

## Quick-Reference Guide

# Nutrition Claims for Dairy Products



NATIONAL DAIRY COUNCIL

**DMAI** DAIRY MANAGEMENT INC.™

# Quick-Reference Guide to Nutrition Claims for Dairy Products



The National Dairy Council® (NDC) has developed this Quick-Reference Guide to provide a basic understanding of nutrition claims and labeling rules. We focus specifically on nutrition and health-related claims that represent potential opportunities for use with fluid milk, cheese and yogurt products.

This guide will review key nutrition labeling terms associated with claims, clarify the categories of claims and serve as an overview for the types of claims manufacturers can choose from for select dairy products.

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Dairy foods represent an important source of nutrients. This table provides an overview of selected nutrients for a variety of dairy foods, including fluid milk products, frozen desserts and cheese.

## Overview of Dairy Product Nutrition Facts

	Total Calories	Total Fat	Saturated Fat	Cholesterol	Sodium	Total Carbohydrates	Sugars	Protein	Vitamin A	Vitamin D	Calcium	Potassium	Magnesium	Phosphorus	Riboflavin	Vitamin B <sub>12</sub>
	Kcal	g	g	mg	mg	g	g	g	IU	IU	mg	mg	mg	mg	mg	mcg
<b>Fluid milk products</b>																
Whole white milk <sup>1</sup>	146	7.9	4.6	24	98	11	12.8	7.9	249	98	276	349	24	222	0.45	1.09
Reduced-fat white milk (2%) <sup>1</sup>	122	4.8	3.1	20	100	11.4	12.3	8.1	461	105	285	366	27	229	0.45	1.12
Low-fat white milk (1%) <sup>1</sup>	102	2.4	1.5	12	107	12.1	12.7	8.2	478	127	290	366	27	232	0.45	1.07
Fat-free white milk <sup>1</sup>	83	0.2	0.3	5	103	12.2	12.5	8.2	500	100	306	382	27	247	0.45	1.30
Reduced-fat chocolate milk <sup>1</sup>	190	4.8	2.9	20	165	30	24	7.5	568	100	272	422	35	255	0.46	0.82
Yogurt, plain, low-fat <sup>2</sup>	143	2.6	1.7	11	120	16	16	11.9	116	N/A	415	531	39	327	0.49	1.27
Yogurt, plain, fat-free <sup>2</sup>	127	0.4	0.3	5	175	17.4	17.4	13.0	16	N/A	452	579	43	356	0.53	1.38
Cottage cheese, low-fat (1%) <sup>3</sup>	81	1.1	0.73	5	459	3	3.0	14.0	46	N/A	69	97	6	151	0.19	0.71
Sour cream <sup>4</sup>	65	6.3	4.0	13	15	1.2	0.0	1.0	195	N/A	35	43	3	34	0.05	0.08
<b>Frozen Desserts<sup>5</sup></b>																
Vanilla ice cream (11% fat)	137	7.3	4.5	29	53	15.6	15.3	2.3	278	N/A	84	131	9	69	0.16	0.26
Vanilla ice cream (16% fat)	266	17.3	11	98	65	23.9	22.1	3.8	699	47	125	168	12	112	0.18	0.42
Vanilla light ice cream	125	3.7	2.2	21	56	19.6	16.8	3.6	340	N/A	122	158	11	78	0.19	0.36
Orange sherbet	107	1.5	0.88	0	34	22.5	18	0.8	33	N/A	40	71	6	30	0.07	0.10
<b>Cheese<sup>6</sup></b>																
Pasteurized process American cheese	106	8.8	5.6	27	422	0.4	0.1	6.3	272	N/A	156	48	8	144	0.02	0.20
Blue	100	8.1	5.3	21	395	0.7	0.1	6.0	216	N/A	150	73	7	110	0.11	0.35
Brick	105	8.4	5.3	27	159	0.8	0.1	6.6	306	N/A	191	39	7	128	0.10	0.36
Brie	95	7.8	4.9	28	178	0.1	0.1	5.9	168	N/A	52	43	6	53	0.15	0.47
Camembert	85	6.9	4.3	20	239	0.1	0.1	5.6	232	N/A	110	53	6	98	0.14	0.37
Cheddar	114	9.4	6.0	30	176	0.4	0.2	7.0	284	N/A	204	28	8	145	0.11	0.24
Cream cheese	97	9.7	5.5	31	91	1.15	0.9	1.7	359	N/A	28	39	3	30	0.04	0.07
Edam	101	7.9	5.0	25	274	0.4	0.4	7.0	234	10	207	53	9	152	0.11	0.44
Feta	75	6.0	4.2	25	316	1.2	1.2	4.0	120	N/A	140	18	5	96	0.24	0.48
Gouda	101	7.8	5.0	32	232	0.6	0.6	7.0	160	N/A	198	34	8	155	0.09	0.44
Mozzarella, low moisture, part skim	86	5.6	3.6	15	150	1.1	0.2	7.4	147	147	207	27	7	149	0.09	0.65
Muenster	104	8.5	5.4	27	178	0.3	0.3	6.6	287	N/A	203	38	8	133	0.09	0.42
Neufchatel	72	6.5	3.6	21	95	1.0	0.9	2.6	338	N/A	33	43	3	39	0.04	0.09
Parmesan (grated) <sup>7</sup>	22	1.4	0.9	4	76	0.2	0.1	1.9	22	N/A	55	6	2	36	0.02	0.11
Provolone	100	7.6	4.8	20	248	0.6	0.2	7.2	249	N/A	214	39	8	141	0.09	0.41
Ricotta, part skim <sup>8</sup>	85	4.9	3.1	19	78	2.8	0.2	7.1	238	N/A	169	78	10	113	0.11	0.18
Romano	110	7.6	4.8	29	340	1.0	0.2	9.0	118	N/A	302	24	12	215	0.10	0.32
Swiss	108	7.9	5.0	26	54	1.5	0.2	7.6	235	N/A	224	22	11	161	0.08	0.95

The nutrient values are provided as examples and should not be used for nutrition labeling.

Values presented per

<sup>1</sup> 1 cup (240 mL)

<sup>5</sup> 1/2 cup (72 g)

<sup>2</sup> 1 container (8 oz or 227 g)

<sup>6</sup> 1 oz (28.35 g)

<sup>3</sup> 4 oz (113 g)

<sup>7</sup> 1 tbsp (5 g)

<sup>4</sup> 2 tbsp (30 g)

<sup>8</sup> 3/4 cup (55 g)

N/A = Not Available

Source: USDA National Nutrient Database for Standard Release 21 (2008). <http://www.ars.usda.gov/nutrientdata>

## Foreword/Introduction

Milk and other dairy foods are the major source of calcium in the U.S. diet, providing more than 70% of the calcium available in the food supply. Dairy also contributes substantial amounts of other essential nutrients to the U.S. diet, including phosphorus, riboflavin, vitamin B<sub>12</sub>, protein, potassium, zinc, magnesium, and vitamins A and D. Dairy foods are “excellent” to “good” sources of many of these nutrients. As a result, many nutrition and health-related claims can be declared on dairy products, providing a valuable marketing tool for establishing a competitive advantage.

Increasingly, nutrition-conscious consumers are looking for healthful components when buying food. Unless they’ve done lots of research before going to the store, they rely on food labels and nutrition claims about the benefits of dairy foods to help guide their choices. Therefore, label claims can provide an important opportunity to showcase the healthy aspects of dairy products.

That’s the purpose of this **Quick-Reference Guide** — to explain how to correctly declare the nutritional benefits of a given product in accordance with current rules. At Dairy Management Inc.<sup>™</sup> (DMI) and the National Dairy Council (NDC), one of our jobs is to help nutrition and healthcare professionals provide both the food industry and consumers with scientifically sound nutrition information on dairy products. The NDC is committed to funding basic and applied health and nutrition research to examine the lifelong role of dairy products in our diet. Key regulatory concepts and definitions that are applicable to dairy nutrition and health-related claims have been added in this update.

It is important to remember that compliance with regulatory requirements and industry standards set forth by the U.S. Food and Drug Administration (FDA) and other governing agencies is critical. ***This reference guide is not a comprehensive guide to FDA regulations covering size and placement of claims, and should not be considered as such.*** (More complete information on FDA regulations can be found in the Code of Federal Regulations, 21 CFR 101.) All health-related claims should be substantiated and in compliance with FDA regulations before being applied to the food label. As regulations are subject to change over time, it is imperative that the most current regulations be consulted prior to making any claims.

# Nutrition Labeling Claim Basics

## Overview of Product Claims

The next three sections discuss various claims that may be used on qualifying products to highlight their nutritional benefits. These claims fall into three general categories:

- ■ ■ Nutrient Content Claims
- ■ ■ Health Claims
- ■ ■ Structure/Function Claims

### ■ ■ ■ Nutrient Content Claims

The nutrient content claims established by the FDA can help determine a product's strongest nutrition selling points. (More information on these claims can be found in the section "Nutrient Content Claims for Dairy Products.") Many dairy products are "excellent" or "good" sources of several vitamins and minerals, including calcium, phosphorus, potassium, riboflavin (vitamin B<sub>2</sub>), vitamin B<sub>12</sub>, vitamins A and D, and protein. Unlike many other food choices, dairy products are nutrient-dense and deliver substantial nutritional value. The FDA's nutrient content claim regulations provide different opportunities that may allow communication of a particular nutritional value contained in dairy products:

- "Excellent Source"  
If the product contains 20% or more of the Daily Value for that nutrient
- "Good Source"  
If the product contains 10% to 19% of the Daily Value for that nutrient
- "Supplies \_\_\_% of the Daily Value of \_\_\_\_."
- "Added/Fortified"  
If the product contains at least 10% of the Daily Value more than another food

Also, keep in mind the allowable synonyms for these claims. Descriptors such as "high in" or "rich in" in lieu of "excellent source" provide some creative leeway.

While FDA regulations place less emphasis on the nutrients designated as "other vitamins and minerals," these nutrients may be of special interest to certain segments of the population. If a product is targeted to these segments, using nutrient content claims may help position dairy products based on their full nutritional value.

Dairy products can also be modified to reduce the amount of certain components such as fat, saturated fat, sodium, cholesterol or calories to meet consumer needs and preferences. FDA regulations provide for certain descriptors such as "reduced," "light" and "low" to describe the nutritionally modified product.

### ■ ■ ■ Health Claims

Health claims describe a relationship between a food or food component and reducing the risk of a disease or health-related condition. To date, the FDA has approved a number of health claims for use on food labels (<http://www.cfsan.fda.gov/~dms/2lg-xc.html>). The good news for certain dairy products is that the link between calcium and vitamin D and prevention of osteoporosis, a bone disease that is a major cause of disability in the United States, is one of the claims allowed and one that many dairy products can claim. Other health claims that certain dairy products may qualify for include those related to: sodium and hypertension, potassium and blood pressure, fat and cancer, and saturated fat and the risk of coronary heart disease. In general, dairy products that typically qualify for health claims are those lower in fat, such as low-fat and fat-free milk, yogurt and other dairy products. For more information, see the section on “Health Claims” (Page 20).

