fat	<ul style="list-style-type: none"> • 3 g or less per RACC (and per 50 g if RACC is small). • Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat.
Saturated fat	<ul style="list-style-type: none"> • 1 g or less per RACC and 15% or less of calories from saturated fat. • Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat.

	<ul style="list-style-type: none"> • Must declare the amount of cholesterol if 2 mg or more per RACC, and the amount of total fat if more than 3 g per RACC (or, for meals and main dishes, the amount of cholesterol if 2 mg or more per labeled serving, and the amount of total fat if more than 3 g per 100 g or more than 30% of calories from fat).
Cholesterol	<ul style="list-style-type: none"> • 20 mg or less per RACC (and per 50 g of food if RACC is small). • Meals and main dishes: 20 mg or less per 100 g. • Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or, for meals and main dishes, per 100 g. • Must declare the amount of total fat next to claim when fat exceeds 13 g per RACC and per labeled serving (or per 50 g if RACC is small), or when fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.
Sodium	<ul style="list-style-type: none"> • 140 mg or less per RACC (and per 50 g if RACC is small). • Meals and main dishes: 140 mg or less per 100g. • “Very Low Sodium”: 35 mg or less per RACC (and per 50 g if RACC is small); for meals and main dishes: 35 mg or less per 100 g.
Sugars	<ul style="list-style-type: none"> • Not defined.
<i>REDUCED/LESS</i>	

To bear a relative claim about the level of a nutrient, the amount of that nutrient must be compared to an amount in an appropriate reference food. For “reduced” claims, the reference food must be (1) an established regular product or average representative product or (2) a similar food. For “less” claims, it must be either of the above or a dissimilar food in the same product category which may generally be substituted for the labeled food (e.g., potato chips for pretzels).

Calories	<ul style="list-style-type: none"> • At least 25% fewer calories per RACC than appropriate reference food (or, for meals and main dishes, at least 25% fewer calories per 100 g). • Reference food may not be “low calorie.” • Uses term “fewer” rather than “less.”
Total fat	<ul style="list-style-type: none"> • At least 25% less fat per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less fat per 100 g). • Reference food may not be “low fat.”
Saturated fat	<ul style="list-style-type: none"> • At least 25% less saturated fat per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less saturated fat per 100 g). • Reference food may not be “low saturated fat.” • Must declare the amount of cholesterol if 2 mg or more per RACC and the amount of total fat if more than 3 g per RACC (or, for meals and main dishes the amount of cholesterol if 2 mg or more per labeled serving and the amount of fat if more than 3 g per 100 g or more than 30% of calories from fat).

Cholesterol	<ul style="list-style-type: none"> • At least 25% less cholesterol per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less cholesterol per 100 g). • Reference food may not be “low cholesterol.” • Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC, or, for meals and main dishes, per 100 g. • Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per RACC and labeled serving (or per 50 g of food if RACC is small), or when the fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.
Sodium	<ul style="list-style-type: none"> • At least 25% less sodium per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less sodium per 100 g). • Reference food may not be “low sodium.”
Sugars	<ul style="list-style-type: none"> • At least 25% less sugars per RACC than an appropriate reference food (or, for meals and main dishes, at least 25% less sugars per 100 g).
<i>HEALTHY</i>	
Individual Food	<ul style="list-style-type: none"> • Low fat (i.e., 3 g or less fat per RACC). • Low saturated fat (i.e., 1 g or less per RACC and 15% or less of calories from saturated fat).

	<ul style="list-style-type: none"> • Sodium: 480 mg or less per RACC and 480 mg or less per labeled serving, except foods with a RACC less than or equal to 30 g or 2 Tbsp must contain 480 mg or less per 50 g. • Cholesterol: 60 mg or less per RACC and 60 mg or less per labeled serving, except foods with a RACC less than or equal to 30 g or 2 Tbsp must contain 60 mg or less per 50 g. • Beneficial nutrients: At least 10% of Daily Value for vitamin A, vitamin C, calcium, iron, protein or fiber per RACC, except for raw fruits and vegetables, single ingredient or a mixture of canned or frozen fruits and vegetables, or enriched cereal grain products that conform to a standard of identity. • Fortification in accordance with Fortification Policy in 21 CFR 104.20.
Seafood/Game Meat	<ul style="list-style-type: none"> • Total fat: Less than 5 g fat per RACC and per 100 g. • Saturated fat: Less than 2 g per RACC and per 100 g. • Sodium: Same as for individual food. • Cholesterol: Less than 95 mg per RACC and per 100 g. • Beneficial nutrients: Same as for individual food. • Fortification in accordance with Fortification Policy in 21 CFR 104.20.
Meal or Main Dish	<ul style="list-style-type: none"> • Low fat (i.e., 3 g or less per 100 g and not more than 30% of calories from fat). • Low saturated fat (i.e., 1 g or less per 100 g and less than 10% of calories from saturated fat). • Sodium: 600 mg or less per labeled serving.

- Cholesterol: 90 mg or less per labeled serving.
- Beneficial nutrients: At least 10% of Daily Value per labeled serving of two of the following nutrients for a main dish and three of the nutrients for a meal: vitamin A, vitamin C, calcium, iron, protein, or fiber per labeled serving.
- Fortification in accordance with Fortification Policy in 21 CFR 104.20.

LIGHT

- If 50% or more of the calories are from fat, fat must be reduced by at least 50% per RACC. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per RACC. Reference food may not be “low calorie” and “low fat.”
- For sodium reduced products, if sodium is reduced by 50% or more and the food does not meet the definition of “low calorie” or “low fat,” claim must say “light in sodium.” If sodium is reduced by 50% or more and the food meets the definition of “low calories” and “low fat,” the claim “light” may be used without further qualification.
- Meals or main dishes must meet the definition for “low calorie” or “low fat” meal and be labeled to indicate which definition is met.
- “Light in sodium”: sodium is reduced by at least 50% per RACC and, except for meals and main dishes, the reference food may not meet the definition of “low in sodium.” For meals and main dishes, “light in sodium” must meet definition for “low in sodium.”
- “Lightly salted”: 50% less sodium than normally added to reference food and if food does not meet definition for “low sodium,” it must state that on the information panel, i.e., “not a low sodium food.”

- The reference food must be representative of the type of food bearing the claim (e.g., average value of top three brands or representative value from valid data base), or a similar food (e.g., potato chips for potato chips).

OTHER NUTRIENT CONTENT CLAIMS

High	<ul style="list-style-type: none"> • Contains 20% or more of the DV per RACC. • May be used on meals or main dishes to indicate that the product contains a food that meets the definition.
Good Source	<ul style="list-style-type: none"> • Contains 10–19% of the DV per RACC. • May be used on meals or main dishes to indicate that the product contains a food that meets the definition.
More	<ul style="list-style-type: none"> • Contains at least 10% more of the DV per RACC than appropriate reference food. • May only be used for vitamins, minerals, protein, dietary fiber, and potassium.

Lean	<ul style="list-style-type: none"> On seafood or game meat products: less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per RACC and per 100 g (for meals and main dishes, meets criteria per 100 g and per labeled serving). On mixed dishes not measurable with a cup (as defined in 21 CFR 101.12(b) in Table 2): less than 8 g total fat, 3.5 g or less saturated fat, and less than 80 mg cholesterol per RACC.
Extra Lean	<ul style="list-style-type: none"> On seafood or game meat products: less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per RACC and per 100 g (for meals and main dishes, meets criteria per 100 g and per labeled serving).
High Potency	<ul style="list-style-type: none"> On foods to describe individual vitamins or minerals that are present at 100% or more of the RDI per RACC or on a multi-ingredient food product that contains 100% or more of the RDI for at least 2/3 of the vitamins and minerals with RDIs and that are present in the product at 2% or more of the RDI (e.g., “High-potency multivitamin, multimineral dietary supplement tablets”).
Modified	<ul style="list-style-type: none"> May be used in statement of identity of a food that bears a relative claim (e.g., “Modified fat cheesecake, contains 35% less fat than our regular cheesecake”).
Fiber Source	<ul style="list-style-type: none"> If a fiber claim is made and the food is not low in total fat, then the label must disclose the level of total fat per labeled serving.

Antioxidants	<ul style="list-style-type: none"> • An RDI must be established for each of the nutrients that are the subject of the claim. • Each nutrient must have existing scientific evidence of antioxidant activity. • The level of each nutrient must be sufficient to meet the definition for “high,” “good source,” or “more.” • Beta-carotene may be the subject of an antioxidant claim when the level of vitamin A present as beta-carotene in the food is sufficient to qualify for the claim.
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NOTES:

* Except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., “* adds a trivial amount of fat”).

RACC = Reference Amounts Customarily Consumed.

Small RACC = Reference Amounts Customarily Consumed of 30 g or less or 2 tablespoons or less. (For dehydrated foods that are typically consumed when rehydrated with water or a diluent containing an insignificant amount, as defined in 21 CFR 101.9(f)(1), of all nutrients per RACC, the per 50 g criterion refers to the prepared form of the food.)

When a claim is made on a food that contains more than 13 g total fat, 4 g saturated fat, 60 mg cholesterol, or 480 mg sodium per RACC, per labeled serving, or, for foods with small RACC, per 50 g, a disclosure statement is required as part of claim (i.e., “See nutrition information for ___ content” with the blank filled in with nutrient(s) that exceed the prescribed levels). The disclosure statement is required on meal products that exceed 26 g total fat, 8 g saturated fat, 120 mg cholesterol, or 960 mg sodium, and on main dish products that exceed 19.5 g total fat, 6 g saturated fat, 90 mg cholesterol, or 720 mg sodium per labeled serving.

For “free,” “very low,” or “low” claims, must indicate if food meets a definition without benefit of special processing, alteration, formulation or reformulation; e.g., “broccoli, a fat-free food” or “celery, a low-calorie food.”

SOURCE: 21 CFR Part 101. Food Labeling Guide: Guidance for Industry. September 1994; revised April 2008. Food and Drug Administration See Appendixes A and B.

(<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm> [accessed September 11, 2010]).

Footnotes

- 1 These are requirements for most nutrient content claims.

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