### ■ ■ ■ Structure/Function Claims

Distinct from health claims is another category of claims known as “structure/function claims.” These claims describe the effect of a nutrient or substance on the normal structure or function of the body (e.g., calcium builds strong bones). They may be used on food products without prior FDA approval. However, like all information on a food label, they must be truthful and not misleading. Current FDA policy permits structure/function claims on traditional foods only if their claimed benefit derives from the food’s nutritive value.

### ■ ■ ■ ‘Reference Amount Customarily Consumed’ and/or ‘Label Serving Size’

For the purpose of nutrition labeling, nutrients and food components must be declared based on the serving size of the food. “Serving” or “serving size” is defined as the amount of food customarily consumed per eating occasion, expressed in an appropriate common household measure [21 CFR 101.9(b)(1)]. The serving size is derived from the “reference amount” for the food but is not always equal to that reference amount. The FDA has established a listing of the “Reference Amount Customarily Consumed” for more than 130 different product categories [21 CFR 101.12(b)]. The reference amounts reflect the amount of food customarily consumed in one eating occasion by people older than 4 years of age and are derived primarily from national food consumption survey data. These reference amounts are the starting point for determining the serving size to be declared on the food label *and* are used to determine whether a product meets the criteria for a nutrition claim. The reference amounts for various dairy products are summarized in the table on the next page.

Most claims are also based on the amount of nutrient provided per reference amount. However, some claims require that the food meet the requirements of the claim based on the reference amount *and* on 50 grams of the product, if the food’s reference amount is 30 grams or less. This will mostly impact cheese products.

## Nutrition Labeling Claim Basics

Reference Amounts Customarily Consumed for Various Dairy Products		
Product	Reference Amount	Suggested Label Statement*
Milk and milk-based drinks	240 mL	8 fl oz (240 mL)
Cheeses (e.g., Cheddar, Swiss and American), including cubes, slices and shreds	30 g	1 oz (28 g) 1 slice (e.g., 21 g) ¼ cup (e.g., 26 g)
Cottage cheese	110 g	½ cup (124 g)
Cheese used primarily as ingredients (e.g., dry cottage cheese and ricotta cheese)	55 g	¼ cup (62 g)
Cheese, grated hard (e.g., Parmesan and Romano)	5 g	1 tbsp (5 g)
Cream cheese, sour cream and cheese spreads	30 g	2 tbsp (28 g)
Yogurt	225 g	1 cup (227 g)
Butter	1 tbsp	1 tbsp (14 g)

\*Use common household measures (cup, tablespoon, piece, slice, etc.) as the FDA requires serving sizes to be listed in both metric and common household measures. The FDA allows the rounding of ounces and household measures for servings of products such as cheese sticks and slices that are close to the approved reference amount.

### ■ ■ ■ ‘Disclosure Statements’ and ‘Disqualifying Levels’

A “disclosure statement” is required when a nutrient content claim is made and the food contains one or more of the following nutrients in excess of the level listed below. These nutrient levels are also the amounts that must not be exceeded per reference amount and per labeled serving for FDA-approved health claims (termed “disqualifying nutrients”). For more information, see the section on “Health Claims.”

Disclosure/ Disqualifying Nutrients	Disclosure/Disqualifying Level per Reference Serving Size
Total fat	13 g
Saturated fat	4 g
Cholesterol	60 mg
Sodium	480 mg

The disclosure statement should read as follows: “See nutrition information for [nutrient requiring disclosure] content.” These levels must not be exceeded per reference amount or per labeled serving without making the required disclosure statement. Foods with a reference amount of 30 g or less, or 2 tbsp or less must not exceed the designated levels per 50 g of product or the disclosure statement will be required. Detailed information on the requirements for the disclosure statement can be found in the nutrient content section at <http://www.cfsan.fda.gov/~dms/2lg-toc.html> or [21 CFR 101.13(h)(1)-(3)].

## Nutrition Labeling Claim Basics

The disclosure statement must appear prominently and in immediate proximity to the claim with no intervening material. If the claim appears on more than one panel, the disclosure statement must accompany it except when the claim appears on the panel that bears the nutrition information, in which case the disclosure statement may be excluded.

### ■ ■ ■ Daily Values Used on the Nutrition Facts Panel

The Daily Value (DV) represents two sets of dietary standards — Daily Reference Values (DRVs) for energy-providing nutrients, sodium and potassium; and Reference Daily Intakes (RDIs) for vitamins and minerals. Only the Daily Value term (shown as % DV) appears on the label, though, to make label reading less confusing. The DV for calcium, for example, is 1,000 mg. The % DV listed in the “Nutrition Facts” panel of a food label tells consumers how much calcium one serving of that food contributes toward meeting this 1,000 mg level. If a food has 200 mg of calcium per serving, the “Nutrition Facts” panel on the food label would show that the food contains 20% DV for calcium.

## Nutrition Labeling Claim Basics

A comprehensive list of the mandatory (boldface) and voluntary nutrients for nutrition labeling and their DVs are listed below. Note that a Daily Value has not been determined for trans fat or sugar.

<b>Nutrients and Daily Values Used on the Nutrition Facts Panel</b>		
<b>Nutrient</b> (mandatory nutrients are in boldface)	<b>Unit Of Measure</b>	<b>Daily Values</b>
<b>Total fat</b>	<b>grams (g)</b>	<b>65*</b>
<b>Saturated fat</b>	<b>grams (g)</b>	<b>20*</b>
<b>Cholesterol</b>	<b>milligrams (mg)</b>	<b>300*</b>
<b>Sodium</b>	<b>milligrams (mg)</b>	<b>2,400*</b>
Potassium	milligrams (mg)	3,500*
<b>Total carbohydrate</b>	<b>grams (g)</b>	<b>300*</b>
<b>Fiber</b>	<b>grams (g)</b>	<b>25*</b>
<b>Protein</b>	<b>grams (g)</b>	<b>50*</b>
<b>Vitamin A</b>	<b>International Unit (IU)</b>	<b>5,000</b>
<b>Vitamin C</b>	<b>milligrams (mg)</b>	<b>60</b>
<b>Calcium</b>	<b>milligrams (mg)</b>	<b>1,000</b>
<b>Iron</b>	<b>milligrams (mg)</b>	<b>18</b>
Vitamin D	International Unit (IU)	400
Vitamin E	International Unit (IU)	30
Vitamin K	micrograms (µg)	80
Thiamin	milligrams (mg)	1.5
Riboflavin	milligrams (mg)	1.7
Niacin	milligrams (mg)	20
Vitamin B <sub>6</sub>	milligrams (mg)	2.0
Folate	micrograms (µg)	400
Vitamin B <sub>12</sub>	micrograms (µg)	6.0
Biotin	micrograms (µg)	300
Pantothenic acid	milligrams (mg)	10
Phosphorus	milligrams (mg)	1,000
Iodine	micrograms (µg)	150
Magnesium	milligrams (mg)	400
Zinc	milligrams (mg)	15
Selenium	micrograms (µg)	70
Copper	milligrams (mg)	2.0
Manganese	milligrams (mg)	2.0
Chromium	micrograms (µg)	120
Molybdenum	micrograms (µg)	75
Chloride	milligrams (mg)	3,400

Nutrients in this table are listed in the order specified by regulations on a label in accordance with 21 CFR 101.9(c). This list includes only those nutrients for which a Daily Reference Value (DRV) has been established in 21 CFR 101.9(c)(9) or a Reference Daily Intake (RDI) in 21 CFR 101.9(c)(8)(iv).

\* Based on intake of 2,000 calories daily.

### Overview/Definitions

A nutrient content claim on a food product defines how much of a specific nutrient or dietary substance is in that food. It does not link that nutrient with a specific disease or health-related condition. Nutrient content claims can only be made if a food product meets the criteria set by the FDA. Here are some of the most frequently used types of nutrient content claims.

#### ■ ■ ■ Absolute Nutrient Content Claims

Absolute nutrient content claims refer to a specific nutrient level in a food. These types of claims, like “high in calcium” or “low in fat” do not make any comparisons to any other food. Descriptive terms used in absolute claims are “free,” “low,” “very low” (sodium only), “high,” “good source,” “percent” and “amount” claims. Also common are claims referring to “percentage” or “amount.” The FDA specifically defines the terms and approved synonyms in conjunction with specific nutrients. The charts on Pages 11-17 show examples of absolute nutrient content claims for select dairy products.

#### ‘High’ and ‘Good Source’ Claims

The terms “high” and “good source” and their synonyms are often used on food products containing qualifying levels of the Daily Value (DV) of protein, vitamins, minerals and dietary fiber per reference amounts. A “high” claim (or “rich in” or “excellent source of”), such as “Milk: an excellent source of calcium,” may be used when a food contains at least 20% of the DV of a nutrient per reference amount — in this case, calcium [21 CFR 101.54(b)]. The term “good source” (or “contains” or “provides”), such as “Milk: a good source of potassium,” may be used when the claimed nutrient is present in the food between 10% and 19% of the DV per reference amount [21 CFR 101.54(c)]. The chart on Pages 11-12 shows examples of select dairy products that may qualify for “high” or “good source” claims.

#### ■ ■ ■ Relative Nutrient Content Claims

A relative claim is one that compares the level of a nutrient in one food to the level in another food called a “comparison food,” such as “50% less fat than regular cheese.” Terms frequently used as relative claims are “light,” “lite,” “reduced,” “less” or “more.” For claims like “light” or “reduced,” similar foods must be compared; for instance, reduced-fat Swiss cheese must be compared with regular Swiss cheese, or lite cream cheese with regular cream cheese. For certain relative claims, such as “more” or “less,” the comparison food may be a dissimilar food in the same product category. Appropriate comparison foods may come from a valid database, an average of the top three brands, a market leader, a manufacturer’s regular product or a competitor’s product. However, light products cannot be compared with a single product, either the company’s own or a competitor’s.

The following comparative statements must accompany all relative claims [21 CFR 101.13(j)]:

- Identity of the comparison food and the percentage (or fraction) of nutrient difference between the product and the comparison food (e.g., 50% less fat than [comparison food], or 1/3 fewer calories than [comparison food]).
- Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the comparison food (e.g., fat content has been reduced from \_\_\_ g to \_\_\_ g per serving).

The charts on Pages 13-18 show examples of relative nutrient content claims for select dairy products.

## Nutrient Content Claims

### **'More' Claims**

Claims such as “more,” “fortified,” “enriched” or “added” are relative claims and may be used to describe the level of protein, vitamins, minerals or dietary fiber present in an individual food. To qualify for such a claim, the food must contain at least 10% more of the Daily Value per reference amount of the claimed nutrient than is found in the appropriate comparison food [21 CFR 101.54(e)]. For “fortified,” “enriched” or “added” the comparison food must be a similar food (e.g., enriched yogurt compared with regular yogurt). For “more” claims, the comparison food may be a dissimilar food in the same category (e.g., milk with more calcium compared with orange juice). The comparative information required for relative claims must accompany the claim.

Some dairy foods qualify for claims using the relative terms “more,” “fortified,” “enriched,” “added,” “extra” or “plus” to describe the level of protein, vitamins or minerals present in a product. Label claims of this nature must state the identity of the comparison food and the percentage (or fraction) of nutrient amount that differs between the two, as well as compare the level of the nutrient in both the product and the comparison food. For example: “Contains twice the calcium as regular cottage cheese.” The Fortification Policy developed by the FDA establishes a uniform set of principles for the rational addition of nutrients to foods [21 CFR 104.20]. See also the fortification section on Page 29.

### **'Reduced' Claims**

A “reduced” claim provides marketing opportunities for dairy products specifically formulated to decrease the amount of fat, sodium, cholesterol, calories, sugar and/or other nutrients. To use a “reduced” claim, there must be a 25% minimum reduction of the nutrient being claimed, per reference amount. Terms like “less” and “lower” are synonyms for “reduced” and follow the same definition. “Fewer” may be used as a synonym for calorie claims only. All “reduced” claims require comparative information to accompany the claim (see facing page). For example, consider a manufacturer wanting to make a “reduced fat” claim for a new reduced-fat Swiss cheese. The accompanying comparative information for this product would read, “Contains 37% less fat than regular Swiss cheese. Fat content has been reduced from 8 g to 5 g per serving.”

### **'Light' or 'Lite' Claims**

The term “light” or “lite,” with regard to calories, fat or sodium, is permitted to describe an individual food under specific conditions as summarized on Page 18.

### **■ ■ ■ Implied Nutrient Content Claims**

The FDA determines on a case-by-case basis whether a product label bears an implied nutrient content claim; that is, whether it communicates that the food, because of its nutrient content, may be useful in maintaining healthy dietary practice, but does so without making a defined nutrient content claim ([21 CFR 101.65] and [58 FR 2302, 2368] [January 6, 1993]). The FDA has identified in the regulations statements or suggestive phrases that are considered implied nutrient content claims:

#### **'Label Statements That Are Implied Claims'**

The FDA has identified the following statements or suggestive phrases that are considered implied nutrient content claims:

## Nutrient Content Claims

- Claims about a food or an ingredient in the food that suggest that a nutrient or an ingredient is absent or present in a certain amount (e.g., “high in oat bran” implies high in dietary fiber).
- A product name that includes the name of a characterizing ingredient associated with a nutritional benefit (e.g., “corn oil margarine” implies low in saturated fat, “oat bran muffins” implies high in dietary fiber) is considered an implied nutrient content claim and must meet the definition of the claim implied. For example, a statement of identity that through statements, symbols, vignettes or other forms of communication suggests that “oat bran” is present in a certain amount in “oat bran muffins” implies that the product is a good source of dietary fiber.
- The phrase “contains the same amount of [nutrient] as a [food] or “as much [nutrient] as a [food]” may be stated provided that the amount of the nutrient in the comparison food is enough to qualify as a good source of the nutrient, and the labeled food, on a per-serving basis, is an equivalent good source of that nutrient (e.g., “as much fiber as an apple,” “contains the same amount of vitamin C as 8 oz of orange juice”).
- A claim that a food contains or is made with an ingredient that is known to contain a particular nutrient, if the finished food is either “low in” or a “good source of” the nutrient that is associated with the ingredient or type of preparation.
- If a specific level of a nutrient is suggested by a claim, that level of the nutrient must be present in the food (e.g., a claim that a food contains oat bran implies that it is a good source of fiber, and a claim that a food contains no oil implies that it is fat-free) [21 CFR 101.65].
- Additionally, the use of certain vignettes — for example, a heart — may be determined to be an implied health claim.

### **‘Healthy’**

The claim “healthy” or any derivation of the word “health” may be used on the label provided all of the qualifying criteria are met [21 CFR 101.65(d)]. The food must meet the definition of “low” fat and saturated fat, and neither cholesterol nor sodium may be present at a level exceeding the disclosure levels per reference amount and per 50 g for reference amounts 30 g or less. Additionally, the food must contain at least 10% of the Daily Value per reference amount for vitamin A, vitamin C, calcium, iron, protein or fiber. The chart on Page 19 provides a partial list of selected dairy products that qualify.

### ■ ■ ■ **Numeric Declaration Nutrient Content Claims**

The FDA permits the use of factual statements that disclose the amount of a nutrient in a product provided that such a statement does not implicitly characterize the level of a nutrient and is not false or misleading (e.g., 100 calories or 5 g of fat).

A statement about amount or percentage that implicitly characterizes the level of a nutrient is permitted if the food qualifies for the defined claim. “Only 3 g of fat” implies that the food qualifies for a “low fat” claim. A food bearing a percent or amount of a nutrient that does not qualify for the implied claim must include a disclaimer that the food is not “low in” or “a good source of” the nutrient for which the claim is made (for example, “Contains only 200 mg of sodium per serving. Not a low sodium food.”).

## Nutrient Content Claims

### ■ ■ ■ General Requirements for Nutrient Content Claims

When making a nutrient content claim for a qualifying product, keep the following general requirements in mind:

- Dairy products making a nutrient content claim must carry nutrition labeling.
- The “**reference amount**” rather than the “**label serving size**” must be used when determining whether a product meets the criteria for a nutrient content claim (see Pages 3-4).
- A nutrition claim may not be larger than twice the type size of the statement of identity (*product name*).
- A “**disclosure statement**,” if applicable, must appear close to the nutrient content claim (see Page 4).
- For relative claims, certain comparative statements must be provided.
- Information on any material difference in performance characteristics must be provided. The FDA requires that the performance characteristics of a nutritionally modified food must be similar to the food for which it substitutes. Performance characteristics are organoleptic, physical and functional attributes (See [21 CFR 101.13(d)(i)]).
- If the product has been altered, reformulated or processed in order to qualify for a nutrition claim, the modified product must be nutritionally equivalent to the regular product. This may require fortifying the product. Otherwise, it must be labeled as an “imitation” food.

### ■ ■ ■ Examples of Claims for Select Dairy Products

The charts on the following pages outline the main nutrient content claims, both absolute and relative, that can be considered for use on selected dairy products. The charts include:

- Approved descriptors and synonyms that the FDA permits on food products carrying a specific nutrient content claim. (No other words may be used on the food label to describe or compare a nutrient.)
- Definitions and criteria the food must meet in order to use a specific descriptor or synonym.
- Disclosure statements that may be required.
- Selected dairy products that may qualify for this claim.

## Nutrient Content Claims

Examples of Dairy Products That May Qualify for 'High' or 'Good Source' Claims*			
	Reference Amount	High** Excellent Source Rich In	Good Source*** Provides Contains
<b>Fluid Milk</b>			
Whole milk	240 mL	Calcium Vitamin D Riboflavin Phosphorus	Vitamin B <sub>12</sub> Potassium Protein
Reduced-fat milk (2% milk fat)	240 mL	Calcium Vitamin D Riboflavin Phosphorus	Vitamin A Vitamin B <sub>12</sub> Potassium Protein
Low-fat milk (1% milk fat)	240 mL	Calcium Vitamin D Riboflavin Phosphorus	Vitamin A Vitamin B <sub>12</sub> Potassium Protein
Fat-free (skim)	240 mL	Calcium Vitamin D Riboflavin Phosphorus	Vitamin A Vitamin B <sub>12</sub> Potassium Protein
<b>Yogurt</b>			
Whole milk, plain	225 g	Calcium Riboflavin Phosphorus	Potassium Protein
Low-fat, plain (1.5% milk fat)	225 g	Calcium Riboflavin Phosphorus Protein	Potassium
Fat-free, plain	225 g	Calcium Riboflavin Phosphorus Protein	Potassium
<b>Cottage Cheese</b>			
Cottage cheese, creamed (4% milk fat)	110 g	Protein	Riboflavin Phosphorus
Low-fat cottage cheese (2% milk fat)	110 g	Protein	Riboflavin Phosphorus
Low-fat cottage cheese (1% milk fat)	110 g	Protein	Riboflavin Phosphorus
<small>* Claims based on values taken from the U.S. Department of Agriculture, Agricultural Research Service, 2008, USDA National Nutrient Database for Standard Reference, Release 21. Nutrient Data Laboratory Home Page: <a href="http://www.ars.usda.gov/nutrientdata">http://www.ars.usda.gov/nutrientdata</a>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only.  <b>Note:</b> Consult the Code of Federal Regulations for specific nutrition labeling requirements for making nutrient content claims.  ** Contains 20% or more of the DV per reference amount.  *** Contains 10% to 19% of the DV per reference amount.</small>			

## Nutrient Content Claims

### Examples of Dairy Products That May Qualify for 'High' or 'Good Source' Claims\* (cont.)

	Reference Amount	High** Excellent Source Rich In	Good Source*** Provides Contains
<b>Cheese</b>			
American cheese food	30 g		Calcium Phosphorus Protein
Pasteurized process American cheese	30 g	Phosphorus	Calcium Protein
Blue	30 g		Calcium Phosphorus Protein
Brick	30 g		Calcium Phosphorus Protein
Cheddar	30 g	Calcium	Phosphorus Protein
Colby	30 g	Calcium	Phosphorus Protein
Edam	30 g	Calcium	Phosphorus Protein
Gouda	30 g	Calcium	Phosphorus Protein
Monterey Jack	30 g	Calcium	Phosphorus Protein
Mozzarella, whole milk	30 g		Calcium Phosphorus Protein
Mozzarella, low moisture, part skim	30 g	Calcium	Phosphorus Protein
Muenster	30 g	Calcium	Phosphorus Protein
Parmesan, hard	30 g (not grated)	Calcium Phosphorus Protein	
Provolone	30 g	Calcium	Phosphorus Protein
Ricotta	55 g	Protein	Calcium Phosphorus
Swiss	30 g	Calcium	Phosphorus Protein

\* Claims based on values taken from the U.S. Department of Agriculture, Agricultural Research Service, 2008, USDA National Nutrient Database for Standard Reference, Release 21. Nutrient Data Laboratory Home Page: <http://www.ars.usda.gov/nutrientdata>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only. **Note:** Consult the Code of Federal Regulations for specific nutrition labeling requirements for making nutrient content claims.

\*\* Contains 20% or more of the DV per reference amount.

\*\*\* Contains 10% to 19% of the DV per reference amount.

## Nutrient Content Claims

Fat and Saturated Fat Claims				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Fat-free	<ul style="list-style-type: none"> <li>- Free of fat</li> <li>- Fat-free</li> <li>- Trivial source of fat</li> <li>- Zero fat</li> <li>- Without fat</li> <li>- Skim (milk only)</li> </ul>	Less than 0.5 g total fat per reference amount and per labeled serving size. No added fat unless ingredient declaration lists a fat-containing ingredient followed by an asterisk and the statement “Adds a trivial amount of fat.”	1, 3	<ul style="list-style-type: none"> <li>- Fat-free milk</li> <li>- Fat-free yogurt</li> </ul>
Low-fat	<ul style="list-style-type: none"> <li>- Low in fat</li> <li>- Low source of fat</li> <li>- Little fat</li> <li>- Contains a small amount of fat</li> </ul>	Maximum of 3 g total fat per reference amount (when reference amount is greater than 30 g or 2 tbsp).	1, 3	<ul style="list-style-type: none"> <li>- Low-fat milk (1% milk fat)</li> <li>- Low-fat yogurt</li> <li>- Low-fat cottage cheese (1% and 2% milk fat)</li> </ul>
		Maximum of 3 g total fat per reference amount and per 50 g (when the reference amount is 30 g or less, or 2 tbsp or less).	1, 3	Few dairy products at this reference amount could make this claim unless specifically reformulated
Reduced-fat	<ul style="list-style-type: none"> <li>- Reduced in fat</li> <li>- Fat reduced</li> <li>- Less fat</li> <li>- Lower fat</li> <li>- Lower in fat</li> </ul>	<p>At least a 25% reduction in total fat per reference amount in comparison to a comparison food.</p> <p>Claim cannot be made if comparison food meets definition for “low-fat.”</p>	1, 2	<ul style="list-style-type: none"> <li>- Reduced-fat milk (2% milk fat)</li> <li>- Many of the “reduced-fat” and “light” cheeses, butters and other dairy products</li> </ul>
Percent fat-free	- ___% fat-free	<p>May be used if the product meets the requirements for “low-fat.”</p> <p>“100% fat-free” can only be used on “fat-free” foods that contain less than 0.5 g of fat per 100 g and contain no added fat.</p>	1, 3	<ul style="list-style-type: none"> <li>- Fat-free milk</li> <li>- Low-fat milk (1% milk fat)</li> <li>- Fat-free yogurt</li> <li>- Low-fat yogurt</li> <li>- Low-fat cottage cheese (1% and 2% milk fat)</li> </ul>
Saturated fat-free	<ul style="list-style-type: none"> <li>- Free of saturated fat</li> <li>- No saturated fat</li> <li>- Trivial source of saturated fat</li> <li>- Zero saturated fat</li> <li>- Without saturated fat</li> </ul>	<p>Less than 0.5 g saturated fat and less than 0.5 trans fatty acids per reference amount and per labeled serving size.</p> <p>The food may not contain any ingredient that is a saturated fatty acid or is generally understood by consumers to contain saturated fat unless the ingredient, as declared in the ingredient statement, is accompanied by an asterisk that refers consumers to the statement “Adds a trivial amount of saturated fat.” or similar specified statement.</p> <p>Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Disclosure of cholesterol and fat is unnecessary if the food contains (per reference amount) less than 2 mg of cholesterol and 0.5 g fat.</p>	1, 3	<ul style="list-style-type: none"> <li>- Fat-free milk</li> <li>- Fat-free yogurt</li> <li>- Fat-free cottage cheese</li> </ul>

## Nutrient Content Claims

### Fat and Saturated Fat Claims (cont.)

Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Low in saturated fat	<ul style="list-style-type: none"> <li>- Low saturated fat</li> <li>- Low source of saturated fat</li> <li>- Little saturated fat</li> <li>- Contains a small amount of saturated fat</li> </ul>	<p>Contains 1 g or less of saturated fatty acids per reference amount and derives no more than 15% of calories from saturated fatty acids.</p> <p>As with all fatty acid claims, manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Disclosure of cholesterol and fat is unnecessary if the food contains less than 2 mg of cholesterol per reference amount and 0.5 g fat per reference amount, respectively.</p>	1, 3	<ul style="list-style-type: none"> <li>- Low-fat cottage cheese (1% milk fat)</li> <li>- Orange sherbet</li> </ul>
Reduced in saturated fat	<ul style="list-style-type: none"> <li>- Reduced saturated fat</li> <li>- Lower saturated fat</li> <li>- Less saturated fat</li> </ul>	At least a 25% reduction in saturated fat per reference amount compared with an appropriate comparison food.	1, 2	<ul style="list-style-type: none"> <li>- Reduced-fat milk (2% milk fat)</li> <li>- Low-fat milk (1% milk fat)</li> <li>- Low-fat yogurt</li> <li>- Some low-fat reduced-fat cheeses on the market</li> </ul>

#### \*Required Statements

- 1 If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): “See nutrition information for [nutrient(s) requiring disclosure] content.”
- 2 For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required), for a product making relative claims — such as “light,” “reduced,” “less,” “fewer” or “lower” — comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For example: “Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving.”
- 3 For “low” and “free” claim only: If a food is “low in” or “free of” a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently “low in” or “free of” whatever nutrient is being claimed for that product. For example: “Whole milk — a low sodium food.”

## Nutrient Content Claims

Cholesterol Claims				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions	Required Statements*	Examples of Eligible Dairy Products
Cholesterol-free	<ul style="list-style-type: none"> <li>- Free of cholesterol</li> <li>- Zero cholesterol</li> <li>- Without cholesterol</li> <li>- No cholesterol</li> <li>- Trivial source of cholesterol</li> </ul>	<p>Contains 2 mg or less of cholesterol per reference amount and per serving size on label. Contains 2 g or less of saturated fat per reference amount.</p> <p>The food contains no ingredient that is generally understood by consumers to contain cholesterol unless the ingredient, as declared in the ingredient statement, is accompanied by an asterisk that refers consumers to the statement “Adds a trivial amount of cholesterol.” or similar specified statement.</p>	1, 3	
Low cholesterol	<ul style="list-style-type: none"> <li>- Low in cholesterol</li> <li>- Contains a small amount of cholesterol</li> <li>- Low source of cholesterol</li> </ul>	<p>Maximum of 20 mg cholesterol per reference amount and per 50 g of food if reference amount is 30 g or less.</p> <p>Maximum 2 g saturated fat per reference amount (when reference amount is greater than 30 g or 2 tbsp).</p>	1, 3, 4	<ul style="list-style-type: none"> <li>- Skim milk</li> <li>- Low-fat milk (1% milk fat)</li> <li>- Fat-free yogurt</li> <li>- Frozen yogurt</li> <li>- Low-fat yogurt</li> <li>- Low-fat cottage cheese (1% and 2% milk fat)</li> <li>- Fat-free, pasteurized, processed cheese</li> </ul>
Reduced cholesterol	<ul style="list-style-type: none"> <li>- Reduced cholesterol</li> <li>- Lower cholesterol</li> <li>- Less cholesterol</li> </ul>	<p>At least a 25% reduction in cholesterol per reference amount compared with an appropriate comparison food. Contains 2 g or less of saturated fat per reference amount.</p> <p>Claim not permitted if the comparison food meets the definition of “low cholesterol” claim.</p>	1, 2	<ul style="list-style-type: none"> <li>- Low-fat cottage cheese (1% milk fat) compared with low-fat cottage cheese (2% milk fat)</li> <li>- Low-fat cottage cheese (2% milk fat) compared with full-fat cottage cheese</li> </ul>

### \*Required Statements

- 1 If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): “See nutrition information for [nutrient(s) requiring disclosure] content.”
- 2 For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required), for a product making relative claims — such as “light,” “reduced,” “less,” “fewer” or “lower” — comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food to the comparison food per labeled serving. For example: “Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving.”
- 3 For “low” and “free” claim only: If a food is “low in” or “free of” a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently “low in” or “free of” whatever nutrient is being claimed for that product. For example: “Whole milk — a low sodium food.”
- 4 If total fat exceeds 13 g per reference amount (or per 50 g when reference amount is 30 g or less, or 2 tbsp or less), the food must declare the total amount of fat in a serving next to the cholesterol claim.

## Nutrient Content Claims

Sodium Claims				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions	Required Statements*	Examples of Eligible Dairy Products
Sodium free	- Salt free - Free of sodium - No sodium - Zero sodium - Without sodium - Trivial source of sodium	Less than 5 mg sodium per reference amount. No added sodium or ingredients containing sodium unless the ingredient is followed by an asterisk and the statement "Adds a trivial amount of sodium."	1, 3	
Very low sodium	- Very low in sodium	Maximum of 35 mg of sodium per reference amount and per 50 g (when reference amount is 30 g or less, or 2 tbsp or less).	1, 3	- Light whipping cream - Heavy cream - Light cream
Low sodium	- Little sodium - Low source of sodium - Contains a small amount of sodium - Low in sodium	Maximum of 140 mg of sodium per reference amount and per 50 g (when reference amount is 30 g or less, or 2 tbsp or less).	1, 3	- All fluid milk - Plain yogurt - Sour cream - Ice cream - Half-and-half - Swiss cheese
Reduced in sodium		At least a 25% reduction in sodium per reference amount compared with an appropriate comparison food.  Claim cannot be made if comparison food meets definition for "low sodium."	1, 2	- Some lower sodium cheeses may qualify
Light in sodium		Comparison food contains more than 40 calories or more than 3 g of fat per reference amount and is reduced in sodium by 50% or more.  Cannot be made if the comparison food meets the definition of "low sodium."	1, 2	- Any dairy product with a 50% reduction in sodium content would qualify; e.g., "light in sodium cottage cheese," "light in sodium Pasteurized process American cheese."

Note: The FDA does not consider "salt" a synonym for "sodium," although it permits the term "salt free" if the food qualifies for the definition of "sodium free." The claim "low salt" has not been defined and cannot be used on the food label.

### \*Required Statements

- 1 If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."
- 2 For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required), for a product making relative claims — such as "light," "reduced," "less," "fewer" or "lower" — comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food to the comparison food per labeled serving. For example: "Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving."
- 3 For "low" and "free" claim only: If a food is "low in" or "free of" a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently "low in" or "free of" whatever nutrient is being claimed for that product. For example: "Whole milk — a low sodium food."

## Nutrient Content Claims

Calorie Claims				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Calorie free	<ul style="list-style-type: none"> <li>- Calorie free</li> <li>- No calories</li> <li>- Zero calories</li> <li>- Free of calories</li> <li>- Without calories</li> </ul>	The food contains less than 5 calories per reference amount and per labeled serving [21 CFR 101.60].	1, 3	
Low calorie	<ul style="list-style-type: none"> <li>- Few calories</li> <li>- Contains a small amount of calories</li> <li>- Low source of calories</li> <li>- Low in calories</li> </ul>	40 calories or less per reference amount (and per 50 g if reference amount is 30 g or less).	1, 3	
Reduced calorie	<ul style="list-style-type: none"> <li>- Reduced in calories</li> <li>- Calorie reduced</li> <li>- Fewer calories</li> </ul>	<p>Minimum of 25% reduction in calories per reference amount compared with an appropriate comparison food.</p> <p>Cannot be made if comparison food meets the definition of “low calorie.”</p>	1, 2	<p>Products formulated using less sugar and fat, such as reformulated:</p> <ul style="list-style-type: none"> <li>- Ice cream</li> <li>- Yogurts</li> <li>- Frozen yogurts</li> <li>- Flavored milk</li> </ul>

### \*Required Statements

- 1 If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): “See nutrition information for [nutrient(s) requiring disclosure] content.”
- 2 For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required) for a product making relative claims — such as “light,” “reduced,” “less,” “fewer” or “lower” — comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For example: “Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving.”
- 3 For “low” and “free” claim only: If a food is “low in” or “free of” a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently “low in” or “free of” whatever nutrient is being claimed for that product. For example: “Whole milk — a low sodium food.”

## Nutrient Content Claims

‘Light’ or ‘Lite’ Claims				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Light or lite for fat or calories	- Light or lite	<p>If the food derives less than 50% of its calories from fat, the number of calories must be reduced by at least 1/3 per reference amount compared with an appropriate comparison food or its fat content must be reduced by 50% or more per reference amount compared with the comparison food. Cannot be made if comparison food meets definition of “low fat” or “low calorie.”</p> <p>If the food derives 50% or more of its calories from fat, its fat content must be reduced by 50% or more per reference amount compared with an appropriate comparison food. Cannot be made if comparison food meets definition of “low fat” or “low calorie.”</p>	1, 2	Reformulated ice cream, yogurts and frozen yogurts using artificial sweeteners or fat substitutes
Light or lite in sodium	- Light or lite	<p>Without further qualification, this term is permitted to highlight reductions in sodium content if the sodium content is reduced by 50% or more and the comparison food contains 40 calories or less and 3 g fat or less per reference amount.</p> <p>If the food contains more than 40 calories or more than 3 g of fat per reference amount, the term “light in sodium” may be used to designate a 50% reduction in sodium. Cannot be made if comparison food meets the “low sodium” definition.</p>	1, 2	
<p><b>Note: Non-nutrient uses of “light”</b></p> <p>Non-nutrient uses of the term “light” still can be used to describe the physical properties of the food product such as texture, color and flavor as long as the label explains the intent — for example, “light in color” and “light and fluffy texture.”</p> <p>Also, if a manufacturer can demonstrate that the term “light” has been associated, through common use, with a particular food to reflect a physical or sensory attribute (e.g., light brown sugar) and has become part of the statement of identity, “light” may be used without a reduction in fat or calories [21 CFR 101.56].</p>				

### \*Required Statements

- 1 If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): “See nutrition information for [nutrient(s) requiring disclosure] content.”
- 2 For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required) for a product making relative claims — such as “light,” “reduced,” “less,” “fewer” or “lower” — comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For “light” claims, comparative information must be provided for both fat and calories. For example: “Contains 25% less fat and 20% fewer calories than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g, and calories have been reduced from 100 to 80 per serving.”

## Nutrient Content Claims

Healthy Claims			
Claim	Nutrient Descriptors and Synonyms	FDA Definition and Criteria	Partial List of Eligible Dairy Products
Healthy	<ul style="list-style-type: none"> <li>- Health</li> <li>- Healthful</li> <li>- Healthfully</li> <li>- Healthfulness</li> <li>- Healthier</li> <li>- Healthiest</li> <li>- Healthily</li> <li>- Healthiness</li> </ul>	<p>Must meet the definition of “low” fat and saturated fat, and neither cholesterol nor sodium may be present at a level exceeding the disclosure levels per reference amount and per 50 g for reference amounts 30 g or less.</p> <p>Contains at least 10% of the Daily Value per reference amount for vitamin A, vitamin C, calcium, iron, protein or fiber.</p>	<ul style="list-style-type: none"> <li>- Low-fat cottage cheese (1% milk fat)</li> <li>- Skim milk</li> <li>- Fat-free yogurt</li> </ul>

Numeric Declaration Claims			
Nutrient Descriptors and Synonyms	FDA Definition	Required Statements*	Partial List of Eligible Dairy Products
<ul style="list-style-type: none"> <li>- Percent</li> <li>- Amount</li> </ul>	The level of a nutrient in a product in absolute or percentage amounts.	1	<p>A number of dairy products can use this claim to describe the level of a particular nutrient, such as:</p> <ul style="list-style-type: none"> <li>- Cheddar cheese: “20% of the DV for calcium”</li> <li>- Fat-free milk: “0 g of fat”</li> <li>- Fat-free milk: “0 g of saturated fat”</li> <li>- Low-fat yogurt: “30% of the DV for calcium”</li> <li>- Reduced-fat milk: “15% of the DV for protein”</li> </ul>

### \*Required Statements

- 1 If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients — total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate — a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): “See nutrition information for [nutrient(s) requiring disclosure] content.”

# Health Claims

## Overview/Definitions

A health claim, by FDA definition, is any statement that characterizes — explicitly or by implication — the relationship of a substance in a food or dietary supplement to a disease or health-related condition [21 CFR 101.14(a)(1)]. There are three ways the FDA determines which health claims may be used on a label or in labeling for a food or dietary supplement.

- The 1990 Nutrition Labeling and Education Act (NLEA) allows the FDA to issue an *Authorized Health Claim* for foods and dietary supplements after the FDA’s careful review of the scientific evidence submitted in health claim petitions.
- The 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an *Authoritative Statement* of a scientific body of the U.S. government or the National Academy of Sciences; such claims may be used after submission of a health claim notification to the FDA. For more information on these types of claims, see <http://www.cfsan.fda.gov/~dms/labfdama.html>.
- The 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for *Qualified Health Claims* where the quality and strength of the scientific evidence fall below the standard of “significant scientific agreement” required for the FDA to issue an *Authoritative Health Claim*. For more information on these types of claims, see <http://www.cfsan.fda.gov/~dms/lab-qhc.html>.

A “health claim,” by definition, has two essential components: (1) a substance (whether a food, food component or dietary ingredient); and (2) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in health are considered to be *Dietary Guidance Statements* rather than health claims, provided that the context of the statement does not suggest that a specific substance is the subject of the claim. *Dietary Guidance Statements* used on food labels must be truthful and non-misleading. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health-related condition. Unlike health claims, *Dietary Guidance Statements* and structure/function claims are not subject to FDA review and authorization.

The FDA has approved a number of health claims — either by regulation (21 CFR 101.72 through 101.83) or as an authorized statement under the FDA Modernization Act or as a *Qualified Health Claim* — that can be used on food products [<http://www.cfsan.fda.gov/~dms/lab-ssa.html>].

There are five FDA-approved health claims that are appropriate for use on selected dairy products.

Dietary Component	Disease or Health-Related Condition
Calcium and vitamin D	Osteoporosis (21 CFR 101.72)
Sodium	Hypertension (21 CFR 101.74)
Dietary fat	Cancer (21 CFR 101.73)
Saturated fat and cholesterol	Coronary heart disease (21 CFR 101.75)
Potassium	High blood pressure and stroke <a href="http://www.cfsan.fda.gov/~dms/hclm-k.html">http://www.cfsan.fda.gov/~dms/hclm-k.html</a>

## Health Claims

### General Requirements for Health Claims

When the FDA adopts a regulation for a health claim, companies may use these claims on products based on the regulation, provided that:

- The food contains, **without fortification**, 10% or more of the Daily Value for one of the six nutrients shown in the table to the right. If none of these nutrients are present in the food, the claim is not allowed.
- The food contains less than the specified levels of the four “disqualifying” nutrients per reference amount for total fat, saturated fat, sodium and cholesterol (see Page 4). Some health claims may have more restrictive levels of disqualifying nutrients. (See subsequent pages for specific health claims and their specified “disqualifying” nutrient levels).
- All information must be in one place without intervening material.
- Only information pertaining to the impact that intake or reduced intake might have on a disease or health-related condition as part of a total dietary pattern is permitted on the label.
- The claim helps the public understand the information provided and the significance of the information in the context of a total daily diet.
- The claim is complete, truthful and not misleading.
- The food is not represented for infants or toddlers younger than 2 years of age.
- The claim uses “may” or “might” to express the relationship between a substance and a disease.
- The claim does not quantify any degree of risk reduction.
- The claim indicates that disease depends on many factors.

10% of Daily Value (DV)	
Vitamin A	500 IU
Vitamin C	6 mg
Iron	1.8 mg
Calcium	100 mg
Protein	5 g
Fiber	2.5 g

Potential Health Claims for Dairy Products*								
Health Claim**	Milk			Yogurt		Cottage Cheese		
	Reduced-fat (2% milk fat)	Low-fat (1% milk fat)	Fat-free (skim)	Plain (low fat)	Plain (fat-free)	Fat-free	1% milk fat	2% milk fat
Calcium, vitamin D and osteoporosis	Yes	Yes	Yes	Yes	Yes	No	No	No
Sodium and hypertension	Yes	Yes	Yes	No	No	No	No	No
Dietary fat and cancer	No	Yes	Yes	Yes	Yes	Yes	Yes	No
Dietary saturated fat and cholesterol, and risk of coronary heart disease	No	No	Yes	No	Yes	Yes	No	No
Potassium and the risk of high blood pressure and stroke	No	No	Yes	No	No	No	No	No

\* Claims based on values taken from the U.S. Department of Agriculture, Agricultural Research Service. 2008, USDA National Nutrient Database for Standard Reference, Release 21. Nutrient Data Laboratory Home Page, <http://www.ars.usda.gov/nutrientdata>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only. **Note:** Consult the Code of Federal Regulations for specific nutrition labeling requirements for making health claims.

\*\* Whole milk, whole milk yogurts, and whole milk and 2% milk fat cottage cheese do not qualify for health claims as they exceed the levels of the disqualifying nutrients specified by the claim and, hence, are not included. (See subsequent pages for disqualifying nutrient levels for specific health claims).

### ■ ■ ■ **Specific Requirements for Health Claims**

The FDA provides model statements for each of its health claims. Although manufacturers are not required to use the exact language the FDA provides for a health claim authorized by regulation, the agency notes that any health statement must address all the information provided in the model claim. For more information, go to the FDA Web site: <http://www.cfsan.fda.gov/~dms/lab-ssa.html>. However, for claims backed by an authoritative statement or a qualified health claim, the exact claim language must be used.

The specific product and message requirements for each of these health claims is shown on the following pages. The first four health claims shown below are authorized by rulemaking; see Pages 23-24 for product and message requirements. The potassium and risk of high blood pressure and stroke health claim is backed by an authoritative statement; see Page 25 for product and message requirements.

### ■ **Model Statements for Health Claims for Dairy Products\***

#### ■ **Calcium, vitamin D and osteoporosis**

*“Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.” or*

*“Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.”*

#### ■ **Sodium and hypertension**

*“Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.” or*

*“Development of hypertension or high blood pressure depends on many factors. [This product] can be a part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.”*

#### ■ **Dietary fat and cancer**

*“Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.”*

#### ■ **Dietary saturated fat and cholesterol, and risk of coronary heart disease**

*“While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.”*

#### ■ **Potassium and the risk of high blood pressure and stroke**

*“Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”*

NOTE: Exact claim language must be used. (For more information see Page 26.)

## Health Claims

### ■ Product and Message Criteria for Specified Health Claims

#### ***Calcium, Vitamin D and Osteoporosis [21 CFR 101.72]***

##### **Product Criteria**

- “High in calcium” (at least 20% of the Daily Value for calcium [200 mg] per reference amount).
- “High in vitamin D” (at least 20% of the Daily Value for vitamin D [80 IU] per reference amount).
- Has phosphorus equal to or less than the calcium content.
- Contains a form of calcium that can be readily absorbed by the body.
- Does not exceed any of the “disqualifying levels” for fat, saturated fat, cholesterol or sodium per reference amount and per serving (total fat: 13 grams; saturated fat: 4 grams; cholesterol: 60 milligrams; sodium: 480 milligrams). If the reference amount is 30 g or less, or 2 tbsp or less, foods must not exceed the “disqualifying levels” per 50 g.
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

##### **Message Criteria**

- The claim makes clear the importance of adequate calcium intake or, when appropriate, adequate calcium and vitamin D intake throughout life, in a healthful diet, which are essential to reduce osteoporosis risk.
- The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake or, when appropriate, an adequate dietary calcium and vitamin D intake throughout life.
- The claim may make reference to physical activity.
- The phrase “build and maintain good bone health” may be used to convey the concept of optimizing peak bone mass.

The claim can also be made regarding calcium only and osteoporosis for products that contain more than 200 mg calcium per reference amount, but do not contain adequate vitamin D for the claim.

#### ***Sodium and Hypertension [21 CFR 101.74]***

##### **Product Criteria**

- Must meet the definition for “low sodium” (maximum of 140 mg sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must not exceed the disqualifying levels for fat, saturated fat or cholesterol per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less.
- Must provide at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

##### **Message Criteria**

- Claim must state that diets low in sodium “may” or “might” reduce the risk of high blood pressure.
- Claim must specify the nutrient “sodium” and must include the term “high blood pressure.”
- Claim must not quantify the degree of reduction in risk of high blood pressure.
- Claim must indicate that development of high blood pressure depends on many factors.

### ***Dietary Fat and Cancer [21 CFR 101.73]***

#### **Product Criteria**

- Must meet the definition for “low fat” (maximum of 3 g of total fat per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Does not exceed the disqualifying levels for saturated fat, cholesterol or sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less.
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

#### **Message Criteria**

- Claim must state that diets low in fat “may” or “might” reduce the risk of some cancers.
- Claim must use the terms “some types of cancer” or “some cancers” in specifying the disease.
- Claim must use the terms “total fat” or “fat” when specifying the total fat component of the food.
- Claim cannot specify the types of fats or fatty acids that may be related to risk of cancer.
- Claim must not quantify the degree of cancer risk reduction.
- Claim must state that the development of cancer depends on many factors.

### ***Dietary Saturated Fat and Cholesterol, and Risk of Coronary Heart Disease [21 CFR 101.75]***

#### **Product Criteria**

- Must meet the definition for “low saturated fat” (maximum of 1 g of saturated fat per reference amount and not more than 15% of the calories from saturated fat).
- Must meet the definition for “low cholesterol” (maximum of 20 mg of cholesterol per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must meet the definition for “low fat” (maximum of 3 g of total fat per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Does not exceed the disqualifying level for sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less.
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

#### **Message Criteria**

- Claim must state that diets low in saturated fat and cholesterol “may” or “might” reduce the risk of heart disease.
- In specifying the nutrient, the claim uses the terms “saturated fat” and “cholesterol” and lists both.
- The claim must use the terms “coronary heart disease” or “heart disease” when specifying the disease.
- The claim must not quantify the degree of risk reduction for coronary heart disease.
- The claim must state that the risk of coronary heart disease depends on many factors.

For more information, go to the FDA Web site: <http://www.cfsan.fda.gov/~dms/lab-ssa.html>.

## Health Claims

### ■ Health Claim Based on Authoritative Statement

The Food and Drug Administration Modernization Act of 1997 (FDAMA) permits food companies to use a health claim or nutrient content claim in food labeling based on an authoritative health statement from a U.S. government scientific body or a federally approved organization. Examples of federal scientific organizations include the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) or the National Academy of Sciences (NAS).

The FDAMA claim, called an “authoritative statement” claim, can be a health claim about the relationship between a nutrient and a disease or health-related condition, or it can be a nutrient content claim. The health claim must be accurate, subject to “significant scientific agreement,” and meet all other existing FDA requirements for health claims.

The FDA requires notification of the proposed FDAMA claim before introduction of the food bearing the claim. The agency intends to notify the submitter by letter as soon as possible within the 120 days after submission when the notification does not comply with the regulations. When a notification does not meet the requirements and the FDA responds by denying the claim, the use of the claim is not authorized under FDAMA.

For information on the requirements for FDAMA claims and how to make use of authoritative statement-based health claims, go to: <http://www.cfsan.fda.gov/~dms/hclmguid.html>.

### ■ Product and Message Criteria for Health Claim Based on an Authoritative Statement

#### ***Potassium and the Risk of High Blood Pressure and Stroke***

##### **Product Criteria**

- Must be a good source of potassium (at least 10% of the DV [350 mg] per reference amount).
- Must meet the definition for “low sodium” (maximum of 140 mg sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must meet the definition for “low fat” (maximum of 3 g of total fat per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must meet the definition for “low saturated fat” (maximum of 1 g of saturated fat per reference amount and not more than 15% of the calories from saturated fat).
- Must meet the definition for “low cholesterol” (maximum of 20 mg of cholesterol per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

##### **Message Criteria**

- Since this claim is authorized by an authoritative statement, the exact wording provided must be used. Required wording for the claim is: “Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”

### ■ ■ ■ **Qualified Health Claims**

In 2003, the FDA launched the Consumer Health Information for Better Nutrition Initiative, which provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component or dietary supplement and reduced risk of a disease or health-related condition. In these cases, the evidence is not well enough established to meet the significant scientific agreement standard required for the FDA to issue an Authorized Health Claim.

Qualifying language is included as part of the claim to indicate that the evidence supporting the claim does not reach the level of Significant Scientific Agreement. Both conventional foods and dietary supplements may use qualified health claims. The FDA uses its enforcement discretion for qualified health claims after evaluating and ranking the quality and strength of the totality of the scientific evidence. Although the FDA's "enforcement discretion" letters are issued to the petitioner requesting the qualified health claim, the qualified claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter. The FDA has prepared a guide on interim procedures for qualified health claims and on the ranking of the strength of evidence supporting a qualified claim. See <http://www.cfsan.fda.gov/~dms/hclmgui3.html>.

A summary of the qualified health claims authorized by the FDA may be found at <http://www.cfsan.fda.gov/~dms/qhc-sum.html>.

For more information, go to the FDA Web site at <http://www.cfsan.fda.gov/~dms/hclmgui3.html>.

For industry guidance, go to <http://www.cfsan.fda.gov/~dms/hclmgui6.html>.

## Structure/Function Claims

### Overview/Definitions

Distinct from health claims, structure/function claims have emerged as a popular category of claims that may be used on food products without prior FDA approval. Although these claims are not subject to the health claim regulations, they must, like all information on a food label, be truthful and not misleading.

Structure/function claims describe the role of a nutrient or dietary ingredient on the normal “structure” or “function” of the human body (e.g., calcium builds strong bones) but do not claim to affect a disease state.

Differentiating structure/function claims from health claims that require preapproval may not always be clear-cut. Guidance on the FDA’s position may be found in a published final rule on structure/function claims for dietary supplements [65 FR 999 – 1050. January 6, 2000]. Although the final rule focuses on dietary supplements, the FDA stated in the preamble that the basic requirements would also apply to structure/function claims made for conventional foods.

The FDA also provides criteria to assist in determining when a statement is a disease claim, that is, a claim to diagnose, cure, mitigate, treat or prevent disease (<http://www.cfsan.fda.gov/~dms/sclmguid.html>).

Current FDA policy permits structure/function claims on conventional food only if their claimed benefit derives from the food’s nutritive value [62 FR 49859, 49863. September 23, 1997]. Structure/function claims should be substantiated to show they are truthful and not misleading. FDA guidance on substantiating claims can be found at <http://www.cfsan.fda.gov/~dms/dsclmg2.html>.

Fortunately, milk and dairy products contain many nutrients that support various physiological functions, and these functions have been scientifically substantiated. The following chart lists examples of structure/function claims that can be used with milk, yogurt, cottage cheese and cheese products that meet a minimum of 10% Daily Value of the nutrient, vitamin or mineral cited in the claim. The expression of structure/function claims may take different forms, and those shown on the following chart are to illustrate examples for select vitamins and minerals.

While regulations do not prohibit the use of structure/function claims on foods that exceed the nutrient disclosure levels set for fat, saturated fat, cholesterol and sodium, it is advisable to adhere to these values and disclose if they exceed 13 g of fat, 4 g of saturated fat, 60 mg of cholesterol or 480 mg of sodium per reference amount and per 50 g if the reference amount is 30 g or less.

For more information on structure/function claims, go to the FDA Web site: <http://www.cfsan.fda.gov/~dms/labstruc.html>.

## Structure/Function Claims

### Examples of Structure/Function Claims for Dairy Products\*

Structure/Function Claim	Milk				Yogurt			Cottage Cheese	Cheese
	Whole	Reduced-fat (2% milk fat)	Low-fat (1% milk fat)	Fat-free (skim)	Plain (whole milk)	Plain (low-fat) (1% milk fat)	Plain (fat-free)	Whole, 2%, 1%, fat-free	Varieties**
The vitamin A in ___ helps promote normal vision.	No	Yes	Yes	Yes	No	No	No	No	No
The vitamin B <sub>12</sub> in ___ helps maintain your body's red blood cells.	Yes	Yes	Yes	Yes	No	No	No	No	No
The calcium and phosphorus in ___ help build strong bones.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
The vitamin D in ___ helps build strong bones.	Yes	Yes	Yes	Yes	No	No	No	No	No
The potassium in ___ helps maintain normal blood circulation.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
The phosphorus and riboflavin in ___ help the body convert food to energy.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
The protein in ___ helps maintain strong muscles.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

\* Claims based on values taken from the U.S. Department of Agriculture, Agricultural Research Service, 2008, USDA National Nutrient Database for Standard Reference, Release 21. Nutrient Data Laboratory Home Page, <http://www.nal.usda.gov/fnic/foodcomp>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only. **Note:** Consult the Code of Federal Regulations for specific nutrition labeling requirements for making structure/function claims.

\*\* Cheese varieties are listed in "High" and "Good" Source Claims Table, Page 12.

### ■ ■ ■ **Nutrient Fortification: General and Dairy-Specific**

Fortification means adding nutrients to conventional foods, including beverages, and is synonymous with enrichment. Since the 1940s, the Food and Drug Administration (FDA) policy has been that fortification in the United States should not be required nor prohibited if there is a documented public health need. The FDA, however, does regulate how much of which nutrients must be added to enriched foods, such as infant formula and fortified milk. Unless it is specifically defined by the FDA, fortification is voluntary and discretionary. In 1980, the FDA codified fortification guidelines in a Fortification Policy to establish a uniform set of principles for the rational addition of nutrients to foods [21 CFR 104.20]. The guideline discourages random fortification of foods, noting that this could result in imbalances in the food supply. The guideline covers, in part, the addition of nutrients to correct dietary insufficiencies when sufficient information to identify the nutritional problem exists; to restore nutrients lost during storage, handling, or processing when normal storage and handling processes cannot prevent the nutrient losses; and to balance the nutrient content of a food under certain specified conditions.

### **Fortification of Fluid Milk Products**

#### ■ **Vitamin A**

Vitamin A (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) may be added to all milk and milk products. Some of the standards of identity for milk products indicate the minimum level of vitamin A that must be present when it is added. If vitamin A is added to milk, it must be added at a level to achieve a minimum of 2000 IU of vitamin A per quart within the limits of good manufacturing practice [21 CFR 131.110 (b)(1)].

The acceptable range for vitamin A is 2000-3000 IU per quart (PMO 2007). If the standard of identity does not indicate a specified level or the product does not have a standard of identity, then the amount of vitamin A that may be added must be in accordance with good manufacturing practice and all applicable regulations.

#### ■ **Vitamin D**

Vitamin D (vitamin D<sub>2</sub> or D<sub>3</sub> in crystalline, resin or crystal form) may be added to all milk and milk products. Many of the standards of identity for milk products indicate the minimum level of vitamin D that must be present when it is added to a product. If vitamin D is added to milk, the amount added should achieve a minimum of 400 IU of vitamin D per quart within the limits of good manufacturing practice [21 CFR 131.110 (b)(2)].

The acceptable range for vitamin D is 400-600 IU per quart of milk (PMO 2007). If the standard of identity does not indicate a specified level or the product does not have a standard of identity, then the amount of vitamin D that may be added must be in accordance with [21 CFR 184.1950].

#### ■ **Protein and other Vitamins and Minerals**

The addition of protein and other vitamins and minerals to fluid milk products is discretionary and falls under the guidelines in the FDA's Fortification Policy [21 CFR 104.20].

### Fortification of Cheese

#### ■ Vitamin A

Vitamin A can be added to cheese with no limitation other than current good manufacturing practice conditions of use [21 CFR 184.1(b)(1)], which state that the ingredient is used in food as a nutrient supplement as defined in [21 CFR 170.3(o)(20)] and at levels not to exceed current good manufacturing practice.

#### ■ Vitamin D

The addition of vitamin D (vitamin D<sub>2</sub> or D<sub>3</sub> in crystalline or resin form) is affirmed as generally recognized as safe (GRAS) for use in milk products under [21 CFR 184.1950], including cheese at 89 IU/100 grams. In 2005, the FDA authorized the use of vitamin D<sub>3</sub> at levels up to 81 IU/30 g in cheese and cheese products that have a reference amount of 30 grams [21 CFR 172.380]. Excluded from this definition are cottage cheese, ricotta cheese, and hard grating cheeses, such as Parmesan and Romano and those cheeses defined by a standard of identity. This level is slightly more than 20% of the RDI for a serving of cheese with a reference amount of 30 grams.

#### ■ Protein and other Vitamins and Minerals

The addition of protein and other vitamins and minerals to cheese and cheese products is discretionary and falls under the guidelines in the FDA's Fortification Policy [21 CFR 104.20].

### Fortification of Yogurt

#### ■ Vitamin A

The addition of vitamin A to yogurt is optional. If added, the minimum amount of vitamin A in each 946 milliliters (quart) of the food must not be less than 2000 IU, within the limits of current good manufacturing practice [21 CFR 131.200, 131.203, 131.206].

#### ■ Vitamin D

The addition of vitamin D to yogurt is optional. If added, the minimum amount of vitamin D in each 946 milliliters (quart) of the food must not be less than 400 IU, within the limits of current good manufacturing practice [21 CFR 131.200, 131.203, 131.206].

#### ■ Protein and other Vitamins and Minerals

The addition of protein and other vitamins and minerals to yogurt products is discretionary and falls under the guidelines in the FDA's Fortification Policy [21 CFR 104.20].

### ■ Federal Standards of Identity for Dairy Foods

Food standards are designed to promote fair competition among food manufacturers and to avoid consumer confusion. The federal standards of identity include definitions; process of producing the product; required and optional ingredients; product nomenclature; required and voluntary label declarations; and method of analysis [21 CFR, Part 130] and [21 CFR 130.3; 130.5].

Since November 20, 1996, all lower-fat versions of fluid milks and cultured products have been subject to the FDA's "general standard," which permits foods to be named by use of a defined nutrient content claim (e.g., "reduced-fat" or "low-fat") and a standardized term (e.g., "milk" or "cottage cheese"). Although fat contents may vary through the use of nutrient content descriptors, other requirements of the standard must be met, unless otherwise exempted.

# Regulatory Concepts and Definitions for Dairy

## ■ ■ ■ Standard of Identity Definitions – Dairy Products

Many dairy products are subject to a standard of identity, which is defined by the FDA in the Code of Federal Regulations [21 CFR, Parts 131, 133 and 135]. A standard of identity can define a specific product (e.g., Cheddar cheese or milk) [21 CFR 133.113 and 133.110] or it can encompass an entire category of food (e.g., grated cheeses) [21 CFR 133.146]. Because the number of dairy products with standard of identity requirements is too numerous to summarize here, the following table is provided as a resource to the sections in the CFR where the requirements for specific standardized dairy products can be found:

Class of Dairy Products	Section in CFR
Milk and Cream - Includes milk, cream, sour cream, eggnog, half-and-half and yogurt	21 CFR 131 Subpart B (131.110 – 131.206)
Cheeses and Related Cheese Products - Includes a wide variety of cheeses	21 CFR 133 Subpart B (133.102 – 133.196)
Frozen Desserts - Includes ice cream, frozen custard, sherbet and water ices	21 CFR 135 Subpart B (135.110 – 135.160)

## Compliance with the Standards of Identity

Compliance with the standards of identity is addressed in [21 CFR 130.8]. Products that have a standard of identity are subject to the regulations under the standard as well as all regulations relating to misbranding and adulteration. Briefly, the three conditions under which a food would not conform to the standard of identity are if the product:

- Contains ingredients that are not provided for in the standard, unless the ingredient is an incidental additive at a nonfunctional and insignificant level
- Does not contain one or more ingredients required by the definition and the standard
- Contains an ingredient or component not within the limitations of the definition or standard

If any of these conditions or any other requirements of the standard of identity are not met, then the product may not be labeled as, or purport to be, such a product. Some conditions where a product may not comply with the federal standard of identity but may still use the name of the standardized food include marketing a product under a temporary marketing permit granted by the FDA (see [21 CFR 130.17]), marketing a product with a standard of identity and a nutrient content claim ([21 CFR 130.10]; see Product Name section below), and marketing a product in a state or area that has been granted an exemption.

## Regulatory Concepts and Definitions for Dairy

### ■ ■ ■ Grade 'A' Pasteurized Milk Ordinance

The Grade "A" Pasteurized Milk Ordinance (PMO 2007; <http://www.cfsan.fda.gov/~ear/pmoo7toc.html>) provides additional guidelines for labeling of Grade A milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products. Since the PMO has been adopted by most states, it is generally advisable to follow PMO labeling requirements for all Grade A dairy foods.

The PMO requires that all bottles, containers and packages enclosing Grade A milk and milk products be labeled in accordance with the requirements of the Federal Food, Drug and Cosmetic Act, the Nutritional Labeling and Education Act of 1990, and all applicable regulations in the Code of Federal Regulations. In addition, the products must be conspicuously marked with:

- The words "Grade A" on the exterior surface, meaning principal display panel, the secondary information panel or the cap/cover.
- Identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried.
- The phrase "Keep refrigerated after opening" on aseptically processed milk and milk products.
- When the product is not from cattle's milk, the common name of the hooved mammal producing the milk or milk products.
- "Reconstituted" or "Recombined" if applicable.
- Additional requirements apply for condensed or dry milk products (see PMO 2007, Section 4).

### ■ ■ ■ Processing and Nutrient Definitions

The following definitions, described here as processing and nutrient or ingredient definitions, are select examples of definitions from the Code of Federal Regulations [21 CFR Parts 130, 131, 133] and/or the latest revision of the Pasteurized Milk Ordinance (PMO 2007) that are relevant to standards of identity.

#### Processing Definitions

- **Pasteurized**, when used to describe a dairy product, means that the product has been heated by properly operated equipment to one of the temperatures specified in the regulation [21 CFR 131.3]. The PMO 2007 offers additional time/temperature relationships for the terms "pasteurization," "pasteurized," and similar terms (PMO 2007, Section 1. *Definitions*). Nothing in the definition bars any other pasteurization process that has been recognized by the FDA to be equally effective and that is approved by the regulatory agency.
- **Ultra-pasteurized** is used to describe a dairy product that has been thermally processed at or above 138°C (28°F) for at least two seconds, either before or after packaging, to produce a product that has an extended shelf life under refrigerated conditions [21 CFR 131.3(c)].
- **Aseptic processing and packaging** is the filling of a commercially sterilized, cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms. The product must maintain commercial sterility under normal non-refrigerated conditions [21 CFR 131.3] *Definition*; PMO 2007, Sections 1 and 7).

## Regulatory Concepts and Definitions for Dairy

- **Reconstituted or recombined milk and/or milk products** are milk or milk products (*Milk and Cream* [21 CFR 131], *Cottage cheese* [21 CFR 133.128] and *Dry curd cottage cheese* [21 CFR 133.129]) that result from reconstituting or recombining of milk constituents with potable water when appropriate. The PMO 2007 addresses circumstances where state law does not permit the sale of reconstituted or recombined milk and/or milk products (PMO 2007, p.126).

### Nutrient and Ingredient Definitions

- **Vitamin A** (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) may be added to food within the limits of good manufacturing practice [21 CFR 184.1930 *Vitamin A*]. The addition of vitamin A is mandatory for lower-fat milk and milk products (except yogurt) to achieve nutritional equivalency with their full-fat counterparts. Other modified milk products in which fat has been removed must be fortified with vitamin A to achieve nutritional equivalency of their full-fat counterpart. When added to specified standardized milk and milk products, vitamin A must be present at a minimum of 2000 IU per quart [21 CFR 131.110; PMO 2007, p.338].
- **Vitamin D** (vitamin D<sub>2</sub> or D<sub>3</sub> in crystalline, resin or crystal form) may be added to all milk and milk products within the limits of good manufacturing practice [21 CFR 184.1950 *Vitamin D*]. Many standards of identity prescribe the minimum level of vitamin D that must be present if it is added to a product. If vitamin D is added to milk, it must be added at a level so that each quart contains 400 IU of vitamin D [21 CFR 131.110; PMO 2007, p.338]. If the standard of identity does not indicate a specified level or the product does not have a standard of identity then, the level at which vitamin D may be added must be in accordance with regulatory restrictions and good manufacturing practices.
- **“Nutritive sweeteners” and “nutritive carbohydrate sweeteners.”** The federal standards of identity make the distinction between nutritive sweeteners and nutritive carbohydrate sweeteners. *Nutritive sweeteners* are substances with more than 2% of the caloric value of sucrose per equivalent unit of sweetening capacity [21 CFR 170.3]. *Nutritive carbohydrate sweeteners* are sweeteners, such as sucrose and corn syrup that provide sweetness through a carbohydrate source. If the standard of identity provides for “nutritive sweeteners,” then any sweetener providing more than 2% of the calories of sucrose per equivalent unit of sweetening capacity, including alternative non-carbohydrate sweeteners such as aspartame or protein-derived sweeteners, may be used.

Non-nutritive sweeteners (e.g., sucralose) provide less than 2% of the caloric value of the sucrose per-equivalent sweetening capacity. These sweeteners may be used in foods for which the standard allows for “safe and suitable” sweeteners.

For foods with standards of identity that do not allow for non-nutritive sweeteners, other options may be considered. If the addition of a non-nutritive sweetener would allow for the use a nutrient content claim (e.g., reduced sugar, no sugar added), the [21 CFR 130.10] provides flexibility in ingredients, including the addition of non-nutritive ingredients. If this is the case, the sweetener must be followed in the ingredient statement by an asterisk referring to a footnote that reads “Ingredient not in regular [food].” The other consideration would involve a food name in two parts: “[standardized food] and [non-nutritive sweetener]” (e.g., “low-fat chocolate milk with sucralose”). All other labeling would remain the same.

- **“Safe and suitable ingredients.”** A *safe and suitable ingredient* is an ingredient that performs an appropriate function in the food in which it is used; is used at a level no higher than necessary to achieve its intended purpose in that food; and is not a food or color additive that is prohibited in foods [21 CFR 130.3(d)].

## Regulatory Concepts and Definitions for Dairy

### ■ ■ ■ Determining a Product Name

The label of a packaged food sold at retail must include an appropriate product name, also called a “statement of identity” [21 CFR 101.3]. The FDA requires that product names accurately identify or describe the basic nature of the food or its characterizing properties or ingredients, be as simple and direct as possible, and not mislead or confuse consumers. When there is not a federal standard of identity that designates the name of the product, the common or usual name of the food must be used. In cases where there is no standard of identity or common or usual name, an appropriately descriptive term with or without a fanciful name may be used. This can be simplified into a three-step process of elimination:

- Is the product covered by a standard of identity?
- Is there a common or usual name?
- If there is no common or usual name, a descriptive term with or without a fanciful name may be used.

### Standard of Identity for a Food

A standard of identity exists for many dairy products [see Standard of Identity section above]. The standard of identity for individual foods provides a definition of that food and also specifies the appropriate product name. *For example*, “The name of the food is ‘Cheddar cheese’” [21 CFR 133.113]. For some foods, descriptive terms that must or may accompany the name of the food are provided. *For example*, for “milk,” the standard of identity specifies both the product name and terms that shall or may accompany the name of the food (e.g., “pasteurized”) may be used on fluid milk products [21 CFR 131.110].

Any food that resembles or claims to be a standardized food must strictly follow the requirements of the standard of identity. In naming any dairy food, therefore, a manufacturer must consider any possible similarities between that food and a standardized food. These include any similarities in appearance, packaging and taste.

A standard of identity can define a specific product (e.g., Cheddar cheese or milk) or it can encompass an entire category of food (e.g., grated cheeses [21 CFR 133.146]).

### Common or Usual Name

A common or usual name is one that is most commonly used by manufacturers and well understood by consumers [21 CFR 101.3(b) and 102.5]. A common or usual name must accurately identify or describe, in simple and direct terms, the basic nature of the food or its characterizing properties or ingredients. In addition, a common or usual name must be uniform among all identical or similar products without being confusingly similar to the name of another food. When the common or usual name is not clear, the following should be considered when determining an appropriate common or usual name: examine current industry practice, consumer understanding of the name, and the ordinary dictionary definition of the term(s) in the name. Companies have some latitude in selecting an appropriate common or usual name and, at the same time, must avoid false and misleading statements.

Consumer recognition of a product name and industry practice plays significant roles in establishing both common or usual names and fanciful names. Product names tend to evolve into one or both of these categories gradually over time. Thus, it is sometimes difficult to determine whether a product name is considered to be a common or usual name or a fanciful name, and there may be some overlap between these categories.

## Regulatory Concepts and Definitions for Dairy

### **Descriptive Terms and/or Fanciful Names**

If both a standard of identity and an identifiable common or usual name are not available, a descriptive term may be used. This may be accompanied by a fanciful name (most commonly used option), or a fanciful name alone (only permitted when the nature of the food is obvious) [21 CFR 101.3(b)(3)].

When a descriptive term is used, it must be both accurate and complete but does not need to restate all the food's ingredients. It should convey the basic nature of the food to consumers. Examples include "Pasteurized Process American Cheese Product" and "Lactose-free Non-dairy Dessert Topping."

Descriptive names alone may be lengthy and difficult to remember, therefore, a fanciful name may be accompanied by a descriptive term. The descriptive term accompanying a fanciful name, like a descriptive term used alone, should convey the basic nature of the product to the consumer and should be accurate and complete. Examples include: "Garden Jack Cheese *Monterey Jack Cheese with Garden Vegetables*" and "Cheeze & Sticks, Pasteurized Process Cheese Dip and Cracker Sticks."

A fanciful name may be used alone, without a descriptive term, only when the nature of the food is obvious and the fanciful name is commonly used and understood by the consumer.

### ■ ■ ■ **Other Considerations for Product Naming**

#### **Standard of Identity and a Nutrient Content Claim**

Foods that vary nutritionally from an FDA standard of identity in certain specified ways can be named using the standardized name (e.g., "Cheddar cheese" or "milk") along with a nutrient content claim (e.g., "low-fat" or "fat-free") [21 CFR 130.10]. The FDA regulation essentially creates a "generic standard" that allows products with a standard of identity to bear an approved nutrient content claim [21 CFR 130.10]. Examples include "reduced-fat," "light," "non-fat," and "fat-free" in conjunction with standardized terms like "milk" or "cottage cheese." Fat-modified versions of the "generic" standard of identity must meet the requirements of a nutrient content claim as defined by the FDA. These lower-fat products must meet the nutrient content descriptor definitions for total fat content, be nutritionally equivalent to the reference (i.e., "full fat") standard of identity, and meet all other provisions of the reference standard.

A product with a standard of identity and a nutrient content claim is considered a type of "substitute food." The FDA requires that a substitute food be nutritionally equivalent to the unaltered product of the same standard of identity, less the nutrient for which the claim is being made. A product with a standard of identity and a nutrient content claim may use safe and suitable ingredients to improve the acceptability and functionality of the substitute food.

#### **Food Form**

When a food is sold in various optional forms (e.g., shredded or cubed cheese; standard or drinkable yogurt), the form of the food must also be stated as part of the product name [21 CFR 101.3(c)] with the type size reasonably related to the name of the food. If the food form is visible through the container or packaging or depicted clearly as a sketch on the label, the form of the food does not need to be disclosed in written form on the label.

## Regulatory Concepts and Definitions for Dairy

### **Imitation Foods**

If a food is a substitute for and resembles another food but is nutritionally inferior to that food, the food must be labeled imitation [21 CFR 101.3(e)]. A product is considered nutritionally inferior if it contains a reduction of 2% or more of the Daily Recommended Value (DRV) of protein and potassium and 2% or more of the U.S. RDI of any vitamin or mineral.

### **Combination Foods or 'Multifood'**

Foods that combine two or more separate foods into one product may follow an industry practice referred to as a “multifood” concept. Examples of product names for combination dairy foods include “cream cheese with vegetables” and “yogurt with fruit.”

### **Flavor Declaration with Product Name**

The FDA has detailed requirements about how the primary recognizable flavor(s) or characterizing flavor(s) of a food are represented on the label. There are general regulations dealing with flavor declarations on food labels [21 CFR 101.22]. In addition, many dairy food standards of identity contain specific requirements about using flavoring(s) and declaring flavors(s). The regulations spell out when a dairy food is required — and when it is permitted — to make a flavor declaration on its label. In addition, there are rules about how the flavor declaration should be made.

Generally, the name of the characterizing flavor(s) must accompany the product name [21 CFR 101.22(i)(1)]. The type size of the flavor designation must be no less than one-half the height of the letters used in the product name. In addition, the flavoring(s) must be declared in the ingredient list.

# Acknowledgment/Resources/Contact Information

## ■ ■ ■ Acknowledgment

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## ■ ■ ■ Resources

Code of Federal Regulations (CFR), Title 21, Parts 100-169 <http://www.cfsan.fda.gov/~dms/reg-2.html>

Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition  
Food Labeling and Nutrition <http://www.cfsan.fda.gov/label.html>

FDA Industry Information, Guidance & Regulations <http://www.cfsan.fda.gov/~dms/lab-ind.html>

International Dairy Foods Association (IDFA) Labeling Manuals: Milk, Cheese and Ice Cream.  
<http://www.idfa.org/reg/stdrds.cfm>

Grade “A” Pasteurized Milk Ordinance 2007: <http://www.cfsan.fda.gov/~ear/pmoo7toc.html>

U.S. Department of Agriculture, Agricultural Research Service, 2008. USDA National Nutrient Database for Standard Reference, Release 21. Nutrient Data Laboratory Home Page:  
<http://www.nal.usda.gov/fnic/foodcomp/search/>

Dairy Management Inc.™, Dairy Research, Technologies, Applications and Nutrition  
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